

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2003

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

For the transition period from _____ to _____

Commission file number: 000-33001

NATUS MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

77-0154833
(I.R.S. Employer
Identification No.)

1501 Industrial Road, San Carlos, CA 94070
(Address of principal executive offices) (Zip Code)

(650) 802-0400
(Registrant's telephone number, including area code)

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

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

The number of issued and outstanding shares of the registrant's Common Stock, \$0.001 par value, as of November 7, 2003, was 16,494,504.

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NATUS MEDICAL INCORPORATED
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	September 30, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,533	\$ 17,768
Short-term investments	30,105	27,150
Accounts receivable, net of allowance for doubtful accounts of \$384 and \$250	4,892	5,395
Inventories	5,561	4,560
Prepaid expenses and other current assets	749	663
	<u>49,840</u>	<u>55,536</u>
Property and equipment, net	2,525	2,247
Long-term investment	339	334
Deposits and other assets	4,790	1,223
	<u>\$ 57,494</u>	<u>\$ 59,340</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Accounts payable	\$ 2,202	\$ 1,788
Accrued liabilities	2,384	2,460
Deferred revenue	864	405
	<u>5,450</u>	<u>4,653</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value, 120,000,000 shares authorized; shares issued and outstanding: 16,456,574 and 16,267,700	86,907	86,593
Deferred stock compensation	(57)	(219)
Accumulated deficit	(34,832)	(31,751)
Accumulated other comprehensive income	26	64
	<u>52,044</u>	<u>54,687</u>
	<u>\$ 57,494</u>	<u>\$ 59,340</u>

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

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NATUS MEDICAL INCORPORATED
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenue	\$ 7,960	\$ 6,781	\$21,684	\$19,327
Cost of revenue	3,544	2,886	8,904	8,322
Gross margin	4,416	3,895	12,779	11,005
Operating expenses:				
Marketing and selling	3,171	3,411	9,656	10,437
Research and development	996	1,298	2,847	3,594
General and administrative	1,364	1,250	3,847	3,520
Total operating expenses	5,531	5,959	16,350	17,551
Loss from operations	(1,115)	(2,064)	(3,570)	(6,546)
Interest income	34	215	362	715
Interest expense	(4)	(2)	(10)	(7)
Other income, net	117	250	139	456
Loss before provision for income taxes	(968)	(1,601)	(3,079)	(5,382)
Provision for income taxes	(1)	—	(2)	—
Net loss	\$ (969)	\$ (1,601)	\$ (3,081)	\$ (5,382)
Basic and diluted net loss per share	\$ (0.06)	\$ (0.10)	\$ (0.19)	\$ (0.34)
Common shares used in computing basic and diluted net loss per share	16,452	16,085	16,388	15,966

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

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NATUS MEDICAL INCORPORATED
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine Months Ended September 30,	
	2003	2002
Operating activities:		
Net loss	\$ (3,081)	\$ (5,382)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,024	818
Amortization of deferred stock compensation	106	412
Loss on disposal of assets	17	—
Changes in operating assets and liabilities:		
Accounts receivable	1,191	916
Inventories	(852)	(768)
Prepaid expenses and other current assets	(86)	(185)
Accounts payable	53	610
Accrued liabilities and deferred revenue	(460)	165
Net cash used in operating activities	<u>(2,088)</u>	<u>(3,414)</u>
Investing activities:		
Acquisition, net of cash acquired	(3,735)	—
Purchase of property and equipment	(770)	(1,239)
Deposits and other assets	(16)	(1,005)
Purchases of short-term investments	(42,615)	(70,784)
Sales of short-term investments	39,627	71,396
Purchase of long-term investments	(4)	—
Net cash used in investing activities	<u>(7,513)</u>	<u>(1,632)</u>
Financing activities:		
Issuance of common stock	370	379
Net cash provided by financing activities	<u>370</u>	<u>379</u>
Exchange rate effect on cash and equivalents	(4)	(22)
Net decrease in cash and equivalents	(9,235)	(4,689)
Cash and cash equivalents, beginning of period	17,768	30,351
Cash and cash equivalents, end of period	<u>\$ 8,533</u>	<u>\$ 25,662</u>
Non-cash investing and financing activities:		
Reversal of deferred stock compensation related to cancellation of unvested stock options	\$ 56	\$ 68
Stock compensation relating to accelerated vesting of stock options	\$ 161	\$ 23
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 10	\$ 7
Cash paid for income taxes	\$ 1	\$ 107

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

NATUS MEDICAL INCORPORATED
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1—Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission. Accordingly, they do not include all of the information and notes required by accounting principles generally accepted in the United States of America for annual financial statements. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Natus Medical Incorporated (“Natus,” “we,” “us,” “our” or “the Company”) believes necessary for fair presentation of our financial position, results of operations and cash flows for the periods presented. These interim financial results are not necessarily indicative of results to be expected for the full fiscal year. The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries; significant intercompany transactions have been eliminated. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2002 included in our Annual Report on Form 10-K.

Reclassification

Certain previously reported amounts have been reclassified to conform to the current presentation format with no impact on net loss.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities in the unaudited condensed consolidated financial statements. Such estimates include allowances for potentially uncollectable accounts receivable, warranty costs and a valuation allowance for deferred tax assets. Actual results could differ from those estimates.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price over the fair value of the net assets, including in-process research and development, of acquired businesses. Upon adoption of Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, in the first quarter of fiscal 2002, the Company no longer amortized goodwill.

Other intangible assets consist primarily of purchased technology, patents, trademarks, tradenames and customer relationships. The Company reviews intangible assets for impairment annually, or more frequently if changes in circumstances or the occurrence of events suggest the undiscounted future cash flows related to the assets are less than their related carrying value. Intangible assets with finite lives are amortized over their economic lives. Intangible assets with indefinite lives are not amortized. Intangible assets acquired as the result of a purchase business combination are subject to adjustment for as much as a year after the acquisition based on the final allocation of the purchase price.

NATUS MEDICAL INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

1—Summary of Significant Accounting Policies (Continued)

Revenue Recognition

The Company recognizes revenue, net of discounts, from sales of medical devices, disposable supplies, and reagents used for metabolic screening, including sales to distributors, when a purchase order has been received, when title transfers (generally upon shipment), when the selling price is fixed or determinable, and when collection of the resulting receivable is probable. Revenue from data management systems, which are generally highly customized, is recognized on the percentage of completion basis. Revenue from extended service and maintenance agreements, for both medical devices and data management systems, is recognized ratably over the service period, which is generally one to three years. Advance payments from customers are recorded as deferred revenue and recognized as revenue as otherwise described above. The Company generally does not provide rights of return on products. The Company accepts trade-ins of its own and competitive medical devices. Trade-ins are recorded as a reduction of the replacement medical device sale. Provisions are made for initial standard warranty obligations of one year, and post-sale training and customer support at the time the related revenue is recognized. The Company recognizes revenue from extended service agreements ratably over the service period.

Recent Accounting Pronouncements

In November 2002, the Financial Accounting Standards Board (FASB) issued Interpretation (FIN) No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantee of Indebtedness of Others*. This interpretation addresses the disclosures to be made by guarantor in its interim and annual financial statements about its obligations under certain guarantees. FIN No. 45 also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The Company adopted the disclosure requirements of FIN No. 45 on December 31, 2002 and the recognition requirements on January 1, 2003. The Company is evaluating the impact on the recognition requirements of this interpretation and does not expect it to have a material impact on its financial position results of operations, EPS or cash flows.

In December 2002, the FASB issued Statement on Financial Accounting Standards (SFAS) No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. This statement amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide companies with alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. Additionally, SFAS No. 148 amends certain disclosure requirements of SFAS No. 123. The Company adopted the annual disclosure requirements of SFAS No. 148 as of December 31, 2002. The transitional provisions of SFAS No. 148 did not have an impact on the Company's financial position, results of operations, EPS, or cash flows, as the fair value method has not been adopted.

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities—an Interpretation of ARB No. 51*. FIN No. 46 requires that variable interest entities be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or is entitled to receive a majority of the entity's residual returns, or both. FIN No. 46 also requires disclosures about variable interest entities that are not required to consolidate, but in which a company has a significant variable interest. The consolidation requirements of FIN No. 46 will apply immediately to variable interest entities created after January 31, 2003. The consolidation requirements will apply to entities established on or prior to January 31, 2003 in the first fiscal year or interim period beginning after June 15, 2003. The disclosure requirements will apply in all financial statements issued after January 31, 2003. The Company has adopted the disclosure requirements of FIN No. 46 and does not believe the application of FIN No. 46 will have a material effect on its financial position, results of operations, EPS, or cash flows.

NATUS MEDICAL INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

1—Summary of Significant Accounting Policies (Continued)

Recent Accounting Pronouncements (continued)

In April 2003, the FASB issued SFAS No. 149 *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* for certain decisions made by the FASB Derivatives Implementation Group. In particular, SFAS No. 149: (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying contract to conform to language used in FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. This Statement is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. In addition, most provisions of SFAS No. 149 are to be applied prospectively. The Company does not expect the adoption of SFAS No. 149 to have a material impact on its financial position, cash flows or results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 established standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective beginning in the third quarter of 2003. The company does not believe the adoption of SFAS No. 150 will have a material effect on its financial position, results of operations, EPS, or cash flows.

Comprehensive Loss

The following are the components of comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss	\$ (969)	\$ (1,601)	\$(3,081)	\$(5,382)
Unrealized gain (loss) on available-for-sale securities	(19)	1	(34)	(47)
Foreign currency translation adjustment	70	6	(4)	(127)
Comprehensive loss	\$ (918)	\$ (1,594)	\$(3,119)	\$(5,556)

2—Inventories

Inventories consisted of (in thousands):

	September 30, 2003	December 31, 2002
Raw materials and subassemblies	\$ 2,679	\$ 2,831
Finished goods	2,882	1,729
Total	\$ 5,561	\$ 4,560

3—Reserve For Product Warranties

The company customarily provides a standard one-year warranty on all medical device products. The company also sells extended service agreements on some of its medical devices, and maintenance agreements on its data management systems. Service for domestic customers is provided by company-owned service centers

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NATUS MEDICAL INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

3—Reserve For Product Warranties (Continued)

that perform all service, repair, and calibration services on medical devices, and maintenance on data management systems. Service for international customers is provided by a combination of company-owned facilities and distributors on a contract basis.

The company has accrued a warranty reserve for the expected future costs, based on historical experience, of servicing medical devices during the initial one-year warranty period. The reserve is increased based on unit sales of various product lines and reduced as warranty costs are incurred.

4—Basic and Diluted Net Loss Per Common Share

Basic net loss per common share excludes dilution and is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding during the respective period. Diluted loss per share reflects the potential dilution that could occur if stock options were exercised. As a result of net losses for all periods presented, there is no difference between basic and diluted net loss per share. Options to purchase 898,656 and 778,038 shares of common stock for the nine-month periods ending September 30, 2003 and 2002, respectively, were not included in the computation of diluted net loss per share because the loss position would have rendered the additional shares antidilutive.

