

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2001

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 77-0154833  
(State or other jurisdiction (I.R.S. Employer Identification Number)  
of incorporation or organization)

1501 Industrial Road, San Carlos, CA 94070  
(Address of Principal Executive Offices) (Zip Code)

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

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

The number of issued and outstanding shares of the Registrant's Common Stock, \$0.001 par value, as of September 30, 2001, was 15,751,453.

NATUS MEDICAL INCORPORATED

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

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

<TABLE>  
<CAPTION>

|  | September 30,<br>2001 | December 31,<br>2000(1) |
|--|-----------------------|-------------------------|
|  | -----<br>(unaudited)  | -----                   |
|  | <C>                   | <C>                     |
| <S>  |                       |                         |
| ASSETS:  |                       |                         |
| Current assets:  |                       |                         |
| Cash and equivalents.....  | \$ 55,942             | \$ 681                  |
| Short-term investments .....   | --                    | 302                     |
| Accounts receivable, net of allowance for doubtful accounts of \$ 214 in 2001<br>and \$203 in 2000 ..... | 4,054                 | 4,400                   |
| Inventories .....  | 3,054                 | 2,194                   |
| Prepaid expenses and other current assets .....  | 594                   | 263                     |
|  | -----                 | -----                   |
| Total current assets .....   | 63,644                | 7,840                   |
| Property and equipment, net .....  | 1,500                 | 1,308                   |
| Convertible notes receivable .....   | --                    | 115                     |
| Long-term investment .....   | 326                   | 321                     |
| Deposits and other assets .....  | 362                   | 1,134                   |
|  | -----                 | -----                   |
| Total assets .....   | \$ 65,832             | \$ 10,718               |
|  | =====                 | =====                   |

LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

Liabilities:

|                           |          |        |
|---------------------------|----------|--------|
| Accounts payable .....    | \$ 1,218 | \$ 750 |
| Accrued liabilities ..... | 2,544    | 2,694  |
| Deferred revenues .....   | 253      | 331    |
|                           | -----    | -----  |
| Total liabilities .....   | 4,015    | 3,775  |
|                           | -----    | -----  |

Commitments and contingencies

Convertible preferred stock:

|   |       |        |
|---|-------|--------|
| Series A convertible preferred stock, \$0.001 par value; 1,241,842 shares<br>authorized in 2000; 1,241,841 shares issued and outstanding in 2000;<br>aggregate liquidation value of \$3,803 in 2000 ..... | --    | 2,227  |
| Redeemable convertible preferred stock, \$0.001 par value; 8,781,412 shares<br>authorized in 2000; aggregate liquidation value of \$25,178 in 2000 and<br>aggregate redemption value of \$22,999 in 2000: |       |        |
| Series B: 3,967,126 shares authorized in 2000; 3,967,120 shares issued and<br>outstanding in 2000 .....   | --    | 12,478 |
| Series C: 3,214,286 shares authorized in 2000; 2,490,181 shares issued and<br>outstanding in 2000 .....   | --    | 5,864  |
| Series D: 1,600,000 shares authorized in 2000; 1,232,392 shares issued and<br>outstanding in 2000 .....   | --    | 4,657  |
|   | ----- | -----  |
| Total convertible preferred stock .....   | --    | 25,226 |
|   | ----- | -----  |

Stockholders' equity (deficit):

Common stock, \$0.001 par value, 120,000,000 shares authorized; shares issued

|  |           |           |
|--|-----------|-----------|
| and outstanding: 15,751,453 in 2001 and 868,034 in 2000 .....  | 85,847    | 2,902     |
| Preferred stock, \$0.001 par value, 10,000,000 shares authorized in 2001; no shares issued and outstanding in 2001 ..... | --        | --        |
| Deferred stock compensation .....  | (1,005)   | (1,532)   |
| Accumulated deficit .....  | (23,005)  | (19,653)  |
| Accumulated other comprehensive loss .....   | (20)      | --        |
|  | -----     | -----     |
| Total stockholders' equity (deficit) .....   | 61,817    | (18,283)  |
|  | -----     | -----     |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) .....                                  | \$ 65,832 | \$ 10,718 |
|  | =====     | =====     |

</TABLE>

(1) Derived from the consolidated audited financial statements at December 31, 2000.

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)

<TABLE>

<CAPTION>

|   | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |            |       |
|---|-------------------------------------|-----------|------------------------------------|------------|-------|
|   | 2001                                | 2000      | 2001                               | 2000       |       |
|   | <C>                                 | <C>       | <C>                                | <C>        |       |
| Revenues .....  | \$ 6,324                            | \$ 6,653  | \$ 19,885                          | \$ 17,662  |       |
| Cost of revenues* .....   | 2,432                               | 2,391     | 7,570                              | 6,299      |       |
|   | -----                               | -----     | -----                              | -----      |       |
| Gross profit .....  | 3,892                               | 4,262     | 12,315                             | 11,363     |       |
|   | -----                               | -----     | -----                              | -----      |       |
| Operating expenses:   |                                     |           |                                    |            |       |
| Marketing and selling .....   | 3,010                               | 2,208     | 8,981                              | 6,640      |       |
| Research and development .....  | 1,184                               | 915       | 3,213                              | 2,520      |       |
| General and administrative .....  | 855                                 | 789       | 2,591                              | 1,941      |       |
| Amortization of deferred stock compensation* .....                                  |                                     | 238       | 188                                | 810        | 429   |
|   | -----                               | -----     | -----                              | -----      |       |
| Total operating expenses .....  | 5,287                               | 4,100     | 15,595                             | 11,530     |       |
|   | -----                               | -----     | -----                              | -----      |       |
| Income (loss) from operations .....   | (1,395)                             | 162       | (3,280)                            | (167)      |       |
| Interest income .....   | 499                                 | 16        | 521                                | 23         |       |
| Interest expense .....  | (14)                                | --        | (35)                               | (6)        |       |
| Other income, net .....   | 217                                 | --        | 206                                | 11         |       |
|   | -----                               | -----     | -----                              | -----      |       |
| Income (loss) before provision for income taxes .....                               | --                                  | (693)     | 178                                | (2,588)    | (139) |
| Provision for income taxes .....  | --                                  | 23        | 1                                  | 23         |       |
|   | -----                               | -----     | -----                              | -----      |       |
| Net income (loss) .....   | (693)                               | 155       | (2,589)                            | (162)      |       |
| Accretion of redeemable convertible preferred stock .....                           |                                     | 71        | 346                                | 763        | 1,038 |
|   | -----                               | -----     | -----                              | -----      |       |
| Net loss available to common stockholders .....                                     | \$ (764)                            | \$ (191)  | \$ (3,352)                         | \$ (1,200) |       |
|   | =====                               | =====     | =====                              | =====      |       |
| Basic and diluted net loss per share .....  | \$ (0.06)                           | \$ (0.25) | \$ (0.71)                          | \$ (1.77)  |       |
|   | =====                               | =====     | =====                              | =====      |       |
| Common shares used in computing basic and diluted net loss per share (Note 3) ..... | 12,287                              | 766       | 4,741                              | 678        |       |

\* Amortization of deferred stock compensation included in:

|                        |       |       |        |        |
|------------------------|-------|-------|--------|--------|
| Cost of revenues ..... | \$ 34 | \$ 58 | \$ 117 | \$ 135 |
|------------------------|-------|-------|--------|--------|

|                                  |        |        |        |        |
|----------------------------------|--------|--------|--------|--------|
| Operating expenses:              |        |        |        |        |
| Marketing and selling .....      | \$ 121 | \$ 44  | \$ 420 | \$ 99  |
| Research and development .....   | 23     | 32     | 83     | 75     |
| General and administrative ..... | 94     | 112    | 307    | 255    |
| Total .....                      | \$ 238 | \$ 188 | \$ 810 | \$ 429 |

