

NeuroMetrix, Inc.  
Form S-1  
May 13, 2004

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As filed with the Securities and Exchange Commission on May 13, 2004

Registration No. 333-

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### FORM S-1 REGISTRATION STATEMENT

UNDER  
THE SECURITIES ACT OF 1933

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## NEUROMETRIX, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**3841**  
(Primary Standard Industrial  
Classification Code Number)

**04-3308180**  
(I.R.S. Employer  
Identification Number)

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**62 Fourth Avenue**  
**Waltham, Massachusetts 02451**  
**(781) 890-9989**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

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**Shai N. Gozani, M.D., Ph.D.**  
**President and Chief Executive Officer**  
**NeuroMetrix, Inc.**  
**62 Fourth Avenue**  
**Waltham, Massachusetts 02451**  
**(781) 890-9989**

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

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*Approximate date of commencement of proposed sale to public:* As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

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If this Form is used to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, \$0.0001 par value per share	\$34,500,000	\$4,372

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated \_\_\_\_\_, 2004

Shares

## NEUROMETRIX, INC.

### Common Stock

We are offering \_\_\_\_\_ shares of our common stock. We have granted the underwriter the right to purchase up to an additional \_\_\_\_\_ shares to cover over-allotments.

This is our initial public offering and no public market currently exists for our shares. We expect that the public offering price will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

We will apply to list our common stock for quotation on the Nasdaq National Market under the symbol "NURO."

**Investing in our common stock involves risks. See "Risk Factors" beginning on page 7.**

	<u>Per Share</u>	<u>Total</u>
Public Offering Price	\$ _____	\$ _____
Underwriting Discount	\$ _____	\$ _____
Proceeds to NeuroMetrix, Inc. (before expenses)	\$ _____	\$ _____

Neither the Securities and Exchange Commission nor any state securities regulators have approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver the shares to purchasers on \_\_\_\_\_, 2004.

## PUNK, ZIEGEL & COMPANY

The date of this prospectus is \_\_\_\_\_, 2004.

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## TABLE OF CONTENTS

	<b>Page</b>
Prospectus Summary	1
Risk Factors	7
Cautionary Note Regarding Forward Looking Statements	24
Use of Proceeds	25
Dividend Policy	25
Capitalization	26
Dilution	27
Selected Financial Data	29
Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Business	44
Scientific Advisory Board	67
Management	68
Certain Relationships and Related Party Transactions	77
Principal Stockholders	79
Description of Capital Stock	82
Shares Eligible for Future Sale	86
Material U.S. Federal Income Tax Consequences	88
Underwriting	91
Legal Matters	93
Experts	93
Where You Can Find More Information	93
Index To Financial Statements	F-1

**You should rely only on the information contained in this prospectus. We have not, and the underwriter has not, authorized anyone to provide you with information that is different. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale of these securities is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.**

**Our estimates of market share and market size in this prospectus are based on, in certain cases, public disclosure, industry and trade publications and reports prepared by third parties, which we believe to be reliable, but the accuracy and completeness of this information is not guaranteed. While we believe that these market data and industry forecasts are reliable, we have not independently verified, and make no representation as to the accuracy of, this information.**

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## PROSPECTUS SUMMARY

*This summary only highlights the more detailed information appearing elsewhere in this prospectus. As this is a summary, it does not contain all of the information that you should consider in making an investment decision. You should read this entire prospectus carefully, including the information under "Risk Factors" and our financial statements and the related notes included elsewhere in this prospectus, before you decide to invest in our common stock. In this prospectus, unless the context requires otherwise, "NEUROMetrix," "we," "us," "our" and "our company" refer to NeuroMetrix, Inc., a Delaware corporation, and its predecessor entities for the applicable periods, considered as a single enterprise.*

### **Our Business**

NEUROMetrix is a medical device company that designs, develops and sells proprietary products 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. We believe that our neuropathy diagnostic system, the NC-stat System, is unique in its ability to provide primary care and specialist physicians with objective information that aids in the rapid and accurate diagnosis of neuropathies at the point of service, that is, in the physician's office at the time the patient is examined. Diagnostic procedures performed with the NC-stat System can generate revenue for the physician and save money for the patient and third-party payer. We believe that the benefits of the NC-stat System will lead to its adoption by a significant number of primary care and specialist physicians, who historically have not had the ability to diagnose these neuropathies at the point of service. This in turn should result in more frequent testing of patients at risk for neuropathies and earlier diagnoses of neuropathies, resulting in improved clinical and economic outcomes. The NC-stat System has been on the market since May 1999 and is presently used in over 1,700 physician's offices, clinics and other health care facilities in the United States. We hold issued utility patents covering a number of important aspects of our NC-stat System. In 2003, we more than doubled our revenues from the prior year, generating \$9.2 million in revenues, of which 85.8% was attributable to sales of the disposable biosensors that physicians use to perform tests with the NC-stat System. Our gross margin percentage in 2003 was 70.5%. Since our inception, more than 210,000 patients have been tested with the NC-stat System.

### **Our Opportunity**

The sensitivity of the nervous system to metabolic and mechanical damage, compounded by its limited regenerative ability, creates a robust market opportunity for a medical device that can produce point-of-service diagnoses of neuropathies in a manner that is cost-effective for the patient and third-party payer. We estimate that there are approximately two million traditional nerve conduction study and needle electromyography, or NCS/nEMG, procedures currently performed each year in the United States. We believe that use of traditional NCS/nEMG procedures is limited by: (1) the need to obtain a referral for the procedure to a neurologist and the resulting delay in availability of diagnostic information; (2) the inconvenience and discomfort of these procedures for the patient; and (3) the expense to the patient and third-party payer. We anticipate that the advantages and increased availability of the NC-stat System will significantly increase the overall 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, or over \$1.0 billion annually for our disposable NC-stat biosensors, in the United States. However, market size is difficult to predict and we cannot assure you that our estimates will prove to be correct. We believe that additional applications of the NC-stat System, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this potential market size. Additionally, although we

have not yet quantified the size of the market, we believe a significant international market opportunity exists for the NC-stat System.

### **Our Solution**

We believe that the NC-stat System represents a significant advance in neurological diagnostics and offers an improvement over traditional diagnostic methods by:

Facilitating performance of nerve conduction studies at the point of service;

Providing a cost-effective diagnostic tool;

Requiring minimal capital investment;

Automating much of the procedure, making it simple to operate; and

Using a patient-friendly, non-invasive procedure.

These benefits address a number of the limitations of the traditional diagnostic methods for assessing patients with or at risk for neuropathies, because these traditional methods typically:

Require a referral to a neurologist;

Are expensive to perform;

Require the use of costly, highly technical equipment; and

Are uncomfortable and painful for the patient.

We believe the benefits of the NC-stat System will expand the use of nerve conduction studies to include at-risk individuals who currently may not be tested because of these limitations. Additionally, new treatments that are under development for neuropathies, such as those for diabetic peripheral neuropathy, may create increased demand for nerve conduction studies to identify patients in need of these treatments. We therefore believe a significant opportunity exists to broaden the market for nerve conduction studies. By incorporating nerve conduction studies early in patients' care episodes through the use of the NC-stat System, we expect better long-term clinical and economic outcomes will emerge because of the ability to implement preventive care measures based on accurate early diagnostic results.

### **Our Strategy**

Our goal is to become the leading provider of innovative, proprietary, high margin medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies. To achieve this objective, we are pursuing the following business strategies:

Establish the NC-stat System as a standard of care for nerve conduction studies;

Expand sales and marketing efforts;

Focus on primary care physician market;

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Continue to strengthen our presence within specific specialty physician markets; and

Continue to introduce new products.

### **Our Products**

We currently market the NC-stat System throughout the United States through a network that consists of 15 regional sales managers and more than 50 independent regional sales agencies employing a total of more than 250 independent sales representatives. 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 to transmit data to our onCall Information System. The onCall Information System formulates the data it receives for each test into a detailed report that is sent to the physician via facsimile or e-mail in three to four minutes on average and aids in the physician's diagnosis. The NC-stat System enables the physician to make rapid and accurate diagnoses that are cost-effective for the patient and third-party payer.

The NC-stat System can be used by primary care and specialist physicians, including neurologists. The complexity and high capital cost of traditional diagnostic methods have limited their use mainly to neurologists. Because of the benefits and advantages of the NC-stat System outlined above, we believe it will be readily adopted by a wide range of physicians.

We also believe that we may be able to adapt and extend our core technology to provide minimally invasive approaches to treating neuropathies. In particular, we believe that many neuropathies can be safely and effectively treated if drugs can be delivered near the disease site without damaging the nerve in the process. We are in the early stages of designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians.

### **Our Corporate Information**

NEUROMetrix was founded in June 1996 by our President & Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. We originally were incorporated in Massachusetts in 1996, and we reincorporated in Delaware in 2001. Our principal offices are located at 62 Fourth Avenue, Waltham, Massachusetts 02451, and our telephone number is (781) 890-9989. Our website address is [www.neurometrix.com](http://www.neurometrix.com). We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider it part of this prospectus.

NEUROMetrix®, NC-stat® and onCall are trademarks of ours.



**The Offering**

Common stock offered by NEUROMetrix	shares
Common stock outstanding after this offering	shares
Use of proceeds	We expect to receive net proceeds from this offering of approximately \$ million. We intend to use the proceeds to expand our sales and marketing activities, to fund research and development relating to potential new products and to repay outstanding debt obligations of approximately \$3.3 million, and for general corporate purposes. See "Use of Proceeds."

Proposed Nasdaq National Market symbol NURO

The number of shares of common stock outstanding after this offering is based on 34,127,072 shares outstanding as of May 10, 2004 and excludes:

2,035,300 shares of common stock issuable upon the exercise of outstanding stock options as of May 10, 2004 at a weighted average exercise price per share of \$0.49;

400,000 shares of common stock issuable upon the exercise of an outstanding warrant as of May 10, 2004 at an exercise price per share of \$1.50;

3,300,000 shares of common stock to be reserved for future issuance upon the exercise of options available for future grant under our 2004 Stock Option and Incentive Plan; and

1,500,000 shares of common stock to be reserved for future issuance under our 2004 Employee Stock Purchase Plan.

Unless otherwise indicated, the information in this prospectus assumes that the underwriter will not exercise the over-allotment option granted to it by us, and has been adjusted to reflect:

the filing of our Second Amended and Restated Certificate of Incorporation and the adoption of our Second Amended and Restated By-Laws immediately prior to the effectiveness of this offering;

a planned for reverse stock split of our common stock immediately prior to the effectiveness of this offering;

conversion of all outstanding preferred stock into 29,955,075 shares of common stock upon the closing of this offering;

automatic conversion of our outstanding warrant to purchase 400,000 shares of our Series E-1 preferred stock into a warrant to purchase 400,000 shares of our common stock upon the closing of this offering; and

the filing of our Third Amended and Restated Certificate of Incorporation immediately following the closing of this offering.

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## Summary Financial Data

The following summary financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. The summary financial data for the years ended December 31, 2001, 2002 and 2003, and as of December 31, 2002 and 2003, are derived from our audited financial statements included elsewhere in this prospectus.

	Year Ended December 31,		
	2001	2002	2003
	(in thousands, except for share and per share data)		
<b>Statement of Operations Data:</b>			
Revenues:			
Diagnostic device	\$ 782	\$ 723	\$ 1,303
Biosensor	2,682	3,502	7,865
	3,464	4,225	9,168
Cost of revenues	1,424	1,370	2,707
	2,040	2,855	6,461
Operating expenses:			
Research and development (1)	2,561	2,146	2,397
Sales and marketing (1)	5,304	2,870	4,768
General and administrative (1)	3,228	2,673	2,850
	11,093	7,689	10,015
Loss from operations	(9,053)	(4,834)	(3,554)
Interest income (expense), net	335	40	(113)
	(8,717)	(4,793)	(3,667)
Accretion of dividend on redeemable convertible preferred stock	(1,757)	(1,893)	(2,009)
Deemed dividend on redeemable convertible preferred stock		(6,873)	
	\$ (10,474)	\$ (13,559)	\$ (5,676)
Net loss per common share:			
Basic and diluted	\$ (2.62)	\$ (3.29)	\$ (1.37)
Weighted average basic and diluted common shares outstanding	4,001,305	4,116,865	4,155,305
Pro forma basic and diluted net loss per common share (2)			\$ (0.13)
Shares used in computing pro forma basic and diluted net loss per common share			27,211,157

(1) Non-cash stock-based compensation expense included in these amounts are as follows:

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Research and development	\$	8	\$	7	\$	35
Sales and marketing		15		6		37
General and administrative		33		37		24
		<u>          </u>		<u>          </u>		<u>          </u>
Total non-cash stock-based compensation	\$	56	\$	50	\$	96
		<u>          </u>		<u>          </u>		<u>          </u>

- (2) Pro forma basic and diluted net loss per common share is calculated assuming the conversion of all outstanding shares of preferred stock into shares of common stock, excluding 7,050,771 shares of our Series E-1 preferred stock issued in March 2004 and assuming the repayment of outstanding debt obligations to Lighthouse Capital Partners IV, L.P. of approximately \$3.3 million.

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As of December 31, 2003

	Actual	Pro Forma (1)	Pro Forma As Adjusted (2)
	(in thousands)		
<b>Balance sheet data:</b>			
Cash and cash equivalents	\$ 1,623	\$ 12,179	\$
Working capital	2,754	13,310	
Total assets	7,218	17,774	
Warrants for redeemable convertible preferred stock	450	450	
Redeemable convertible preferred stock	47,694	58,250	
Total stockholders deficit	(45,502)	(45,502)	

(1) The pro forma balance sheet data as of December 31, 2003 gives effect to the sale of 7,050,771 shares of Series E-1 preferred stock in March 2004 for net proceeds of \$10.6 million, as if such sale had occurred on December 31, 2003.

(2) The pro forma as adjusted balance sheet data as of December 31, 2003 gives effect to (a) the conversion of all outstanding shares of preferred stock into shares of common stock upon the closing of this offering, including the conversion of 7,050,771 shares of our Series E-1 preferred stock issued in March 2004, (b) the sale of \_\_\_\_\_ shares of common stock offered by this prospectus at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the expected public offering price range on the front cover of this prospectus, after deducting the estimated underwriting discount and estimated offering expenses payable by us, (c) the repayment of outstanding debt obligations to Lighthouse Capital Partners IV, L.P. of approximately \$3.3 million and (d) the automatic conversion of a warrant to purchase 400,000 shares of our Series E-1 preferred stock into a warrant to purchase 400,000 shares of common stock upon the closing of this offering, as if such events had occurred on December 31, 2003.

## RISK FACTORS

*An investment in our common stock involves a high degree of risk. Accordingly, you should carefully consider the following risks and all other information contained in this prospectus before purchasing 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 prospectus 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 prospectus.*

### Risks Relating to Our Business

#### **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 and \$3.7 million in 2003. At December 31, 2003, we had an accumulated deficit of approximately \$44.9 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability.

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

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

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

We believe that the drawbacks of traditional nerve conduction studies, including those related to the referral process, and the limited treatment options for diabetic peripheral neuropathy, or DPN, have limited the number of nerve conduction studies that are performed. For our future growth, we are relying, in part, on increased use of 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 clinical results experienced by physicians using the NC-stat System;

physicians' reluctance to alter their existing practices; and

the failure of other companies' existing drug development programs to produce an effective treatment for DPN, which may limit the perceived need and the actual use of the NC-stat System in connection with this disease.

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 50% 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. 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 do have a one-year, automatically renewable contract manufacturing agreement with AEI. However, under the agreement, either party may elect not to renew the agreement upon 90 days' prior written notice prior to 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 2004. If any of the changes in our relationship 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, which 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. 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.**



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In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, confidentiality, nondisclosure and assignment of invention agreements and other contractual provisions and technical measures to protect our intellectual property rights. In particular, we have sought no patent protection for the technology and algorithms we use in our onCall Information System, and we rely on trade secrets to protect this information. While we currently require employees, consultants and

other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements or a combination thereof where appropriate, any of the following could still occur:

the agreements may be breached;

we may have inadequate remedies for any breach;

trade secrets and other proprietary information could be disclosed to our competitors; or

others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

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

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

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

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

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

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

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



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

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

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current clinical applications for which we market our products. However, our clearances can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. We also are subject to numerous 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.

