

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

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**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 March 31, 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)

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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 March 31, 2003, was 16,337,569.

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**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(in thousands, except share amounts)**

	March 31, 2003	December 31, 2002(1)
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,631	\$ 17,768
Short-term investments	33,917	27,150
Accounts receivable, net of allowance for doubtful accounts of \$258 in 2003 and \$250 in 2002	4,403	5,395
Inventories	5,287	4,560
Prepaid expenses and other current assets	914	663
	<u>54,152</u>	<u>55,536</u>
Total current assets	54,152	55,536
Property and equipment, net	2,017	2,247
Long-term investment	335	334
Deposits and other assets	1,167	1,223
	<u>57,671</u>	<u>59,340</u>
Total assets	\$ 57,671	\$ 59,340
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities:		
Accounts payable	\$ 1,120	\$ 1,788
Accrued liabilities	2,354	2,460
Deferred revenue	363	405
	<u>3,837</u>	<u>4,653</u>
Total current liabilities	3,837	4,653
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value, 120,000,000 shares authorized; shares issued and outstanding: 16,338,069 in 2003 and 16,267,700 in 2002	86,710	86,593
Deferred stock compensation	(155)	(219)
Accumulated deficit	(32,668)	(31,751)
Accumulated other comprehensive income (loss)	(53)	64
	<u>53,834</u>	<u>54,687</u>
Total stockholders' equity	53,834	54,687
Total liabilities and stockholders' equity	\$ 57,671	\$ 59,340

(1) Derived from the consolidated audited financial statements at December 31, 2002.

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

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**NATUS MEDICAL INCORPORATED AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(in thousands, except per share amounts)**  
**(unaudited)**

	Three Months Ended March 31,	
	2003	2002
Revenue	\$ 6,661	\$ 6,076
Cost of revenue	2,512	2,516
Gross profit	4,149	3,560
Operating expenses:		
Marketing and selling	3,057	3,441
Research and development	1,031	1,070
General and administrative	1,145	1,074
Total operating expenses	5,233	5,585
Loss from operations	(1,084)	(2,025)
Interest income	163	262
Interest expense	(3)	(2)
Other income, net	7	(22)
Loss before provision for income taxes	(917)	(1,787)
Provision for income taxes	—	—
Net loss available to common stockholders	\$ (917)	\$(1,787)
Basic and diluted net loss per share	\$ (0.06)	\$ (0.11)
Common shares used in computing basic and diluted net loss per share	16,328	15,887

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

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**NATUS MEDICAL INCORPORATED AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

	Three Months Ended March 31,	
	2003	2002
<b>Operating activities:</b>		
Net loss	\$ (917)	\$ (1,787)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	316	224
Amortization of deferred stock compensation	64	165
Loss on disposal of assets	6	—
Changes in operating assets and liabilities:		
Accounts receivable	992	987
Inventories	(727)	(604)
Prepaid expenses and other current assets	(251)	(205)
Accounts payable	(668)	117
Accrued liabilities and deferred revenue	(148)	(182)
Net cash used in operating activities	<u>(1,333)</u>	<u>(1,285)</u>
<b>Investing activities:</b>		
Acquisition of property and equipment	(61)	(130)
Deposits and other assets	25	2
Purchases of short-term investments	(15,774)	(35,764)
Sales of short-term investments	9,001	22,580
Purchase of long-term investments	(1)	(2)
Net cash used in investing activities	<u>(6,810)</u>	<u>(13,314)</u>
<b>Financing activities:</b>		
Issuance of common stock	117	22
Net cash provided by financing activities	<u>117</u>	<u>22</u>
Exchange rate effect on cash and equivalents	(111)	—
Net decrease in cash and equivalents	(8,137)	(14,577)
Cash and cash equivalents, beginning of period	17,768	30,351
Cash and cash equivalents, end of period	<u>\$ 9,631</u>	<u>\$ 15,774</u>
<b>Non-cash investing and financing activities:</b>		
Issuance of notes payable for acquisition of other assets	\$ —	\$ 1,000
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	3	\$ 2
Cash paid for income taxes	\$ —	\$ 57

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

**NATUS MEDICAL INCORPORATED**  
**NOTES TO 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” 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 condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries; significant intercompany transactions have been eliminated. These 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.