5—Stock-Based Compensation

The Company accounts for stock-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees*, as interpreted by FASB Interpretation No. 44, *Accounting for Transactions Involving Stock Compensation—an Interpretation of APB Opinion No. 25*. The Company accounts for stock-based awards to non-employees in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* and Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

The Company typically grants stock option awards at market value; consequently, no compensation expense is recorded. In 2001, options were granted at an exercise price deemed to be less than their fair market value which resulted in the recording of deferred stock compensation of \$2,659,000, based on the difference between the exercise price and the deemed fair value of the options. The difference was recorded as stock-based compensation in stockholders' equity and is being amortized on a straight-line basis over the vesting period of the related options. Amounts amortized during the three and nine months ended September 30, 2003 and 2002 (in thousands) are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Amortization of stock compensation included in:				
Cost of revenue	\$ (2)	\$ 32	\$ 15	\$ 71
Operating expenses				
Marketing and selling	\$ (30)	\$ 38	\$ 31	\$ 190
Research and development	1	(16)	8	9
General and administrative	8	39	52	142
Total	\$ (21)	\$ 61	\$ 91	\$ 341

NATUS MEDICAL INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

5—Stock-Based Compensation (continued)

Had compensation expense for the Company's stock option awards been determined based on the Black-Scholes fair value method at the grant dates, consistent with the fair value method of SFAS No. 123, *Accounting for Stock-Based Compensation*, the Company would have recorded additional compensation expense and its net income and earnings per share (EPS) would have been reduced to the pro forma amounts presented in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss, as reported	\$ (969)	\$ (1,601)	\$(3,081)	\$(5,382)
Add: Stock based employee compensation, net of related tax effects	(23)	93	106	412
Less:—Compensation expense for stock options determined under the fair value method, net of related tax effects	(384)	(528)	(1,054)	(1,590)
Pro forma net loss	\$(1,376)	\$ (2,036)	\$(4,029)	\$(6,560)
Basic and diluted EPS				
As reported	\$ (0.06)	\$ (0.10)	\$ (0.19)	\$ (0.34)
Pro forma	\$ (0.08)	\$ (0.13)	\$ (0.25)	\$ (0.41)

6—Customer and Geographic Information

The company operates in one reportable segment and is engaged in the design, manufacture, and marketing of products for the detection, treatment, monitoring and tracking of common medical disorders that may occur during the critical development period of infants. The nature of its products and production processes, as well as the type of customers and distribution methods, are consistent among all of its products.

Revenue from customers by geographic area was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
United States	\$ 6,788	\$ 5,666	\$16,914	\$16,373
All other	1,172	1,115	4,770	2,954
Total	\$ 7,960	\$ 6,781	\$21,684	\$19,327

For both the three and nine months ended September 30, 2003 and 2002, no sales to a single end-user customer or distributor accounted for greater than 10% of total revenue.

7—Business Combinations

In July 2003, the Company purchased substantially all of the assets of Neometrics, Inc. and its affiliate Neogenesis Corporation for \$3.6 million in cash plus the assumption of certain liabilities, with the potential for additional consideration contingent upon Neometrics achieving certain financial results over the three-year period following the acquisition. The Neometrics line of reagents used for metabolic screening uses blood

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NATUS MEDICAL INCORPORATED

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

7—Business Combinations (continued)

samples taken from newborns to test for metabolic disorders such as Phenylketonuria (PKU), galactosemia, hypothyroidism and hemoglobinopathies, and is marketed to government health laboratories domestically and internationally. The Neometrics line of newborn screening data management systems consists of proprietary software that collects, tracks, manages and reports newborn screening data to regional government health laboratories and national disease control centers. This acquisition enhances the Company's core newborn screening business, complements our focus on providing products used to identify and monitor common newborn medical disorders.

The following table summarizes the estimated fair value of the assets acquired and liabilities assumed in the acquisition:

Net assets acquired as follows (in thousands):

Current assets	\$ 790
Property, plant and equipment	415
Intangible assets	2,000
Goodwill	1,671
Other assets—long-term	15
	<hr/>
Total assets acquired	\$4,891
	<hr/>
Current liabilities	\$ 389
Deferred revenue	767
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Total liabilities assumed	\$1,156
	<hr/>
Net assets acquired	\$3,735
	<hr/>

8—Indemnifications

Under its bylaws, the Company has agreed to indemnify its officers and directors for certain events or occurrences arising as a result of the officer or director's serving in such capacity. The Company has a directors and officers liability insurance policy that limits the Company's exposure and enables it to recover a portion of any future amounts paid resulting from the indemnification of its officers and directors. In addition, the Company enters into indemnification agreement with other parties in the ordinary course of business. In some cases the Company has obtained liability insurance providing coverage that limits its exposure for these other indemnified matters. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. The Company believes the estimated fair value of these indemnification agreements is minimal and has not recorded a liability for these agreements as of September 30, 2003.

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

This report, including the following sections, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, particularly statements concerning our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. The words “may,” “will,” “continue,” “estimate,” “project,” “intend,” “believe,” “expect,” “anticipate,” and other similar expressions generally identify forward-looking statements. Forward-looking statements in this report include, but are not limited to, statements regarding the following: our intention to expand international operations; our belief that international revenue will increase as a percent of revenue; our belief that our ability to grow revenue related to our ALGO products will increasingly depend upon success in the international market; our belief that our net income or loss is impacted by allocation of resources; our intention to support the CO-Stat® user base in place; our belief that our acquisition of Neometrics™, Inc. products enhance our core screening business, compliments our business focus and provides us with a platform for additional growth opportunities; our belief that our current cash and cash equivalent balances, cash provided from operations and financing are sufficient to meet our capital requirements; our intention to invest in the development of new products, the enhancement of existing products, product distribution, the increase of our selling activities, the increase in size and number of locations of our customer support organization, the development of infrastructure and hiring management and other employees; our belief as to the effect of recent accounting pronouncements; possible expenses in connection with the future acquisition of business or assets of other companies; our beliefs as to the factors that will affect our future growth; our belief that we may in the future enter into agreement with customers that purchase high volumes of our products or with group purchasing organizations; our intention to continue efforts to increase sales in Europe, Japan and other countries with a high level of health care spending on infants; our belief with respect to the identity of our competition; our belief that as to the factors for our future success; our expectation regarding the consolidation of the medical testing industry; the impact of future changes in foreign currency exchange rates; our belief that resolution of legal proceedings and claims will not have a significant adverse effect on our financial condition.

Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results predicted in the forward-looking statements as well as our future financial condition and results of operations to differ materially from our historical results or currently anticipated results. Investors should carefully review the information contained under the caption “Risk Factors” for a description of risks and uncertainties. The risks and uncertainties include, but are not limited to, the possibility that we continue to incur net losses; lack of adoption and acceptance of our products; lack of demand for our products; our dependence on our ALGO products for substantially all of our revenue; adverse economic conditions in the United States and internationally; the importance of reimbursement for procedures conducted with our products and reimbursement policies; our limited experience selling products other than our ALGO products; adverse changes in our relationships with distributors and suppliers; manufacturing difficulties; our dependence upon distributors in international markets; increased costs relating to international operations; exchange rate fluctuations; failure to obtain clearances or approvals from the FDA or other regulatory bodies; failure to comply with the regulations of the FDA or other regulatory bodies; failure and difficulty to obtain foreign regulatory approvals; increased competition; integration of acquired businesses and performance of newly acquired products and technologies; loss of and inability to protect intellectual property rights; intellectual property, products liability and other suits; and our ability to attract, hire and retain key employees. The following discussion and analysis also should be read in conjunction with “Selected Consolidated Financial Data” and our Consolidated Financial Statements and Notes thereto included elsewhere in this report.

Overview

We develop, manufacture, distribute and market products for the detection, treatment, monitoring and tracking of common medical disorders in newborns. Currently, our principal product lines consist of our ALGO screening products for hearing screening, our CO-Stat analyzer for the analysis of hemolysis, our neoBLUE™ LED Phototherapy device (“neoBLUE phototherapy device”) for the treatment of jaundice, our MiniMuffs® Neonatal Noise Attenuators (“MiniMuffs”) products for the attenuation of noise for newborns, our

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Neometrics reagents used for metabolic screening, Neometrics newborn screening data management systems, and the Nascor product line.

Our revenue is derived from sales of medical devices and systems, disposable supplies, reagents used for metabolic screening, extended service agreements and maintenance agreements. We currently derive substantially all of our revenue from sales and service of a limited number of products. The majority of our revenue during the nine months ended September 30, 2003 and 2002 was derived from sales of our ALGO screening products, and we expect that this will continue to be true for at least the next two years.

Domestic sales accounted for 85% and 84% of our revenue during the three months ended September 30, 2003 and 2002 respectively. Domestic sales accounted for 78% and 85% of our revenue during the nine months ended September 30, 2003 and 2002 respectively. We intend to continue expansion of our international operations because we believe international markets represent a significant growth opportunity. We acquired the distribution operations of our United Kingdom distributor and top-tier Japan distributor in January 2001 and July 2001, respectively. We anticipate that international revenue will increase as a percent of revenue in the future. If international sales increase, we may not experience corresponding growth in operating income due to the higher cost of selling outside of the United States. We sell our products through a direct sales force in the U.S., through our subsidiaries in the U.K. and Japan, and through distributors in 28 other countries. International sales that are made to distributors are characterized by lower gross margins due to the discount the distributors receive from our list prices.

Our net income or loss can be markedly impacted by the decisions of management regarding the level of resources applied to our business. Management and our board of directors make these decisions on the basis of sales forecasts, expected customer orders, economic conditions and other factors. These costs are primarily personnel and facilities costs that are relatively fixed in the short-term and directly impact net income.

In 2001 and the first half of 2002, we increased our level of spending on the marketing and sales of our CO-Stat analyzer products. We spent a considerable amount of time and resources on education of governments, hospitals and clinicians regarding the benefit of our CO-Stat analyzer products. Despite these expenditures, we have not achieved the level of sales of our CO-Stat analyzer products that we had anticipated. In the third quarter of 2002, we began to reduce marketing and sales expenditures associated with our CO-Stat analyzer products in order to adjust our expenses to more accurately reflect our expectations regarding near term revenue. In the fourth quarter of 2002, we also recorded a write-down of excess parts and materials we had purchased for our CO-Stat analyzer products. We continue to move forward with clinical research for the newborn jaundice detection market and for additional clinical applications. While we intend to continue to support the user base now in place, we are not currently devoting significant resources to market our CO-Stat analyzer products and we do not expect to recognize material revenue from our CO-Stat analyzer products in 2003.

In September 2002, we received clearance from the U.S. Food and Drug Administration ("FDA") to market our neoBLUE phototherapy device for the treatment of newborn jaundice, a condition in which the body produces an excessive amount of a potentially toxic substance called bilirubin. We introduced the neoBLUE phototherapy device in October 2002 at the American Academy of Pediatrics National Conference and Exhibition in Boston, Massachusetts. Our neoBLUE phototherapy device adds to our products and services that assist clinicians with the management of newborn jaundice. Because we do not have significant experience marketing the neoBLUE phototherapy device for the treatment of newborn jaundice, we cannot be certain that it will be well received by our customers. We do not expect to recognize material revenue from our neoBLUE phototherapy device in 2003.

In July 2003 we purchased substantially all of the assets of Neometrics Inc. and its affiliate Neogenesis Corporation for \$3.6 million in cash with the potential for additional consideration contingent upon Neometrics achieving certain financial results. The Neometrics line of reagents used for metabolic screening uses blood samples taken from newborns to test for metabolic disorders such as Phenylketonuria (PKU), galactosemia, hypothyroidism and hemoglobinopathies, and is marketed to government health laboratories domestically and internationally. The Neometrics line of newborn screening data management systems consists of proprietary

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software that collects, tracks, manages and reports newborn screening data to regional government health laboratories and national disease control centers. While all states have laws and/or regulations requiring newborn screening for metabolic disorders, the laws and regulations vary widely in the extent of screening required. We believe that our acquisition of the Neometrics lines of business enhances our core newborn screening business, complements our focus on providing products used to identify and monitor common newborn medical disorders, and provides us with a platform for additional growth opportunities.