**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 on 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; Nicholas J. Alessi, Director of Finance; and our other key employees. We maintain a \$5.0 million key person life insurance policy on Dr. Gozani, 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 51 employees, and our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining our future performance. We may not be able to meet our future hiring needs or retain existing personnel. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, as well as independent regional sales agencies and sales representatives, most of whom are geographically dispersed and must be trained in the use and benefits of our products. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

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

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

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

We presently employ 15 regional sales managers who lead more than 50 independent regional sales agencies employing a total of more than 250 sales representatives. We are highly dependent on our

regional sales managers to generate our revenues. We currently intend to increase our existing sales force significantly using part of the net proceeds from this offering. Our ability to build and develop a strong sales force will be affected by a number of factors, including:

our ability to attract, integrate and motivate sales personnel;

our ability to effectively train our sales force;

the ability of our sales force to sell an increased number of products;

the length of time it takes new sales personnel to become productive;

the competition we face from other companies in hiring and retaining sales personnel;

our ability to effectively manage a multi-location sales organization;

our ability to enter into agreements with prospective members of our sales force on commercially reasonable terms; and

our ability to get our independent sales agencies, who may sell products of multiple companies, to commit the necessary resources to effectively market and sell our products.

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

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

All of our current revenues are derived from selling the NC-stat System. Our future business and financial success will depend, in part, on our ability to continue to introduce new products and upgraded products into the marketplace. Developing new products and upgrades to existing and future products imposes burdens on our research and development department and our management. This process is costly, and we cannot assure you that we will be able to successfully develop new products or enhance the NC-stat System or any future products. In addition, as we develop the market for point-of-service nerve conduction studies, future competitors may develop desirable product features earlier than we do, which could make our competitors' products less expensive or more effective than our products and could render our products obsolete or unmarketable. If our product development efforts are unsuccessful, we will have incurred significant costs without recognizing the expected benefits and our business prospects may suffer.

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

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





companies, Viasys Healthcare, Medtronic and Oxford Instruments, in particular, enjoy significant competitive advantages, including:

greater resources for product development, sales and marketing

more established distribution networks;

greater name recognition;

more established relationships with health care professionals, customers and third-party payers; and

additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives.

Other than Neumed, we do not know if these companies or others are engaged in research and development efforts to develop products to perform point-of-service nerve conduction studies that would be directly competitive with the NC-stat System. As we develop the market for point-of-service nerve conduction studies, we may be faced with competition from these companies or others that decide and are able to enter this market. Some or all of our future competitors in the point-of-service market may enjoy competitive advantages such as those described above. If we are 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, including the proceeds from this offering, together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 24 months. However, we may seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. Our capital requirements will depend on many factors, including:

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

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;

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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.

### **Risks Related to this Offering**

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

After this offering, our officers, directors and principal stockholders will together control approximately % of our outstanding common stock or % if the over-allotment option is exercised in full. If 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 following this offering 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. There will be approximately additional shares of common stock, excluding shares issuable upon exercise of outstanding options and an outstanding warrant, eligible for sale beginning 180 days after the effective date of this prospectus upon the expiration of lock-up agreements between our stockholders and the underwriter. These shares could be eligible for sale sooner if these shares are released from these lock-up agreements earlier. Moreover, after this offering, the holders of 29,955,075 shares of our common stock, including shares issued upon conversion of our preferred stock, and the holder of a warrant to purchase 400,000 shares of common stock, will have rights, subject to various conditions and limitations, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all common stock that we may





issue under our existing Amended and Restated 1998 Equity Incentive Plan and our 2004 Stock Option and Incentive Plan and 2004 Employee Stock Purchase Plan adopted in connection with this offering. Once we register these shares, and in some cases sooner, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described in "Underwriting." 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. Please see "Shares Eligible for Future Sale" for a description of sales that may occur in the future.

**Our common stock has not been publicly traded, and we expect that the price of our common stock will fluctuate substantially.**

Prior to this offering, there has been no public market for shares of our common stock. An active public trading market may not develop following completion of this offering or, if developed, may not be sustained. The price of the shares of common stock sold in this offering will be determined by negotiation between the underwriter and us. This price will not necessarily reflect the market price of our common stock following this offering. The market price of our common stock following this offering will be affected by a number of factors, including:

- changes in the availability of third-party reimbursement in the United States or other countries;
- volume and timing of orders for our products;
- developments in administrative proceedings or litigation related to intellectual property rights;
- issuance of patents to us or our competitors;
- the announcement of new products or product enhancements by us or our competitors;
- the announcement of technological or medical innovations in the treatment or diagnosis of neuropathies;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- developments in our industry;
- publication of clinical studies relating to our products or a competitor's product;
- quarterly variations in our or our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

**New investors will experience immediate and substantial dilution in the net tangible book value of their common stock following this offering.**

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution of \$ \_\_\_\_\_ per share, because the price you pay, assuming an initial public offering price of \$ \_\_\_\_\_, would be substantially greater than the net tangible book value per share of common stock that you acquire. This dilution is due in large part to the fact that our existing investors paid substantially less than the assumed initial public offering price for their shares of our capital stock. If the holders of outstanding options or warrants exercise their rights to acquire common stock, you will incur further dilution.



**Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a return.**

Our management will have considerable discretion in the application of the net proceeds of this offering. We expect to use some of the net proceeds from this offering to expand our sales and marketing activities, to fund research and development relating to potential new products and to repay outstanding debt obligations of approximately \$3.3 million. We cannot specify with certainty how we will use all of the net proceeds of this offering or our existing cash balance. The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce income or that lose value.

**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 restated certificate of incorporation and restated bylaws to be in effect upon completion of this offering 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 restated certificate of incorporation, restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer, or proxy contest involving our company. Any delay

or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

**We do not intend to pay cash dividends.**

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

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

The statements contained in this prospectus, including under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other sections of this prospectus that are not purely historical, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future. Forward-looking statements in this prospectus may include, for example, statements about:

the expected rate and degree of market acceptance of the NC-stat System;

the expected size and growth of the market for nerve conduction studies and procedures using the NC-stat System;

our estimates regarding revenues, expenses, capital requirements and needs for additional financing;

implementation of our business strategies, including the expansion of our sales and marketing efforts;

our research, development, commercialization and other activities and projected expenditures;

the advantages of the NC-stat System as compared to other products, and our ability to compete with our competitors;

our ability to obtain regulatory approvals for any future products;

our intellectual property position;

our use of proceeds from this offering;

our cash needs; and

our financial performance.

The forward-looking statements contained in this prospectus 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 under the heading "Risk Factors." 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.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of \_\_\_\_\_ shares of common stock we are offering will be approximately \$ \_\_\_\_\_ million, based on an assumed initial public offering price of \$ \_\_\_\_\_ per share and after deducting the estimated underwriting discount and estimated offering expenses payable by us. If the underwriter's over-allotment option is exercised in full, we estimate that we will receive net proceeds of approximately \$ \_\_\_\_\_ million.

We intend to use the proceeds from this offering for:

the expansion of our sales and marketing activities, including an increase in our direct sales force;

research and development activities relating to potential new products, including the design of a drug development system for the minimally invasive treatment of neuropathies;

the repayment of outstanding debt obligations to Lighthouse Capital Partners IV, L.P. of approximately \$3.3 million; and

general corporate purposes, including potential acquisitions of complementary products, technologies or businesses, as described below.

Our debt obligations to Lighthouse Capital Partners were incurred in several advances between August 2003 and December 2003 under a secured line of credit, which we entered into in May 2003. The total amount of our borrowings was \$3.0 million and these borrowings bear interest at a nominal rate of 11% per annum. We used the proceeds from these borrowings for general corporate purposes. Under the terms of the agreement governing this secured line of credit, we must repay each advance, plus outstanding interest, in equal monthly installments beginning approximately six months after the date of the advance and continuing for a period of 30 months, or until the full amount of the principal is repaid. Upon the final maturity date or the earlier prepayment of each advance, we also must pay Lighthouse Capital Partners an additional amount equal to 11% of the advance. We also granted Lighthouse Capital Partners a seven-year warrant to purchase up to 400,000 shares of our Series E-1 preferred stock at an exercise price of \$1.50 per share as additional payment for the secured credit line. As of May 10, 2004, we had approximately \$2.9 million in advances outstanding under this secured line of credit, with final maturity dates ranging from August 2006 to December 2006.

Although we have no current plans, agreements or commitments with respect to any acquisition, we may, if the opportunity arises, use an unspecified portion of the net proceeds to acquire or invest in new products, technologies or businesses.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the status of our product development efforts, our sales and marketing activities, the amount of cash generated or used by our operations and competition. Accordingly, our management will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

Until we use the net proceeds of this offering for the above purposes, we intend to invest the funds in short-term, investment grade, interest-bearing securities. We cannot predict whether these investments will yield a favorable return.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, we intend to retain any earnings in our business, and we do not anticipate paying any cash dividends. Whether or not to declare any dividends will be at the discretion of our board of directors, considering then-existing conditions, including our financial condition and results of operations, capital requirements, business prospects and other factors that our board of directors considers relevant.

## CAPITALIZATION

The following table presents our cash and cash equivalents and capitalization as of December 31, 2003:

on an actual basis;

on a pro forma basis to give effect to the issuance of 7,050,771 shares of our Series E-1 preferred stock at \$1.50 per share for aggregate net proceeds of \$10.6 million, which occurred in March 2004; and

on a pro forma as adjusted basis to reflect: (1) the conversion of all outstanding preferred stock into 29,955,075 shares of common stock, which is to occur upon the closing of this offering, (2) the automatic conversion of an outstanding warrant to purchase 400,000 shares of our Series E-1 preferred stock into a warrant to purchase 400,000 shares of common stock upon the closing of this offering and (3) the sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, after deducting the estimated underwriting discount and estimated offering expenses payable by us and the application of those net proceeds as described under "Use of Proceeds," including the repayment of outstanding debt obligations to Lighthouse Capital Partners IV, L.P. of approximately \$3.3 million.

You should read this table together with our financial statements and related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

	As of December 31, 2003		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share data)		
Long-term debt, net of current portion	\$ 2,047	\$ 2,047	\$
Warrants for redeemable convertible preferred stock	450	450	
Redeemable convertible preferred stock, \$0.001 par value; 21,164,763 shares authorized, actual; 17,498,099 shares issued and outstanding, actual; 27,615,630 shares authorized, pro forma 24,548,870 shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	47,694	58,250	
Stockholders' deficit:			
Common stock, \$0.0001 par value; 30,000,000 shares authorized, actual; _____ shares authorized pro forma and pro forma as adjusted; 4,171,997 shares issued and outstanding, actual and pro forma; _____ shares issued and outstanding pro forma as adjusted			
Additional paid-in capital			
Subscriptions receivable	(2)	(2)	
Deferred compensation	(599)	(599)	
Accumulated deficit	(44,902)	(44,902)	
Total stockholders' deficit	(45,502)	(45,502)	
Total capitalization	\$ 4,689	\$ 15,245	\$

The number of shares of common stock outstanding after this offering is based on 4,171,997 shares outstanding as of December 31, 2003 on an actual basis and excludes:

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1,751,710 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2003 at a weighted average exercise price per share of \$0.45; and

400,000 shares of common stock issuable upon the exercise of an outstanding warrant as of December 31, 2003 at an exercise price per share of \$1.50, assuming the automatic conversion of the existing warrant to purchase 400,000 shares of our Series E-1 preferred stock into a warrant to purchase 400,000 shares of common stock, which is to occur upon the closing of this offering.



**DILUTION**

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share you will pay in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of December 31, 2003 was approximately \$(45.5) million, or \$(10.91) per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of common stock outstanding as of December 31, 2003.

Our pro forma net tangible book value per share as of December 31, 2003 was approximately \$0.39 per share. Pro forma net tangible book value per share gives effect to the conversion of all outstanding preferred stock, including the 7,050,771 shares of our Series E-1 preferred stock that we issued in March 2004 for \$1.50 per share with aggregate net proceeds to us of \$10.6 million, into 29,955,075 shares of common stock, which is to occur upon the closing of this offering, the automatic conversion of a warrant to purchase 400,000 shares of our Series E-1 preferred stock into a warrant to purchase 400,000 shares of common stock upon the closing of this offering and the repayment of outstanding debt obligations to Lighthouse Capital Partners IV, L.P. of approximately \$3.3 million.

After giving effect to the sale of the \_\_\_\_\_ shares of common stock we are offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, and after deducting the estimated underwriting discount and our estimated offering expenses, our pro forma as adjusted net tangible book value as of December 31, 2003 would have been approximately \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in pro forma net tangible book value of \$ \_\_\_\_\_ per share and an immediate dilution of \$ \_\_\_\_\_ per share to new investors. The following table illustrates this calculation on a per share basis:

Assumed initial public offering price per share	\$
Net tangible book value per share as of December 31, 2003	\$ (10.91)
Increase in net tangible book value per share attributable to conversion of preferred stock	11.30
	<hr/>
Pro forma net tangible book value per share of common stock as of December 31, 2003	0.39
Increase per share attributable to this offering	<hr/>
	<hr/>
Pro forma as adjusted net tangible book value per share of common stock after this offering	<hr/>
	<hr/>
Pro forma dilution per share to new investors	\$
	<hr/>

If the underwriter exercises its over-allotment option in full, pro forma as adjusted net tangible book value will increase to \$ \_\_\_\_\_ per share, representing an increase to existing holders of \$ \_\_\_\_\_ per share, and there will be an immediate dilution of \$ \_\_\_\_\_ per share to new investors.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2003, after giving effect to this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, and the pro forma adjustments referred to above, the total number of shares of our common stock purchased from

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us and the total consideration and average price per share paid by existing stockholders and by new investors:

	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percentage	Amount	Percentage	
Existing Stockholders	34,127,072	%	\$ 43,498,315	%	\$1.27
New Investors					
		100%		100%	

If the underwriter exercises its over-allotment option in full, the following will occur:

the pro forma as adjusted percentage of shares of our common stock held by existing stockholders will decrease to approximately % of the total number of pro forma as adjusted shares of our common stock outstanding after this offering; and

the pro forma as adjusted number of shares of our common stock held by new public investors will increase to , or approximately % of the total pro forma as adjusted number of shares of our common stock outstanding after this offering.

The tables and calculations above are based on 4,171,997 shares of our common stock outstanding as of December 31, 2003, on an actual basis, and exclude:

1,751,710 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2003 at a weighted average exercise price per share of \$0.45, and

400,000 shares of common stock issuable upon the exercise of an outstanding warrant as of December 31, 2003 at an exercise price per share of \$1.50, assuming the automatic conversion of the existing warrant to purchase 400,000 shares of our Series E-1 preferred stock into a warrant to purchase 400,000 shares of common stock, which is to occur upon the closing of this offering.

If all of our outstanding options and our outstanding warrant as of December 31, 2003 had been exercised as of that date, the pro forma as adjusted net tangible book value per share after this offering would be \$ per share and total dilution to new investors would be \$ per share.

## SELECTED FINANCIAL DATA

The selected financial data shown below for the years ended December 31, 2001, 2002 and 2003 and as of December 31, 2002 and 2003 have been derived from our financial statements audited by PricewaterhouseCoopers LLP, independent auditors, and included elsewhere in this prospectus. The selected financial data shown below for the years ended December 31, 1999 and 2000 and as of December 31, 1999, 2000 and 2001 have been derived from our financial statements not included in this prospectus. The selected financial data should be read in conjunction with our financial statements and related notes, "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," which are included elsewhere in this prospectus.