**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 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.

**Revenue Recognition**

The Company recognizes revenue, net of discounts, from product sales, including sales to distributors, when a purchase order has been received, when title transfers (generally upon shipment), when the selling price is fixed and determinable, and when collection of the resulting receivable is probable. Rights of return are generally not provided. Advance payments from customers are recorded as deferred revenue until shipment of the related product. The Company provides for trade-ins of its own or competitive equipment. Trade-ins are recorded as a reduction of revenue at the time of shipping the replacement equipment. 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 warranty contracts ratably over the warranty period.

**Recent Accounting Pronouncements**

In April 2002, the FASB issued SFAS No. 145, which, among other things, changed the presentation of gains and losses on the extinguishment of debt. Any gain or loss on extinguishment of debt that does not meet the criteria in APB Opinion 30, “Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions,” shall be included in operating earnings and not presented separately as an extraordinary item. We adopted SFAS No. 145 on January 1, 2003.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, which addresses accounting for restructuring and similar costs. SFAS No. 146 supersedes previous accounting guidance, principally Emerging Issues Task Force Issue, or EITF, No. 94-3 *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit on Activity (including Certain Costs Incurred in a Restructuring)*. SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost was recognized at the date of the Company’s commitment to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. Accordingly, SFAS 146 may affect the timing of recognizing future restructuring costs as well as the amount recognized. We will adopt the provisions of SFAS 146 for any future restructurings.

**NATUS MEDICAL INCORPORATED**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**1—Summary of Significant Accounting Policies (Continued)****Recent Accounting Pronouncements (continued)**

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 addresses the disclosures to be made by guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. 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, the Company adopted the disclosure requirements on December 31, 2002 and the recognition requirements on January 1, 2003. The adoption of the recognition requirements of this interpretation did not 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. The Company adopted the annual and quarterly disclosure requirements of SFAS No. 148 on December 31, 2002 and March 31, 2003, respectively. 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 statements.

**Comprehensive Loss**

In accordance with SFAS No. 130, *Reporting Comprehensive Income*, we are required to report by major components and as a single total, the change in our net assets during the period from non-owner sources. The following are the components of comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2003	2002
Net loss	\$ (917)	\$ (1,787)
Unrealized gain (loss) on available-for-sale securities	(6)	(122)
Foreign currency translation adjustment	(111)	(24)
<b>Comprehensive Loss</b>	<b>\$ (1,034)</b>	<b>\$ (1,933)</b>

**2—Inventories**

Inventories consisted of (in thousands):

	March 31, 2003	December 31, 2002
Raw materials and subassemblies	\$ 3,040	\$ 2,831
Finished goods	2,247	1,729
<b>Total</b>	<b>\$ 5,287</b>	<b>\$ 4,560</b>

**NATUS MEDICAL INCORPORATED**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**3—Reserve For Product Warranties**

The company customarily provides a standard one-year warranty on all products. The company also sells extended service agreements on all of its products. Service for domestic customers is provided by a company-owned service center that performs all service, repair, and calibration services. Service for international customers is provided by a combination of company-owned facilities and third party vendors on a contract basis.

The company has accrued a warranty reserve for the expected future costs of servicing products during the initial one-year warranty period. Amounts are added to the reserve based on unit sales of various product lines. As warranty costs are incurred, they are relieved from the reserve.

**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 2,268,187 and 1,939,412 shares of common stock for the three month periods ending March 31, 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 Financial Accounting Standards Board (“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 Statement of Financial Accounting Standards (“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 months ended March 31, 2003 and 2002 (in thousands) are as follows:



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**NATUS MEDICAL INCORPORATED**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**5—Stock-Based Compensation (continued)**

	Three Months Ended March 31,	
	2003	2002
Amortization stock compensation included in:		
Cost of revenue	\$ 8	\$ 21
Operating expenses		
Marketing and selling	\$ 30	\$ 74
Research and development	4	14
General and administrative	22	56
Total	\$ 56	\$ 144

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 March 31,	
	2003	2002
Net loss, as reported	\$ (917)	\$ (1,787)
Add: Stock based employee compensation, net of related tax effects	64	165
Less: Compensation expense for stock options determined under the fair value method, net of related tax effects	(299)	(555)
Pro forma net loss	\$ (1,152)	\$ (2,177)
Basic and Diluted EPS:		
As reported	\$ (0.06)	\$ (0.11)
Pro forma	\$ (0.07)	\$ (0.14)

**6—Customer and Geographic Information**

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

**NATUS MEDICAL INCORPORATED**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**6—Customer and Geographic Information (continued)**

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

	Three Months Ended March 31,	
	2003	2002
United States	\$ 4,842	\$ 5,118
All other	1,819	958
<b>Total</b>	<b>\$ 6,661</b>	<b>\$ 6,076</b>

For both the three months ended March 31, 2003 and 2002, no sales to a single end-user customer or distributor accounted for greater than 10% of total revenue.