In October 2003 we began marketing and distributing the Nascor family of products, consisting of the Oxydome™, Oxypod™, Oxy-Igloo™, and Foldadome™ neonatal oxygen delivery hoods, the Igloo™ neonatal heatshield, as well as the Biliband™ Eye Protector. These products are licensed from Nascor Pty Ltd. Used in hospital neonatal units and nurseries, Nascor's oxygen hoods are designed to provide a stable environment of oxygen and humidity for newborns with special needs. In many cases, they are a non-invasive alternative to nasal cannulas, which deliver oxygen via a tube held in place at the nasal opening with a strong adhesive. Additionally, Nascor's oxygen hoods are designed to allow hospital staff and parents to easily monitor and access the baby. Heatshields are intended for babies who need to be placed under radiant warmers, in incubators, or under phototherapy lights. Biliband eye-shields are designed to block visible light to a baby's eyes while undergoing phototherapy treatment. We do not expect to recognize material revenue from the Nascor product line in 2003.

As of December 31, 2002, we had total federal and state net operating loss carryforwards of approximately \$13.1 million and \$4.2 million, respectively, available to reduce future taxable income. If not utilized to offset taxable income in future periods, our federal net operating loss carryforwards will expire in various amounts beginning in 2007 through 2022, and our state net operating loss carryforwards will expire through 2010. If we continue to have net losses, we may not be able to utilize some or all of our net operating loss carryforwards before they expire. In addition, United States income tax law imposes limitations on the amount of net operating loss carryforwards we can use in any given year and on the ability to use net operating loss carryforwards if we experience a more than 50% change in ownership during any three-year period.

Application of Critical Accounting Policies

We prepare our financial statements in accordance with generally accepted accounting principles. In so doing, we must often make estimates and use assumptions that can be subjective, and consequently our actual results could differ from those estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable.

We believe that the following critical accounting policies require the use of significant estimates, assumptions, and judgments. The use of different estimates, assumptions, and judgments could have a material affect on the reported amounts of assets, liabilities, revenue, expenses and related disclosures at the date of the financial statements and during the reporting period.

Revenue Recognition

We recognize revenue, net of discounts, from sales of medical devices and disposable supplies, and reagents used for metabolic screening, including sales to distributors, when a purchase order has been received, when title transfers (generally upon shipment), when the selling price is fixed or determinable, and when collection of the resulting receivable is probable. Revenue from data management systems, which are generally highly customized, is recognized on the percentage of completion basis. Revenue from extended service and maintenance agreements, for both medical devices and data management systems, is recognized ratably over the service period. Advance payments from customers are recorded as deferred revenue and recognized as revenue as otherwise described above. We generally do not provide rights of return on our products. We accept trade-ins of our own and competitive medical devices. Trade-ins are recorded as a reduction of the replacement medical device sale. Provisions are made for initial standard warranty obligations of one year, and post-sale training and customer support at the time the related revenue is recognized. We recognize revenue from extended service agreements ratably over the service period.

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We must exercise judgment when assessing the sufficiency of our allowance for estimated uncollectible accounts receivable. Our estimates are based on our historical collection experience within the markets in which we operate as well as assessment of our average accounts receivable aging days and any other specific information of which we may be aware, such as bankruptcy filings or liquidity problems of our customers. Any future determination that our allowance for estimated uncollectible accounts receivable is understated could result in increased operating expense and reduce our results of operations.

At September 30, 2003 our deferred revenue under extended service and maintenance agreements was approximately \$864,000. Other advance payments from customers were not material at September 30, 2003. Our allowance for estimated uncollectible accounts receivable was \$384,000 at September 30, 2003.

Inventory is carried at the lower of cost or market value

As a medical device manufacturer, we may be exposed to a number of factors that could result in portions of our inventory becoming either obsolete or in excess of anticipated usage. These factors include, but are not limited to, technological changes in our markets, competitive pressures in products and prices, and our own introduction of new product lines.

We regularly evaluate our ability to realize the value of our inventory based on a combination of factors, including historical usage rates, forecasted sales, product life cycles, and market acceptance of new products. When we identify inventory that is obsolete or in excess of anticipated usage we write it down to realizable salvage value or provide for inventory valuation reserves. The estimates we use in projecting future product demand may prove to be incorrect. Any future determination that our inventory is overvalued could result in increases to our cost of revenue and decreases to our gross margin and results of operations.

Carrying value of intangible assets

Under generally accepted accounting principles we are required to write down intangible assets if such assets are determined to be impaired. Under current accounting standards, an impairment of an intangible is considered to have occurred when the estimated undiscounted future cash flows related to the asset are less than the carrying value of the asset. Estimates of future cash flows involve consideration of many factors including the marketability of new products, product acceptance and lifecycle, competition, and gross margins. We amortize intangible assets with finite lives over their useful lives; any future changes that would limit their useful lives could result in additional charges to our research and development costs and decrease our operating results. We carry intangibles with indefinite lives at original cost; any future determination that these assets are carried at greater than their expected future undiscounted cash flows could result in additional charges to our research and development costs and decrease our operating results. Intangible assets acquired as the result of a purchase business combination are subject to adjustment for as much as a year after the acquisition based on the final allocation of the purchase price.

At September 30, 2003 we had intangible assets with a carrying value of approximately \$4.8 million.

Liability for product warranties

Our products are covered by standard one-year limited product warranties. A liability has been established for the expected cost of servicing our products during these service periods. We base the liability in part upon our historical experience; however, estimates of the costs to honor our warranties are often difficult to determine due to uncertainty surrounding the extent to which new products will require servicing and the costs that will be incurred to service those products. Until we have historical experience of the cost to honor warranties on new products, we base additions to the reserve on a combination of factors including the standard cost of the product and other judgments. The estimates we use in projecting future product service costs may prove to be incorrect. Any future determination that our product warranty reserves are understated could result in increases to our cost of revenue and decreases to our gross margin and results of operations.

At September 30, 2003 our reserve for product warranties was approximately \$177,000.

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Valuation allowance for deferred tax assets

We record a valuation allowance against our deferred tax assets, which result primarily from net operating loss and credit carryforwards that expire over time, and timing differences between book and tax results. In evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed any future taxable income in the tax jurisdictions in which we operate. To the extent we establish a valuation allowance, or increase this allowance in a period, we include an offsetting expense within the tax provision in the consolidated statement of operations. Future income generation in these tax jurisdictions could lead to the reversal of these valuation allowances and additional income recognition. At September 30, 2003, we continue to maintain a valuation allowance against all of our deferred tax assets.

Results of Operations

The following table sets forth, for the periods indicated, selected unaudited condensed consolidated statements of operations data as a percentage of total revenue. Our historical operating results are not necessarily indicative of the results for any future period.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenue	100.0%	100.0%	100.0%	100.0%
Cost of revenue	44.5	42.6	41.0	43.1
Gross margin	55.5	57.4	59.0	56.9
Operating expenses:				
Marketing and selling	39.8	50.3	44.5	54.0
Research and development	12.5	19.1	13.1	18.6
General and administrative	17.2	18.4	17.8	18.2
Total operating expenses	69.5	87.8	75.4	90.8
Loss from operations	(14.0)	(30.4)	(16.4)	(33.9)
Interest income	0.4	3.1	1.7	3.7
Interest expense	(0.1)	—	(0.1)	—
Other income, net	1.5	3.7	0.6	2.3
Loss before provision for income taxes	(12.2)	(23.6)	(14.2)	(27.4)
Provision for income taxes	—	0.4	—	0.5
Net loss available to common stockholders	(12.2)%	(23.6)%	(14.2)%	(27.9)%

Three and Nine Months Ended September 30, 2003 and 2002

Revenue

Our revenue is derived almost exclusively from the sale of supplies and services, which are generally recurring, and related devices and systems. Supplies and services revenue is derived from sales of disposable supplies for our ALGO and CO-Stat medical devices, our MiniMuffs, the Nascor product line, our Neometrics reagent used for metabolic screening, software maintenance agreements for our Neometrics data management systems, as well as extended service agreements on our medical devices. Devices and systems revenue is derived from the sale of our ALGO, CO-Stat and neoBLUE medical devices, and our Neometrics data management systems.

As a result of the acquisition of Neometrics on July 2, 2003, and the resultant increase in revenue in the quarter ended September 30, 2003, comparison with revenue in the same period in 2002 may not be meaningful.

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Our revenue increased \$1.2 million, or 17%, to \$8.0 million in the three months ended September 30, 2003 from \$6.8 million in the same period in 2002. This was primarily attributable to approximately \$1.1 million in incremental revenue from our Neometrics product lines. Our revenue increased \$2.4 million, or 12%, to \$21.7 million in the nine months ended September 30, 2003 from \$19.3 million in the same period in 2002. The increase was attributable to stronger demand for our disposable supplies in Europe, Asia and Oceania, and incremental revenue from our Neometrics product lines. No end customer accounted for more than 10% of our revenue in the nine months ended September 30, 2003 and 2002.

Revenue from supplies and services increased by \$982,000, or 20%, to \$6.0 million in the three months ended September 30, 2003 from \$5.0 million in the same period in 2002. Revenue from disposable supplies and service fees increased by \$1.9 million, or 13%, to \$16.0 million in the nine months ended September 30, 2003 from \$14.1 million in the same period in 2002. The increase resulted primarily from increased demand for our disposable supplies due to our greater international installed base of ALGO hearing screening devices.

Revenue from devices and systems increased by \$195,000, or 12%, to \$1.9 million in the three months ended September 30, 2003 from \$1.7 million in the same period in 2002. This was due primarily to sales of our Neometrics data management systems, partially offset by decreased sales of medical devices in our international markets. Revenue from devices and systems increased by \$434,000, or 9%, to \$5.3 million in the nine months ended September 30, 2003 from \$4.9 million in the same period in 2002. The increase resulted from greater unit sales of medical devices in Europe, Asia and Oceania and incremental revenue from our Neometrics data management systems.

Revenue from sales outside the United States increased by \$57,000, or 5%, to \$1.2 million in the three months ended September 30, 2003 from \$1.1 million in the same period in 2002. During the three months ended September 30, 2003, sales of ALGO disposable were up due to an increased installed base in Oceania. Revenue from sales outside the United States increased by \$1.8 million, or 62%, to \$4.8 million in the nine months ended September 30, 2003 from \$3.0 million in the same period in 2002. The increase in revenue for the nine months ended September 30, 2003 was primarily the result of the sales mentioned above as well as general stronger demand for our products in Europe and Asia.

Cost of Revenue and Operating Expenses

Cost of revenue includes material costs, personnel expenses, amortization of deferred stock compensation, packaging and shipping costs, other manufacturing and systems development costs, warranty expenses, and acquired technology rights. Our cost of revenue increased \$658,000, or 23%, to \$3.5 million in the three months ended September 30, 2003 from \$2.9 million in the same period in 2002. Our cost of revenue increased \$582,000, or 7%, to \$8.9 million in the nine months ended September 30, 2003 from \$8.3 million in the same period in 2002. Cost of revenue as a percent of total revenue was 45% in the three months ended September 30, 2003, compared with 43% reported in the three months ended September 30, 2002. Cost of revenue as a percent of total revenue was 41% in the nine months ended September 30, 2003, compared with 43% reported in the nine months ended September 30, 2002. In the three months ended September 30, 2003, we identified and reserved for additional obsolete inventory of approximately \$150,000, which resulted in an increase to our cost of sales during the period. Our gross margin has been adversely affected by increased participation by domestic customers buying under group purchasing organization contracts. While providing an opportunity for increased unit sales, group purchasing organization contracts typically also have the impact of lowering the gross margins on such sales transactions.