</TABLE>

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)

<TABLE>  
<CAPTION>

|   | Nine Months Ended<br>September 30, |          |
|---|------------------------------------|----------|
|   | 2001                               | 2000     |
|   | <C>                                | <C>      |
| Operating activities:   |                                    |          |
| Net loss .....  | \$ (2,589)                         | \$ (162) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: |                                    |          |
| Depreciation and amortization .....   | 574                                | 435      |
| Amortization of deferred stock compensation .....   | 927                                | 564      |
| Changes in operating assets and liabilities:  |                                    |          |
| Accounts receivable .....   | 276                                | (302)    |
| Inventories .....   | (855)                              | (717)    |
| Prepaid expenses and other current assets .....   | (339)                              | (120)    |
| Accounts payable .....  | 468                                | 92       |
| Accrued liabilities and deferred revenues .....   | (284)                              | 1,253    |
| Net cash provided by (used in) operating activities .....                                 | (1,822)                            | 1,043    |
| Investing activities:   |                                    |          |
| Acquisition of property and equipment .....   | (646)                              | (506)    |
| Purchase of convertible notes receivable .....  | --                                 | (20)     |
| Deposits and other assets .....   | (103)                              | 17       |
| Purchases of short-term investments .....   | --                                 | (302)    |
| Sales of short-term investments .....   | 302                                | 289      |
| Cash paid for acquisition of business .....   | (9)                                | --       |
| Net cash used in investing activities .....   | (456)                              | (522)    |
| Financing activities:   |                                    |          |
| Issuance of common stock .....  | 58,928                             | 125      |
| Deferred offering costs .....   | (1,383)                            | (725)    |
| Borrowings on bank loans .....  | 2,000                              | --       |
| Repayments of borrowings .....  | (2,000)                            | (112)    |
| Net cash provided by (used in) financing activities .....                                 | 57,545                             | (712)    |
| Exchange rate effect on cash and equivalents .....  | (6)                                | --       |
| Net increase (decrease) in cash and equivalents .....                                     | 55,261                             | (191)    |
| Cash and equivalents, beginning of period .....   | 681                                | 2,087    |
| Cash and equivalents, end of period .....   | \$ 55,942                          | \$ 1,896 |

Noncash investing and financing activities:

|   |        |          |
|---|--------|----------|
| Accretion of redeemable convertible preferred stock .....   | \$ 763 | \$ 1,038 |
|   | =====  | =====    |
| Forgiveness of convertible notes receivable and accounts receivable for acquisition of business ..... | \$ 189 | \$ --    |
|   | =====  | =====    |
| Supplemental disclosure of cash flow information:   |        |          |
| Cash paid for interest .....  | \$ 35  | \$ 8     |
|   | =====  | =====    |
| Cash paid for income taxes .....  | \$ 59  | \$ 18    |
|   | =====  | =====    |

</TABLE>

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

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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 generally accepted accounting principles for interim financial information and with the rules and regulations of the Securities and Exchange Commission. Accordingly, they do not include all of the information and notes required by generally accepted accounting principles for annual financial statements. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Natus Medical Incorporated (the "Company") believes necessary for fair presentation of the Company's 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 and significant intercompany transactions have been eliminated. The accompanying financial information should be read in conjunction with the audited financial statements and notes thereto for the fiscal year ended December 31, 2000 included in the Company's Registration Statements on Form S-1, as amended (Registration Nos. 333-44138 and 333-65478).

Use of Estimates

Preparing financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Examples include allowances for potentially uncollectable accounts receivable, warranty costs, and a valuation allowance for deferred tax assets. Actual results may differ from these estimates.

Recently Issued Accounting Pronouncements

In October 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, or SFAS No. 144. SFAS No. 144 requires that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and broadens the presentation of discontinued operations to include more disposal transactions. SFAS No. 144 will be effective for fiscal years beginning after December 15, 2001. The Company intends to adopt the provisions of SFAS No. 144 as of the effective date and does not expect SFAS No. 144 will have material effect on its financial position or results of operations.

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations, or SFAS No. 143. SFAS 143 requires that the liability for an asset retirement obligation be recognized at its fair market value when the liability is incurred. SFAS No. 143 will be effective for fiscal years beginning after

June 15, 2002. The Company intends to adopt the provisions of SFAS No. 143 as of the effective date and does not expect SFAS No. 143 will have a material effect on its financial position or results of operations.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 141, Business Combinations, or SFAS No. 141, and Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, or SFAS No. 142. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives will not be amortized, but will rather be tested at least annually for impairment. Under the provisions of SFAS No. 142, any impairment loss identified upon adoption of this standard is recognized as a cumulative effect of a change in accounting principle, which is charged directly to retained earnings. Any impairment loss incurred subsequent to initial adoption of SFAS No. 142 is recorded as a change to current period earnings. The Company will adopt SFAS No. 142 in 2002 and, at that time, will stop amortizing goodwill that resulted from business combinations completed prior to June 30, 2001. The Company believes that the adoption of SFAS No. 141 and SFAS No. 142 will not have a material effect on the Company's financial position and results of operations.

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In December 1999, the staff of the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, or SAB No. 101, which summarizes certain of the SEC staff's views in applying accounting principles generally accepted in the United States of America to revenue recognition in financial statements. The adoption of SAB No. 101 had no impact on the Company's financial position or results of operations.

In June 1998, the Financial Accounting Standard Board issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. SFAS No. 133 defines derivatives, requires all derivatives to be carried at fair value and provides for hedge accounting when certain conditions are met. SFAS No. 133 is effective for the Company in fiscal year 2001. The Company does not utilize derivative instruments and had no such instruments at January 1, 2001. Therefore, the adoption of SFAS 133 did not have an impact on the Company's financial position or results of operations.

#### Comprehensive Loss

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

<TABLE>  
<CAPTION>

|   | Three Months Ended<br>September 30, |        | Nine Months Ended<br>September 30, |          |    |
|---|-------------------------------------|--------|------------------------------------|----------|----|
|   | 2001                                | 2000   | 2001                               | 2000     |    |
| <S>   | <C>                                 | <C>    | <C>                                | <C>      |    |
| Net loss .....                              | \$ (693)                            | \$ 155 | \$ (2,589)                         | \$ (162) |    |
| Net foreign currency translation loss ..... |                                     | (28)   | --                                 | (20)     | -- |
| Comprehensive loss .....                    | \$ (721)                            | \$ 155 | \$ (2,609)                         | \$ (162) |    |

</TABLE>

#### 2 -- Inventories

Inventories consisted of (in thousands):

<TABLE>  
<CAPTION>

|                                       | September 30, 2001 | December 31, 2000 |
|---------------------------------------|--------------------|-------------------|
|                                       | -----              | -----             |
| <S>                                   | <C>                | <C>               |
| Raw materials and subassemblies ..... | \$ 1,787           | \$ 1,017          |
| Finished goods .....                  | 1,267              | 1,177             |
|                                       | -----              | -----             |
| Total inventories .....               | \$ 3,054           | \$ 2,194          |
|                                       | =====              | =====             |

</TABLE>

### 3 -- Basic and Diluted Net Loss Per Common Share

For all periods presented, both basic and diluted net loss per common share were computed by dividing the net loss available to common stockholders by the number of weighted average common shares outstanding during the respective periods. The impact of convertible preferred stock and stock options could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per common share as their effect is antidilutive for the periods presented.