**7—Restructuring Charges**

In September 2002, the Company recorded a restructuring charge of approximately \$255,000 relating to an operating cost reduction plan that resulted in a reduction of 18 employees and the accrual of associated employee termination-related benefits. During the three months ended March 31, 2003, the Company paid immaterial amounts related to the restructuring. To date, the Company has paid approximately \$234,000 of costs related to the restructuring.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, 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 Item 2 include, but are not limited to, statements regarding the following: the future composition of our revenue, future revenue from international operations, international markets as a growth opportunity, our CO-Stat® End-Tidal Breath Analyzer ("CO-Stat analyzer) product strategy and alternative uses for our CO-Stat analyzer products, the CO-Stat analyzer product as a platform technology, the impact of adoption of accounting standards, acceptance of our products and the products of our competitors, fluctuation of our operating results and gross margins, expansion in and opportunities relating to international markets, future marketing and selling expenses, future operating results, warranty allowances, impact of our application of resources, spending relating to our products, sufficiency of future resources such as employees, future investments, investment in and development of new products and enhancement of existing products, future liquidity and capital requirements, our investment policy, sufficiency of cash and cash equivalents and availability of funds, effect of and exposure to foreign currency exchange rates, market risk exposure, cost-effectiveness of our products, third-party reimbursement, consolidation of our industry and consequences of intellectual property disputes.*

*You are cautioned not to place undue reliance on forward-looking statements. Forward-looking statements are not guarantees of future performance. The forward-looking statements are subject to substantial risks and uncertainties that could cause our future business, financial condition, or 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" of this "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in or incorporated by reference into this report. 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. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. These forward-looking statements are made in reliance upon the safe harbor provision of The Private Securities Litigation Reform Act of 1995.*

### **Overview**

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

Our revenue results from sales of equipment and disposable supplies. We currently derive substantially all of our revenue from sales of a limited number of products. Nearly all of our revenue was from sales of our ALGO screening products in the three months ended March 31, 2003 and 2002. Although we commercially launched our CO-Stat analyzer product in January 2001, we expect that a substantial majority of our revenue will continue to be generated from sales of our ALGO products for at least the next two years. In addition, on September 19, 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. This product was introduced to the market on October 17, 2002. We do not expect to recognize material revenue from this product during 2003.

Historically we have sold our products directly through our sales force in the United States and indirectly through distributors internationally. Domestic sales accounted for 73% and 84% of our revenue during the three months ended March 31, 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. Historically, our international sales have been indirect and through distributors and have been characterized by lower gross margins due to the discount the distributors receive from our list prices.

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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, makes 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 expenses 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 believe that our CO-Stat analyzer product represents a platform technology and are moving forward with clinical research for the newborn jaundice market and for additional applications, most notably its use for the detection of medical conditions leading to pre-term delivery. While we intend to continue to support the user base now in place, we are currently evaluating the viability of marketing our CO-Stat analyzer products in the newborn jaundice market. We do not expect to recognize material revenue from our CO-Stat analyzer product in 2003.

We introduced our neoBLUE phototherapy device in October 2002 at the American Academy of Pediatrics National Conference and Exhibition in Boston, Massachusetts. Our neoBLUE phototherapy device analyzer adds to the line of products and services that we provide to assist clinicians with the management of newborn jaundice. Our current sales and marketing force offers our neoBLUE phototherapy device as part of our jaundice management product offering. Because we have not previously marketed the neoBLUE phototherapy device or devices for the treatment of newborn jaundice, we cannot be certain that it will be well received by our clinician customers. We do not expect to recognize material revenue from our neoBLUE phototherapy device 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 product sales, 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. We generally do not provide rights of return on our products. Revenue from extended warranty contracts is recognized ratably over the warranty period. Advance payments from customers are recorded as deferred revenue until shipment of the related product. We have established an allowance for estimated uncollectible accounts receivable.

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

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allowance for estimated uncollectible accounts receivable is understated could result in increased operating expense and reduce our results of operations.