Marketing and selling expenses consist primarily of salaries, commissions, travel, promotional and advertising costs. Our marketing and selling expenses decreased \$240,000, or 7%, to \$3.2 million in the three months ended September 30, 2003 from \$3.4 million in the same period in 2002. Our marketing and selling expenses decreased \$781,000, or 8%, to \$9.7 million in the nine months ended September 30, 2003 from \$10.5 million in the same period in 2002. The decrease is primarily attributable to reductions in our domestic field organization personnel expenses, as well as reduced spending for advertising and travel related costs. This decrease was partially offset by expenses related to a promotional offer to transition customers to our new Flexicoupler[®] earphones ("Flexicoupler") supply and patient cables for our ALGO newborn hearing screener.

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Research and development expenses consist of engineering costs to develop new products, enhance existing products, and validate the design of new or enhanced products. Our research and development expenses decreased \$302,000, or 23%, to \$996,000 in the three months ended September 30, 2003 from \$1.3 million in the same period in 2002. Our research and development expenses decreased \$747,000, or 21%, to \$2.8 million in the nine months ended September 30, 2003 from \$3.6 million in the same period in 2002. The decrease is primarily attributable to reductions in salaries and costs of outside consultants.

General and administrative expenses consist of corporate, finance, information technology, human resources, administrative and legal expenses. Our general and administrative expenses increased \$114,000, or 9%, to \$1.4 million in the three months ended September 30, 2003 from \$1.3 million in the same period in 2002. Our general and administrative expenses increased \$327,000, or 9%, to \$3.8 million in the nine months ended September 30, 2003 from \$3.5 million in the same period in 2002. In prior years, personnel and other associated costs of our information technology group were allocated to all departments; in 2003 we began treating these costs as general and administrative expenses. Costs associated with insurance and outside accounting services have increased.

We recorded aggregate amortization of deferred stock compensation of (\$23,000) and \$93,000 in the three months ended September 30, 2003 and 2002, respectively. We recorded aggregate amortization of deferred stock compensation of \$106,000 and \$412,000 in the nine months ended September 30, 2003 and 2002, respectively. For the three months ended September 30, 2003 and 2002, (\$2,000) and \$32,000, respectively, was included in cost of revenue and (\$21,000) and \$61,000, respectively, was allocated to operating expenses. For the nine months ended September 30, 2003 and 2002, \$15,000 and \$71,000, respectively, was included in cost of revenue and \$91,000 and \$341,000, respectively, was allocated to operating expenses. The credits represent an adjustment for employees who terminated employment during the nine months ended September 30, 2003.

Other income and expenses consist of interest income, interest expense, net capital gains and losses from our investment portfolio, net currency exchange gains and losses and other miscellaneous income and expenses. Other income and expenses decreased \$316,000, or 68%, to \$147,000 in the three months ended September 30, 2003 from \$463,000 for the same period in 2002. Other income and expenses decreased \$673,000, or 58%, to \$491,000 in the nine months ended September 30, 2003 from \$1.2 million for the same period in 2002. The decrease in other income and expenses was primarily due to a decrease in investment income resulting from current market conditions, and to a lesser extent, our decreased cash balances.

Foreign exchange gains were \$3,000 and \$44,000 in the three months ended September 30, 2003 and 2002, respectively. Foreign exchange gains were \$1,000 and \$251,000 in the nine months ended September 30, 2003 and 2002, respectively. The gains resulted primarily from fluctuations in local currency equivalents of the U.S. dollar in Europe and Asia. Unrealized translation gains and losses are not included in net income, but are reported as a component of other comprehensive income.

Liquidity and Capital Resources

As of September 30, 2003, we had cash, cash equivalents and short-term investments of \$38.6 million, stockholders' equity of \$52.0 million and working capital of \$44.4 million, compared with cash, cash equivalents and short-term investments of \$44.9 million, stockholders' equity of \$54.7 million and working capital of \$50.9 million as of December 31, 2002.

Net cash used in operating activities was \$2.1 million for the nine months ended September 30, 2003 and was \$3.4 million for the nine months ended September 30, 2002. Cash used in operating activities for the nine months ended September 30, 2003 resulted primarily from the net loss during the period, increases in inventories, and a decrease in accrued liabilities which were offset by a decrease in accounts receivable. The increase in inventories was due primarily to maintaining greater quantities of our disposable supplies. Net cash used in operating activities for the same period in 2002 resulted primarily from the net loss during the period and an increase in inventories.

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Net cash used in investing activities was \$7.5 million for the nine months ended September 30, 2003 compared to \$1.6 million for the same period in 2002. Net cash used in investing activities during the nine months ended September 30, 2003 resulted from the purchase of the assets of Neometrics, Inc., including direct costs of the acquisition paid to outside service providers, which together totaled approximately \$3.7 million, and the purchase of short-term investments in excess of those that were redeemed. Net cash used in investing activities during the nine months ended September 30, 2002, was primarily due to purchases of property and equipment and an increase in deposits and other assets. Because of our investment policy, the types of investments we may make are limited. Primarily all of our short-term investments are available-for-sale securities with maturities of less than fifteen months, and fluctuations between cash equivalents and short-term investments are often attributable to investment decisions. We had no material capital expenditure commitments as of September 30, 2003. We have an interest-bearing certificate of deposit with a bank that matures in April 2004; the investment is valued at \$339,000 at September 30, 2003 and is classified as a hold-to-maturity investment. This investment was assigned to a bank in February 1999 to guarantee a loan to an officer totaling \$250,000 plus accrued interest. The guarantee is collateralized by 26,688 shares of our stock owned by the officer and held in escrow.

Net cash provided by financing activities was \$370,000 for the nine months ended September 30, 2003, compared to \$379,000 for the same period in 2002. Net cash provided by financing activities for both periods resulted from the proceeds of sale of our stock to employees pursuant to our stock option and employee stock purchase plans.

In July 2003, we purchased substantially all of the assets of Neometrics Inc. and its affiliate Neogenesis Corporation for \$3.6 million in cash with the potential for additional consideration contingent upon Neometrics achieving certain financial results.

Our future liquidity and capital requirements will depend on numerous factors, including:

- the amount and timing of revenue;
- the extent to which our existing and new products gain market acceptance;
- the extent to which we make acquisitions;
- the cost and timing of expansion of product development efforts and the success of these development efforts;
- the cost and timing of expansion of marketing and selling activities; and
- available borrowings under line of credit arrangements and the availability of other means of financing.

We believe that our current cash and cash equivalent balances, any cash provided by or used in operations, and from current or future debt financing will be sufficient to meet our operating and capital requirements for at least the next 18 months. However, it is possible that we may require additional financing within this period. We intend to continue to invest in the development of new products, enhancements to our existing products, and in both existing and new product distribution domestically and overseas. The factors described above will affect our future capital requirements and the adequacy of our available funds. In addition, even if our current funds are sufficient to meet our anticipated cash needs during the next 18 months, we may need to raise additional funds beyond this time, particularly if we invest significant amounts in the acquisition of businesses and products. We may be required to raise those funds through public or private financings, strategic relationships or other arrangements. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants.

Recent Accounting Pronouncements

In November 2002, the FASB issued Interpretation (FIN) No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantee of Indebtedness of Others*. This interpretation

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addresses the disclosures to be made by guarantor in its interim and annual financial statements about its obligations under certain guarantees. FIN No. 45 also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. In accordance with FIN No. 45, we adopted the disclosure requirements on December 31, 2002 and are required to adopt the recognition requirements effective on January 1, 2003. We are evaluating the impact on the recognition requirements of this interpretation and do not expect it to have a material impact on our financial position, results of operations, EPS or cash flows.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. This statement amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide companies with alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation. Additionally, SFAS No. 148 amends certain disclosure requirements of SFAS No. 123. We adopted the annual disclosure requirements of SFAS No. 148 as of December 31, 2002. The transitional provisions of SFAS No. 148 did not have an impact on our financial position, results of operations, EPS, or cash flows, as the fair value method has not been adopted.

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities—an Interpretation of ARB No. 51*. FIN No. 46 requires that variable interest entities be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or is entitled to receive a majority of the entity's residual returns, or both. FIN No. 46 also requires disclosures about variable interest entities that are not required to consolidate, but in which a company has a significant variable interest. The consolidation requirements of FIN No. 46 will apply immediately to variable interest entities created after January 31, 2003. The consolidation requirements will apply to entities established on or prior to January 31, 2003 in the first fiscal year or interim period beginning after June 15, 2003. The disclosure requirements will apply in all financial statements issued after January 31, 2003. We adopted the disclosure requirements of FIN No. 46 and do not believe the application of FIN No. 46 will have a material effect on our financial position, results of operations, EPS, or cash flows.

In April 2003, the FASB issued SFAS No. 149 *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* for certain decisions made by the FASB Derivatives Implementation Group. In particular, SFAS No. 149: (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying contract to conform to language used in FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. This Statement is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. In addition, most provisions of SFAS No. 149 are to be applied prospectively. We do not expect the adoption of SFAS No. 149 to have a material impact on our financial position, cash flows or results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 established standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective beginning in the third quarter of 2003. We do not believe the adoption of SFAS No. 150 will have a material effect on our financial position, results of operations, EPS, or cash flows.

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Risk Factors

We have a history of losses and may experience losses in the future, which may result in the market price of our common stock declining

Since our inception, we have incurred significant net losses and we may incur net losses in 2003. We anticipate that our expenses may increase substantially in the foreseeable future as we:

- continue to invest in research and development to enhance our ALGO screener, neoBLUE phototherapy device and other products and technologies;
- develop additional applications for our current or newly acquired technology;
- increase our marketing and selling activities, particularly outside the United States;
- continue to increase the size and number of locations of our customer support organization, particularly outside the United States; and
- develop additional infrastructure and hire required management and other employees.

In addition, we may incur expenses in connection with the acquisition of businesses or assets of other companies. As a result of the possible increased expenses, we may need to generate significantly higher revenue to achieve profitability. We cannot be certain that we will achieve profitability in the future or, if we achieve profitability, sustain it. If we do not achieve and maintain profitability, the market price of our common stock is likely to decline, perhaps substantially.

We have relied, and expect to continue to rely, on sales of our ALGO screening product family for substantially all of our revenue, and a decline in sales of these products could cause our revenue to fall

Historically, we have derived substantially all of our revenue from sales of our ALGO screening products. We expect that the revenue from our ALGO screening product family will continue to account for a substantial majority of our revenue for at least the next two years. To date, our MiniMuffs product, which is a disposable ear cover for newborns, and our CO-Stat analyzer product, which is a jaundice management device for newborns, have accounted for only a small percentage of our revenue. We have not derived any significant revenue from sales of our CO-Stat analyzer products and have recently decreased sales and marketing resources devoted to these products. We are currently evaluating the viability of marketing our CO-Stat products in the newborn jaundice market and may determine to cease these marketing efforts altogether. We introduced our neoBLUE phototherapy device in October 2002 and do not expect to recognize material revenue from this product during 2003. Any factors adversely affecting the pricing of our ALGO screening devices and related disposables or demand for our ALGO screening products, including physician acceptance or the selection of competing products, could cause our revenue to decline and our business to suffer.