	Year Ended December 31,				
	1999	2000	2001	2002	2003
(in thousands, except for share and per share data)					
<b>Statement of Operations Data:</b>					
Revenues	\$ 112	\$ 979	\$ 3,464	\$ 4,225	\$ 9,168
Cost of revenues	133	634	1,424	1,370	2,707
Gross margin	(21)	345	2,040	2,855	6,461
Operating expenses:					
Research and development (1)	1,483	1,984	2,561	2,146	2,397
Sales and marketing (1)	1,331	3,477	5,304	2,870	4,768
General and administrative (1)	1,492	2,325	3,228	2,673	2,850
Total operating expenses	4,306	7,786	11,093	7,689	10,015
Loss from operations	(4,327)	(7,441)	(9,053)	(4,834)	(3,554)
Interest income (loss), net	476	459	335	40	(113)
Net loss	(3,851)	(6,982)	(8,717)	(4,793)	(3,667)
Accretion of dividend on redeemable convertible preferred stock	(1,058)	(1,104)	(1,757)	(1,893)	(2,009)
Deemed dividend on redeemable convertible preferred stock				(6,873)	
Net loss attributable to common stockholders	\$ (4,909)	\$ (8,086)	\$ (10,474)	\$ (13,559)	\$ (5,676)
Net loss per common share:					
Basic and diluted	\$ (1.33)	\$ (2.09)	\$ (2.62)	\$ (3.29)	\$ (1.37)
Weighted average basic and diluted common shares outstanding	3,685,978	3,869,748	4,001,305	4,116,865	4,155,305
Pro forma basic and diluted net loss per common share (2)				\$	(0.13)
Shares used in computing pro forma basic and diluted net loss per common share					27,211,157

(1) Non-cash stock-based compensation expense included in these amounts as follows:

Research and development	\$ 1	\$ 5	\$ 8	\$ 7	\$ 35
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Sales and marketing	4	10	15	6	37
General and administrative	58	37	33	37	24
	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>
Total non-cash stock-based compensation	\$ 63	\$ 52	\$ 56	\$ 50	\$ 96
	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>

(2) Pro forma basic and diluted net loss per common share is calculated assuming the conversion of all outstanding shares of preferred stock into shares of common stock, excluding 7,050,771 shares of our Series E-1 preferred stock issued in March 2004 and assuming the repayment of outstanding debt obligations to Lighthouse Capital Partners IV, L.P. of approximately \$3.3 million.

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As of December 31,

	1999	2000	2001	2002	2003
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(in thousands)

**Balance Sheet Data:**

Cash and cash equivalents	\$ 11,305	\$ 5,389	\$ 5,396	\$ 2,701	\$ 1,623
Working capital	11,084	4,996	6,380	3,724	2,754
Total assets	12,242	7,158	9,899	7,053	7,218
Long-term debt and other long-term liabilities	18	964	331	124	2,232
Warrants for redeemable convertible preferred stock					450
Redeemable convertible preferred stock	19,712	20,816	34,995	45,684	47,694
Accumulated deficit	(8,098)	(16,185)	(26,322)	(39,860)	(44,902)
Total stockholders' deficit	(7,983)	(16,014)	(26,431)	(39,928)	(45,502)

30

**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 selected financial data, our financial statements and the accompanying notes to those financial statements included elsewhere in this prospectus. 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 entitled "Risk Factors" and elsewhere in this prospectus, 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 the 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.

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. 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 2003, we more than doubled our revenues from the prior year, generating \$9.2 million in revenues, of which 85.8% was attributable to sales of the disposable biosensors that physicians use to perform tests with the NC-stat System. Our gross margin percentage in 2003 was 70.5%. In 2004, we introduced a new biosensor to test the ulnar nerve at the elbow, as well as components for the NC-stat monitor to utilize this biosensor.

We derive our revenues from the sale of NC-stat biosensors, monitors and docking stations directly to end users, which are generally physicians. 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. Our NC-stat biosensors are disposable products that are used once and inactivated after use. 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 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 receivables is probable 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.

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 and \$3.7 million in 2003, and we do not know whether or when we will become profitable. At December 31, 2003, we had an accumulated deficit of

approximately \$44.9 million. We have financed our operations through the private placement of equity and debt securities. At December 31, 2003, we had \$3.0 million of secured debt outstanding. As of December 31, 2003, we had received net proceeds of \$32.9 million from the issuance of redeemable convertible preferred stock. In March 2004, we sold an additional 7,050,771 shares of our Series E-1 redeemable convertible preferred stock to existing preferred stockholders with net proceeds to us of \$10.6 million.

Our financial objective is to achieve profitable growth. Our efforts in 2004 will be focused primarily on expanding our sales and marketing for the NC-stat System and continuing our ongoing program of making enhancements and improvements to the NC-stat System, including the introduction of new biosensors. 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. Executing these objectives is expected to require the hiring of additional sales personnel, additional investments in research and development and the introduction of new and enhanced product offerings, with the goal of increasing our market penetration.

## Results of Operations

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

	Year Ended December 31,		
	2003	2002	2001
<b>Revenues:</b>			
Diagnostic device	14.2%	17.1%	22.6%
Biosensor	85.8	82.9	77.4
<b>Total revenues</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>
<b>Cost of revenues</b>	<b>29.5</b>	<b>32.4</b>	<b>41.1</b>
<b>Gross margin</b>	<b>70.5</b>	<b>67.6</b>	<b>58.9</b>
<b>Operating expenses:</b>			
Research and development	26.1	50.8	73.9
Sales and marketing	52.0	67.9	153.1
General and administrative	31.1	63.3	93.2
<b>Total operating expenses</b>	<b>109.2</b>	<b>182.0</b>	<b>320.2</b>
<b>Loss from operations</b>	<b>-38.8</b>	<b>-114.4</b>	<b>-261.3</b>
<b>Interest income (expense), net</b>	<b>-1.2</b>	<b>1.0</b>	<b>9.7</b>
<b>Net loss</b>	<b>-40.0%</b>	<b>-113.4%</b>	<b>-251.6%</b>

## Comparison of Years Ended December 31, 2003 and December 31, 2002

## Revenues

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

	Year Ended December 31,		Change	% Change
	2003	2002		
Customers	1,736	1,390	346	24.9%
Biosensor units	203,000	116,200	86,800	74.7
(in thousands)				
<b>Revenues:</b>				
Diagnostic device	\$ 1,302.3	\$ 722.6	\$ 579.7	80.2
Biosensor	7,865.3	3,502.4	4,362.8	124.6
Total revenues	\$ 9,167.6	\$ 4,225.0	\$ 4,942.5	117.0

Diagnostic device revenues were \$1.3 million and \$722,600 in 2003 and 2002, respectively, representing a year-over-year increase of \$579,700, or 80.2%. Of this increase, approximately \$240,000 is attributable to a greater number of units sold, as a result of an increase in our regional sales managers and expanded clinical uses for the NC-stat System, and \$285,000 is attributable to an increase in the list price of our NC-stat monitors and docking stations. Diagnostic device revenues accounted for 14.2% and 17.1% of our total revenues in 2003 and 2002, respectively.

Biosensor revenues were \$7.9 million and \$3.5 million in 2003 and 2002, respectively, representing a year-over-year increase of \$4.4 million, or 124.6%. The increase was primarily due to an increased customer base for our biosensors, increased frequency of testing by our customers, and the introduction in May 2003 of higher functionality biosensors that test both motor and sensory nerve conduction. These biosensors have an average selling price that is 60-80% higher than our comparable motor-only biosensors. Our customers used 203,000 biosensor units in 2003, compared to 116,200 units in 2002, an increase of 86,800 units, or 74.7%. Biosensor revenues accounted for 85.8% and 82.9% of our total revenues in 2003 and 2002, respectively.

Our total revenues were \$9.2 million and \$4.2 million in 2003 and 2002, respectively, representing a year-over-year increase of \$4.9 million, or 117.0%. During 2003, we had a total of 1,736 customers using our NC-stat System, compared to 1,390 customers during 2002. This represents a 24.9% year-over-year increase in the number of customers using our NC-stat System.

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



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Costs and expenses

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

	Year Ended December 31,		Change	% Change
	2003	2002		
	(in thousands)			
<b>Cost of revenues:</b>				
Diagnostic device	\$ 658.1	\$ 420.1	\$ 238.0	56.7%
Biosensor	2,048.4	950.0	1,098.4	115.6
Total cost of revenues	2,706.5	1,370.1	1,336.4	97.5
<b>Gross margin:</b>				
Diagnostic device	644.2	302.5	341.7	113.0
Biosensor	5,816.8	2,552.4	3,264.4	127.9
Total gross margin	6,461.0	2,854.9	3,606.1	126.3
<b>Gross margin %:</b>				
Diagnostic device	49.5%	41.9%		
Biosensor	74.0	72.9		
Total gross margin %	70.5	67.6		
<b>Operating expenses:</b>				
Research and development (1)	\$ 2,396.8	\$ 2,146.1	\$ 250.7	11.7
Sales and marketing (1)	4,767.6	2,869.7	1,897.9	66.1
General and administrative (1)	2,850.5	2,672.7	177.8	6.7
Total operating expenses	10,014.9	7,688.5	2,326.4	30.3
Loss from operations	(3,553.9)	(4,833.6)	1,279.7	-26.5
Interest income	23.5	80.3	(56.8)	-70.7
Interest expense	(136.3)	(40.2)	(96.1)	239.1
Net loss	(3,666.7)	(4,793.5)	1,126.8	-23.5
Accretion on redeemable convertible preferred stock	(2,009.5)	(1,892.7)	(116.8)	6.2
Deemed dividend on redeemable convertible preferred stock		(6,872.9)	6,872.9	
Net loss available to common stockholders	\$ (5,676.2)	\$ (13,559.1)	\$ 7,882.9	-58.1

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

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Research and development	\$ 35.1	\$ 7.7
Sales and marketing	36.8	5.8
General and administrative	24.5	36.7
	<hr/>	<hr/>
Total non-cash stock-based compensation	\$ 96.4	\$ 50.2
	<hr/>	<hr/>

Gross Margin

Diagnostic device gross margin percentage was 49.5% and 41.9% in 2003 and 2002, respectively. The increase in the gross margin percentage in 2003 compared to 2002 is partially attributed to an increase in the list price of our NC-stat monitor and docking station, and partially to a decrease in third-party manufacturing costs resulting from a change in our supplier.

Biosensor gross margin percentage increased to 74.0% in 2003 from 72.9% in 2002. Our higher functionality biosensors, introduced in 2003, provide improved performance, resulting in lower overall warranty costs and higher gross margin. We believe that, as an increasing portion of our revenues are generated from these higher functionality biosensors, it will continue to have a positive impact on our overall biosensor margin in 2004.

Our overall gross margin percentage was 70.5% in 2003 compared to 67.6% in 2002. A favorable mix towards higher gross margin biosensor revenues in 2003 contributed to this increase in overall gross margin percentage, along with those factors discussed above.

At the beginning of 2004, we raised the list price of our NC-stat monitor and docking station by 40%. We anticipate that our overall gross margin percentage will continue to improve in 2004 as compared to 2003. However, if sales volumes do not increase, if biosensor revenues as a percent of total revenues do not increase, or if pricing pressures increase, then gross margin may be negatively impacted in 2004.

#### Research and Development

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

R&D expenses increased \$250,700, or 11.7%, to \$2.4 million in 2003 from \$2.1 million in 2002. As a percentage of revenues, R&D expenses were 26.1% and 50.8% in 2003 and 2002, respectively. The increase in expenses was due to the hiring of two additional employees in our R&D department and an increase in consulting and prototype costs related to new product development, including our two new biosensors introduced in 2003 and another biosensor introduced in the first half of 2004.

For 2004, we expect our spending on R&D will increase due to the hiring of additional personnel. We expect R&D expenses, as a percentage of total revenues, to continue to decrease slightly as revenues increase. This percentage may vary, however, depending primarily on our 2004 revenues.

#### Sales and Marketing

Sales and marketing expenses increased \$1.9 million, or 66.1%, to \$4.8 million in 2003 from \$2.9 million in 2002. As a percentage of revenues, sales and marketing expenses were 52.0% and 67.9% in 2003 and 2002, respectively. The increase in expenses was primarily due to the hiring of two additional employees in our sales and marketing functions, and to increased internal sales commissions and increased sales commissions to our independent regional sales agencies, which were directly related to our higher revenues in 2003. Because our independent regional sales agencies are compensated exclusively on a commission basis, their compensation is linked directly to our revenues. The compensation of our internal sales force is significantly dependent on meeting internal performance goals and, therefore, also linked to our revenues, although to a lesser degree.

We expect to hire additional sales and marketing personnel during 2004. For 2004, we expect sales and marketing expenses, as a percentage of total revenues, to remain reasonably consistent with 2003 levels. This percentage may vary, however, depending primarily on our 2004 revenues.

#### General and Administrative

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

General and administrative expenses increased \$177,800, or 6.7%, to \$2.9 million in 2003 from \$2.7 million in 2002. As a percentage of revenues, general and administrative expenses were 31.1% and 63.3% in 2003 and 2002, respectively. The increase in expenses was primarily due to salary increases and general cost increases in 2003. General and administrative staffing levels remained consistent during 2003 and 2002.

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

Interest Income

Interest income was \$23,500 and \$80,300 in 2003 and 2002, respectively. Interest income was earned from investments in cash equivalents and short-term investments (with maturities of 90 to 180 days). Interest income decreased in 2003 compared to 2002 because of lower average cash balances available for investment and lower yields on outstanding investment balances.

Interest Expense

Interest expense was \$136,300 and \$40,200 in 2003 and 2002, respectively, representing an increase of \$96,100 or 239.1%. The increase in interest expense was primarily due to increased borrowing under a new credit line obtained in May 2003.

As a result of applying part of the proceeds from this offering to repayment of the current credit line, we expect interest expense to be lower in 2004 as compared to 2003.

Deemed Dividend on Redeemable Convertible Preferred Stock

In 2002, we recorded a \$6.9 million deemed dividend as a result of the December 2002 Series E-1 redeemable convertible preferred stock financing and the anti-dilution provisions associated with the Series D and Series E redeemable convertible preferred stock. The \$6.9 million deemed dividend resulted from an adjustment to the conversion ratios as a result of anti-dilution protection associated with the Series D and Series E redeemable convertible preferred stock. There was no deemed dividend in 2003.

**Comparison of Years Ended December 31, 2002 and December 31, 2001***Revenues*

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

	Year Ended December 31,			
	2002	2001	Change	% Change
Customers	1,390	1,225	165	13.5%
Biosensor Units	116,200	73,900	42,300	57.2
	(in thousands)			
<b>Revenues:</b>				
Diagnostic device	\$ 722.6	\$ 782.5	\$ (59.9)	-7.7
Biosensor	3,502.4	2,681.9	820.5	30.6
Total revenues	\$ 4,225.0	\$ 3,464.4	\$ 760.6	22.0

Diagnostic device revenues were \$722.6 and \$782.5 in 2002 and 2001, respectively, representing a year-over-year decrease of \$59.9 or 7.7%. The decrease was due to a reduction in new customer device sales resulting from an approximately 50% reduction in the number of regional sales managers in 2002 compared to 2001, partially offset by an increase in device list price. Diagnostic device revenues contributed 17.1% and 22.6%, respectively, of our total revenues in 2002 and 2001.

Biosensor revenues were \$3.5 million and \$2.7 million in 2002 and 2001, respectively, representing a year-over-year increase of \$820,500, or 30.6%. The increase was mainly due to the expansion in our customer base and the increased frequency of testing by our customers, and partially due to the introduction of two new biosensors to our product line in July 2002. Our customers used 116,200 biosensor units in 2002, compared to 73,900 units in 2001, an increase of 42,300 units, or 57.2%. Biosensor revenues contributed 82.9% and 77.4%, respectively, of our total revenues in 2002 and 2001.



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Our total revenues were \$4.2 million and \$3.5 million in 2002 and 2001 respectively, representing an increase of \$760,700, or 22.0%. During 2002, we had a total of 1,390 customers using our NC-stat System, compared to 1,225 customers during 2001. This represents a 13.5% year-over-year increase in the number of customers using our NC-stat System.