### 4 -- Customer and Geographic Information

The Company operates in one reportable segment and is engaged in the design, manufacture, and marketing of newborn screening products for the identification and monitoring of common medical disorders that may occur during the critical development period of infants. The nature of the Company's products and production process as well as the type of customers and distribution methods are consistent among all of the Company's devices.

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The following table summarizes total revenues by geographic region. Revenues were attributable to countries based on the location of the Company's customer (in thousands):

<TABLE>  
<CAPTION>

|                     | Three Months Ended    |                       | Nine Months Ended     |                       |
|---------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                     | September 30,<br>2001 | September 30,<br>2000 | September 30,<br>2001 | September 30,<br>2000 |
|                     | -----                 | -----                 | -----                 | -----                 |
| <S>                 | <C>                   | <C>                   | <C>                   | <C>                   |
| United States ..... | \$ 5,563              | \$ 5,802              | \$ 16,593             | \$ 15,313             |
| Japan .....         | 640                   | 661                   | 2,568                 | 1,984                 |
| All other .....     | 121                   | 190                   | 724                   | 365                   |
|                     | -----                 | -----                 | -----                 | -----                 |
| Total .....         | \$ 6,324              | \$ 6,653              | \$ 19,885             | \$ 17,662             |
|                     | =====                 | =====                 | =====                 | =====                 |

</TABLE>

For the nine months ended September 30, 2001 and 2000, revenues from one customer, a distributor, accounted for approximately 10% and 11% of total revenues, respectively.

### 5 - Initial Public Offering

In July 2001, the Company completed an initial public offering of 5,000,000 shares of its common stock at \$11.00 per share. Proceeds to the Company from this offering, net of issuance costs, were approximately \$51.2 million after underwriting discounts and commissions, but before any expenses payable by the Company in connection with the offering. In August 2001, the underwriters of the offering exercised their overallotment option to purchase an additional 750,000 shares at \$11.00 per share for net proceeds to the Company of approximately \$7.7 million after underwriting discounts and commissions, but before any expenses payable by the Company in connection with the offering. Upon the closing of the Company's initial public offering, all of the then outstanding shares of the Company's preferred stock were automatically converted into 8,931,534 shares of common stock. In connection with its initial public offering, the Company also filed its Restated Certificate of Incorporation which, among other things,

authorizes the Company to issue 10,000,000 shares of Preferred Stock with such rights, preferences and privileges as the board of directors of the Company may determine.

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## 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, as amended. These statements include, among other things, statements concerning our future operations, financial condition and prospects, and business strategies. The words "believe," "expect," "anticipate," and other similar expressions generally identify forward-looking statements. These 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. You should carefully review the information contained under "Factors Affecting Future Results," beginning on page 15 of this Management's Discussion and Analysis of Financial Condition and Results of Operation," and elsewhere in or incorporated by reference into this report.

The following information should be read in conjunction with the condensed consolidated financial statements and notes thereto set forth in Item 1 of this quarterly report. We also urge you to review and consider our disclosures describing various factors that could affect our business, including the disclosures under Management's Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors and the audited financial statements and notes thereto contained in our Registration Statements on Form S-1 (File Nos. 333-44138 and 333-65478) filed in connection with our initial public offering.

### Overview

We develop, manufacture and market screening products for the detection and monitoring of common medical disorders in infants. Currently, we sell our ALGO products for hearing screening and our CO-Stat products for the analysis of hemolysis and management of jaundice.

Our revenues consist of revenues from sales of equipment and disposable supplies. We currently derive substantially all of our revenues from sales of a limited number of products. Nearly all of our revenues were from sales of our ALGO products in the three and nine months ended September 30, 2001 and 2000. Although we commercially launched our CO-Stat product in January 2001, we expect that a substantial majority of our revenues will continue to be generated from sales of our ALGO products for at least the next two years.

Historically we have sold our products directly through our sales force in the United States and indirectly through distributors internationally. Domestic sales were 88% and 87% of our revenues during the three months ended September 30, 2001 and 2000, respectively. Domestic sales were 83% and 87% of our revenues during the nine months ended September 30, 2001 and 2000, respectively. We plan to expand our international operations significantly because we believe international markets represent a significant growth opportunity. We acquired the distribution operations of our United Kingdom distributor in January 2001 and also began direct distribution operations in Japan in July 2001, when we acquired the activities of our Japanese distributor. The results of our operations in the United Kingdom and Japan were immaterial and have been included in our consolidated results from those dates. We anticipate that international revenues will increase as a percent of revenues 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 through distributors and have been characterized by lower gross margins due to the discount the distributors receive from our list prices.

We recognize revenues from product sales, including sales to distributors, upon shipment when a purchase order has been received, the sales price is fixed and determinable and collection of the resulting receivable is probable. We generally do not provide rights of return on our products. We, however, do make

provision for initial standard warranty obligations of one year and post-sale training and customer support at the time the related revenues are recognized. Revenues from extended warranty contracts are recognized ratably over the warranty period. Advance payments from customers are recorded as deferred revenues until shipment of the related product. Allowances for estimated warranty costs are estimated based on our historical results. To date, warranty and extended warranty costs have been in line with projected amounts. However, our past product warranty experience may not be indicative of the warranty costs we may experience in the future. We provide ALGO screening equipment to our customers on loan without charge while we repair or service their screening equipment.

In January 2001, we reorganized and expanded our domestic sales force to commercially launch and focus on our CO-Stat products. We expect to increase spending on the marketing of our CO-Stat products in 2001 and beyond. Because we have not previously marketed newborn jaundice management products, we cannot be certain that our planned resources will be sufficient to support the launch of our CO-Stat products.

Our net loss available to common stockholders includes accretion charges to increase the carrying amount of our redeemable convertible preferred stock to the amount we would have been required to pay if the preferred stock had been redeemed prior to the date of our initial public offering in July 2001. Our redeemable convertible preferred stock converted to common stock on a one-for-one basis upon the closing of our initial public offering in July 2001. We did not pay accrued dividends on the redeemable convertible preferred stock when it converted, and accrued but unpaid dividends became additional paid-in capital.

#### Results of Operations

The following table sets forth the results of our operations expressed as a percent of revenues. Our historical operating results are not necessarily indicative of the results for any future period.

<TABLE>  
<CAPTION>

|   | Percent of Total Revenues           |         |                                    |         |        |
|---|-------------------------------------|---------|------------------------------------|---------|--------|
|   | Three Months Ended<br>September 30, |         | Nine Months Ended<br>September 30, |         |        |
|   | 2001                                | 2000    | 2001                               | 2000    |        |
|   | <C>                                 | <C>     | <C>                                | <C>     |        |
| Revenues .....  | 100.0%                              | 100.0%  | 100.0%                             | 100.0%  |        |
| Cost of revenues* .....                                   | 38.5                                | 35.9    | 38.1                               | 35.7    |        |
| Gross profit .....  | 61.5                                | 64.1    | 61.9                               | 64.3    |        |
| Operating expenses:                                       |                                     |         |                                    |         |        |
| Marketing and selling .....                               | 47.6                                | 33.2    | 45.2                               | 37.5    |        |
| Research and development .....                            | 18.7                                | 13.8    | 16.1                               | 14.3    |        |
| General and administrative .....                          | 13.5                                | 11.9    | 13.0                               | 11.0    |        |
| Amortization of deferred stock compensation* .....        |                                     | 3.8     | 2.8                                | 4.1     | 2.4    |
| Total operating expenses .....                            | 83.6                                | 61.7    | 78.4                               | 65.2    |        |
| Income (loss) from operations .....                       | (22.1)                              | 2.4     | (16.5)                             | (0.9)   |        |
| Interest income (expense), net .....                      | 7.7                                 | 0.2     | 2.4                                | 0.1     |        |
| Other income, net .....                                   | 3.4                                 | --      | 1.0                                | --      |        |
| Income (loss) before provision for income taxes .....     |                                     | (11.0)  | 2.6                                | (13.1)  | (0.8)  |
| Provision for income taxes .....                          | --                                  | 0.3     | --                                 | 0.1     |        |
| Net income (loss) .....                                   | (11.0)                              | 2.3     | (13.1)                             | (0.9)   |        |
| Accretion of redeemable convertible preferred stock ..... |                                     | 1.1     | 5.2                                | 3.8     | 5.9    |
| Net loss available to common stockholders .....           |                                     | (12.1)% | (2.9)%                             | (16.9)% | (6.8)% |