If more physicians do not adopt our ALGO screening products, CO-Stat analyzer products and neoBLUE phototherapy device, we will not achieve future sales growth

We acquired the ALGO screening product technology in 1987, introduced our CO-Stat analyzer product in January 2001 and introduced our neoBLUE phototherapy device in October 2002. More neonatologists and pediatricians must adopt these products for our sales to increase. To date, we have not achieved the revenue levels we previously anticipated with respect to our CO-Stat analyzer products and have decreased the resources devoted to these products. We believe that physicians will not use our products unless they determine, based on published peer-reviewed journal articles, long-term clinical data and experience, that the products provide an accurate and cost-effective alternative to other means of testing for hearing impairment or jaundice management. There are currently alternative hearing screening and jaundice management products, which may be less expensive or may be quicker on a per test basis. Physicians are traditionally slow to adopt new products, testing practices and treatments, partly because of perceived liability risks and the uncertainty of third party

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reimbursement. If more neonatologists and pediatricians do not adopt our products, we may never have significant revenue or achieve and maintain profitability. Factors that may affect the medical community's acceptance of our products, some of which are beyond our control, include:

- the changing governmental and physician group guidelines for screening of newborns, particularly with respect to full term babies;
- the performance, quality, price and total cost of ownership of our screening and jaundice management products relative to other screening and jaundice management products for newborns;
- our ability to maintain and enhance our existing relationships and to form new relationships with leading physician organizations, hospitals and third party payors;
- changes in state and third party payor reimbursement policies for newborn screening devices; and
- the adoption of state and foreign laws requiring universal newborn screening.

If more governments do not adopt the data management, software and reagents used for metabolic screening we acquired from Neometrics, we will not achieve sales growth or the benefits we expected in connection with the acquisition

In July 2003 we acquired data systems, software and reagents used for metabolic screening from Neometrics. We sell the data systems and software products to state governments to assist them in collecting, tracking, managing and reporting newborn screening data. Currently, 18 state health departments (some of which serve multiple states) use the Neometrics software and data systems products for this purpose. We sell the reagents used for metabolic screening to state governments in connection with state testing programs for metabolic disorders in newborns. These programs typically are implemented through state laws or regulations. While all states require newborn testing for these disorders, most state laws and regulations allow for exemptions from testing for various reasons, such as religious belief. Moreover, the laws and regulations vary widely with respect to the disorders for which tests are required to be conducted and the segment of the population that is required to be screened. The state governments typically conduct the tests in state-run laboratories after a blood sample has been collected or contract with private laboratories to conduct the tests. If the state and foreign governments do not use our reagents used for metabolic screening, or adopt the software and data systems products we acquired, or we are not able to develop additional uses for these products, our revenues may not grow and we will not achieve the benefits we expected in connection with the acquisition. Factors that may affect the use and adoption of the products we acquired in the Neometrics acquisition include:

- changing governmental laws and regulations for the screening of metabolic disorders in newborns, including with respect to the disorders for which tests are to be conducted;
- the performance, quality, price and total cost of ownership of our data systems and related support services and the performance, quality and price of our reagents used for metabolic screening;
- our ability to maintain and enhance our existing relationships with the state governments that were Neometrics customers, to sell the products we acquired to additional state governments and to sell these products in foreign countries;
- the adequacy of federal and state government budgets to fund, or other changes with respect to funding for, the testing for metabolic disorders in newborns and the purchase of our data systems; and
- the improvement of existing methods, or the development of new methods, superior to reagents used for metabolic screening to test for metabolic disorders.

A continuation of the general economic downturn in the United States or abroad may reduce our revenue and harm our business

The primary customers for our products are neonatologists, physicians, audiologists, hospitals and government agencies. Any significant downturn in domestic or global economic conditions which results in the reduction of the

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capital spending budgets of our customers or a delay in capital equipment purchases would likely result in a decline in demand for our products and could be detrimental to our business. Economic growth in the United States and other countries has slowed significantly. Overall, customer spending is getting tighter and spending decisions are being more closely scrutinized. These conditions have negatively impacted our business and may continue to do so if they persist. Like other companies, we currently have very limited visibility with respect to our near term quarters and are having difficulty predicting our revenue and operating results during these periods.

Our quarterly operating results may fluctuate, which could cause our stock price to fluctuate

Our revenue and operating results have varied significantly from quarter to quarter in the past and may continue to fluctuate in the future. The following are among the factors that could cause our revenue, gross margin and operating results to fluctuate significantly from quarter to quarter:

- the budgeting cycles of our customers;
- the size and timing of specific sales, such as large purchases of medical devices or disposable supplies by government agencies or hospital systems;
- product and price competition;
- trade-in allowances or other concessions in connection with the introduction of new products or improvements to existing products;
- the timing and market acceptance of new product introductions and product enhancements by us and our competitors, such as the expected reduction in demand for and potential inventory obsolescence relating to our existing ALGO screener prior to or after the announced launch date of our next generation ALGO screener;
- the length of our sales cycle;
- the loss of key sales personnel or international distributors; and
- changes caused by the rapidly evolving market for newborn screening products.

In addition, if a majority of our customers were to implement enterprise-wide evaluation programs or purchase products for the entire organization at once, our sales cycle could lengthen and our revenue could be erratic from quarter to quarter.

We have limited historical experience selling our products other than our hearing screening products and cannot determine how the sales cycle for these products will affect our revenue. The sales cycle, however, could be protracted and could result in further unpredictability in our revenue from quarter to quarter.

Many of these factors are beyond our control, and we believe that you should not rely on our results of operations for interim periods as an indication of our expected results in any future period. If our revenue varies significantly from quarter to quarter, our business could be difficult to manage and our quarterly results could be below expectations of investors and stock market analysts, which could cause our stock price to fluctuate.

Our operating results have been and may continue to be subject to seasonal fluctuations

We experience seasonality in the sale of our medical devices. For example, our sales typically decline from our fourth fiscal quarter to our first fiscal quarter. We anticipate that we will continue to experience relatively lower sales in our first fiscal quarter due to patterns in the capital budgeting and purchasing cycles of our current and prospective customers, many of which are government agencies. We may also experience declining sales in the third fiscal quarter due to summer holiday and vacation schedules. These seasonal factors may lead to fluctuations in our quarterly operating results. It is difficult for us to evaluate the degree to which the summer slow down and capital budgeting and customer purchasing cycle variations may make our revenue unpredictable in the future.

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Our operating results may decline if we do not succeed in developing, acquiring and marketing additional newborn products or improving our existing products

We intend to develop additional products relating to the diagnosis and monitoring of common medical conditions in infants and pregnant women. Developing new products and improving our existing products requires significant investments in research and development. If we fail to successfully develop and market new products and update our existing products, our operating results may decline as our existing products reach the end of their commercial life cycles.

Our future growth and profitability will depend, at least in part, on our ability to achieve volume sales of our CO-Stat analyzer products, neoBLUE phototherapy device and the products we acquired from Neometrics

We introduced our CO-Stat analyzer product family for clinical research uses in July 1999. We introduced our neoBLUE phototherapy device in October 2002. We acquired new data systems and reagents used for metabolic screening from Neometrics in July 2003. To date, our CO-Stat analyzer products and neoBLUE phototherapy devices have accounted for only a limited portion of our revenue. We have experienced limited success in marketing and selling our CO-Stat analyzer products and have limited experience marketing and selling our neoBLUE phototherapy device and data systems and reagents used for metabolic screening acquired from Neometrics. We are currently evaluating the viability of marketing our CO-Stat analyzer products in the newborn jaundice market. While we are not currently devoting significant resources to market our CO-Stat products, we continue to support clinical research and development relating to our CO-Stat analyzer products in this area and for other clinical applications. Our future growth and profitability will depend, in part, on our ability to commercially sell our CO-Stat analyzer products, our neoBLUE phototherapy device, and the products acquired from Neometrics in volume. We cannot be certain that any of these products will be successful, that a market for these products will develop at all or that physicians, governments or other third party vendors will accept and adopt these products.

Physicians may not adopt or continue to use our CO-Stat analyzer products or neoBLUE phototherapy device if we cannot show that these products are cost-effective or if clinical data does not support our products, which would harm our operating results

One clinical study has concluded that our CO-Stat analyzer product is more cost-effective than another test for detecting hemolysis in jaundiced newborns. Our safety, effectiveness, reliability, sensitivity and specificity data for the use of our CO-Stat analyzer products for purposes of newborn jaundice management is based in part on a study of over 1,300 newborns conducted in 1998. In addition, clinical research is ongoing with respect to additional clinical applications for our CO-Stat analyzer. With respect to our neoBLUE phototherapy device, initial data from clinical research suggests that the device may be more effective in treating hyperbilirubinemia than other currently marketed phototherapy products. We cannot be certain that clinical studies will produce results that are favorable to our products. If studies and clinical experience do not support our products or demonstrate their cost-effectiveness, our products may not gain commercial acceptance and may not be accepted by physicians and governments, which would harm our operating results. In addition, we could be subject to significant liability for any failure of our products to perform properly, and could have similar problems with any other product we offer in the future.

If the guidelines for recommended universal newborn hearing screening do not continue to develop in the United States and foreign countries, and governments do not require testing of all newborns as we anticipate, our revenue may decline because our products will not be needed for universal newborn screening

The demand for our screening products depends, in part, upon state and foreign governments' adoption of universal screening requirements for the disorders for which our ALGO products screen. Some state governments

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only recently have adopted the guidelines for universal newborn screening for hearing impairment. We cannot predict the outcome or the impact that statutes and government regulations requiring universal newborn hearing screening will have on our sales. The widespread adoption of these guidelines will depend on our ability to educate government agencies, neonatologists, pediatricians, third party payors and hospital administrators about the benefits of universal newborn screening, as well as the use of our ALGO products to perform the screening and monitoring.

Our revenue may not grow if densely populated states and developed foreign countries do not adopt guidelines requiring universal newborn screening or if those guidelines have a long phase-in period

If the governments in the most densely populated states and developed foreign countries do not require universal screening for the disorders for which our ALGO, CO-Stat analyzer and Neometrics reagents used for metabolic screening test, our business would be harmed and our revenue may not grow. As of September 30, 2003, 37 states and the District of Columbia had mandated universal newborn hearing screening, but the phase-in of these guidelines varies widely from six months to four years. To date, there has been only limited adoption of newborn hearing screening prior to hospital discharge by foreign governments. Our revenue may not grow if hospitals are slow to comply with these guidelines or the applicable government provides for a lengthy phase-in period for compliance.

State guidelines for the testing of newborns for metabolic disorders vary widely. For instance, some states require testing for only a small number of disorders and may only require testing for certain disorders in selected populations. In addition, state laws and regulations vary with respect to the allowable exemptions from testing for metabolic disorders, from exemptions for religious reasons to exemptions for any reason. Most foreign countries do not have laws or rules that regulate metabolic screening of newborns. Our revenues may not grow if guidelines requiring the testing for disorders for which our reagents used for metabolic screening screen are not maintained and do not further develop to require testing for additional metabolic disorders.