### Costs and expenses

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

	Year Ended December 31,		Change	% Change
	2002	2001		
(in thousands)				
<b>Cost of revenues:</b>				
Diagnostic device	\$ 420.1	\$ 643.3	\$ (223.2)	-34.7%
Biosensor	950.0	781.0	169.0	21.6
	<u>1,370.1</u>	<u>1,424.3</u>	<u>(54.2)</u>	<u>-3.8</u>
<b>Total cost of revenues</b>				
<b>Gross margin:</b>				
Diagnostic device	302.5	139.2	163.3	117.3
Biosensor	2,552.4	1,900.8	651.6	34.3
	<u>2,854.9</u>	<u>2,040.0</u>	<u>814.9</u>	<u>39.9</u>
<b>Total gross margin</b>				
<b>Gross margin %:</b>				
Diagnostic device	41.9%	17.8%		
Biosensor	72.9	70.9		
Total gross margin %	67.6	58.9		
<b>Operating expenses:</b>				
Research and development (1)	\$ 2,146.1	\$ 2,561.0	\$ (414.9)	-16.2
Sales and marketing (1)	2,869.7	5,304.4	(2,434.7)	-45.9
General and administrative (1)	2,672.7	3,227.6	(555.0)	-17.2
	<u>7,688.5</u>	<u>11,093.0</u>	<u>(3,404.6)</u>	<u>-30.7</u>
<b>Total operating expenses</b>				
Loss from operations	(4,833.6)	(9,053.0)	4,219.5	-46.6
Interest income	80.3	388.7	(308.4)	-79.3
Interest expense	(40.2)	(53.3)	13.1	-24.6
	<u>(4,793.5)</u>	<u>(8,717.6)</u>	<u>3,924.2</u>	<u>-45.0</u>
Net loss	(4,793.5)	(8,717.6)	3,924.2	-45.0
Accretion on redeemable convertible preferred stock	(1,892.7)	(1,756.7)	(136.0)	7.7
Deemed dividend on redeemable convertible preferred stock	(6,872.9)		(6,872.9)	
	<u>(13,559.1)</u>	<u>(10,474.3)</u>	<u>(3,084.7)</u>	<u>29.5</u>
<b>Net loss available to common stockholders</b>				

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

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Research and development	\$	7.7	\$	8.6
Sales and marketing		5.8		14.8
General and administrative		36.7		32.7
		<u>          </u>		<u>          </u>
Total non-cash stock-based compensation	\$	50.2	\$	56.1
		<u>          </u>		<u>          </u>

37

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### Gross Margin

Diagnostic device gross margin percentage was 41.9% and 17.8% in 2002 and 2001, respectively. The increase in the gross margin percentage in 2002 compared to 2001 is primarily attributed to a 25% increase in the average list price of our NC-stat monitor and docking station.

Biosensor gross margin percentage increased to 72.9% in 2002 from 70.9% in 2001. This increase was primarily due to a reduction in the manufacturing cost of our biosensors during 2002.

Our overall gross margin percentage was 67.6% in 2002 compared to 58.9% in 2001. A favorable mix towards higher gross margin biosensor revenues in 2002 contributed to the increase in overall gross margin, along with those factors discussed above.

### Research and Development

In 2002 and 2001, our research and development expenses included expenses from research, product development, clinical, regulatory and quality assurance departments.

R&D expenses decreased \$414,900, or 16.2%, to \$2.1 million in 2002 from \$2.6 million in 2001. As a percentage of revenues, R&D expenses were 50.8% and 73.9% in 2002 and 2001, respectively. The decrease in R&D expenses was result of fewer personnel in our R&D functions.

### Sales and Marketing

Sales and marketing expenses decreased \$2.4 million, or 45.9%, to \$2.9 million in 2002 from \$5.3 million in 2001. As a percentage of revenues, sales and marketing expenses were 67.9% and 153.1% in 2002 and 2001, respectively. The decrease in expenses was primarily due to fewer sales and marketing personnel. The reduction in personnel resulted in decreased compensation, sales commission and employee benefits expenses included in the sales and marketing expenses for 2002.

### General and Administrative

In 2002 and 2001, our general and administrative expenses included expenses from general, finance and administrative, customer services and information technology departments.

General and administrative expenses decreased \$555,000 million, or 17.2%, to \$2.7 million in 2002 from \$3.2 million in 2001. As a percentage of revenues, general and administrative expenses were 63.3% and 93.2% in 2002 and 2001, respectively. Fewer personnel in 2002 as compared to 2001 resulted in decreased compensation and employee benefits expenses included in our general and administrative expenses.

### Interest Income

Interest income was \$80,300 and \$388,700 in 2002 and 2001, respectively. Interest income was earned from investments in cash equivalents and short-term investments (with maturities of 90 to 180 days). Interest income decreased in 2002 compared to 2001 because of lower average cash balances available for investment and lower yields on outstanding investment balances.

### Interest Expense

Interest expense was \$40,200 and \$53,300 in 2002 and 2001, respectively, representing a decrease of \$13,100 or 24.6%. The decrease in interest expense was primarily due to a decrease in borrowing.

### Deemed Dividend on Redeemable Convertible Preferred Stock

In 2002, we recorded a \$6.9 million deemed dividend as a result of the December 2002 Series E-1 redeemable convertible preferred stock financing and the anti-dilution provisions associated with the Series D and Series E redeemable convertible preferred stock. The \$6.9 million deemed dividend resulted from an adjustment to the conversion ratios as a result of anti-dilution protection associated



with the Series D and Series E redeemable convertible preferred stock. There was no deemed dividend in 2001.

*Liquidity and Capital Resources*

We commenced operations in June 1996 and have financed our operations since inception through the private placement of equity and debt. As of December 31, 2003, we have received aggregate net proceeds of \$32.9 million from the issuance of redeemable convertible preferred stock. As of December 31, 2003, we had \$3.0 million of secured debt outstanding. At December 31, 2003, we had \$1.6 million in cash and cash equivalents.

In March 2004, we sold an additional 7,050,771 shares of our Series E-1 redeemable convertible preferred stock to existing preferred stockholders for net proceeds of \$10.6 million. These shares will convert into shares of common stock upon the closing of this offering. These shares contain a beneficial conversion feature, as the estimated fair value of our common stock at the date of the sale is in excess of the conversion price associated with Series E-1 redeemable convertible preferred stock share price. The total value of the beneficial conversion feature of approximately \$8.5 million will be recognized in the form of a preferred stock dividend in the first quarter of 2004. In addition, we will recognize a dividend of approximately \$756,500 in the first quarter of 2004 as a result of an adjustment in the conversion rate of the Series D redeemable convertible preferred stock associated with anti-dilution provisions in connection with the March 2004 Series E-1 redeemable convertible preferred stock offering.

Cash and cash equivalents were \$1.6 million at December 31, 2003 compared to \$2.7 million at December 31, 2002, representing a decrease of \$1.1 million.

Cash used in operating activities was \$3.9 million in 2003 compared to \$4.6 million in 2002, representing a decrease of \$686,600. The decrease is primarily attributable to the reduction in net losses of \$1.1 million, and also attributable to an increase in accounts payable of \$329,400 and an increase in accrued compensation expense of \$303,900 associated with higher revenues. The decrease was partially offset by an increase in accounts receivable balances resulting from the significant growth in revenues, and by an increase in inventories associated with the new products introduced in 2003.

Cash used in investing activities was \$203,600 and \$29,900 in 2003 and 2002, respectively. The increase in investing activities is attributable to an increase in capital expenditures representing tooling costs for our new device manufacturer of the NC-stat monitor and docking station. Cash provided by financing activities was \$3.0 million and \$1.9 million in 2003 and 2002, respectively. The increase in cash from financing activities was due to the issuance of long-term debt provided by Lighthouse Capital Partners, as described below, was partially offset by a decrease in proceeds from the issuance of preferred stock.

In May 2003, we entered into a loan and security agreement with Lighthouse Capital Partners that provided us with a secured line of credit of up to \$3.0 million. This line of credit is secured by all of our tangible and intangible assets and was available to us through December 31, 2003. On December 31, 2003, we had a total outstanding balance of \$3.0 million under this secured line of credit as a result of several advances made between August 2003 and December 2003. We initially paid a \$10,000 commitment fee to obtain this line of credit and, in addition, we paid a facility fee of 1% of each advance on the date the advance was made. Our borrowings under this line of credit bear interest at a rate of 11% per annum. Under the terms of the loan and security agreement, we must repay each advance in equal monthly installments beginning approximately six months after the date of the advance and continuing for a period of 30 months, or until the full amount of the principal is repaid. Upon the final maturity date or the earlier prepayment of each advance, we also must pay the lender an additional amount equal to 11% of the advance. Additionally, in May 2003, we granted the lender a seven-year warrant to purchase up to 400,000 shares of our Series E-1 preferred stock at an exercise

price of \$1.50 per share as additional payment for the secured credit line. The warrant automatically converts into a warrant to purchase common stock at a one-for-one basis upon the closing of this offering. We intend to use a portion of the proceeds from this offering to prepay all amounts owed under this secured credit line.

In connection with our lease that we entered into with a term beginning January 1, 2001, we are required to maintain, for the benefit of the lessor, an irrevocable standby letter of credit stating the lessor as the beneficiary in the amount of \$1,860,000 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. The certificate of deposit is renewable in 30-day increments. The amount is classified as restricted cash in the balance sheet.

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

As of December 31, 2003, we have federal and state net operating loss carryforwards available to offset future taxable income of \$28.6 million and \$28.0 million, respectively, and federal and state research and development credits of \$302,000 and \$226,000, respectively, available to offset future taxes. The net operating loss and research and development credit carryforwards expire at various dates beginning in 2011 for federal and 2003 for state. Ownership changes in our company, as defined in the Internal Revenue Code, may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes. Subsequent changes in our ownership could further affect the limitation in future years.

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

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

As of December 31, 2003, we did not have any off-balance sheet financing arrangements.

The following table summarizes our principal contractual obligations as of December 31, 2003 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual Obligations	Payments due in				
	Total	2004	2005 and 2006	2007 and 2008	After 2008
Short- and long-term debt	\$ 3,540,000	\$ 949,000	\$ 2,591,000		
Operating lease obligations	4,762,500	810,000	1,860,000	\$ 1,860,000	\$ 232,500
<b>Total contractual cash obligations</b>	<b>\$ 8,302,500</b>	<b>\$ 1,759,000</b>	<b>\$ 4,451,000</b>	<b>\$ 1,860,000</b>	<b>\$ 232,500</b>

In addition to the above-listed items, we have entered into two separate license agreements. The first license agreement is with the Massachusetts Institute of Technology, or M.I.T. We have obtained a right to use certain technology through the term of the M.I.T.'s patent rights on such technology, which is exclusive for a period of 15 years from the date of the license agreement. In exchange, we issued shares of common stock to M.I.T. and are required to pay royalties of 2.15% of net sales of products incorporating the licensed technology. In addition, we are required to pay royalties ranging from 25% to 50% of payments received from sublicensees, depending on the degree to which the licensor's technology was incorporated into the products sublicensed by us. In addition, we are obligated to pay M.I.T. annual license maintenance fees. On or before December 31, 2002, we have paid M.I.T. annual license maintenance fees totaling \$50,000 in the aggregate. For each year after 2004, we are obligated

to pay M.I.T. annual license maintenance fees of \$75,000 if minimum sales requirements are not met. All annual license maintenance fees that we pay can be used to offset future royalties payable under the agreement. As of December 31, 2003, we were obligated to pay M.I.T. license maintenance fees of \$175,000 in 2004 covering 2002 through 2004. We have the right to terminate this license agreement at any time upon six months' notice. Through the year ended December 31, 2003, we have not incorporated this licensed technology into our products.

The second license agreement is with an unrelated third party. We obtained the right to use certain proprietary technology of this third party. This technology is used in the manufacture of our NC-stat biosensors. The term of this agreement is perpetual, subject to rights of termination. In exchange, we are required to pay the licensor \$50,000 every year for the first three years of the agreement. In subsequent years, we are required to pay \$10,000 per year as long as we continue to use the licensed technology. We paid \$10,000 during the year ended December 31, 2003. We have the right to terminate this license agreement upon written notice not later than 30 days prior to any anniversary date.

### **Critical Accounting Policies**

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ from those estimates, and any such differences may be material to our financial statements. We believe that the policies set forth below may involve a higher degree of judgment and complexity in their application than our other accounting policies and represent the critical accounting policies used in the preparation of our financial statements. If different assumptions or conditions were to prevail, the results could be materially different from our reported results. Our significant accounting policies are presented within Note 2 to our Financial Statements.

#### *Revenue Recognition*

Our revenue recognition policy is to recognize revenues from our monitor and biosensors upon shipment if the fee is fixed and determinable, persuasive evidence of an arrangement exists, collection of the resulting receivables is probable 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.

Revenue recognition involves judgments, including assessments of expected returns, allowance for doubtful accounts and expected customer relationship periods. We analyze various factors, including a review of specific transactions, our historical returns, average customer relationship periods, and market and economic conditions. Changes in judgments or estimates on these factors could materially impact the timing and amount of revenues and costs recognized. Should market or economic conditions deteriorate, our actual return or bad debt experience could exceed our estimate.

#### *Warranty Costs*

We accrue for device and biosensor warranty costs at the time of sale. While we engage in extensive product quality programs and processes, our warranty obligation is affected by product failure rates, user error, variability in physiology and anatomy of customers' patients, material usage and delivery costs. Should actual product failure and user error rates, material usage or delivery costs differ from our estimates, the amount of actual warranty costs could materially differ from our estimates.

### *Asset Valuation*

Asset valuation includes assessing the recorded value of certain assets, including accounts receivable, inventories and fixed assets. We use a variety of factors to assess valuation, depending upon the asset. Accounts receivable are evaluated based upon our historical experience, the age of the receivable and current market and economic conditions. Should current market and economic conditions deteriorate, our actual bad debt experience could exceed our estimate. The recoverability of inventories is based upon the types and levels of inventory held, forecasted demand, pricing, competition and changes in technology. Should current market and economic conditions deteriorate, our actual recovery could be less than our estimate.

### *Accounting for Income Taxes*

As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax exposure, including assessing the risks associated with tax audits, together with assessing temporary differences resulting from the different treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our balance sheet. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and to the extent we believe that recovery is more likely than not, do not establish a valuation allowance. In the event that actual results differ from these estimates, our provision for income taxes could be materially impacted.

### **New Accounting Pronouncements**

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

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

**Quantitative and Qualitative Disclosures about Market Risk**

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

## BUSINESS

We design, develop and sell 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. We believe that our neuropathy diagnostic system, the NC-stat System, improves the quality and efficiency of patient care by offering all physicians the ability to diagnose patients with neuropathies at the point of service; that is, in the physician's office at the time the patient is examined; resulting in earlier and more accurate detection, greater patient comfort and convenience, and improved clinical and economic outcomes.

Neuropathies traditionally have been evaluated by simple clinical examination by the primary care physician, and, in some cases, subsequently diagnosed by a nerve conduction study and needle electromyography, or 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 currently performed each year in the United States. We believe that use of traditional NCS/nEMG procedures is limited by the referral process and the resulting delay in availability of diagnostic information, the inconvenience and discomfort of these procedures for the patient, and the expense to the patient and third-party payer. 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 diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be as great as approximately 9.5 million annual patient tests, or over \$1.0 billion annually for our disposable biosensors, in the United States.

Our goal is to become the leading provider of innovative, proprietary, high margin medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies. To date, our primary focus has been on the diagnosis of neuropathies. We also believe that our core technology can be adapted and extended to provide minimally invasive approaches to treating neuropathies. We are in the early stages of designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians.

All of our current products have received 510(k) clearance by the FDA. The NC-stat System has been on the market since May 1999 and is presently used in over 1,700 physician's offices, clinics and other health care facilities. We hold issued utility patents covering a number of important aspects of our NC-stat System. In 2003, we more than doubled our revenues from the prior year, generating \$9.2 million in revenues, of which approximately 85.8% was attributable to sales of the disposable biosensors that physicians use to perform tests with our NC-stat System. Our gross margin percentage in 2003 was 70.5%. Since our inception, more than 210,000 patients have been tested with the NC-stat System.

### **Disorders of the Peripheral Nerves and Spine**

#### *The Nervous System*

The nervous system is a collection of interconnected specialized cells called neurons, supported by other complementary cells. The basic function of the nervous system is to convert physical stimuli into neural signals, to process these neural signals, and to generate an appropriate motor response. The classic reflex obtained by tapping on the knee and eliciting a mild kick is a simple example of this function.

The nervous system is divided into the central nervous system, or CNS, and the peripheral nervous system, or PNS. The CNS is comprised of the neurons in the brain and spine, while the PNS consists of neurons and related elements outside the spine and within the extremities, such as the hands or feet.