\* Amortization of deferred stock compensation included in:

|                                  |      |      |      |      |
|----------------------------------|------|------|------|------|
| Cost of revenues .....           | 0.5% | 0.9% | 0.6% | 0.8% |
| Marketing and Selling .....      | 1.9% | 0.6% | 2.1% | 0.6% |
| Research and development .....   | 0.4  | 0.5  | 0.4  | 0.4  |
| General and administrative ..... | 1.5  | 1.7  | 1.6  | 1.4  |
| Operating expenses .....         | 3.8% | 2.8% | 4.1% | 2.4% |

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### Three and Nine Months Ended September 30, 2001 and 2000

#### Revenues

Our revenues consist almost exclusively of revenues from the sale of ALGO screening equipment and its related disposable supplies. Our revenues decreased \$329,000, or 5%, to \$6.3 million in the three months ended September 30, 2001 from \$6.7 million in the three months ended September 30, 2000. This decrease primarily was attributable to a decrease in revenues from sales of our screening equipment. Our revenues increased \$2.2 million, or 13%, to \$19.9 million in the nine months ended September 30, 2001 from \$17.7 million in the nine months ended September 30, 2000. This increase was primarily due to an increase in the quantities of disposable supplies sold. No end customer accounted for more than 10% of our revenues in the three months ended September 30, 2001 and 2000. Sales to our Japanese distributor, Nippon Eurotec, accounted for 10% of our revenues in the nine months ended September 30, 2001 and 11% of our revenues in the nine months ended September 30, 2000.

Revenues from screening equipment decreased \$712,000, or 30%, to \$1.7 million in the three months ended September 30, 2001 from \$2.4 million in the three months ended September 30, 2000. Revenues were adversely impacted by the terrorist attacks in the United States on September 11, 2001 and by delays in the implementation of screening programs in Europe, particularly in the United Kingdom. Revenues from screening equipment remained fairly constant and were \$6.3 million in each of the nine months ended September 30, 2001 and 2000.

Revenues from disposable supplies increased \$317,000, or 8%, to \$4.4 million in the three months ended September 30, 2001 from \$4.1 million in the three months ended September 30, 2000. Revenues from disposable supplies increased \$2.0 million, or 19%, to \$13.0 million in the nine months ended September 30, 2001 from \$10.9 million in the nine months ended September 30, 2000.

Revenues from sales outside the United States decreased by \$90,000, or 11%, to \$761,000 in the three months ended September 30, 2001 from \$851,000 in the three months ended September 30, 2000. The decrease primarily was attributable to lower sales in Europe. Revenues from sales outside the United States increased \$943,000, or 40%, to \$3.3 million in the nine months ended September 30, 2001 from \$2.3 million in the nine months ended September 30, 2000. These increases were due primarily to increased screening equipment sales in Japan, and, to a lesser extent, to revenues from our newly formed subsidiary in the United Kingdom.

#### Costs of Revenues and Operating Expenses

Cost of revenues 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 revenues increased \$41,000, or 2%, to \$2.4 million in the three months ended September 30, 2001 from \$2.4 million in the three months ended September 30, 2000. The increase in cost of revenues in absolute dollars was primarily attributable to increased manufacturing costs related to early production runs of our ALGO 3 product, which we released in October 2001. Our cost of revenues increased \$1.3 million, or 20%, to \$7.6 million in the nine months ended September 30, 2001 from \$6.3 million in the nine months ended September 30, 2000. The increase in the cost of revenues in absolute dollars was primarily due to the higher volume of disposable supplies sold relative to sales of screening

equipment as well as increases in manufacturing costs that were primarily associated with early production runs of our ALGO 3 product. As a percent of revenues, the cost of revenues increased to 38.5% in the three months ended September 30, 2001 from 35.9% in the three months ended September 30, 2000 and to 38.1% in the nine months ended September 30, 2001 from 35.7% in the nine months ended September 30, 2000. The increase in cost of revenues as a percent of revenues was attributable to the higher percentage of international sales and

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the lower per unit selling prices associated with those sales, a promotion on our ALGO Portable product in the United States during the three months ended March 31, 2001 and September 30, 2001 and the increased manufacturing costs. The impact of temporary price increases on certain ALGO components earlier in the year and costs associated with production of our ALGO 3 product later in the year further increased costs and reduced gross margin percentages during the nine months ended September 30, 2001.

Marketing and selling expenses consist primarily of salaries, commissions, travel and promotional and advertising costs. Our marketing and selling expenses increased \$802,000, or 36%, to \$3.0 million in the three months ended September 30, 2001 from \$2.2 million in the three months ended September 30, 2000. Our marketing and selling expenses increased \$2.3 million, or 35%, to \$9.0 million in the nine months ended September 30, 2001 from \$6.6 million in the nine months ended September 30, 2000. The increase in marketing and selling expenses was primarily attributable to the hiring of additional marketing and selling personnel associated with the commercial introduction of our CO-Stat product, and costs associated with our international expansion.

Research and development expenses consist of engineering costs to develop new products, enhance existing products and validate the design of our new or enhanced products. Our research and development expenses increased \$269,000, or 29%, to \$1.2 million in the three months ended September 30, 2001 from \$915,000 in the three months ended September 30, 2000. Our research and development expenses increased \$693,000, or 28%, to \$3.2 million in the nine months ended September 30, 2001 from \$2.5 million in the nine months ended September 30, 2000. This increase in research and development expenses was primarily attributable to the hiring of consultants and additional engineers and staff and other costs associated with the development of new products.

General and administrative expenses consist of corporate, finance, human resource, administrative and legal expenses. Our general and administrative expenses increased \$66,000, or 8%, to \$855,000 in the three months ended September 30, 2001 from \$789,000 in the three months ended September 30, 2000. Our general and administrative expenses increased \$650,000, or 33%, to \$2.6 million in the nine months ended September 30, 2001 from \$1.9 million in the nine months ended September 30, 2000. The increase in general and administrative expenses was primarily attributable to the hiring of additional personnel, as well as increased accounting fees and fees for other outside services.

Other income and expense consists of interest income and capital gains and losses associated with changes in our investment portfolio, interest expense, currency exchange loss and other miscellaneous income and expenses. Interest income increased \$483,000 to \$499,000 in the three months ended September 30, 2001 from \$16,000 for the three months ended September 30, 2000. Interest income increased \$498,000 to \$521,000 in the nine months ended September 30, 2001 from \$23,000 for the nine months ended September 30, 2000. Due to the investments made in expanding our operations, we drew down on our bank line early in the quarter ended September 30, 2001 and incurred interest charges. We repaid our total borrowing of \$2.0 million in July 2001 out of the proceeds of our initial public offering and invested the net remaining proceeds in short term cash equivalent investments. During the three months ended September 30, 2001 we also received a one-time settlement from a component supplier which, net of estimated product improvement costs, totaled \$147,000.