At March 31, 2003 our deferred revenue under extended warranty contracts was approximately \$363,000. Advance payments from customers were not material at March 31, 2003. Our allowance for estimated uncollectible accounts receivable was \$258,000 at March 31, 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. 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 sales and decreases to our operating margins 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 operating 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.

At March 31, 2003 we had intangible assets with a carrying value of approximately \$1.0 million.

### ***Liability for product warranties***

Our products are covered by standard one-year product warranty plans. A liability has been established for the expected cost of servicing our products during these warranty 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. The estimates we use in projecting future product warranty costs may prove to be incorrect. Any future determination that our product warranty reserves are understated could result in increases to our cost of sales and decreases to our operating margins and results of operations.

At March 31, 2003 our reserve for product warranties was approximately \$197,000.

### ***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 carry forwards 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 March 31, 2003, our net deferred tax assets were zero, net of an \$8.4 million valuation allowance.

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[Table of Contents](#)**Results of Operations**

The following table sets forth, for the periods indicated, selected 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 March 31,	
	2003	2002
Revenue	100.0%	100.0%
Cost of revenue	37.7	41.4
Gross profit	62.3	58.6
Operating expenses:		
Marketing and selling	45.9	56.6
Research and development	15.5	17.6
General and administrative	17.2	17.7
Total operating expenses	78.6	91.9
Loss from operations	(16.3)	(33.3)
Other income, net	2.5	3.9
Loss before provision for income taxes	(13.8)	(29.4)
Provision for income taxes	—	—
Net loss	(13.8)	(29.4)
Accretion of redeemable convertible preferred stock	—	—
Net loss available to common stockholders	(13.8)	(29.4)

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### Three Months Ended March 31, 2003 and 2002

#### Revenue

Our revenue is generated almost exclusively from the sale of ALGO screening equipment and related disposable supplies. Our revenue increased \$585,000, or 10%, to \$6.7 million in the three months ended March 31, 2003 from \$6.1 million in the same period in 2002. The increase was primarily attributable to stronger demand for our products in Europe and Oceania. No end customer accounted for more than 10% of our revenue in the three months ended March 31, 2003 and 2002.

Revenue from ALGO hearing screening equipment increased by \$327,000, or 22%, to \$1.8 million in the three months ended March 31, 2003 from \$1.5 million in the same period in 2002. The increase resulted from greater unit sales in Europe and Oceania.

Revenue from ALGO disposable supplies increased by \$181,000, or 4%, to \$4.5 million in the three months ended March 31, 2003 from \$4.3 million in the same period in 2002. The increase resulted primarily from our greater international installed base.

Revenue from sales outside the United States increased by \$861,000, or 90%, to \$1.8 million in the three months ended March 31, 2003 from \$1.0 in the same period in 2002. The increase in revenue for the three months ended March 31, 2003 was primarily the result of stronger demand in Europe and Oceania.

#### 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 costs, warranty expenses, and technology license fees. Our cost of revenue remained substantially unchanged at \$2.5 million in the three months ended March 31, 2003 and 2002; however, cost of revenue as a percent of total revenue was 38% in the three months ended March 31, 2003, compared with 41% reported in the three months ended March 31, 2002. Cost of revenue as a percentage of total revenue was favorably impacted by materials cost savings associated with our ALGO 3 product line as well as a realignment of three production-engineering employees to our research and development department. Cost of revenue continues to be 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 \$384,000, or 11%, to \$3.1 million in the three months ended March 31, 2003 from \$3.4 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.

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 \$39,000, or 4%, to \$1.0 million in the three months ended March 31, 2003 from \$1.1 million in the same period in 2002. The decrease is attributable to reductions in salaries, offset partly by an increase in the cost of outside consultants related to new product development.

General and administrative expenses consist of corporate, finance, information technology, human resources, administrative, and legal expenses. Our general and administrative expenses increased \$71,000, or 7%, to \$1.1 million in the three months ended March 31, 2003 from \$1.1 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 these costs are treated as a general and administrative expense. We also reduced our outside legal expenses significantly by adding new in-house staff, although these savings were partially offset by the new salaries. Our outside accounting fees and local taxes have also increased.

In September 2002, we recorded a restructuring charge of approximately \$255,000 relating to an operating cost reduction plan that resulted in a reduction of 18 employees and the accrual of associated employee termination-related benefits. During the three months ended March 31, 2003, we paid immaterial amounts related to the restructuring. To date, we have paid approximately \$234,000 of costs related to the restructuring.