Neurons, which are the primary components of the nervous system, typically have three elements: (1) the dendrites, or input region; (2) the cell body, where the cell nucleus resides; and (3) the axon, or output region. The dendrites and the cell body of most neurons reside within the CNS (e.g., in the spine), while the axons may reside within the CNS, the PNS or both. The axon carries information from one neuron to another or to a muscle. Axons can exceed one meter in length yet represent the same cell. The term "nerve" generally refers to a collection of axons encased within a common sheath. Axons combine into nerves in the extremities that are considered part of the PNS.

All neurons, and particularly their axons, are highly susceptible to metabolic or mechanical damage and have limited regenerative ability. Disorders of the nervous system lead to symptoms which can range from numbness and weakness in the extremities if confined to the PNS, to changes in cognition, speech and personality if the CNS is involved.

#### *Neuropathies*

Disorders of the nerves are broadly described by the term neuropathies. There are two basic types of neuropathies, those that are focal in nature and those that are systemic. Focal neuropathies are typically caused by a compression of one or more specific nerves. Systemic neuropathies are typically caused by a metabolic disturbance that results in widespread damage to nerves throughout the body. The most common clinical conditions associated with neuropathies include:

*Diabetes.* Diabetes is a disease in which the body either does not produce or does not properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily body function. Diabetes often results in a high level of glucose in the blood, called hyperglycemia. Chronic hyperglycemia is associated with complications of diabetes including nerve, eye and kidney disease. The most common form of diabetes-related nerve disease is a systemic neuropathy called diabetic peripheral neuropathy, or DPN. The symptoms of DPN include impaired sensation or pain in the feet and hands. The American Diabetes Association currently estimates that 60% to 70% of people with diabetes are affected by DPN, although a majority of these individuals are unaware of their nerve disease because they have no symptoms. Clinical studies have demonstrated that nerve conduction studies can detect DPN in cases where symptoms are not present. DPN, if left undiagnosed and unmanaged, can result in the development of lower extremity ulcers and, in severe cases, amputation.

*Low back pain.* Low back pain can have many causes. When low back pain has a neurological source, it is often focal in nature and associated with pain that radiates from the lower back region into the leg, called sciatica. In some cases, the patient may also experience loss of sensation and weakness in the lower leg. In advanced cases, these symptoms can become disabling. The symptoms result from pressure on the nerve roots, the precursors of the nerve, as they exit the spine. The source of the pressure is usually part of an intervertebral disc that is displaced from its normal location between the vertebral bodies. These disorders are often called herniated or ruptured discs.

*Carpal tunnel syndrome.* Carpal tunnel syndrome, or CTS, is caused by swelling of the tendons that traverse the wrist alongside the median nerve. The swollen tendons compress the median nerve, resulting in damage to the nerve that leads to numbness in the first three fingers of the hand, weakness in the thumb, and occasionally wrist and hand pain. CTS is the most common focal neuropathy.

*Other medical conditions associated with neuropathies.* Common chronic disorders such as obesity; rheumatoid arthritis; and spinal stenosis, or narrowing of the spinal canal; are commonly associated with neuropathies. In these complicated cases, it is particularly important to confirm or exclude neuropathies in order to develop effective treatment programs.

*Nerve damage caused by chemotherapy.* A number of widely used chemotherapeutic agents are toxic to nerves. Unfortunately, by the time patients report symptoms, significant nerve damage has often already occurred.

## Market Opportunity

The sensitivity of the nervous system to metabolic and mechanical damage, compounded by its limited regenerative ability, creates a robust market opportunity for a medical device that can produce point-of-service diagnoses of neuropathies in a manner that is cost-effective for the patient and third-party payer. We believe the ease of use, accuracy and convenience provided by the NC-stat System position it to become a standard of care for the assessment of neuropathies at the point of service. We believe that the availability of point-of-service nerve conduction studies, through the NC-stat System, will result in earlier detection of neuropathies, leading to earlier therapeutic intervention and improved clinical and economic outcomes. We believe that use of traditional NCS/nEMG procedures is limited by the referral process and the resulting delay in availability of diagnostic information, the inconvenience and discomfort of these methods for the patient, and the expense to the patient and third-party payer. Our policy is to promote and support the utilization of nerve conduction studies in a manner strictly consistent with prevailing guidelines on the medically appropriate use of this diagnostic procedure. We estimate that there are approximately two million traditional NCS/nEMG procedures currently performed each year in the United States. 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 patient data, we estimate that the potential market size for the NC-stat System in diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be as great as approximately 9.5 million annual patient tests, or over \$1.0 billion annually for our disposable biosensors, in the United States. However, market size is difficult to predict and we cannot assure you that our estimates will prove to be correct. We believe that additional applications of the NC-stat System, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this potential market size. Additionally, although we have not yet quantified the size of the market, we believe a significant international market opportunity exists for the NC-Stat System.

## Assessment and Treatment Methods for Neuropathies

### *Traditional Methods for Detecting Neuropathies*

Neuropathies traditionally have been evaluated using clinical and diagnostic methods. The clinical examination of a patient with a potential neuropathy focuses on the nature, location and duration of the symptoms. The physician will also perform a physical examination of the patient to corroborate and qualify the patient's symptoms. In many cases, the physician will use simple instruments such as a reflex hammer or a tuning fork. Although the clinical examination is essential to the evaluation of the patient with a potential neuropathy, it has a number of important disadvantages, including the following:

*It is qualitative.* A clinical examination provides qualitative rather than quantitative information, and results can vary greatly depending on the physician performing the examination. In this respect, it has limited use as an objective and repeatable measure of disease.

*It is subjective.* Much of the clinical examination relies on the patient experiencing and reporting symptoms or perceptions. As a result, it depends greatly on the investigative efforts of the physician in interviewing the patient, is highly variable because of individual differences in recollection and discomfort thresholds, and requires an alert, cooperative patient. Because of the subjective nature of the clinical examination, the results must be interpreted cautiously.

*It often does not detect pre-clinical or early stage disease.* Because the clinical examination relies on the patient reporting symptoms or physical signs of disease, the physician typically cannot



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detect early stage disease with this evaluation. The progressive nature of neurological damage is such that pre-clinical or early detection creates the optimal opportunity for intervention and successful clinical outcomes.

The limitations of the clinical examination in detecting and monitoring neuropathies suggest that an objective and quantitative diagnostic procedure would be of value for many patients. The role of an objective diagnostic procedure in a patient at risk for a neuropathy or experiencing common symptoms of a neuropathy, such as numbness, unusual sensations, pain and weakness, is shown in the diagram below.

The cause of symptoms in many of these patients will not be disorders of the nervous system, but rather arthritic pain, musculo-skeletal disturbances, inflammatory conditions, psychiatric disorders and others. The importance of an objective diagnostic procedure in this type of patient is to determine if the patient does in fact have a neuropathy, and if so, of what type and severity. Only with this information can appropriate therapy be determined.

The principal diagnostic method used today to assess patients with or at risk for neuropathies is a traditional nerve conduction study and a needle electromyography, or nEMG. Traditional nerve conduction studies and nEMGs are distinct studies and can be performed independently, but are collectively described as traditional NCS/nEMG procedures. In a traditional nerve conduction study, electrodes are placed on the patient's skin surface and the physician performing the study electrically stimulates the nerve, evoking a neural impulse that travels along the nerve, thereby enabling the physician to measure a series of nerve conduction parameters. In an nEMG, recording needles are inserted through the skin's surface into a muscle and the physician performing the study reviews the electrical activity of those muscles. From these data, the physician can determine whether or not the patient has a neuropathy, and if so, its characteristics and severity. The traditional nerve conduction study, in some cases combined with an nEMG, is considered by most physicians to be the "gold standard" in terms of diagnostic accuracy for most neuropathies.

*Limitations of Traditional Diagnostic Methods*

Traditional NCS/nEMG procedures have a number of limitations, which together have generally resulted in these procedures not being performed until late in patients' care episodes. These limitations include the following:

*Referral process.* Traditional NCS/nEMG procedures typically are performed under a referral from a primary care physician to a neurologist. This process may lead to loss of control of the patient's care by the primary care physician, higher expense for the patient and third-party payer, and the likely delay and inconvenience for the patient associated with a separate office visit to a new physician.

*Expense.* When the patient visits a new physician under a referral for the purpose of a traditional NCS/nEMG procedure, the physician is less familiar with the patient's medical history and condition than the primary care physician. Therefore, these physicians may need to perform more extensive testing consisting of multiple nerves and muscles. Because of the breadth of these studies, the cost per study can exceed \$1,000 per patient, which leads to greater expense for the patient and third-party payer.

*Equipment.* The equipment used to perform a traditional NCS/nEMG procedure is a complex and expensive electromedical apparatus that typically ranges in cost from \$15,000 to \$40,000. For this reason, it is generally only purchased by neurologists and physicians in related specialties, who expect high utilization to offset this cost.

*Complexity.* Traditional procedures require familiarity with equipment and engineering principles that most physicians do not acquire during their medical training. This fact, combined with high equipment cost, has meant that only a small number of physicians, such as neurologists and physicians in related specialties, perform testing under traditional methods, making this type of testing not generally widely available.

*Discomfort.* The traditional NCS/nEMG procedure is considered uncomfortable or painful by most patients. In particular, the nEMG component can be very painful because it involves a physician inserting needles into specific muscles of the patient, often in close proximity to the site of pain. Patients are sometimes therefore reluctant to undergo these procedures, and neuropathies may go undiagnosed.

*Current Methods for Treating Neuropathies*

Addressing the limitations of traditional methods for detecting neuropathies is important because of the expanding number of treatments for common neuropathies currently under development. We believe earlier and more accurate detection of neuropathies would allow more patients to benefit from these treatments, which include the following:

*Diabetic Peripheral Neuropathy.* Optimal clinical management of DPN is based on earliest possible detection so as to limit the degree of nerve damage. At the present time, most people with diabetes are evaluated for DPN with simple clinical procedures that generally do not identify the disease in its early stages. Although treatment options for DPN are presently limited, there are interventions designed to slow down the progression of nerve degeneration and to minimize the complications of the nerve disease. Current interventions consist primarily of increased attention to the individual's blood glucose through monitoring and administration of insulin and other medications. In addition, greater attention to the existence and progression of foot ulcers that are often triggered by nerve disease has been shown to be valuable in preventing amputation. A number of pharmaceutical companies and researchers are investigating and developing drugs specifically designed to treat DPN. The following table summarizes the leading

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drug development programs in DPN known to us, as described, for each company, in current publicly available information released by that company.

Company Name	Drug Name	Status
Eli Lilly and Company	ruboxistaurin mesylate	U.S. Phase III clinical trial
Sanwa Kagaku Kenkyusho Co., Ltd., Sankyo Co., Ltd., and NK Curex	fidarestat	U.S. Phase II clinical trial
Dainippon Pharmaceutical Co., Ltd.	AS-3201	U.S. Phase II clinical trial
Johnson & Johnson	topiramate	Approved in the United States as anticonvulsant; studies being conducted to determine efficacy in the treatment of DPN
Vitaris GmbH	a-lipoic acid	Approved in Germany; studies being conducted to determine efficacy in the treatment of DPN

*Sciatica.* The widespread incidence of low back pain and intense discomfort associated with the condition makes the detection of true sciatica difficult. However, treatment decisions require a clear delineation between those patients that have non-neuropathic back pain, such as muscle strains or spasms, and those that have underlying neuropathies. Mild sciatica may be treated with non-steroidal anti-inflammatory drugs, or NSAIDs, rest and physical therapy. More advanced sciatica is often treated with steroid injections and eventually a minimally invasive or more involved surgical procedure may be required.

*Carpal Tunnel Syndrome.* Mild CTS is treated conservatively using wrist splints, NSAIDs, and physical and occupational therapy. Moderate to severe CTS is treated by injecting steroids into the carpal tunnel in the immediate vicinity of the median nerve, or ultimately by a surgical procedure called a carpal tunnel release, or CTR. Most physicians and third-party payers require confirmation of median nerve damage by a nerve conduction study, like that performed using the NC-stat System, prior to performing CTR. According to the Centers for Disease Control and Prevention, or CDC, over 350,000 CTR procedures were performed in 1997.

### NEUROMetrix Solution

Recognizing the opportunity created by the limitations of traditional diagnostic methods coupled with the availability of current and potential new treatments for certain neuropathies, NEUROMetrix has developed the NC-stat System for the performance of non-invasive nerve conduction studies at the point of service. Our proprietary technology provides physicians with an in-office diagnostic system that enables physicians to make rapid and accurate diagnoses that are cost-effective for the patient and third-party payer. We believe that the NC-stat System represents a significant advance in neurological diagnostics and offers an improvement over traditional diagnostic procedures with the following benefits:

*Facilitates performance of nerve conduction studies at the point of service.* The complexity and high capital cost of traditional diagnostic methods generally has limited their use to neurologists and physicians in related specialties. We believe the features of the NC-stat System facilitate the performance of nerve conduction studies within the offices of a wide range of physicians. By moving nerve conduction studies to the primary care physician's office, the patient can avoid the expense and inconvenience of a referral visit to a neurologist. Additionally, the NC-stat System

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enables primary care physicians to retain greater control over their patients by eliminating the need to refer them out for a traditional NCS/nEMG procedure.

*Provides a cost-effective diagnostic tool.* We believe that the NC-stat System should reduce the cost to the patient and the third-party payer of many nerve conduction studies. This belief is based on our observation that when these procedures are performed by the physician with primary clinical responsibility for the patient, the study is more directed so that generally fewer nerves are tested without compromising the accuracy of the diagnosis. A study performed in this manner can result in a lower cost to the patient and the third-party payer.

*Requires minimal capital investment.* We sell the NC-stat System, which has equivalent technical specifications to the more expensive traditional instruments, for under \$5,000, which is less than a third of the cost of traditional NCS/nEMG equipment. We believe the lower capital cost of the NC-stat System will aid in the expansion of nerve conduction studies beyond neurologist offices.

*Simple to operate.* The NC-stat biosensors are designed for ease in placement, which allows a wide range of physician office personnel to administer the technical parts of the study under supervision of a physician. The NC-stat monitor utilizes software algorithms that perform each step of a nerve conduction study in a reliable manner, with embedded automation technology that addresses and minimizes the technical training requirements for performing nerve conduction studies, while also ensuring that the end diagnostic result is accurate and reliable. We believe that, in combination, these features allow accurate and reliable nerve conduction studies to be performed in 10 to 20 minutes on average.

*Patient-friendly, non-invasive procedure.* The NC-stat System allows for reduced patient discomfort during the nerve conduction study by minimizing the magnitude of the electrical stimulus to the nerve via a proprietary patient-specific calibration procedure. In most cases, the sophisticated signal processing and automation capabilities of the NC-stat System provide sufficient diagnostic information to eliminate the need for an nEMG procedure. This saves the patient the discomfort, stress and risk of this invasive procedure. The non-invasive nature and convenient features of the NC-stat System also facilitate repeat testing in patients to demonstrate response to treatment interventions.

We believe point-of-service testing will expand the use of nerve conduction studies to include at-risk individuals who may have early-stage neuropathies but may not be experiencing symptoms, a population that would be unlikely to be tested under the current inconvenient, expensive referral system. Because traditional NCS/nEMG procedures are typically not performed until late in patients' care episodes, permanent nerve damage may have already occurred, which may limit treatment options. We believe that more widespread use of nerve conduction studies would lead to earlier detection of neuropathies. Clinical studies published in peer-reviewed medical journals have demonstrated that nerve conduction studies conducted with the NC-stat System result in comparable accuracy to traditional NCS/nEMG procedures, as described below in "Clinical Studies." By incorporating nerve conduction studies early in patients' care episodes through the use of the NC-stat System, we expect better long-term clinical and economic outcomes will emerge because of the ability to implement available preventive care based on accurate early diagnostic results.

### **The NC-stat System**

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 to transmit data to our onCall Information System. The onCall Information System formulates the data it receives for each test into a detailed report that is sent to the physician via facsimile or e-mail in three to four minutes on average and aids in the physician's diagnosis. The NC-stat System enables the physician to make rapid and accurate diagnoses that are cost-effective for the patient and third-party payer.