We recorded aggregate amortization of deferred stock compensation of \$272,000 and \$246,000 in the three months ended September 30, 2001 and 2000, respectively, and \$927,000 and \$564,000 in the nine months ended September 30, 2001 and 2000, respectively.

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## Liquidity and Capital Resources

As of September 30, 2001, we had cash and equivalents of \$55.9 million, an accumulated deficit of \$23.0 million and working capital of \$59.6 million. 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 was \$1.8 million for the nine months ended September 30, 2001, compared to net cash provided by operating activities of \$1.0 million for the nine months ended September 30, 2000. Cash used in operating activities for the nine months ended September 30, 2001 resulted primarily from the net loss during the period reduced by non-cash items such as deferred stock compensation and depreciation and amortization and reduced by an increase in inventories and a decrease in accrued liabilities. Increases in inventories primarily are associated with the increased working capital needs of our wholly owned, foreign operations in the United Kingdom and Japan. Net cash provided by operating activities for the nine months ended September 30, 2000 resulted primarily from non-cash items such as deferred stock compensation and depreciation and amortization, plus an increase in accrued liabilities, reduced by an increase in accounts receivable and inventories.

Net cash used in investing activities was \$456,000 for the nine months ended September 30, 2001 and \$522,000 for the nine months ended September 30, 2000. Net cash used in investing activities during these periods was primarily for the purchase of new computers, equipment and furniture as we expanded operations. We had no material capital expenditure commitments as of September 30, 2001.

Net cash provided by financing activities was \$57.5 million for the nine months ended September 30, 2001 and net cash used by financing activities was \$712,000 for the nine months ended September 30, 2000. The net cash provided by financing activities for the nine months ended September 30, 2001 resulted primarily from the proceeds of our initial public offering. The net cash used in financing activities for the nine months ended September 30, 2000 resulted primarily from deferred offering costs and repayment of borrowings.

We have a \$3.0 million revolving line of credit that expires in June 2002. In July 2001, we repaid the \$2.0 million borrowed under the line of credit using a portion of the proceeds from our initial public offering. As of September 30, 2001, we had no outstanding borrowings under this line of credit. Borrowings under the line of credit are limited to our eligible accounts receivable and are collateralized by substantially all of our assets and bear interest at the bank's prime rate plus 2.25%. We are also obligated to reimburse the bank for certain costs the bank incurs to administer our loan. We are required to meet certain financial ratios, including minimum tangible net worth, a minimum quick ratio and total debt to tangible net worth. We must also meet an operating profitability requirement. We believe that we were in compliance with these covenants as of September 30, 2001.

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

- . the amount and timing of revenues;
- . the extent to which our existing and new products gain market acceptance;
- . the extent to which we make acquisitions;

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- . the cost and timing of expansion of product development efforts and the success of these development efforts;
- . the cost and timing of expansion of marketing and selling activities; and
- . available borrowings under line of credit arrangements and the

availability of other means of financing.

We believe that our current cash and 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 heavily in the development of new products and enhancements to our existing products. The factors described above will affect our future capital requirements and the adequacy of our available funds. In addition, even if we raise sufficient funds to meet our anticipated cash needs during the next 18 months, we may need to raise additional funds beyond this time. 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 October 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, or SFAS No. 144. SFAS No. 144 requires that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and broadens the presentation of discontinued operations to include more disposal transactions. SFAS No. 144 will be effective for fiscal years beginning after December 15, 2001. We intend to adopt the provisions of SFAS No. 144 as of the effective date, and do not expect SFAS No. 144 will have a material effect on our financial position or results of operations.

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations, or SFAS No. 143. SFAS 143 requires that the liability for an asset retirement obligation be recognized at its fair market value when the liability is incurred. SFAS No. 143 will be effective for fiscal years beginning after June 15, 2002. We intend to adopt the provisions of SFAS No. 143 as of the effective date and do not expect SFAS No. 143 will have a material effect on our financial position or results of operations.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 141, Business Combinations, or SFAS No. 141, and Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, or SFAS No. 142. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method and addresses the initial recognition and measurement of goodwill and other intangible assets acquired in a business combination. SFAS No. 142 addresses the initial recognition and measurement of intangible assets acquired outside of a business combination and the accounting for goodwill and other intangible assets subsequent to their acquisition. SFAS No. 142 provides that intangible assets with finite useful lives be amortized and that goodwill and intangible assets with indefinite lives will not be amortized, but will rather be tested at least annually for impairment. Under the provisions of SFAS No. 142, any impairment loss identified upon adoption of this standard is recognized as a cumulative effect of a change in accounting principle, which is charged directly to retained earnings. Any impairment loss incurred subsequent to initial adoption of SFAS No. 142 is recorded as a change to current period earnings. We will adopt SFAS No. 142 in 2002 and, at that time, will stop amortizing goodwill that resulted from business combinations completed prior to June 30, 2001. The Company believes that the adoption of SFAS No. 141 and SFAS No. 142 will not have a material effect on the Company's financial position and results of operations.

In December 1999, the staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, or SAB No. 101, which summarizes certain of the SEC staff's views in applying accounting principles generally accepted in the United States of America to revenue recognition in financial statements. The adoption of SAB No. 101 had no impact on our financial position or results of operations.

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities, or SFAS No. 133. SFAS No. 133 defines derivatives, requires all derivatives to be carried at fair value and provides for hedge

accounting when certain conditions are met. SFAS No. 133 is effective for our company in fiscal year 2001. We generally do not utilize derivative instruments and had no such instruments at January 1, 2001. Therefore, the adoption of SFAS 133 did not have an impact on our financial position or results of operations.

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#### Factors Affecting Future Results

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, including net losses available to common stockholders of \$1.4 million in 1999, \$1.1 million in 2000 and \$3.4 million in the nine months ended September 30, 2001. In addition, we had an accumulated deficit of \$23.0 million as of September 30, 2001. We expect to incur net losses for the 2001 fiscal year.

We anticipate that our expenses will increase substantially in the foreseeable future as we:

- . continue to invest in research and development to enhance our ALGO and CO-Stat products and develop new technologies;
- . develop additional applications for our current technology, such as the use of our CO-Stat breath analyzer for the detection of pregnancy induced hypertension;
- . 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; and
- . develop additional infrastructure and hire additional management and other employees to keep pace with our growth.

As a result of these increased expenses, we will need to generate significantly higher revenues 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 product family for substantially all of our revenues, and a decline in sales of these products could cause our revenues to fall

Historically, we have derived substantially all of our revenues from sales of our ALGO products. Revenues from our ALGO products accounted for approximately 98% of our revenues in 2000 and approximately 97% of our revenues in the nine months ended September 30, 2001. We expect that the revenues from our ALGO product family will continue to account for a substantial majority of our revenues for at least the next two years. To date, our MiniMuff product, which is a disposable ear cover for newborns, has accounted for only a small percentage of our revenues. We have not derived any significant revenues from sales of our CO-Stat products. Any factors adversely affecting the pricing of our ALGO screening equipment and related disposables or demand for our ALGO products, including physician acceptance or the selection of competing products, could cause our revenues to decline and our business to suffer.