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We recorded aggregate amortization of \$64,000 of deferred stock compensation in the three months ended March 31, 2003, of which \$8,000 was included in cost of revenue and \$56,000 was allocated to operating expenses. We recorded \$165,000 deferred stock compensation in the three months ended March 31, 2002, of which \$21,000 was included in cost of revenue and \$144,000 was allocated to operating expenses.

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 \$71,000, or 30%, to \$167,000 in the three months ended March 31, 2003 from \$238,000 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 losses were \$3,000 and \$20,000 in the three months ended March 31, 2003 and 2002, respectively. The losses 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 March 31, 2003, we had cash, cash equivalents and short-term investments of \$43.5 million, stockholders' equity of \$53.8 million and working capital of \$50.3 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. We completed an initial public offering of 5,000,000 shares of our common stock at \$11.00 per share in July 2001 and raised \$51.2 million after underwriting discounts and commissions, but before expenses payable by us. In August 2001, our managing underwriters exercised their right to purchase an additional 750,000 shares of our common stock at \$11.00 per share for net proceeds of \$7.7 million after underwriting discounts and commissions but before any expenses payable by us.

Net cash used in operating activities for the three months ended March 31, 2003 and 2002 was substantially unchanged at \$1.3 million. Cash used in operating activities for the three months ended March 31, 2003 resulted primarily from the net loss during the period, increases in inventories and prepaid expenses, and decreases in accounts payable and accrued liabilities which were offset by a decrease in accounts receivable. The increase in inventories was due primarily to maintaining greater quantities of our new ALGO Flexicoupler disposable supply product. Net cash used in operating activities of \$1.3 million for same period in 2002 resulted primarily from the net loss during the period and an increase in inventories.

Net cash used in investing activities was \$6.8 million for the three months ended March 31, 2003 compared to \$13.3 million for the same period in 2002. Net cash used in investing activities in both periods was primarily the result of purchasing short-term investments in excess of those that were redeemed. 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 March 31, 2003. We have an interest-bearing certificate of deposit with a bank that matures in April 2004; the investment is valued at \$335,000 at March 31, 2003 and is classified as a hold-to-maturity investment. This investment was assigned to a bank in February 1999 to guarantee a loan on a primary residence of an officer totaling \$250,000 plus accrued interest. The guarantee is collateralized by 26,688 shares of our stock held by the officer.

Net cash provided by financing activities was \$117,000 for the three months ended March 31, 2003, compared to \$22,000 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.

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.



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We believe that our current cash and cash equivalent balances and any cash generated from 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, and 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 April 2002, the FASB issued SFAS No. 145, which, among other things, changed the presentation of gains and losses on the extinguishment of debt. Any gain or loss on extinguishment of debt that does not meet the criteria in APB Opinion 30, "Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," shall be included in operating earnings and not presented separately as an extraordinary item. We adopted SFAS No. 145 on January 1, 2003.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, which addresses accounting for restructuring and similar costs. SFAS No. 146 supersedes previous accounting guidance, principally Emerging Issues Task Force Issue, or EITF, No. 94-3 *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit on Activity (including Certain Costs Incurred in a Restructuring)*. SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost was recognized at the date of the Company's commitment to an exit plan. SFAS No. 146 also establishes that the liability should initially be measured and recorded at fair value. Accordingly, SFAS 146 may affect the timing of recognizing future restructuring costs as well as the amount recognized. We adopted the provisions of SFAS 146 on January 1, 2003.

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 addresses the disclosures to be made by guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. 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, the Company adopted the disclosure requirements on December 31, 2002, and the recognition requirements on January 1, 2003. Adoption of the recognition requirements of this interpretation did not 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. The Company adopted the annual and quarterly disclosure requirements of SFAS No. 148 on December 31, 2002 and March 31, 2003, respectively. 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 statements.

### **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 technology, such as the use of our CO-Stat analyzer for the detection of pre-term delivery and pre-eclampsia;
- 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

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- develop additional infrastructure and hire required management and other employees to keep pace with our growth.

As a result of these 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 also 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 any material revenue from this product during 2003, if ever. Any factors adversely affecting the pricing of our ALGO screening equipment 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 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 equipment; and
- the adoption of state and foreign laws requiring universal newborn screening.