Our revenue may not grow if state and foreign governments do not mandate hemolysis monitoring as the standard of care for newborn jaundice screening, or if we are not able to successfully establish other uses for our CO-Stat analyzer products

To date, physician groups and federal, state and local governments have not mandated the screening methodology to be used for newborn jaundice management or established monitoring of hemolysis as the best practice. If these mandates or practice recommendations are not issued, or we are unable to successfully establish other uses for our CO-Stat analyzer products, a market may not develop for our CO-Stat analyzer products.

Any failure in our efforts to educate clinicians, government agencies and other third party payors could significantly reduce our product sales

It is critical to the success of our sales efforts that we educate a sufficient number of clinicians, hospital administrators and government agencies about our products and the costs and benefits of their use. The success of our products depends upon physician, government agency and other third party payor confidence in the benefits of our products as well as their comfort with the reliability, sensitivity and specificity of our products. The impact of our products will not be demonstrable unless highly sensitive and specific evaluations are performed on a substantial number of newborns, including, for example, those who do not have risk factors for metabolic disorders, hearing impairment or who do not display signs of jaundice. If we fail to demonstrate the effectiveness of our products and the potential long-term benefits to patients and third party payors of universal newborn screening, our products will not be adopted.

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If health care providers are not adequately reimbursed for procedures conducted with our medical devices or for our products, we may never achieve significant revenue

Physicians, hospitals and state agencies are unlikely to purchase our ALGO, CO-Stat analyzer, neoBLUE and reagents used for metabolic screening if clinicians are not adequately reimbursed for the procedures conducted with our medical devices or the disposable products needed to conduct screenings. Unless a sufficient amount of positive, peer-reviewed clinical data about our products has been published, third party payors, including insurance companies and government agencies, may refuse to provide reimbursement for the cost of newborn hearing screening and jaundice management with our products. Furthermore, even if reimbursement is provided, it may not be adequate to fully compensate the clinicians or hospitals. Some third party payors may refuse adequate reimbursement unless the infant has demonstrable risk factors. If health care providers and government agencies cannot obtain sufficient reimbursement from third party payors for our products or the screenings conducted with our products, it is unlikely that our products will ever achieve significant market acceptance.

With respect to our reagents used for metabolic screening, state programs for the testing of newborns for metabolic disorders are funded in part by reimbursement of screening fees by third party payors such as government agencies and insurance companies. Should government agencies and third party payors refuse to provide reimbursement in connection with testing for metabolic disorders or reduce the level of support for metabolic screening programs, it is unlikely that we will achieve significant revenue from our reagents used for metabolic screening.

Acceptance of our products in international markets will be dependent upon the availability of adequate reimbursement or funding, as the case may be, within prevailing health care payment systems. Reimbursement, funding and health care payment systems vary significantly by country and include both government-sponsored health care and private insurance. Although we intend to seek international reimbursement or funding approvals, we may not obtain these approvals in a timely manner or at all.

Even if third party payors provide adequate reimbursement for procedures conducted with our medical devices or for our products, adverse changes in reimbursement policies in general could harm our business

We are unable to predict changes in the reimbursement methods used by third party health care payors or in state programs that fund testing for metabolic disorders. For example, some payors are moving toward a managed care system in which providers contract to provide comprehensive health care for a fixed cost per person. We cannot assure you that in a managed care system the cost of our products will be incorporated into the overall payment for childbirth and newborn care or that there will be adequate reimbursement for our medical devices and disposable products separate from reimbursement for the procedure. Unless the cost of screening is reimbursed as a standard component of the newborn's care, universal screening is unlikely to occur and the number of infants likely to be screened with our products will be substantially reduced.

We have very limited experience selling and marketing products other than our ALGO screening products, and failure to develop and manage our sales force or to effectively market and distribute our CO-Stat analyzer, neoBLUE phototherapy device and hardware, software and screening products acquired from Neometrics or other products could hurt our revenue and quarterly results

Our sales force has achieved limited success selling our CO-Stat analyzer, and has limited experience selling our neoBLUE phototherapy device and related products, and we cannot predict how successful our sales force will be in selling them in the future. In order to successfully introduce and penetrate the market for our CO-Stat analyzer and neoBLUE phototherapy device products, we must sell our products to hospital administrators accustomed to the use of laboratory bench medical devices rather than portable point of care screening devices for jaundice management. While we hired employees from Neometrics, including sales personnel, we have no

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previous experience in selling the newborn metabolic screening data management hardware, software and reagents used for metabolic screening we recently acquired from Neometrics. Because the sales of these products are often made to state health departments, some of which we may not historically have had commercial relationships with, we cannot be certain that we will achieve the level of sales that we anticipate from the products we acquired from Neometrics.

We market almost all of our products in the United States through a direct sales force. There are significant risks involved in building and managing our sales force and marketing our products. We may be unable to hire a sufficient number of qualified sales people with the skills and training to sell our newborn screening, jaundice management, data systems and reagents used for metabolic screening effectively. Furthermore, we do not have any agreements with distributors for domestic sales of our products.

We may not be successful in generating revenue from our CO-Stat analyzer, neoBLUE phototherapy device or reagents used for metabolic screening because we may encounter difficulties in manufacturing them in commercial quantities

We do not have experience manufacturing our CO-Stat analyzer, neoBLUE phototherapy device or reagents used for metabolic screening in commercial quantities, and we may encounter difficulties in the manufacturing of these products. We may also increase our manufacturing personnel or increase the volume of products we purchase from contract manufacturers that produce these products for us. If we encounter difficulties in the manufacture of our products, we may not be successful in marketing them, and our revenue and financial condition may be harmed.

If we lose our relationship with any supplier of key product components or our relationship with a supplier deteriorates or key components are not available in sufficient quantities, our manufacturing could be delayed and our business could suffer

We contract with third parties for the supply of some of the components used in our products and the production of our disposable products. Some of our suppliers are not obligated to continue to supply us. For certain of these materials and components, relatively few alternative sources of supply exist. In addition, the lead-time involved in the manufacturing of some of these components can be lengthy and unpredictable. During 2002, we experienced delays on the part of a supplier to provide us with volume production of our new ALGO 3 screening Flexicoupler supplies. If these suppliers become unwilling or unable to supply us with our requirements, it might be difficult to establish additional or replacement suppliers in a timely manner or at all. This would cause our product sales to be disrupted and our revenue and operating results to suffer.

Replacement or alternative sources might not be readily obtainable due to regulatory requirements and other factors applicable to our manufacturing operations. Incorporation of components from a new supplier into our products may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product sales. This process may take a substantial period of time, and we cannot be assured that we would be able to obtain the necessary regulatory clearance or approval. This could create supply disruptions that would harm our product sales and operating results.

There is only one Natus approved supplier that provides hydrogel, the adhesive used in most of our disposable products. In addition, we have relied on a single supplier for the electrochemical sensors used in our CO-Stat analyzer and we have not qualified another vendor for this component. A disruption in the supply of hydrogel or electrochemical sensors could negatively affect our revenue. If we or our contract manufacturers were unable to locate another supplier, it could significantly impair our ability to sell our products. In addition, we may be required to make new or supplemental filings with applicable regulatory authorities prior to our marketing a product containing new materials or produced in a new facility. If we fail to obtain regulatory approval to use a new material, we may not be able to continue to sell the affected products and revenue and operating results could suffer.

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Our sales efforts through group purchasing organizations and sales to high volume purchasers may reduce our average selling prices, which would reduce our revenue and gross margins from these sales

We have entered, and may in the future enter, into agreements with customers who purchase high volumes of our products. Our agreements with these customers may contain discounts off of our normal selling prices and other special pricing considerations, which could cause our revenue and profit margins to decline. In addition, we have entered into agreements to sell our products to members of group purchasing organizations, which negotiate volume purchase prices for medical devices and supplies for member hospitals, group practices and other clinics. While we make sales directly to group purchasing organization members, the members of these group purchasing organizations now receive volume discounts off our normal selling price and may receive other special pricing considerations from us from time to time. Sales to members of one group purchasing organization, Novation, LLC, accounted for approximately 23% of our total revenue in the nine months ended September 30, 2003, and approximately 29% and 25% of our total revenue in the twelve months ended December 31, 2002 and 2001 respectively. Sales to members of group purchasing organizations accounted for approximately 41% of our total revenue during the nine months ended September 30, 2003, and approximately 47% and 35% of our total revenue during the twelve months ended December 31, 2002 and 2001 respectively. Other of our existing customers may be members of group purchasing organizations with which we do not have agreements. Our sales efforts through group purchasing organizations may conflict with our direct sales efforts to our existing customers. If we enter into agreements with new group purchasing organizations and some of our existing customers begin purchasing our products through those group purchasing organizations, our revenue and profit margins could decline.

We rely on sales to existing customers for a majority of our revenue, and if our existing customers do not continue to purchase products from us, our revenue may decline

We rely on sales of additional screening products to our existing customers for a majority of our revenue. If we fail to sell additional screening products to our existing customers directly or indirectly, we would experience a material decline in revenue.

Because we rely on distributors or sub-distributors to sell our ALGO screening and neoBLUE phototherapy device products in some markets outside of the United States, our revenue could decline if our existing distributors reduce the volume of purchases from us or if our relationship with any of these distributors is terminated

We currently rely on our distributors or sub-distributors for a majority of our sales of our ALGO screening and neoBLUE phototherapy device products outside the United States. Some distributors also assist us with regulatory approvals and education of physicians and government agencies. Neither our CO-Stat analyzer products nor the data systems and reagents used for metabolic screening we acquired from Neometrics have been sold outside the United States. We intend to continue our efforts to increase our sales in Europe, Japan and other countries with a relatively high level of health care spending on infants, and to attempt to expand sales of the data systems and reagents used for metabolic screening into these countries. If we fail to sell these products through our international distributors, we would experience a decline in revenue growth unless we begin to sell our products directly in those markets. We cannot be certain that we will be able to attract new international distributors that market our products effectively or provide timely and cost-effective customer support and service. Even if we are successful in selling our products through new distributors, the rate of growth of our revenue could be harmed if our existing distributors do not continue to sell a large dollar volume of our products.

If we terminate our relationships with distributors for poor performance, as we have done in the past, we may be subject to foreign laws governing our relationships with our distributors. These laws may require us to make payments to our distributors even if we terminate our relationship for cause. Some countries require termination payments under common law or legislation that may supercede our contractual relationship with the distributor. These payments could be equal to a year or more of gross margin on sales of our products that the distributor would have earned. Any required payments would adversely affect our operating results.

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In light of a maturing domestic market for our ALGO screening products, we plan to expand our international operations, which will result in increased costs; if our efforts to expand our international operations are not successful, this could harm our business

We believe our ability to grow our revenue related to our ALGO screening products will increasingly depend on our success in the international market, as the market in the United States for our ALGO screening products is beginning to mature. We must expand the number of distributors who sell our products or increase our direct international sales presence to significantly penetrate international markets. We have only recently begun to develop a direct sales force outside the United States. For example, we acquired the distribution operations of our United Kingdom distributor and top-tier Japan distributor in January 2001 and July 2001, respectively, and during 2002 we appointed two new top-tier Japan redistributors. As we continue to increase our direct international sales presence, we will incur higher personnel costs that may not result in additional revenue. A higher percentage of our sales to international distributors could also impair our revenue due to discounts available to these distributors. We may not realize corresponding growth in operating results from growth in international sales, due to the higher costs of sales outside of the United States. Even if we are able to successfully expand our direct and indirect international selling efforts, we cannot be certain that we will be able to create or increase demand for our products outside of the United States.