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

We acquired the ALGO product family in 1987, and we introduced our CO-Stat product in January 2001. More neonatologists and pediatricians must adopt our products for us to increase our sales. We believe that physicians will not continue to 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-

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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 and may be quicker on a per test basis. Physicians are traditionally slow to adopt new products and testing practices, 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 revenues 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 products relative to other screening 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.

A 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 harm our business. Economic growth in the United States and other countries has slowed significantly and many commentators believe that the United States economy is experiencing a recession. 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 revenues and operating results during these periods.

A sluggish economy and recent terrorist attacks in New York and Washington D.C. could have an adverse effect on our business

The September 11, 2001 terrorist attacks in New York and Washington D.C. could further contribute 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. Economic and political uncertainties, both domestically and abroad, resulting from these attacks or otherwise could result in declines in new technology investments by our customers, including investment in our products. In addition, at least during the short term, some hospitals may focus their resources on community preparedness and issues related to readiness for disasters rather than on compliance with newborn hearing screening mandates to take effect. For example, we did not receive product orders that we anticipated in the weeks after the terrorist attacks, which resulted in a decline in revenues in the quarter ended September 30, 2001. New rules and regulations that went into effect in New York in October 2001 require inpatient hearing screening for newborns under certain circumstances. We did not receive the orders we anticipated that we would receive late in the quarter ended September 30, 2001 from the adoption of these rules and regulations. We do not know what further effect the terrorist attacks, or resulting military actions by the United States, could have on our business, revenues or results of operations. If our customers or potential

adversely affected, which would harm our results of operations and financial condition.

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

Our revenues 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 revenues, 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 revenues could be erratic from quarter to quarter. This could make our business difficult to manage. For example, in the fourth quarter of 1997, a local government agency in Belgium made a one time purchase of equipment for each of the hospitals in its jurisdiction and approximately one year's supply of disposables. This purchase resulted in an abnormally high level of sales during that period and the following quarter.

We have limited historical experience selling our CO-Stat products and cannot determine how the sales cycle for the CO-Stat products will affect our revenues. The sales cycle, however, could be protracted and could result in further unpredictability in our revenues from quarter to quarter.

Many of these factors are beyond our control, and we believe that you should not rely on our results of operations for interim periods as any indication of our expected results in any future period. If our revenues vary 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 decline.

Our operating results have been and may continue to be subject to seasonal fluctuations during the first fiscal quarter of each year

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 revenues unpredictable in the future.

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

We intend to develop additional testing 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 on our ability to begin commercial, volume sales of our CO-Stat products

We introduced our CO-Stat product family for clinical research uses in July 1999 and began commercially marketing it in January 2001. To date, CO-Stat products have accounted for only a limited portion of our revenues. We have limited experience marketing our CO-Stat product for commercial use. However, our future growth and profitability will depend on our ability to commercially sell our CO-Stat products and to sell our CO-Stat products in volume. We cannot be certain that our entry into the hemolysis monitoring segment of the newborn testing market with our CO-Stat products will be successful, that the hemolysis monitoring market will develop at all or that physicians, governments or other third party payors will accept and adopt these products.

Physicians may not adopt our CO-Stat products if we cannot show that these products are cost-effective or if long-term clinical data does not support our early results, which would harm our operating results

While one clinical study has concluded that our CO-Stat product is more cost-effective than another test used for jaundice monitoring, we cannot be certain that additional clinical studies of the cost-effectiveness of our CO-Stat product compared to other tests used for jaundice monitoring will produce results that are favorable to our products. The commercial acceptance of our CO-Stat products depends in part upon favorable results from these studies if they are conducted. If our CO-Stat products are not shown to be cost-effective, we may not be able to persuade clinicians to adopt our products and our results of operations may suffer.

If clinical studies do not continue to produce satisfactory clinical data supported by the independent efforts of clinicians, our new products may not be accepted by physicians or government agencies as meeting

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the standards of care for universal newborn screening. Our safety, effectiveness, reliability, sensitivity and specificity data for the CO-Stat product is based in part on a study of over 1,300 children conducted in 1998. We may find that data from longer-term follow-up studies or studies involving a larger number of children is inconsistent with our relatively short-term data. If longer-term studies or clinical experience indicate that the CO-Stat product does not provide sensitive, specific and reliable results, our products may not gain commercial acceptance and our revenues could decline. In addition, we could be subject to significant liability for screening that failed to detect hemolysis leading to jaundice or costs and emotional distress incurred by families whose children received results indicating elevated hemolysis when none existed. We could have similar problems with any other products we offer in the future.

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 revenues 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 and jaundice monitoring 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 revenues may not grow if densely populated states and foreign countries do not adopt guidelines requiring universal newborn hearing screening or jaundice monitoring 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 sales may not grow. As of September 30, 2001, 35 states 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 revenues 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 revenues may not grow if state and foreign governments do not mandate hemolysis monitoring as the standard of care for newborn jaundice screening

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, a market may not develop for our CO-Stat products.

Any failure in our efforts to educate clinician, 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 universal newborn hearing testing and universal newborn jaundice management using hemolysis monitoring. We rely

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on physician, government agency and other third party payor confidence in the benefits of testing with 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 the screening procedures or for screening equipment itself, we may never achieve significant revenues

Physicians, hospitals and state agencies are unlikely to purchase our products if clinicians are not adequately reimbursed for the screening procedures conducted with our equipment or the disposable products needed to conduct the 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 hemolysis monitoring 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 for screening 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.

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 some newborn hearing screening or hemolysis monitoring for jaundice management, 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 screening 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 products, and our failure to build and manage our sales force or to market and distribute our CO-Stat products or other products effectively will hurt our revenues and quarterly results

Since we only recently began to market our CO-Stat products, our sales force has little experience selling these products, and we cannot predict how successful they will be in selling them. In order to successfully introduce and build market share for our CO-Stat 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.

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We market almost all of our newborn hearing screening products in the United States through a small direct sales force of 18 persons as of September 30, 2001. During the first quarter of 2001, we expanded our sales force by four persons in order to market our CO-Stat products along with our other products. 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 sales of our CO-Stat products.

We may not be successful in generating revenues from our CO-Stat products because we may encounter difficulties in manufacturing our CO-Stat products in commercial quantities

We do not have experience manufacturing our CO-Stat products in commercial quantities, and we may encounter difficulties in the manufacturing of these products. We must also increase our manufacturing personnel or increase the volume of products we purchase from contract manufacturers that produce the CO-Stat products for us. If we encounter any of these difficulties, we may not be successful in marketing our CO-Stat products, and our revenues 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. 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 revenues 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 assure you that we would be able to obtain the necessary regulatory clearance or approval. This could create supply disruptions that would harm our product sales and operating results.

There is only one Natus approved supplier that provides hydrogel, the adhesive used in 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 the adhesive or electrochemical sensors could negatively affect our revenues. 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 revenues and operating results could suffer.

We rely on a continuous power supply to conduct our operations and California's current energy crisis could disrupt our operations and increase our expenses

California is in the midst of an energy crisis that could disrupt our operations and increase our expenses. In the event of an acute power shortage, that is, when power reserves for the State of California fall

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below one and one-half percent, the State of California has on some occasions implemented, and may in the future continue to implement, rolling blackouts throughout the state. We currently do not have backup generators or alternate sources of power in the event of a blackout, and our current insurance does not provide coverage for any damages we or our customers may suffer as a result of any interruption in our power supply. If blackouts interrupt our ability to continue operations at our facilities, our reputation could be damaged, our ability to retain existing customers could be harmed and we could fail to obtain new customers. These interruptions could also result in lost revenue, any of which could substantially harm our business and results of operations.