*NC-stat biosensors.* The NC-stat biosensors are single use, self-adhesive, nerve-specific, patch-like devices that are placed on the body and connected to the NC-stat monitor. Through the use of a specialized gel and a temperature sensor, both of which are contained within the biosensor, NC-stat biosensors convert nerve signals to electronic data that can be received and displayed by the NC-stat monitor. Currently we sell seven different types of biosensors:

Median motor;

Median motor and sensory;

Ulnar motor at wrist;

Ulnar motor and sensory;

Combination ulnar motor and sensory at wrist and ulnar at elbow;

Peroneal; and

Tibial.

The biosensors are designed to be positioned according to common anatomical landmarks with a configuration that facilitates correct placement. We designed the sensors so that they could be easily applied with minimal training by members of a physician's office staff. The biosensors are encoded with a unique electronic serial number, which allows us to track each biosensor throughout the manufacturing, shipping and end-use stages. The biosensors also are electronically inactivated after use, thus preventing re-use. This inactivation is essential since prior use of the biosensor adhesive and specialized gel would significantly degrade the quality of the measurements. In a typical nerve conduction study, multiple nerves are evaluated and multiple biosensors are used according to general guidelines established by CMS and physician associations.

The table below provides sample testing protocols for several common clinical indications.

<b>Clinical Indication</b>	<b>Specific Biosensors Utilized</b>	<b>Total Number of Biosensors Utilized</b>	<b>Price of Biosensors Utilized</b>
Diabetic peripheral neuropathy	Peroneal Motor (2) Median Motor/Sensory (1)	3	\$ 110
Low back pain with bilateral sciatica	Peroneal Motor (2) Tibial Motor (2)	4	\$ 120
Bilateral carpal tunnel syndrome	Median Motor/Sensory (2) Ulnar Motor/Sensory (2)	4	\$ 180

*NC-stat monitor.* The NC-stat monitor is designed for efficient and easy use by the physician or a member of the physician's clinical staff. The NC-stat monitor can only be operated with our NC-stat biosensors. This instrument, which is lightweight and slightly larger than a cordless telephone, customizes and calibrates the test for each patient, analyzes neurophysiological signals collected from the biosensor and displays the pertinent results on an LCD screen immediately at the conclusion of each nerve conduction study. It also stores data from multiple patients for optional transmission to the onCall Information System. We also sell optional related components that allow for the testing of long nerve segments, such as those between the elbow and wrist or the knee and foot. The monitor is powered for several months by two AA batteries. The NC-stat monitor contains software that performs all the control and analysis algorithms necessary to carry out a nerve conduction study. A complete nerve conduction study may be performed with just the monitor and the biosensors.

*NC-stat docking station and onCall Information System.* The NC-stat docking station is an optional device that automatically transmits data from the NC-stat monitor via any available telephone line, such as those used by facsimile machines, to the onCall Information System that we maintain. The docking station has its own data storage so it does not lose data if the telephonic connection to the onCall Information System cannot be established for some time or is disrupted during transmission.

The data is processed and analyzed by the onCall Information System and stored in a central database, and a detailed report is generated for each patient that is then sent to the physician via facsimile or e-mail in three to four minutes on average. The report includes the raw waveform data, comparisons to an age- and height-adjusted normal range population, study reference table and text summaries of the study, which facilitate rapid and accurate diagnosis by the physician examining the patient. Although the study data presented in the onCall report can be generated manually by the physician using the numerical measurements displayed by the NC-stat monitor, the report is a convenient and fast alternative. Whether using the information from the onCall report or the NC-stat monitor display, the actual clinical interpretation of the NC-stat results is always performed by the physician ordering the study. The onCall Information System can also provide daily, monthly and quarterly reports to customers. These reports provide assistance in correct submission for third-party reimbursement and assist in tracking overall clinical utilization. The onCall Information System generally is available 24 hours per day, seven days per week. Although purchase of the NC-stat docking station and utilization of the onCall Information System are entirely optional, we believe substantially all of our customers use this system in all studies they conduct with the NC-stat System. We currently have a record of over 500,000 individual nerve studies within the onCall information system database. We believe that this information provides us with the ability to continually improve our products and provide our customers with a very high level of customer service and value.

## Strategy

Our goal is to become the leading provider of innovative, proprietary, high margin medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies. To achieve this objective, we are pursuing the following business strategies:

*Establish the NC-stat System as a Standard of Care.* Our primary objective is to establish the NC-stat System as the standard of care for point-of-service assessment of neuropathies. To accomplish this goal, we dedicate significant efforts to the development of marketing and educational materials that encourage the medically appropriate use of the NC-stat System by a broad range of physicians. We also support clinical studies that are designed to demonstrate the clinical accuracy and cost-effectiveness of the NC-stat System.

*Expand Sales and Marketing Efforts.* We currently sell our products through 15 regional managers who are our direct employees. We invest significant amounts of time and money in technical, clinical and business practices training for our regional managers. We also have established a sales network with more than 50 independent regional sales agencies employing a total of more than 250 sales representatives. Our regional managers utilize sales agencies to identify selling opportunities and to assist in the ongoing servicing of our customers, in order to enhance and leverage their selling efforts. We intend to hire more direct regional managers and expand the number of independent sales agencies and representatives selling our products, in order to increase the market penetration of our products. Based on our experience, there has been a direct relationship between the number of regional managers we employ and the number of NC-stat Systems we sell.

*Focus on Primary Care Market.* We intend to capitalize on the trend towards the utilization of more sophisticated diagnostic and therapeutic procedures by primary care physicians. To achieve this goal, we have expended and are continuing to expend significant resources to establish a physician office distribution channel. This channel focuses on primary care physicians, comprising general internists, family practice physicians, rheumatologists and endocrinologists. By offering our system to primary care physicians, we are also capitalizing on the trend towards convenient and efficient medical care created by having multiple clinical services provided within one facility.

*Strengthen Our Presence within Selected Specialty Markets.* We intend to continue to strengthen our presence within specific physician specialty markets that are complementary to our major focus on the primary care market. These markets provide both revenue opportunities and additional product validation within the marketplace. We believe that the orthopedic, neurology, pain medicine and occupational medicine markets represent the most suitable specialty markets for expansion.

*Continue to Introduce New Products.* We believe that one of our strengths is our ability to develop and commercialize innovative products for neurological applications. We have an ongoing program of making enhancements and improvements to the NC-stat System, including the introduction of new biosensors. We also are in the early stages of designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. These potential new products build upon our mission of enhancing the clinical and business practices of our customers. We believe that these potential new products will improve patient care, allowing us to generate more revenues at attractive margins from our existing customer base, as well as to attract new customers.

## Market Size

We estimate that there are approximately two million traditional NCS/nEMG procedures currently performed each year in the United States. We anticipate that the advantages and increased availability of the NC-stat System will significantly increase the number of nerve conduction studies performed.

*We estimate the potential diabetic peripheral neuropathy, or DPN, market could be as great as six million annual NC-stat patient tests.* The number of individuals with diabetes in the United States was estimated to be 18.2 million, or 6.3% of the population, in 2002. Among this group, 5.2 million were undiagnosed. According to the CDC, there are about 26 million annual patient visits to office-based physicians for diabetes. We anticipate that the increasing focus on early detection and prevention of the chronic complications of diabetes will lead to increased nerve conduction studies for DPN. We believe that the estimated 50% rate of annual foot exams in patients known to have diabetes is a reasonable estimate for the addressable testing market in diabetes. If these examinations were replaced by a nerve conduction study, or a nerve conduction study were added to the examination, the diabetes arena would represent an opportunity for over six million annual NC-stat patient tests.

The number of Americans with diabetes is projected to more than double over the next 40 to 50 years. At the present time, there are no treatments targeted specifically at DPN, and therefore nerve conduction studies are performed on a selective basis in order to address specific clinical issues. If a targeted therapy for DPN were successfully developed and marketed, we believe the rate of testing would further increase. Based on current clinical trial activity, we anticipate that drugs for the treatment of DPN will become increasingly available in the marketplace over the next few years, accelerating the need to detect DPN at its earliest stages to allow for earlier therapeutic intervention and a decrease in the adverse clinical and economic

outcomes associated with DPN. We believe that the NC-stat System is uniquely suited to provide physicians with this diagnostic capability.

*We estimate the potential low back pain market could be as great as three million annual NC-stat patient tests.* Low back pain is one of the most common medical conditions in the United States. Over 63 million people report experiencing at least one day of serious low back pain in the prior three months. Furthermore, back disorders account for over one quarter of all nonfatal occupational injuries and illnesses that result in days away from work. According to the CDC, there are about nine million annual patient visits to office-based physicians specifically for low back symptoms. The CDC further estimates that about one-third of office visits are initial visits, at which time we believe utilization of the NC-stat System is most likely. We thus anticipate that there may be as many as approximately three million testing opportunities for the NC-stat System related to low back pain. We believe that the number of testing opportunities may be even higher, as there are many patients that visit physicians for symptoms and medical conditions that must be differentiated from sciatica, such as leg and foot symptoms, rheumatoid arthritis and diabetes.

*We estimate the potential carpal tunnel syndrome market could be as great as 650,000 annual NC-stat patient tests.* CTS is a significant occupational issue, as the disorder results in the most days away from work among all major disabling workplace injuries and illnesses. In a recent health care survey published in the Journal of the American Medical Association, approximately 14% of adults reported symptoms characteristic of CTS. It was further estimated that 2.5% of adults have true CTS, which could be confirmed by clinical examination and nerve conduction studies. This is equivalent to approximately five million individuals in the United States. Over 350,000 surgeries are performed annually for CTS. The surgical procedure is called a carpal tunnel release, or CTR. Most third-party payers require a nerve conduction study prior to authorizing the surgery. According to the CDC, there are more than two million annual visits to office-based physicians for which CTS is the primary diagnosis. The CDC further estimates that about one third of CTS-related office visits are initial visits, at which time we believe utilization of the NC-stat System is most likely. We thus anticipate that there may be as many as 650,000 testing opportunities for the NC-stat System related to CTS. We further believe that this estimate is conservative, as there are many patients that visit physicians for hand and wrist pain, or medical conditions with a high association with CTS such as rheumatoid arthritis, diabetes and obesity. We also anticipate that the high costs of CTS-related workers' compensation claims could motivate employers to increasingly use the NC-stat System to pre-screen and monitor employees for CTS.

Based on the data outlined above, we estimate that the potential market size for the NC-stat System in the diabetes, low back pain and CTS markets in the aggregate could be as great as approximately 9.5 million annual patient tests in the United States. The NC-stat biosensor revenue generated per patient test typically exceeds \$110, with variations depending on the specific clinical application. Using this conservative revenue estimate of \$110 per patient test, we estimate that the potential market for NC-stat biosensors could be over \$1.0 billion annually in the United States. However, market size is difficult to predict and we cannot assure you that our estimates will prove to be correct. We believe that additional applications of the NC-stat System, including the clinical assessment of patients with neuropathies caused by or associated with other clinical disorders, could further increase this market size. Additionally, although we have not yet quantified the size of the market, we believe a significant international market opportunity exists for the NC-stat System.



## Clinical Studies

The performance of the NC-stat System has been substantiated in clinical studies that we have supported, the results of which have been published in peer-reviewed medical journals or presented at major medical conferences.

In studies published in the April 2000 issue of the *Journal of Occupational & Environmental Medicine*, the September 2000 issue of *Neurology and Clinical Neurophysiology*, and the May 2004 issue of the *Journal of Hand Surgery*, the correlation between the results generated by the NC-stat System and traditional nerve conduction studies in measuring nerve function of 198 patients was examined. The correlation was equivalent to that found between different neurologists performing traditional nerve conduction studies.

Two abstracts to be presented at the American Diabetes Association Meeting in June 2004 outline the results of a study of 1,000 patients with diabetes. In this study, the NC-stat System was found to detect DPN at the same level and stage as would have been expected from traditional NCS/nEMG procedures.

A study published in the December 2002 issue of *Spine* evaluated the ability of the NC-stat System to detect neurological impairment in 25 patients with sciatica, confirmed by MRI and clinical examination. The diagnostic accuracy of the NC-stat System was equivalent to traditional NCS/nEMG procedures as documented in several other published studies.

We continue to support well-designed clinical research studies utilizing the NC-stat System that are designed to demonstrate its clinical accuracy and cost-effectiveness. In addition, several clinical studies and trials have been performed, and others are underway, in which the NC-stat System is used to measure changes in nerve function.

## Products Under Development

### *Devices for the Treatment of Neuropathy*

In pursuit of our objective to develop medical devices that provide comprehensive solutions for the diagnosis and treatment of patients with neuropathies, we are seeking to expand our product base beyond the diagnostic and into the treatment arena. We believe that our core technology can be adapted and extended to provide minimally invasive approaches to treating neuropathies. In particular, we believe that neuropathies that are focal in nature can be safely and effectively treated if drugs can be delivered near the disease site without damaging the nerve in the process. Some of these types of treatments are performed today, but they are performed manually by a limited number of physicians. Our product development program includes the design of a product that we believe will reduce the risk involved in providing these treatments. We are in the early stages of designing this product to enable a broad base of physicians to provide this type of minimally invasive neuropathy therapy at the point of service.

### *NC-stat System*

We have an ongoing program of making enhancements and improvements to the NC-stat System. We are developing new NC-stat biosensors and associated software for the medically appropriate testing of additional nerves, including a biosensor for the sural nerve that we expect to introduce by the end of 2004. We also are developing our third generation NC-stat monitor and docking station with an improved user interface, along with new features for the onCall Information System, that allow our customers to perform more complex analyses of diagnostic data. In addition, we continually seek ways to reduce the manufacturing costs and improve the performance of the NC-stat biosensors.

## **Sales, Marketing & Distribution**

Our sales team is led by our Chief Operating Officer. We presently employ 15 regional sales managers who lead more than 50 independent regional sales agencies employing a total of more than 250 independent sales representatives. At present, our products are marketed and distributed solely within the United States. We select our sales agencies and representatives based on their expertise and experience calling on primary care or specialty physicians, their reputation within the targeted physician community and their sales coverage. Each sales agency is assigned a sales territory for the NC-stat System and is subject to periodic performance reviews. Our current operating practice is to limit coverage overlap within most regions. Through this, we believe we gain a more focused sales approach and more dedicated sales agency organization.

We invest significant efforts in technical, clinical and business practices training for our regional managers. We work closely with our sales agencies and their sales representatives in order to provide them with the information and assistance that they need in order to successfully sell our products. We also require each sales representative to attend periodic sales and product training programs. The efforts of our regional sales managers and independent sales representatives are enhanced by proprietary software tools that are accessed via a secure website, which we refer to as the sales and sales partner portals respectively. These portals give our sales personnel access to real time customer sales and product usage information, various applications to help identify and close new business, and marketing materials. The portals also provide customer relationship management functions. Our corporate management and reimbursement team has access to the same information, as well as portal usage information by all sales personnel.

We market our products directly to physicians. The NC-stat System provides primary care physicians, who previously were not performing a nerve conduction study at the point of service or were referring these patients to a neurologist for a traditional NCS/nEMG procedure, with a potential new source of revenues. We believe that this potential revenue stream is an essential marketing advantage of the NC-stat System. We also market our products at various industry conferences in order to accelerate the market awareness of our products, our customer accrual efforts and market adoption for our products.

We invoice products directly to physician offices and other customers, typically at list prices. The independent regional sales agencies and their sales representatives are compensated by commissions that we pay directly to them. Our regional managers are compensated by a combination of base salary, commission and goal-based bonus compensation.

As we launch new products and increase our marketing efforts with respect to existing products, we intend to expand the reach of our marketing and sales force. We plan to accomplish this by increasing the number of direct regional managers and independent sales agencies and representatives. The establishment and development of a broader sales force will be expensive and time consuming. Because of the intense competition for their services, we may be unable to enter into agreements with additional qualified independent sales agencies and representatives on commercially reasonable terms or at all. Even if we are able to enter into agreements with additional independent sales agencies, these parties may not commit the necessary resources to effectively market and sell our products or ultimately be successful in selling our products. Promotion and sales of medical devices are also highly regulated not only by the FDA, but also by the Federal Trade Commission, and are subject to federal and state fraud and abuse enforcement activities.