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### **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 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.

### **A sluggish economy as a result of the 2001 terrorist attacks, the uncertainty of continued war and the recent outbreak of Severe Acute Respiratory Syndrome (SARS) could have an adverse effect on our business**

The September 11, 2001 terrorist attacks in New York and Washington D.C. contributed to the slowdown in the United States economy and the economies of other countries. At the time of the attacks, capital investment by businesses, particularly capital investment in technology, had been experiencing substantial weakness. Continuing economic and political uncertainties, both domestically and abroad, resulting from these attacks and the uncertainty of war have resulted in declines in new technology investments by our customers, including investment in our products. We do not know what further effect future terrorist attacks, or resulting military actions by the United States and war, could have on our business, revenue or results of operations. If our customers or potential customers defer or cancel purchases of our products, our revenue will be adversely affected, which would harm our results of operations and financial condition. In addition, the recent outbreak of SARS, and in particular its impact on Asian countries, could have an adverse effect on our business.

### **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, operating results and margins to fluctuate significantly from quarter to quarter:

- the budgeting cycle of our customers;
- the size and timing of specific sales, such as large purchases of screening equipment or disposables 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.

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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 screening equipment. 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.

### **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 for the diagnosis and monitoring of common medical conditions in infants and pregnant women. Developing new products and improving our existing products to meet the needs of neonatologists and pediatricians 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 and neoBLUE phototherapy device products**

We introduced our CO-Stat analyzer product family for clinical research uses in July 1999 and began commercially marketing it in January 2001. We introduced our neoBLUE phototherapy device in October 2002. To date, 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. We are currently evaluating the viability of marketing our CO-Stat analyzer products in the newborn jaundice market, but 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 CO-Stat analyzer products and the neoBLUE phototherapy device in volume. We cannot be certain that our CO-Stat analyzer products or our neoBLUE phototherapy device 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 or neoBLUE phototherapy device products 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 applications for our CO-Stat analyzer, most notably the detection of medical conditions leading to pre-term delivery. 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.

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### **If the guidelines for recommended universal newborn 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 not grow 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 products screen. The guidelines for universal newborn screening for hearing impairment have been adopted by some physician groups and governments only recently. We cannot predict the outcome or the impact that statutes and government regulations requiring universal newborn 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 hearing testing and the benefits of universal newborn hemolysis monitoring, as well as the use of our products to perform the screening and monitoring.

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

If the governments in the most densely populated states and foreign countries do not require universal screening for the disorders for which our products test, our business would be harmed and our revenue may not grow. As of March 31, 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.

### **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 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 those who do not have risk factors for 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.

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

Physicians, hospitals and state agencies are unlikely to purchase our products if clinicians are not adequately reimbursed for the procedures conducted with our equipment 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 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.

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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 equipment, 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. 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 equipment 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 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 equipment rather than portable point of care screening devices for jaundice management.

We market almost all of our newborn hearing screening 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 hearing screening and jaundice management products 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 or neoBLUE phototherapy device products because we may encounter difficulties in manufacturing them in commercial quantities**

We do not have experience manufacturing our CO-Stat analyzer or neoBLUE phototherapy device products 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 the CO-Stat analyzer or neoBLUE phototherapy device products for us. If we encounter any of these difficulties, we may not be successful in marketing our CO-Stat analyzer or neoBLUE phototherapy device products, 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™ Earphones ("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

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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.

### **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 profits 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 26% of our total revenue in the three months ended March 31, 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 43% of our total revenue during the three months ended March 31, 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 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 outside the United States. Some distributors also assist us with regulatory approvals and education of physicians and government agencies. 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. If we fail to sell our products through our international distributors, we would experience a decline in revenue 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

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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.

**In light of a maturing domestic market for our ALGO 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 newborn hearing screening products will increasingly depend on our success in the international market, as the market in the United States for our ALGO products is beginning to mature. As of March 31, 2003, 37 states and the District of Columbia had mandated universal newborn hearing screening. 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 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 or CO-Stat analyzer products, 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; and
- criminal prosecution.

### **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 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.

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### **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, 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 equipment products. 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 equipment; 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 phototherapy device product, our competitors are companies that market phototherapy devices.

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 equipment products, have lower-priced hearing screening equipment 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 equipment, 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 equipment. The sales of these products have adversely impacted our revenue from sales of our disposable products and we cannot assure you that the sales of these products will not have an adverse effect on our revenue and operating results in the future. We also cannot assure you that competitors will not develop and receive FDA approval for the sale of disposable products to use with our new screening equipment.