Furthermore, the deregulation of the energy industry instituted in 1996 by the California state government has caused power prices to increase. Under deregulation, utilities were encouraged to sell their plants, which traditionally had produced most of California's power, to independent energy companies that were expected to compete aggressively on price. Instead, due in part to a shortage of supply, wholesale prices have skyrocketed over the past year. If wholesale prices continue to increase, our operating expenses will likely increase, as our primary North American facilities are located in California.

Some of our component suppliers are also located in California. While our orders from our suppliers have not been affected by power failure to date, the continuance of blackouts may affect our suppliers' ability to manufacture our products and meet scheduled delivery needs.

Our sales efforts through group purchasing organizations or sales to high volume purchasers may reduce our average selling prices, which would reduce our revenues 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 revenues 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. For instance, in the quarter ended September 30,

2001 we entered into agreements relating to our hearing screening products with Joint Purchasing Corporation and Healthtrust Purchasing Group, two group purchasing organizations. While we still 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. Sales to members of one group purchasing organization, Novation, LLC, accounted for approximately 22% of our total revenues in 2000 and 28% and 25% of our revenues in the three and nine month periods ended September 30, 2001, respectively. Approximately 79% of the customers who bought from us under the Novation agreement in 2000 were also our customers prior to the time we entered into the Novation agreement. 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 group purchasing organizations and our existing customers begin purchasing our products through those group purchasing organizations, our revenues and profit margins could decline.

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

We rely on sales of additional screening products to our existing customers for a majority of our revenues. Of our customers that purchased products from us in 1999, 90% also purchased products from us in 2000. If we fail to sell additional screening products to our existing customers directly or indirectly, we would experience a material decline in revenues.

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Because we rely on distributors to sell our products in some markets outside of the United States, our revenues could decline if our existing distributors do not continue to purchase products from us or if our relationship with any of these distributors is terminated

We rely on our distributors for a majority of our sales outside the United States. These distributors also assist us with regulatory approvals and education of physicians and government agencies. Our revenues from sales through international distributors outside the United States represented approximately 10% of our revenues in 1999, approximately 14% of our revenues in 2000 and approximately 10% of our revenues in the nine months ended September 30, 2001. 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 revenues 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 revenues could be harmed if our existing distributors do not continue to sell a large dollar volume of our products. None of our existing distributors are obligated to continue selling our products.

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

Our plan to expand in international markets will result in increased costs and may not be successful, which could harm our business

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 our United Kingdom distributor in January 2001. Effective in July 2001, we assumed our Japanese distributor's sales and support activities, allowing us direct access to redistributors of our

products in Japan. As we continue to increase our direct international sales presence, we will incur higher personnel costs that may not result in additional revenues. A higher percentage of our sales to international distributors could also impair our revenues 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 U.S. dollar relative to local currencies

Although historically substantially all of our sales contracts provide for payment in United States dollars, we expect that we will incur expenses related to international sales denominated in the respective local currency. We established a Japanese subsidiary in July 2000 and a United Kingdom subsidiary in December 2000. These operations will incur expenses in the applicable local currency. We also expect to begin selling our products in 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 revenues 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.

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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 terrorist attacks in the United States and abroad;
- . contractual provisions governed by foreign law, such as common law rights to sales commissions by terminated distributors;
- . the dependence of demand for our products on health care spending by local 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.

Our failure to obtain necessary U.S. Food and Drug Administration clearances or approvals or to comply with Food and Drug Administration 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 Food and Drug Administration 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 Food and Drug Administration has determined that the medical device in question poses a greater risk of injury.

The Food and Drug Administration's 510(k) clearance process usually takes

from four 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 Food and Drug Administration will ever grant either 510(k) clearance or premarket approval for any product we propose to market. Furthermore, if the Food and Drug Administration 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 Food and Drug Administration 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 Food and Drug Administration takes an enforcement action against us for off-label uses

We may not promote or advertise the ALGO, MiniMuff or CO-Stat products, or any future cleared or approved devices, for uses not within the scope of our clearances or approvals or make unsupported

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promotional claims about the benefits of our products. If the Food and Drug Administration 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 Food and Drug Administration, our sales could be delayed, our revenues could decline and our reputation among clinicians could be harmed.

Our business would be harmed if the Food and Drug Administration 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 Food and Drug Administration concerning compliance with pertinent regulatory requirements. If the Food and Drug Administration 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 Food and Drug Administration and are subject to regulatory requirements similar to the Food and Drug Administration's regulatory requirements in foreign countries. 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 Food and Drug Administration requirements. We may not be able to obtain these approvals without incurring significant expenses or at all.

If we or our suppliers fail to comply with applicable regulations, sales of our

products could be delayed and our revenues 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 Food and Drug Administration's quality system regulation and comparable regulations of states and other countries. The Food and Drug Administration 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 Food and Drug Administration 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.

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We may experience intense competition from other medical device companies, and this competition could adversely affect our revenues and our business

Our most significant current and potential competitors for the ALGO products include companies that market hearing screening equipment. For the CO-Stat products, we anticipate that our competitors will be large medical device companies that market laboratory bench equipment used for blood-based antibody and bilirubin tests and companies that sell devices that analyze the amount of yellow in the skin to estimate the level of bilirubin.

We believe that Bio-logic Systems Corp., Intelligent Hearing Systems and Sonamed Corp., each of which is also currently marketing enhanced auditory brainstem response and otoacoustic hearing screening equipment products, could introduce new, lower priced hearing screening equipment that may not require an audiologist or physician to interpret its results or review its recommendations, similar to our products. For example, Bio-logic recently announced that it received FDA approval to sell its disposable products for use with our ALGO hearing screeners. We do not know the impact this FDA approval or sales efforts by Bio-logic will have on our revenues from sales of our disposable products. We believe that Chromatics Color Sciences International, Inc., 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. 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 or hemolysis monitoring 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.

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 hemolysis monitoring products with features similar to ours, and this could reduce demand for our products.

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We protect our intellectual property through a combination of patent, copyright, trade secret and trademark laws. We have eight issued United States patents, seven patent applications pending before the United States Patent and Trademark Office and seven patent applications pending before foreign governmental bodies of which one European Patent Office application has been allowed and will be registered in nine European countries. We have one patent granted in Japan, six patent applications pending in Japan and one patent application pending in Hong Kong. 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 hemolysis monitoring 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. 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 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.

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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 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 the likely 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.

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. In September 2001 our stock price fell by more than 45%. 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.

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 including Tim C. Johnson, our chief executive officer, and William New, Jr., M.D., Ph.D., our chief technology officer, chairman and a founder. The loss of any of our key employees could adversely affect our business and slow our product development process. Although we maintain key person life insurance on Dr. New, we do not maintain key person life insurance on any of our other employees, and the amount of the policy on Dr. New may be inadequate to compensate us for his loss.

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 losses, which may adversely affect our financial results

As of December 31, 2000, we had total net operating loss carryforwards of approximately \$6.7 million for income tax purposes. These net operating loss carryforwards, if not utilized to offset taxable income in future periods, will expire in various amounts beginning in 2007 through 2019. 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, applicable 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 are unable to use our net operating loss carryforwards to offset our taxable income, our future tax payments will be higher and our financial results may suffer.

### 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, Japan and Europe. Our revenues for sales outside the United States were approximately 10% of our revenues in 1999, approximately 14% of our revenues in 2000 and approximately 17% of our revenues in the nine months ended September 30, 2001. 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. Historically, our sales have been generally denominated in United States dollars; however, with the formation of our Japanese subsidiary and the acquisition of our United Kingdom distributor, we expect that a portion of our operating expenses and revenues in international locations will be denominated in local currencies in the future. Historically, our exposure to foreign exchange fluctuations has been minimal. As our international sales and operations expand, however, we anticipate that our exposure to foreign currency fluctuations will increase. As all of our sales are currently made in United States dollars, a strengthening of the dollar could make our products less competitive in foreign markets.