## **Manufacturing and Supply**

We rely on outside contractors for the manufacture and servicing of our products and their components and we do not currently maintain alternative manufacturing sources for the NC-stat monitor, docking station or biosensors or any other finished goods products. In outsourcing, we target

companies that meet FDA, International Organization for Standardization, or ISO, and other quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a corrective action program ensuring all product requirements are met or exceeded. We believe these manufacturing relationships minimize our capital investment, provide us with manufacturing expertise and help control costs.

Following the receipt of products or product components from our third-party manufacturers, we conduct the necessary inspection and packaging and labeling at our corporate headquarters facility. We may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it appropriate to do so. We currently have no plans to manufacture any products or product components internally.

We seek to obtain products from our manufacturers in order to maintain sufficient inventory to satisfy our customer obligations. We did not experience any inventory shortages on any established products in 2003. We occasionally experience transient inventory shortages, typically lasting less than one month, on new products during the initial production ramp-up phase. We are currently working with our third-party manufacturers to increase manufacturing capabilities to meet the demand we expect as we increase our sales efforts. Manufacturers often experience difficulties in scaling-up production, including problems with production yields and quality control and assurance. If our third-party manufacturers are unable to manufacture our products to keep up with demand, we would not meet expectations for growth of our business.

Polyflex Circuits, Inc., a wholly owned subsidiary of the Parlex Corporation, has been manufacturing NC-stat biosensors under general purchase orders since early 1999. While our relationship with Polyflex Circuits is good, we have no supply agreement in place with Polyflex, and it could cease manufacturing NC-stat biosensors at any time. We have identified alternative suppliers capable of manufacturing NC-stat biosensors should this become necessary. However, if we are forced to engage an alternative supplier, we may incur additional expense, higher cost per unit, delays in delivery and quality control problems.

Advanced Electronics, Inc., or AEI, has been manufacturing our NC-stat monitors and docking stations since November 2002. In October 2003, we entered into a one-year contract manufacturing agreement with AEI that automatically renews each year unless either party elects not to renew the agreement upon 90 days' prior written notice. The current term of the agreement expires in November 2004. Both AEI and NEUROMetrix have been performing to the terms of the agreement; however, AEI could cease manufacturing NC-stat monitors and docking stations for us when the current term of the agreement expires. We have identified alternative suppliers capable of manufacturing the NC-stat monitor and docking station should this become necessary. However, if we are forced to engage an alternative supplier, we may incur additional expense, higher cost per unit, delays in delivery and quality control problems.

We and our third-party manufacturers are registered with the FDA and subject to compliance with FDA quality system regulations. We are also ISO registered and undergo frequent quality system audits by European agencies. Our products are cleared for market within the United States and Canada, and are also approved for distribution in the European Union, although to date we have sales only in the United States. Our facility and the facilities of our manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. We experienced an FDA inspection in May 2003. During its inspection, the FDA issued a Form 483, which is a notice of inspection observations. Two minor items were identified and the corrective action for both were initiated prior to the completion of the audit. The responses provided to the FDA were deemed adequate and no further action has been requested. As a registered device manufacturer, we and our manufacturers will undergo regularly scheduled FDA

quality system inspections; however, additional FDA inspections may occur if deemed necessary by the FDA.

### **Information Technology Infrastructure**

Our information technology infrastructure is designed to support the requirements of our onCall Information System. The onCall Information System employs a high performance, scalable platform consisting of standard hardware, off-the-shelf system software components, database servers, proprietary application servers, a modem bank and desktop applications. The in-bound infrastructure consists of telephone lines and proprietary communications gateway software to collect data from the remote NC-stat Systems. The gateway assembles the data sent from each remote NC-stat System, stores it and queues it for processing by our proprietary software. The processing infrastructure consists of proprietary software to process each nerve conduction study. The out-bound infrastructure consists of a proprietary report server application and a fax and email server that is an off-the shelf product.

The onCall Information System utilizes sophisticated expert system technology to provide real-time quality control monitoring and reporting of nerve conduction study results. onCall's applications include:

a communications gateway for receiving test files and updating the software of remote NC-stat Systems;

a relational database server to store and retrieve nerve conduction studies;

an application server to analyze and maintain the nerve conduction study data;

an application server to format and produce nerve conduction reports;

a fax and email server to send reports to remote users; and

a client application that is designed to monitor quality and service customer requests.

The application servers and client applications use a common set of software components that form the onCall class library.

The onCall Information System is physically secured in our restricted-access computer room at our facilities in Waltham, Massachusetts. Our computer facility's electrical power is backed up with auxiliary power in the event of a power outage. Automated backups of the databases and computer files are maintained both on- and off-site. We also maintain a lock box at an off-site location that contains copies of the business continuity plan and application server software vital to the operation of the onCall Information System that will be needed in a disaster recovery situation.

### **Research and Development**

Our research and development efforts are focused in the near term on further enhancing our existing products and developing the third generation NC-stat monitor and docking station and new biosensors, as well as designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. Our research and development staff consists of 12 people, including four who hold Ph.D. degrees. Our research and development group has extensive experience in neurophysiology, biomedical instrumentation, signal processing, biomedical sensors and information systems. These individuals work closely with our marketing group, our clinical support group (led by a board-certified neurologist), our scientific advisors and our customers to design products that are intended to improve clinical and economic outcomes.

## Customer Service and Clinical Support

Our customer service group consists of four representatives. These representatives are available by telephone 12 hours per day, five days per week to address a wide range of technical questions from customers on the use of the NC-stat System, respond to customer requests for product and clinical materials that have been released by our marketing department, take orders, and provide customers with order status information. Our customer service representatives receive specialized ongoing product and clinical training. We also maintain a clinical support group consisting of three individuals. Our clinical support group is available to address questions from our customers relating to test results and use of our products. This group is led by a board-certified neurologist, who is a full-time employee of ours.

## Intellectual Property

We rely on a combination of patents, trademarks, copyrights, trade secrets and other intellectual property laws, nondisclosure agreements and other measures to protect our proprietary technology, intellectual property rights and know-how. We hold issued utility patents covering a number of important aspects of our NC-stat System. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, developed using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

### *Patents*

As of May 10, 2004, we had 11 issued U.S. patents, one issued Australian patent and 17 pending patent applications, including 10 U.S. applications and seven foreign national applications. We also hold an exclusive license to two issued U.S. patents and two foreign national applications. The issued and pending patents that we own and license cover, among other things:

Nerve conduction biosensors and related methods;

Nerve conduction hardware;

Algorithms for performing and analyzing nerve conduction studies; and

NC-stat System industrial design.

Our issued design patents begin to expire in 2015, and our issued utility patents begin to expire in 2017. In particular, seven of our issued U.S. utility patents covering important aspects of our current products will expire on the same date in 2017. Although the patent protection for material aspects of our products covered by the claims of the patents will be lost at that time, we have additional patents and patent applications directed to other novel inventions that will have patent terms extending beyond 2017.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on

our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of these potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

As the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. Although we have not received notice of any claims, and are not aware, that our products infringe other parties' patents and proprietary rights, our products and methods may be covered by U.S. patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

A patent infringement suit brought against us may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party's intellectual property, unless that party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

#### *Trademarks*

We hold domestic and certain foreign trademark registrations for the marks NEUROMETRIX and NC-STAT. The U.S. registration for NEUROMETRIX is on the Supplemental Register. We also use onCall as a trademark but have not sought its registration in the United States or any foreign countries.

#### **Competition**

We consider the primary competition for our products to be traditional NCS/nEMG procedures. Our success depends in large part on convincing physicians to adopt the NC-stat System in order to perform nerve conduction studies at the point of service.

There are a number of companies that sell traditional NCS/nEMG equipment, typically to neurologists. These companies include the Nicolet Biomedical division of Viasys Healthcare Inc., the Functional Diagnostics division of Medtronic, Inc., Oxford Instruments, Plc., and Cadwell Laboratories, Inc. Viasys Healthcare, Medtronic and Oxford Instruments have substantially greater financial resources than we do, and they have established reputations as worldwide distribution channels for medical instruments to neurologists and other physicians. We do not know if these companies are engaged in research and development efforts to develop products to perform point-of-service nerve conduction studies that would be competitive with the NC-stat System. We are aware of one company, Neumed Inc., that markets a nerve conduction study system to the point-of-service market.

We believe that among systems marketed for performance of nerve conduction studies today, only the NC-stat System provides both the level of diagnostic accuracy and the ease of use required for successful penetration of the point-of-service market. We also believe that the reporting and data repository functions provided by the onCall Information System, although entirely optional, provide our customers who use this service with significant added clinical and economic value that is not matched by other currently marketed products. We further believe that the expanding database of nerve conduction study data captured by the onCall Information System facilitates our ability to improve the performance of the NC-stat System. We anticipate that the size of our database and ongoing improvements provide us with a significant competitive advantage.

### **Third Party Reimbursement**

We anticipate that sales volumes and prices of our products will continue to be dependent in large part on the availability of reimbursement from third-party payers. Third-party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers' compensation plans. These third-party payers may deny reimbursement for a diagnostic procedure if they determine that the diagnostic test was not medically appropriate or necessary. The third-party payers may also place limitations on the types of physicians that can perform specific types of diagnostic procedures. Also, third-party payers are increasingly challenging the prices charged for medical products and services. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that procedures performed using our products will be reimbursed as separate procedures under existing Current Procedural Terminology, or CPT, codes, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

A key component in the reimbursement decision by most private insurers and CMS, which administers Medicare, is the assignment of a CPT code. This code is used in the submission of claims to insurers for reimbursement for medical services. CPT codes are assigned, maintained and revised by the CPT Editorial Board administered by the American Medical Association, or AMA. According to present Medicare guidelines, nerve conduction studies may be performed by medical doctors, or M.D.s, and doctors of osteopathic medicine, or D.O.s, and are reimbursable under the three CPT codes: 95900, 95903, and 95904. We believe that the nerve conduction measurements performed by the NC-stat System meet the requirements stipulated in the code descriptions published by the AMA and that these codes are currently used by physicians performing nerve conduction studies with the NC-stat System. If the CPT codes that apply to the procedures performed using our products are changed, reimbursement for performances of these procedures may be adversely affected.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use our products.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis.

The unavailability or inadequacy of third-party payer coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition.

## **FDA and Other Governmental Regulation**

### *FDA Regulation*

Our products are medical devices subject to extensive regulation by the FDA under the U.S. Food, Drug, and Cosmetic Act, as well as other regulatory bodies. FDA regulations govern, among other things, the following activities that we or our contract manufacturers perform and will continue to perform to ensure that medical devices distributed domestically or exported internationally are safe and effective for their intended use:

product design and development;

product testing;

product manufacturing;

product labeling;

product safety;

product storage;

pre-market clearance or approval;

advertising and promotion;

production; and

product sales and distribution.

The FDA classifies medical devices into one of three classes on the basis of the controls deemed necessary to reasonably ensure their safety and effectiveness:

Class I, requiring general controls, including labeling, device listing, reporting and, for some products, adherence to good manufacturing practices through the FDA's quality system regulations and pre-market notification;

Class II, requiring general controls and special controls, which may include performance standards and post-market surveillance; and

Class III, requiring general controls and pre-market approval.

Before being introduced into the market, our products must obtain market clearance through either the 510(k) pre-market notification process, the *de novo* review process or the pre-market approval process.



510(k) Pre-Market Notification Process

To obtain 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use, safety and effectiveness to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not yet required the submission of a pre-market approval application. In some cases, we may be required to perform clinical trials to support a claim of substantial equivalence. It generally takes from three to 12 months from the date of submission to obtain 510(k) clearance, but it may take longer.

After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires a new 510(k) clearance or could require *de novo* classification or pre-market approval. The FDA allows each company to make this determination, but the FDA can review the decision. If the FDA disagrees with a company's decision not to seek FDA authorization, the FDA may retroactively require the company to seek 510(k) clearance, *de novo* classification or pre-market approval. The FDA also can require the company to cease marketing until 510(k) clearance, *de novo* classification or pre-market approval is obtained or take other action.

#### De Novo Review Process

If a previously unclassified medical device does not qualify for the 510(k) pre-market notification process because there is no predicate device to which it is substantially equivalent, and if the device may be adequately regulated through general controls or special controls, the device may be eligible for *de novo* classification through what is called the *de novo* review process. In order to use the *de novo* review process, a company must receive a letter from the FDA stating that, because the device has been found not substantially equivalent to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not yet required the submission of a pre-market approval application, it has been placed into Class III. After receiving this letter, the company, within 30 days, must submit to the FDA a request for *de novo* classification into Class I or II. The FDA then has 60 days in which to approve or deny the *de novo* classification request. If the FDA grants *de novo* classification, the device will be placed into either Class I or Class II, and allowed to be marketed. If a product is classified into Class I or II through the *de novo* review process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

#### Pre-Market Approval Process

If a medical device does not qualify for the 510(k) pre-market notification process and is not eligible for clearance through the *de novo* review process, a company must file a pre-market approval application. The pre-market approval process generally requires more extensive pre-filing testing than is required in the 510(k) pre-market notification process and is more costly, lengthy and uncertain. The pre-market approval process can take one to three years or longer. The pre-market approval process requires the company to prove the safety and effectiveness of the device to the FDA's satisfaction through extensive submissions, including pre-clinical and clinical trial data, and information about the device, its design, manufacture, labeling and components. Before granting pre-market approval, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the FDA's quality system regulations. After any pre-market approval, a new pre-market approval application or application supplement may be required in the event of modifications to the device, its labeling, intended use or indication, or its manufacturing process.

#### Clinical Studies

A clinical study is almost always required to support a pre-market approval application and is sometimes required to obtain 510(k) clearance. These trials generally require submission to the FDA of an application for an investigational device exemption, or IDE, if a medical device presents a "significant risk" as defined by the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. If a medical device is considered a "non-significant" risk, an IDE application to the FDA is not required. Instead, only approval from the Institutional Review Board overseeing the clinical trial is required. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the appropriate institutional review boards at the clinical study sites. All

clinical studies must be conducted in accordance with FDA regulations and federal regulations concerning human subject protection and healthcare privacy. The results of our clinical testing may not support or may not be sufficient to obtain approval of our product.

#### NC-stat System

The NC-stat System has received four 510(k) clearances as a Class II medical device, the first of which was received in 1998, and the most recent (K013459) in January 2002. The NC-stat System has the following intended use:

*The NEUROMetrix NC-stat is intended to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.*

We believe that this intended use is consistent with the manner in which the NC-stat System is marketed and used by our customers. Since we received our most recent 510(k) clearance for the NC-stat System in January 2002, we have enhanced the NC-stat System by making changes to the software it employs. We do not believe that these changes require new 510(k) clearances. We further believe that the addition of new indications and enhancements to the NC-stat System in the future either will not require new FDA authorization or will be able to be cleared using the 510(k) pre-market notification process.

#### Post-market Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

quality system regulations, which require manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and

medical device reporting regulations, which require that manufacturers, which term includes companies such as us that create the specifications for the regulated products, report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Also, we are subject to unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our contractor manufacturers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refund, recall or seizure of our products;

operating restrictions, suspension or shutdown of production;

refusing our request 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 already have been granted; and

criminal prosecution.

*International Regulations*

International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

The primary regulatory environment in Europe is that of the European Union, which consists of 25 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive are entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but may involve self-assessment by the manufacturer, a third-party assessment by a Notified Body, which is a third-party organization appointed by a member of the European Union, or some combination thereof. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body in one country within the European Union generally is required in order for a manufacturer to distribute the product commercially throughout the European Union. In 2000, we were certified by TUV Product Service, a Notified Body, under the European Union Medical Device Directive allowing the CE conformity marking to be applied to the NC-stat System. We had a successful renewal audit in 2003.

*U.S. Anti-Kickback and False Claims Laws*

In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of medical devices, such as us, and hospitals, physicians and other potential purchasers of medical devices. Other provisions of state and federal law provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. Although we plan to structure our future business relationships with purchasers of our products to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by federal or state enforcement officials under these laws. This type of challenge could have a material adverse effect on our business, financial condition and results of operations.

*Health Insurance Portability and Accountability Act of 1996 and Related Laws*

Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under 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 protected 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, we nevertheless seek to comply with a number of these rules. We believe that we are not in violation of federal or state health information privacy or confidentiality statutes or regulations.

However, if we are found to have violated any of these laws, we could be subject to civil or criminal penalties. Additionally, changes in these laws could adversely affect our business.