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 equipment 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. 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 equipment vendors or rapidly acquire market share through industry consolidation or by bundling other products with their hearing screening or jaundice monitoring products**

Large medical testing equipment 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 equipment 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 with other newborn hearing screening, hemolysis monitoring or jaundice management products and sell 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.

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### **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 may have additional acquisitions of products, technology assets or acquisitions in the future as part of 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;
- the failure to realize expected synergies;
- the failure of acquired products to achieve projected sales;
- 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.

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 acquisitions will positively impact our business.

### **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 hearing screening or jaundice management 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 have nineteen issued United States patents and seven patent applications pending before the United States Patent and Trademark Office. We have one patent granted in Canada and four patent applications pending in Canada. We have one patent issued with the European patent office, which we intend to register in ten countries and eleven patent applications pending with the European patent office. We have one patent granted in France and one patent application pending in France. We have three patent applications granted in Japan and twelve patent applications pending in Japan. We have two patents granted in Germany, one patent granted in Iceland, one patent granted in the Netherlands, one patent granted in Switzerland, and two patents granted in the United Kingdom. We have four patent applications pending in Australia, two patent applications pending in the Czech Republic, one patent application pending in Hong Kong, two patent applications pending in Hungary, one patent application pending in Italy and one patent application pending in Norway. 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 hearing screening or jaundice management 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. In addition, we cannot assure you that the patent applications we have filed to protect the features of our products that we have subsequently developed will be allowed, or will deter others from using the auditory brainstem response technology.

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

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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 equipment 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 medical device 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 medical testing products could lead to the filing of a product liability claim if someone were to be injured using one of our devices or if one of our devices 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;
- 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; and
- general market conditions, particularly for companies with a relatively small number of shares available for sale in the public market.

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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 March 31, 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. 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.

On September 4, 2002, our Board of Directors 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.

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 and neonatal 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.

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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 three months ended March 31, 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 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 March 31, 2003.

We do not use 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 March 31, 2003, the fair value of our portfolio would decline by an immaterial amount. At March 31, 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 March 31, 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 Rule 13a-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), within 90 days of the filing date of this report. Based on their 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.

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There have been no significant changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referenced in paragraph above.

**PART II. OTHER INFORMATION**

**Item 2. Changes in Securities and Use of Proceeds**

None.

**Item 6. Exhibits and Reports on Form 8-K**

**(a) Exhibits**

- 99.1 Certification of Chief Executive Officer and Chief 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 Current Report on Form 8-K dated February 24, 2003 to report that we had entered into a Voting Agreement with Perry Corp. and amended our Stockholder Rights Plan to permit Perry Corp. to acquire up to 34% of our outstanding Common Stock.

**SIGNATURES**

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

NATUS MEDICAL INCORPORATED

Dated: May 14, 2003

/s/ TIM C. JOHNSON

By:

\_\_\_\_\_  
**Tim C. Johnson**  
**Chief Executive Officer, President,**  
**Chief Operating Officer and Director**  
**(Principal Executive Officer)**

Dated: May 14, 2003

/s/ GLENN A. BAUER

By:

\_\_\_\_\_  
**Glenn A. Bauer,**  
**Chief Financial Officer**  
**(Principal Financial and**  
**Accounting Officer)**



**CERTIFICATIONS**

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 quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures 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 quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

By: /s/ Tim C. Johnson

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Tim C. Johnson  
President and Chief Executive Officer

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I, Glenn A. Bauer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Natus Medical Incorporated;
2. Based on my knowledge, this quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures 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 quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

By: /s/ Glenn A. Bauer

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Glenn A. Bauer,  
Chief Financial Officer

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**NATUS MEDICAL INCORPORATED**  
**INDEX TO EXHIBITS**

**Exhibit No.**

99.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U. S. C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF 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 March 31, 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

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Print Name: Tim C. Johnson  
Title: President and Chief Executive Officer  
Date: May 14, 2003

In connection with the Quarterly Report of Natus Medical Incorporated (the "Company") on Form 10-Q for the quarterly period ended March 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Glenn A. Bauer, Chief Financial 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/ Glenn A. Bauer

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Print Name: Glenn A. Bauer  
Title: Chief Financial Officer  
Date: May 14, 2003