Our operating results may suffer because of foreign currency exchange rate fluctuations or strengthening of the United States dollar relative to local currencies

Prior to January 2001, substantially all of our sales contracts provided for payment in United States dollars. However, with the acquisition of the distribution operations of our United Kingdom distributor and top-tier Japan distributor in January 2001 and July 2001, respectively, our revenue and expenses in those countries have become largely denominated in their applicable foreign currency. We may also sell our products in other local currencies as we expand our direct international sales. To date, we have not undertaken any foreign currency hedging transactions, and as a result, our future revenue and expense levels from international operations may be unpredictable due to exchange rate fluctuations. Furthermore, a strengthening of the dollar could make our products less competitive in foreign markets, and fluctuations in currencies could result in foreign exchange gains and losses associated with the translation of assets denominated in foreign currencies.

We face other risks from foreign operations, which could reduce our operating results and harm our financial condition

Our international operations are subject to other risks, which include:

- the impact of possible recessions in economies outside the United States;
- political and economic instability, including instability related to war and terrorist attacks in the United States and abroad;
- contractual provisions governed by foreign law, such as legal rights in some countries to sales commissions by terminated distributors;
- the dependence of demand for our products on health care spending by foreign governments;
- greater difficulty in accounts receivable collection and longer collection periods;
- difficulties of staffing and managing foreign operations;
- reduced protection for intellectual property rights in some countries and potentially conflicting intellectual property rights of third parties under the laws of various foreign jurisdictions; and
- difficulty in obtaining foreign regulatory approvals.

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Our failure to obtain necessary FDA clearances or approvals or to comply with FDA regulations could hurt our ability to commercially distribute and market our products in the United States, and this would harm our business and financial condition

Unless an exemption applies, each medical device that we wish to market in the United States, including our Neometrics reagents used for metabolic screening, must first receive one of the following types of FDA premarket review authorizations:

- 510(k) clearance via Section 510(k) of the federal Food, Drug, and Cosmetics Act of 1938, as amended; or
- premarket approval via Section 515 of the Food, Drug, and Cosmetics Act if the FDA has determined that the medical device in question poses a greater risk of injury.

The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining premarket approval is much more costly, lengthy and uncertain. Premarket approval generally takes from one to three years, but can take even longer. We cannot assure you that the FDA will ever grant either 510(k) clearance or premarket approval for any product we propose to market. Furthermore, if the FDA concludes that these future products using our technology do not meet the requirements to obtain 510(k) clearance, we would have to seek premarket approval. We cannot assure you that the FDA will not impose the more burdensome premarket approval requirement on modifications to our existing products or future products, which in either case could be costly and cause us to divert our attention and resources from the development of new products or the enhancement of existing products.

Our business may suffer if we are required to revise our labeling or promotional materials or the FDA takes an enforcement action against us for off-label uses

We may not promote or advertise the ALGO screener, MiniMuffs, neoBLUE phototherapy device, CO-Stat analyzer products or Neometrics reagents used for metabolic screening, or any future cleared or approved devices, for uses not within the scope of our clearances or approvals or make unsupported promotional claims about the benefits of our products. If the FDA determines that our claims are outside the scope of our clearances or are unsupported it could require us to revise our promotional claims or take enforcement action against us. If we were subject to such an action by the FDA, our sales could be delayed, our revenue could decline and our reputation among clinicians could be harmed.

Our business would be harmed if the FDA determines that we have failed to comply with applicable regulations or we do not pass an inspection

We are subject to inspection and market surveillance by the FDA concerning compliance with pertinent regulatory requirements. If the FDA finds that we have failed to comply with these requirements, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions and civil penalties;
- the recall or seizure of our products;
- the issuance of public notices or warnings;
- the imposition of operating restrictions, partial suspension or total shutdown of production;
- the refusal of our requests for 510(k) clearance or premarket approval of new products;
- the withdrawal of 510(k) clearance or premarket approvals already granted; or
- criminal prosecution.

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If we fail to obtain necessary foreign regulatory approvals in order to market and sell our products outside of the United States, we may not be able to sell our products in other countries

Our products, including our reagents used for metabolic screening, are regulated outside the United States as medical devices by foreign governmental agencies similar to the FDA and are subject to regulatory requirements similar to the FDA's. The time and cost required to obtain market authorization from other countries and the requirements for licensing a product in another country may differ significantly from the FDA requirements. We may not be able to obtain these approvals without incurring significant expenses, or at all.

If we or our suppliers fail to comply with applicable regulations, sales of our products could be delayed and our revenue could be harmed

Every manufacturer of a finished medical device, including us and some of our contract manufacturers and suppliers, is required to demonstrate and maintain compliance with the FDA's quality system regulation and comparable regulations of states and other countries. The FDA enforces the quality system regulation through periodic inspections. Although we have passed inspections in the past, we cannot assure you that we or our contract manufacturers will pass any future quality system regulation inspections. If we or our contract manufacturers fail one of these inspections in the future, our operations could be disrupted and our manufacturing and sales delayed significantly until we can demonstrate adequate compliance. If we or our contract manufacturers fail to take adequate corrective action in a timely fashion in response to a quality system regulations inspection, the FDA could shut down our or our contract manufacturers' manufacturing operations and require us, among other things, to recall our products, either of which would harm our business.

We may experience intense competition from other medical device companies or state-funded programs, and this competition could adversely affect our revenue and our business

Our most significant current and potential competitors for our ALGO screening products include companies that market enhanced auditory brainstem response and otoacoustic hearing screening devices. For jaundice management products, our competition falls into the following categories: for blood-based antibody and bilirubin tests, we anticipate our competitors to be large medical diagnostics companies that market laboratory bench devices; for noninvasive analysis of skin tones to estimate the level of "jaundice yellowing" present in the skin, medium to large in vitro diagnostics companies that market point of care, handheld monitoring devices. With respect to our neoBLUE product, our competitors are companies that market phototherapy devices. For the products we acquired from Neometrics, we anticipate our competitors to be indigenous state-developed data systems and several private companies that develop and market neonatal data management software, and large companies that make reagents used for metabolic screening of newborns for various metabolic disorders. In addition, we expect that manufacturers of tandem mass spectrometers, instruments that can measure small amounts of material and can detect disorders from blood samples, to be competitors with respect to certain of our reagents used for metabolic screening. Tandem mass spectrometry may be more efficient and effective than the use of reagents used for metabolic screening for the testing of certain disorders. However, it may not be suitable for testing for some disorders included in state screening programs for metabolic disorders in newborns.

Bio-logic Systems Corp., Intelligent Hearing Systems, GN Otometrics (including Madsen Electronics), and Sonamed Corp., each of which is also currently marketing enhanced auditory brainstem response and otoacoustic hearing screening devices, have lower-priced hearing screening devices that may not require, similar to our products, an audiologist or physician to interpret its results or review its recommendations. A determination of the cost of screening also needs to address the accuracy and reliability of the medical devices, the cost of disposable products used for the screening, as well as the professional service fees of the health care provider giving the screening. Some of our competitors sell lower-priced disposable products for use with our screening devices. The sales of these products have adversely impacted our revenue from sales of our disposable products and may have an adverse effect on our revenue and operating results in the future. Our competitors may develop and receive FDA approval for the sale of disposable products to use with our new screening devices.

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We believe that Minolta Co., Ltd. and SpectRx, Inc., each of which is currently marketing skin color analysis products for bilirubin monitoring, or Johnson & Johnson and F. Hoffman-La Roche Ltd., each of which is currently marketing medical devices for blood-based bilirubin or antibody tests, could also introduce new, lower-priced options for the management of newborn jaundice. We expect that competitors to our neoBLUE phototherapy device product include these companies.

Our competitors with respect to our reagents used for metabolic screening include companies that are currently marketing reagents used for metabolic screening for screening newborns for various metabolic disorders. Some of these companies could introduce new, lower-priced reagents used for metabolic screening. In addition, we believe that it would not be difficult for larger companies to enter into the reagents used for metabolic screening business, which would decrease our revenue from these products. Several private entities are developing and marketing software designed to track and manage information on newborn screening including hearing screening. Some states also have developed their own software for tracking and management of information on newborn screening. States could decide to outsource neonatal metabolic screening including tracking and management of the data pertaining to neonatal screening. Some of our competitors may have greater financial resources and name recognition or larger, more established distribution channels than we do.

We believe our future success depends on our ability to enhance existing products, develop and introduce new products, satisfy customer requirements and achieve market acceptance. We cannot be certain that we will successfully identify new product opportunities. We may not be able to develop and bring new products to market before our competitors or in a more cost-effective manner. Increased competition may negatively affect our business and future operating results by leading to price reductions, higher selling expenses or a reduction in our market share.

Our business could be harmed if our competitors establish cooperative relationships with large medical testing device vendors or rapidly acquire market share through industry consolidation or by bundling together, or with other products, their hearing screening, jaundice monitoring, data systems or reagents used for metabolic screening

Large medical testing device vendors, such as Johnson & Johnson or F. Hoffman-La Roche Ltd., may acquire or establish cooperative relationships with our current competitors. We expect that the medical testing device industry will continue to consolidate. New competitors or alliances among competitors may emerge and rapidly acquire significant market share, which would harm our business and financial prospects.

Other medical device companies may decide to bundle their products, for example, by bundling together, or with other products, their newborn hearing screening, hemolysis monitoring, jaundice management, data systems or reagents used for metabolic screening and selling the bundle at lower prices. If this happens, our business and future operating results could suffer if we were no longer able to offer commercially viable or competitive products.

We may not be successful in integrating the businesses or technologies that we acquire, or the businesses or technologies may not perform as projected

In March 2002, we acquired intellectual property assets and technology patents from Pemstar, and in July 2003 we purchased substantially all of the assets of Neometrics Inc. and its affiliate Neogenesis Corporation. Neometrics was a supplier of data systems consisting of hardware and proprietary software used in 18 state health departments (some of which serve multiple states) to collect, track, manage and report newborn screening data, including hearing screening data. Neometrics also provided reagents used for metabolic screening of infants. Reagents used for metabolic screening are used to test blood samples from newborns to screen for certain medical conditions. We may acquire additional products, technology assets or businesses in the future as part of

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our efforts to increase revenue and expand our product offerings. In addition to direct costs, acquisitions pose a number of risks, including:

- integration of the acquired products into our business;
- integration of the personnel of the acquired company into our business;
- the failure to realize expected synergies;
- the failure of acquired products to achieve projected sales;
- the failure to maintain customers of, or other relationships existing with respect to the acquired business;
- the failure of our development agreement with Pemstar or other contract developers to result in the desired product developments;
- assumption of unknown liabilities;
- failure to understand and compete effectively in markets in which we have limited previous experience; and
- write-offs of goodwill and associated technologies or costs associated with such failed new products or businesses.

Acquisitions could subject us to significant asset or impairment charges. While we make efforts to analyze potential acquisitions carefully and to value assets and their related future lives appropriately, we cannot be certain that any completed acquisition will positively impact our business. If we fail to achieve the anticipated financial, strategic and other benefits of acquisitions or investments, our operating results may suffer.