**Employees**

We currently employ 51 people, of which eight are employed in operations, 12 in research and development, six in clinical and regulatory, 21 in sales and marketing and four in general and administrative. Two employees hold both M.D. and Ph.D. degrees, four additional employees hold Ph.D. degrees and one additional employee holds an M.D. degree. None of our employees is represented by a labor union and we believe our employee relations are good.

**Facilities**

Our operations are headquartered in an approximately 30,000 square foot facility in Waltham, Massachusetts that is leased to us until March 31, 2009. We believe that our existing facility is adequate for our current needs.

**Legal Proceedings**

We are not currently party to any material legal proceedings.

**SCIENTIFIC ADVISORY BOARD**

Our scientific advisory board provides specific expertise in the areas of research and development, clinical applications and physician education relevant to our business. Scientific advisory board members meet with our scientific, clinical and marketing management personnel from time to time to discuss our present and long-term activities in these areas. Our scientific advisory board members include:

*Joseph C. Arezzo, Ph.D.* is Professor, Departments of Neuroscience and Neurology at Albert Einstein College of Medicine. Dr. Arezzo is a leading neurophysiologist and an internationally recognized thought leader in the use of nerve conduction studies to track systemic and toxic neuropathies. He has extensive experience in the evaluation of new treatments to prevent or reverse the progression of neuropathic disease.

*Robert L. Goldberg, M.D.* is Associate Clinical Professor of Medicine at University of California, San Francisco, Division of Occupational and Environmental Medicine. Dr. Goldberg is a past President of the American College of Occupational and Environmental Medicine. Dr. Goldberg's work in the UC Ergonomics Program is currently focused on research and education in ergonomics and the prevention and medical management of work-related musculoskeletal disorders (MDSs). He is a Co-Principal Investigator of a four-year NIOSH-supported study on Upper Extremity MSDs in the workplace.

*Thomas J. Graham, M.D.* is Chief, Hand Surgery; Vice Chairman, Orthopaedics; and Director at The Curtis National Hand Center. Dr. Graham is also Vice-Chairman of Orthopaedic Surgery at Union Memorial Hospital, Clinical Associate Professor of both Orthopaedic and Plastic Surgery at Johns Hopkins University, and the Medical Director of the Washington Redskins. Dr. Graham's expertise includes surgery of the hand, wrist and elbow, with a concentration on difficult reconstructions.

*James W. Strickland, M.D.* is Clinical Professor of Orthopaedic Surgery at Indiana University School of Medicine. Dr. Strickland is a past President of the American Society for Surgery of the Hand and of the American Academy of Orthopaedic Surgeons. He has authored or edited nine hand surgery textbooks and published over 170 scientific articles. His research interests include nerve compression disorders, tendon reconstruction and restoration following arthritic conditions.

*Mark Upfal, M.D.* is Corporate Medical Director at Detroit Medical Center, Department of Occupational Health Services and Associate Professor at Wayne State University, where he developed its residency training program in occupational medicine. Dr. Upfal is board certified in Occupational Medicine and serves on the Board of Directors of the American College of Occupational and Environmental Medicine (ACOEM). He chairs the ACOEM Academic Council, as well as the Examination Development Committee for the Medical Review Officer Certification Council.

*Dr. Aaron I. Vinik, M.D., Ph.D., FCP, FACP* is Professor of Internal Medicine and Pathology/Neurobiology, Director, Strelitz Diabetes Research Institutes, Eastern Virginia Medical School. Dr. Vinik is an internationally acclaimed expert on diabetic neuropathy and is the author of numerous papers on this subject. Dr. Vinik is actively involved in basic research on the molecular basis of diabetic neuropathy and also in the clinical management of patients with diabetes.

## MANAGEMENT

The following table shows information about our executive officers and directors as of May 10, 2004.

Name	Age	Position
Shai N. Gozani, M.D., Ph.D.	40	President, Chief Executive Officer and Director
Gary L. Gregory	41	Chief Operating Officer
Guy Daniello	59	Senior Vice President of Information Technology
Michael Williams, Ph.D.	48	Senior Vice President of Engineering
Nicholas J. Alessi	33	Director of Finance
David L. Douglass	52	Director
Charles E. Harris	61	Director
William Laverack, Jr.	47	Director

*Shai N. Gozani, M.D., Ph.D.* founded our company in 1996 and currently serves as Chairman of our board of directors and as our President and Chief Executive Officer. Since founding our company in 1996, Dr. Gozani has served in a number of positions at our company including Chairman since 1996, President from 1996 to 1998 and from 2002 to the present and Chief Executive Officer since 1997. Dr. Gozani holds a B.S. degree in Computer Science, an M.S. degree in Biomedical Engineering and a Ph.D. in Neurobiology, from the University of California, Berkeley. He also received an M.D. from Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences at M.I.T. Prior to forming our company, Dr. Gozani completed a neurophysiology research fellowship in the laboratory of Dr. Gerald Fischbach at Harvard Medical School. Dr. Gozani has published articles in the areas of basic and clinical neurophysiology, biomedical engineering and computational chemistry.

*Gary L. Gregory* has served as our Chief Operating Officer since July 2003 and, prior to that time, as our Executive Vice President, Worldwide Sales since July 2002. From 2001 to 2002, Mr. Gregory served as Senior Vice President of Sales & Marketing for PrimeSource Healthcare, Inc., a manufacturer and distributor of specialty medical devices. From 1994 to 2001, Mr. Gregory held a number of senior roles within Johnson & Johnson and its Cordis Divisions, including Director of Strategic Marketing for its Corporate Division which represents all of its Medical Device businesses, Director of Sales where he co-directed its Cardiology Sales organization, and Director of Corporate Accounts where he built the Corporate Account Department and business spanning all of the Cordis Divisions. From 1989 to 1994, Mr. Gregory held a number of management positions at Baxter Healthcare, within Baxter's CardioVascular Group where he advanced from Sales to Marketing to Corporate Accounts to Sales Management. Mr. Gregory holds a B.S. degree in Economics from the Pennsylvania State University.

*Guy Daniello* has served as our Senior Vice President of Information Technology since July 2003, and prior to that time, as our Vice President of Information Technology and Director of Information Technology since 1998. Prior to joining NeuroMetrix, Mr. Daniello was an independent software consultant, the Senior Vice President of Engineering at Shiva Corporation from 1996 to 1997, and the Chief Technology Officer & Vice President of Product Development at Gandalf Technologies from 1993 to 1996. In 1991 he founded Network Architects, a software company. Prior to starting Network Architects, he served as President and CEO of Datamedia Corp. and the Director of Small Systems Development at Honeywell Information Systems. Mr. Daniello holds a B.S. in business administration from Northeastern University.

*Michael Williams, Ph.D.* has served as our Senior Vice President of Engineering since July 2003 and, prior to that time, as our Vice President of Engineering since May 2000. From March 1996 to



January 2000, Dr. Williams served as Division President at Radionics, where he was responsible for all software-based products, including treatment planning and image-guided surgery. Prior to Radionics, he served as an engineer at Hughes Aircraft Space & Communications Group. Dr. Williams received a B.S. from University of Puget Sound and M.S. and Ph.D. degrees in Physics from Brown University.

*Nicholas J. Alessi* has served as our Director of Finance since March 2004 and, prior to that time, as our Corporate Controller since November 2000. From 1999 to 2000, Mr. Alessi worked as Controller for TriPath Imaging, Inc. (formerly AutoCyte, Inc.), a publicly traded manufacturer of medical devices and related consumables. From 1995 to 1999, Mr. Alessi worked as a certified public accountant with Ernst & Young, LLP in its Entrepreneurial Services group, where he specialized in emerging and growth-stage companies in the high-tech, healthcare and software industries. Mr. Alessi received a B.A. from the College of the Holy Cross, and an M.S. in Accounting and an M.B.A. from the Graduate School of Professional Accounting at Northeastern University.

*David L. Douglass* has served as a member of our board of directors since 1999. Since 1990, Mr. Douglass has been a General Partner with Delphi Ventures, a venture capital firm, focusing on healthcare investments. From 1986 until 1990, Mr. Douglass was a General Partner at Matrix Partners, a venture capital firm, focusing on healthcare investments. From 1984 to 1986, Mr. Douglass served as Chief Operating Officer at Paladin Software Corporation, responsible for operations, research and development, finance and administration. From 1979 to 1983, Mr. Douglass served as Vice President of Finance and Administration at Collagen Corporation, where he was responsible for several private equity financings, as well as Collagen's initial public offering. Before joining Collagen, Mr. Douglass was a consultant with McKinsey & Company, a business consulting firm. Mr. Douglass received his M.B.A. and M.A. from Stanford University and his B.A., *cum laude*, from Amherst College in 1974.

*Charles E. Harris* has served as a member of our board of directors since 1997. Since 1984, Mr. Harris has served as Chairman and Chief Executive Officer of Harris & Harris Group, Inc., a publicly traded venture capital company. Prior to 1984, he served as Chairman of Wood, Struthers and Winthrop Management Corp., the investment advisory subsidiary of Donaldson, Lufkin & Jenrette. Mr. Harris currently serves as a Trustee and Chairman of the Audit Committee of Cold Spring Harbor Laboratory, a private not-for-profit institution that conducts research and education programs in the fields of molecular biology and genetics, and as a Trustee and Chairman of the Audit Committee of the Nidus Center, a life sciences business incubator, and he is a life-sustaining fellow of the Massachusetts Institute of Technology and a Shareholder of its Entrepreneurship Center. Mr. Harris received a B.A. from Princeton University and an M.B.A. from the Columbia University Graduate School of Business.

*William Laverack, Jr.* has served as a member of our board of directors since 1998. Mr. Laverack is a Managing Partner of Whitney & Co., LLC, which he joined in 1993. Mr. Laverack is also a director of Knology, Inc., Grande Communications, Inc. and several private companies. Mr. Laverack holds a B.A. from Harvard College and an M.B.A. from Harvard Business School.

#### **Board of Directors**

Our amended and restated certificate of incorporation, which will be in effect upon the effectiveness of this offering, will provide for a classified board of directors consisting of three staggered classes of directors (Class I, Class II and Class III). The members of each class of our board of directors will serve for staggered three-year terms, with the terms of our Class I, Class II and Class III directors expiring upon the election and qualification of directors at the annual meetings of stockholders held in 2005, 2006 and 2007, respectively. Prior to the effectiveness of this offering, we will determine which of our directors will serve in each class.

Our board of directors has determined that Messrs. Douglass, Harris and Laverack are independent directors for purposes of the recently adopted corporate governance rules contained in the

Marketplace Rules of the National Association of Securities Dealers, Inc., or the Nasdaq rules. Prior to the effectiveness of this offering, we intend to add additional directors, who will be independent directors for purposes of the Nasdaq rules, to our board of directors.

Currently, each of our directors serves on our board of directors pursuant to a stockholders' agreement. The provisions of the stockholders' agreement relating to the nomination and election of directors will terminate upon the closing of this offering.

#### **Board Committees**

Upon the effectiveness of this offering, our board of directors will have an audit committee, a compensation committee and a nominating committee.

##### *Audit Committee*

Upon the effectiveness of this offering, our board of directors will have an audit committee consisting of three independent members. Prior to the effectiveness of this offering, we will designate the members of our board of directors who will serve on the audit committee. The audit committee will operate pursuant to a charter that was approved by our Board of Directors on April 8, 2004. The purposes of the audit committee will be to, among other functions, (1) oversee our accounting and financial reporting processes and the audits of our financial statements, (2) take, or recommend that our board of directors take, appropriate action to oversee the qualifications, independence and performance of our independent auditors, and (3) prepare the audit committee report required to be included in our annual proxy statements. Upon the effectiveness of this offering, we expect that each member of the audit committee will be "independent" as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and our audit committee will otherwise meet the applicable requirements of the rules of the SEC and the Nasdaq rules. Prior to the effectiveness of this offering, our board of directors will determine whether at least one member of the audit committee will qualify as an "audit committee financial expert" as such term is defined in the rules of the SEC.

##### *Compensation Committee*

Upon the effectiveness of this offering, our board of directors will have a compensation committee consisting of three independent members. Prior to the effectiveness of this offering, we will designate the members of our board of directors who will serve on the compensation committee. The compensation committee will operate pursuant to a charter that was approved by our board of directors on April 8, 2004. The purposes of the compensation committee will be to, among other functions, (1) discharge our board of directors' responsibilities relating to compensation of our directors and executives, (2) oversee our overall compensation programs and (3) be responsible for producing an annual report on executive compensation for inclusion in our annual proxy statement.

##### *Nominating Committee*

Upon the effectiveness of this offering, our board of directors will have a nominating committee consisting of three independent members. Prior to the effectiveness of this offering, we will designate the members of our board of directors who will serve on the nominating committee. The nominating committee will operate pursuant to a charter that was approved by our board of directors on April 8, 2004. The purposes of the nominating committee will be to, among other functions, identify individuals qualified to become board members, consistent with criteria approved by our board of directors, and recommend that our board of directors select the director nominees for election at each annual meeting of stockholders.

**Directors' Compensation**

Currently, the non-employee members of our board of directors are not compensated for serving as directors, although we do reimburse these directors for all reasonable out-of-pocket expenses incurred by them in attending board or committee meetings. Dr. Gozani, the only employee member of our board of directors, is not separately compensated for his service on our board of directors. We expect to provide compensation to the new members of our board of directors that we expect to add prior to the effectiveness of this offering. Additionally, prior to the effectiveness of this offering, we may establish policies regarding the compensation of some or all of our existing non-employee directors.

**Compensation Committee Interlocks and Insider Participation**

Upon the effectiveness of this offering, none of our executive officers will serve as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the persons who will be members of our compensation committee upon the effectiveness of this offering will have ever been employed by NEUROMetrix.

**Executive Compensation***Summary of Cash and Certain Other Compensation*

The following table sets forth the compensation paid to our Chief Executive Officer and each of our four other most highly compensated executive officers whose total compensation exceeded \$100,000 for the year ended December 31, 2003. We refer to these individuals as our "named executive officers."

**Summary Compensation Table**

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation Awards	
		Salary	Bonus	Other Annual Compensation	Securities Underlying Options Granted	All Other Compensation
Shai N. Gozani, M.D., Ph.D. President and Chief Executive Officer	2003	\$ 206,250		\$ 7,200 (1)		
Gary L. Gregory Chief Operating Officer	2003	200,000	\$ 100,000	7,200 (1)	88,000	\$ 45,364(2)
Guy Daniello Senior Vice President of Information Technology	2003	150,000	28,875		10,862	
Michael Williams, Ph.D. Senior Vice President of Engineering	2003	160,000	2,880		78,200	
Nicholas J. Alessi Director of Finance	2003	95,000	5,700		44,292	

(1) Represents automobile allowance.

(2) Represents moving expenses of \$20,364 and cost of living adjustment of \$25,000.



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Stock Option Grants in 2003

The following table sets forth information concerning the individual grants of stock options to each of the named executive officers who received grants during fiscal 2003.

Option Grants In Year Ended December 31, 2003

Name	Individual Grants		Exercise price per share	Expiration Date	Potential realizable value at assumed annual rates of stock price appreciation for option term (2)	
	Number of securities underlying options granted	Percent of total options granted to employees in fiscal year (1)			5%	10%
Shai N. Gozani, M.D., Ph.D.						
Gary L. Gregory	88,000 (3)	18.3%	\$ 0.5625	1/1/2013	\$	\$
Guy Daniello	10,862 (3)	2.3	0.5625	1/1/2013		
Michael Williams, Ph.D	18,200 (3)	3.8	0.5625	1/1/2013		
	60,000 (4)	12.5	0.5625	9/18/2001		
Nicholas J. Alessi	4,292 (3)	0.9	0.5625	1/1/2013		
	40,000 (5)	8.3	0.5625	9/18/2013		

(1) Based on the grant to employees of options to purchase an aggregate of 480,875 shares of common stock in 2003.

(2) The potential realizable value is calculated based on the term of the stock option at the time of grant. Stock price appreciation of 5% and 10% is assumed pursuant to rules promulgated by the SEC and does not represent our prediction of our stock price performance. The potential realizable values at 5% and 10% appreciation are calculated by:

multiplying the number of shares of common stock subject to a given stock option by the assumed initial public offering price per share