We may not be able to preserve the value of our products' intellectual property because we may not be able to protect access to our intellectual property or we may lose our intellectual property rights due to expiration of our licenses or patents

If we fail to protect our intellectual property rights or if our intellectual property rights do not adequately cover the technology we employ, other medical device companies could sell products with features similar to ours, and this could reduce demand for our products. We protect our intellectual property through a combination of patent, copyright, trade secret and trademark laws. We attempt to protect our intellectual property rights by filing patent applications for new features and products we develop. We enter into confidentiality or license agreements with our employees, consultants and corporate partners and seek to control access to our intellectual property and the distribution of our products, documentation and other proprietary information. However, we believe that these measures afford only limited protection. Others may develop technologies that are similar or superior to our technology or design around the patents, copyrights and trade secrets we own. The original patent for an algorithm for analyzing auditory brainstem responses, which we licensed on a nonexclusive basis from a third party and upon which we developed our automated auditory brainstem response technology, expired in late 1999, and that subject matter is in the public domain. With respect to our neoBLUE phototherapy device, the basic concept of using blue lights for phototherapy is well established in the technical literature and is therefore not patentable. However, we have one patent pending that pertains to some of the features in our neoBLUE phototherapy device, and the design and manufacturing methods we use are proprietary to us. We cannot assure you that the patent applications we have filed to protect the features of our products will be allowed, or will deter others from using the auditory brainstem response technology.

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Despite our efforts to protect our proprietary rights, others may attempt to copy or otherwise improperly obtain and use our products or technology. Policing unauthorized use of our technology is difficult and expensive, and we cannot be certain that the steps we have taken will prevent misappropriation, particularly in foreign countries where the laws may not protect our proprietary rights as fully. Our means of protecting our proprietary rights may be inadequate. Enforcing our intellectual property rights could be costly and time consuming and may divert our management's attention and resources. Enforcing our intellectual property rights could also result in the loss of our intellectual property rights.

Our operating results would suffer if we were subject to a protracted infringement claim or a significant damage award

Substantial intellectual property litigation and threats of litigation exist in our industry. We expect that medical screening devices and related products may become increasingly subject to third party infringement claims as the number of competitors in our industry segment grows and the functionality of products in different industry segments overlaps. Third parties such as individuals, educational institutions or other companies may claim that we infringe their intellectual property rights. Any claims, with or without merit, could have any of the following negative consequences:

- result in costly litigation and damage awards;
- divert our management's attention and resources;
- cause product shipment delays or suspensions; or
- require us to seek to enter into royalty or licensing agreements, which may not be available on terms acceptable to us, if at all.

A successful claim of infringement against us could result in a substantial damage award and materially harm our financial condition. Our failure or inability to license the infringed or similar technology could prevent us from selling our products and adversely affect our business and financial results.

Product liability suits against us could result in expensive and time consuming litigation, payment of substantial damages and an increase in our insurance rates

The sale and use of our products could lead to the filing of a product liability claim against us if someone were to be injured using one of our products or if one of our products fails to perform properly or to detect a disorder for which it was being used to screen. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing any coverage in the future.

We may incur significant costs related to a class action lawsuit due to volatility of the public market price of our stock

Our stock price may fluctuate for a number of reasons including:

- quarterly fluctuations in our results of operations;
- our ability to successfully commercialize our products;
- announcements of technological or competitive developments by us or our competitors;
- announcements regarding patent litigation or the issuance of patents to us or our competitors;
- announcements regarding state screening mandates or third party payor reimbursement policies;

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- regulatory developments regarding us or our competitors;
- acquisitions or strategic alliances by us or our competitors;
- changes in estimates of our financial performance or changes in recommendations by securities analysts; or
- general market conditions, particularly for companies with a relatively small number of shares available for sale in the public market.

Securities class action litigation is often brought against a company after a period of volatility of the market price of its stock. If our future quarterly operating results are below the expectations of securities analysts or investors, the price of our common stock would likely decline. Stock price fluctuations may be exaggerated if the trading volume of our common stock is low. Any securities litigation claims brought against us could result in substantial expense and damage awards and divert our management's attention from running our business.

Our executive officers, directors, principal stockholders and their affiliates hold a substantial portion of our stock and could exercise significant influence over matters requiring stockholder approval, regardless of the wishes of other stockholders

Our executive officers, directors, principal stockholders and individuals or entities affiliated with them beneficially own a substantial portion of our outstanding common stock as of September 30, 2003. If these stockholders act together, they could significantly influence all matters that our stockholders vote upon, including the election of directors and determination of significant corporate actions. Among other things, this concentration of ownership could delay or prevent a change of control transaction that could otherwise be beneficial to our stockholders.

Anti-takeover provisions in our charter documents and under Delaware law may affect the price of our common stock, and make it more difficult to remove our management. Further, these provisions may make it more difficult to acquire a large portion of our securities, to initiate a tender offer or a proxy contest or to acquire us, even though such events may be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws may affect the price of our common stock, and could make it more difficult for a third party to remove our management. Further, these provisions may make it more difficult to acquire a large portion of our securities, to initiate a tender offer or a proxy contest or acquire us, even if doing so would benefit our stockholders. Among other things, these provisions:

- authorize the issuance of "blank check" preferred stock that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt; and
- limit who may call a special meeting of stockholders.

Our Board of Directors has adopted a preferred share purchase rights plan, commonly known as a "poison pill." The provisions described above, our preferred share purchase rights plan and provisions of the Delaware General Corporation Law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from removing our management. Further, they may discourage, delay or prevent a third party from acquiring a large portion of our securities, initiating a tender offer or proxy contest or acquiring us, even if our stockholders might receive a premium for their shares in the acquisition over then current market prices.

We depend upon key employees in a competitive market for skilled personnel and, without additional employees, we cannot grow or achieve and maintain profitability

Our products and technologies are complex, and we depend substantially on the continued service of our senior management team. The loss of any of our key employees could adversely affect our business and slow our product development process.

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Our future success also will depend in part on the continued service of our key management personnel, software engineers and other research and development employees and our ability to identify, hire, and retain additional personnel, including customer service, marketing and sales staff. Hiring sales, marketing and customer service personnel in our industry is very competitive due to the limited number of people available with the necessary technical skills and understanding of pediatric audiology, neonatal metabolic screening and jaundice management. We may be unable to attract and retain personnel necessary for the development of our business.

We could lose the ability to use net operating loss carryforwards, which may adversely affect our financial results

We currently have federal and state net operating loss carryforwards available to reduce future taxable income. If not utilized to offset taxable income in future periods, these net operating loss carryforwards will expire in various amounts beginning in 2007 through 2022. If we continue to have net losses, we may not be able to utilize some or all of our net operating loss carryforwards before they expire.

In addition, United States income tax law imposes limitations on the ability of corporations to use net operating loss carryforwards if the corporation experiences a more than 50% change in ownership during any three-year period. We cannot assure you that we will not take actions, such as the issuance of additional stock, that would cause an ownership change to occur. Accordingly, we may be limited to the amount we can use in any given year, so even if we have substantial net income, we may not be able to use our net operating loss carryforwards before they expire. In addition, the net operating loss carryforwards are subject to examination by the Internal Revenue Service, or IRS, and are thus subject to adjustment or disallowance resulting from any such IRS examination.

If we have taxable income in the future, and we are unable to fully utilize our net operating loss carryforwards, our future tax payments could be higher and our financial results may suffer.

If earthquakes and other catastrophic events strike, our business may be negatively affected.

Our corporate headquarters, including a substantial portion of our research and development operations, are located in the Silicon Valley area of Northern California, a region known for seismic activity. A significant natural disaster such as an earthquake could have a material adverse impact on our business, operating results, and financial condition.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We develop products in the United States and sell those products primarily in the United States, Europe and Asia. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. Prior to our acquisition of the distribution operations of our United Kingdom distributor and top-tier Japan distributor in January 2001 and July 2001, respectively, our sales generally were denominated in United States dollars. Since that time, our revenue and expenses in those countries have increasingly been denominated in the applicable foreign currency. As our operations in the United Kingdom and Japan increase, we expect that our exposure to foreign currency fluctuations will increase. Changes in exchange rates also may affect the volume of our sales or our foreign currency sales prices compared to those of our foreign competitors and could make our products less competitive in those countries. If the United States dollar uniformly increased or decreased in strength by 10% relative to the currencies in which our sales were denominated, our net loss would not have changed by a material amount for the nine months ended September 30, 2003. For purposes of this calculation, we have assumed that the exchange rates would change in the same direction relative to the United States dollar.

Our interest income is sensitive to changes in interest rates in the United States, particularly since the majority of our investments are in short-term instruments. However, as substantially all of our short-term

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investments carry a fixed rate of interest, a hypothetical decrease of 10% in market interest rates would not result in a material decrease in interest income earned through maturity on investments held at September 30, 2003.

We have not used derivative financial instruments for speculative or trading purposes. However, the fair value of our available-for-sale securities is sensitive to changes in interest rates in the United States, and the fair value of our portfolio will fall if market interest rates increase. However, since we generally have the ability to hold these investments to maturity, these declines in fair value may never be realized. If market interest rates were to increase by 10% from levels at September 30, 2003, the fair value of our portfolio would decline by an immaterial amount. At September 30, 2003 our available-for-sale securities consist of federal agency bonds with maturities of less than fifteen months.

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of September 30, 2003. Actual results may differ as our analysis of the effects of changes in interest rates does not account for, among other things, sales of securities prior to maturity and repurchase of replacement securities, the change in mix or quality of the investments in the portfolio and changes in the relationship between short-term and long-term interest rates.

Item 4. Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report. Based upon that evaluation, our principal executive officer and principal accounting officer concluded that our disclosure controls and procedures are effective to ensure that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms.

There was no significant change in our internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We may from time to time become a party to various legal proceedings or claims that arise in the ordinary course of business. Our management has reviewed these matters and believes that the resolution of them will not have a significant adverse effect on our financial condition.

Item 2. Changes in Securities and Use of Proceeds

None.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

- 31.1 Certification of Principal Executive Officer pursuant Section 302 of Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Principal Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

We filed a report on Form 8-K on July 2, 2003 announcing our acquisition of Neometrics Inc. We filed a report on Form 8-K on August 7, 2003 and an amendment thereto on August 8, 2003, furnishing a copy of our news release regarding our earnings for the second quarter of 2003 pursuant to Items 7 and 12 of Form 8-K. We filed a report on Form 8-K on September 18, 2003 announcing a change in our certifying accountants.

NATUS MEDICAL INCORPORATED
INDEX TO EXHIBITS

Exhibit No.	
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U. S. C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

CERTIFICATION

I, Tim C. Johnson, certify that:

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

Date: November 13, 2003

/s/ TIM C. JOHNSON

Tim C. Johnson
President and Chief Executive Officer
Principal Executive Officer

CERTIFICATION

I, Steven J. Murphy, certify that:

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

Date: November 13, 2003

/s/ STEVEN J. MURPHY

Steven J. Murphy
Vice President, Finance
Principal Financial Officer

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO TITLE 18, UNITED STATES CODE, SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Natus Medical Incorporated (the "Company") on Form 10-Q for the quarterly period ended September 30, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Tim C. Johnson, President and Chief Executive Officer of the Company, certify, pursuant to Title 18, United States Code, Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ TIM C. JOHNSON

Print Name: Tim C. Johnson
Title: President and Chief Executive Officer
Principal Executive Officer
Date: November 13, 2003

In connection with the Quarterly Report of Natus Medical Incorporated (the "Company") on Form 10-Q for the quarterly period ended September 30, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven J. Murphy, Vice President, Finance of the Company, certify, pursuant to Title 18, United States Code, Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN J. MURPHY

Print Name: Steven J. Murphy
Title: Vice President, Finance
Principal Financial Officer
Date: November 13, 2003