Our interest income is sensitive to changes in the general level of interest rates in the United States. However, due to the nature of our short-term investments, we believe that we do not have material market risk exposure.

Our investment policy permits us to invest funds in excess of current operating requirements in:

- corporate securities including commercial paper, rated A1, P1 or better, and corporate debt instruments, including medium term notes and floating rate notes issued by foreign and domestic corporations, that pay in United States dollars and carry a rating of A or better;

- . bank certificates of deposit and banker's acceptances that are rated at least A1 or P1;
- . United States treasury bills, notes and bonds and United States AAA-rated agency securities that carry the direct or implied guarantee of the United States government, including notes, discount notes, medium term notes and floating rate notes;
- . asset-backed securities rated A or better;
- . repurchase agreements with major banks and dealers that are recognized as primary dealers by the Federal Reserve Bank of New York;
- . money market mutual funds that offer daily purchase and redemption; and
- . tax exempt/tax advantage investments in money market funds, variable rate demand notes, municipal notes or bonds and auction preferred municipal and corporate securities.

In July and August 2001, we received \$58.8 million in aggregate net proceeds in connection with our initial public offering after deducting underwriting discounts and commissions, but before deducting offering expenses payable by us. We are currently investing net offering proceeds from the offering pursuant to our investment policy.

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## PART II. OTHER INFORMATION

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

Between June 30, 2001 and September 30, 2001, we issued 33,633 shares of unregistered common stock upon the exercise of outstanding options to nine persons and entities at an average exercise price of \$0.74 per share. The sale of the above securities was deemed to be exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701. Each recipient had adequate access to information about us through his or her relationship with us.

We have used approximately \$2.0 million of the proceeds from our initial public offering to repay the outstanding amounts on our revolving bank line of credit. The offering expenses incurred by us was approximately \$2.4 million. There were no direct or indirect payments to any of our directors or officers or any other person or entity. None of the offering proceeds have been used for the construction of plant, building or facilities or the purchase or installation of machinery or equipment or for purchases of real estate or the acquisition of other businesses. We are currently investing the net offering proceeds for further use as additional working capital. The net proceeds have been invested pursuant to our investment policy. A portion of the net proceeds may be used for the acquisition of technologies, businesses or products that are complementary to ours. Other than these amounts and future estimated capital expenditures in the amount of approximately \$1.0 million in the next 12 months, we have no specific plan for the proceeds from our initial public offering.

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

#### (a) Exhibits

10.18 Leasing Agreement dated June 11, 2001 between Natus Japan and Sanwa Radiator, Co. Ltd.  
(Japanese to English translation)

#### (b) Reports on Form 8-K

The Company did not file any reports on Form 8-K during the three months ended September 30, 2001.

SIGNATURES

Pursuant to the requirements of the Securities and 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: November 9, 2001            By: /s/Tim C. Johnson

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Tim C. Johnson  
Chief Executive Officer, President  
Chief Operating Officer, Secretary  
and Director  
(Principal Executive Officer)

Dated: November 9, 2001            By: /s/William H. Lawrenson

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William H. Lawrenson  
Vice President, Finance  
and Chief Financial Officer  
(Principal Financial and Accounting  
Officer)

EXHIBIT 10.18

Leasing agreement

Second Floor, Sanwa Building

Period of leasing agreement  
from June 11, 2001  
until June 10, 2003

Lessor: Sanwa Radiator, Co. Ltd.

Lessee: Natus Japan, Co. Ltd.

office

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Contract for leasing of space

The lessor, Sanwa Radiator, Co. Ltd. (hereinafter called the "lessor" ), and the lessee, Natus Japan, Co. Ltd. (hereinafter called "the lessee"), hereby enter into a leasing agreement in accordance with the following conditions.

Article Number One (Announcement of leased space)

The lessor, the owner of the leased space described elsewhere (hereinafter called the "leased space"), will lease this space to the lessee, who has leased it.

Article Number Two (Purpose of use)

The lessee will use the leased space only for the purpose of running an office, and will not use the space for any other purposes.

Article Number Three (Period of lease/Notice of termination of lease/Period of lease renewal)

(1.) The period of this lease extends from June 10, 2001 until June 11, 2003, a period of two years.

(2.) When either the lessor or lessee has decided to end this contract at the end of the period of this lease, advance notice must be given to the other party six months prior to the end of the leasing period, in accordance with this document.

(3.) In a case where either the lessor or lessee does not provide notice as described in the previous item to the other party six months prior to the end of the leasing period, this contract will be extended for an additional two years. After this, the end of the leasing period will be handled in the same manner.

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Article Number Four (Rental fees)

The monthly rental fees shall be 1,315,625 yen, and the lessee will deliver or send payment to the lessor or its designated representative the rental fees for the following month by the last day of the preceding month. However, the rental fees for a period that is less than a full month shall be determined by calculating the pro-rated payment for the number of days in that period.

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Article Number Five (Responsibility for various expenses)

The lessee shall be responsible for the various expenses laid out in each of the items that follow, and payment for these various expenses shall be delivered to or payment shall be sent to the lessor or its designated representative by the last day of each month.

1. Monthly management fees in the sum of 315,750 yen (payment for the following month shall be made by the last day of the current month)
2. Charges for gas, water, and electricity usage (including monthly base charges) and heating and cooling expenses
3. Installation charges and activation fees related to fixtures and facilities specially requested by the lessee, and charges for the use of the same
4. Among the shared expenditures from usage that benefit the lessee along with other lessees, expenses set by the lessor as the lessee's share of the financial

responsibility

#### Article Number Six (Adjustment of rental fees)

In response to general fluctuations in prices, increases in public levies and taxes on land and buildings, or in comparison to other rental fees in the local area, when it has been determined that the rental fees in Article Four and the group expenditures in Article Six Item 1 are insufficient, even during the period of the lease agreement, these fees can be adjusted based on discussion between the lessor and lessee.

#### Article Number Seven (Prohibitions)

The lessee and its employees shall not carry out activities to which the following items apply.

1. Activities that interfere with the business operations or administration of the lessor or other lessees
2. Transfer and storage of materials in the building or its vicinity that may have explosive or flammable properties, or other materials that are dangerous, unclean, malodorous or unsightly
3. Entry into the building of animals, or the feeding and care of animals inside the building

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4. Cigarette butts and other flammable paper and trash materials that could pollute the building shall be disposed of only in the locations designated by the lessor

5. Cooking and sleeping overnight inside the building

6. Other activities that the lessor has posted as being prohibited for the purpose of maintaining the safety, attractiveness, and quality of maintenance and management of the building

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#### Article Number Eight (Limitations)

At times when the lessee proposes to carry out activities to which the following items apply, prior approval must be obtained in advance from the lessor in writing by those who intend to carry out these activities or their workers; expenses shall be borne by the lessee.

1. Renovation of the leased spaced, partitioning of rooms, and other various fixtures and facilities such as new installations, additions, removal or other changes in the facilities
2. The new installation, addition, changes to or removal of wiring, piping or equipment for electric lights, electric power, telephone, gas, water, or changes in the capacity of the same
3. The installation or removal of safes, steel cabinets or other heavy items
4. The installation of signboards or other public display boards inside the building, on the roof, in the vicinity of the building or in the glass windows; or the installation, posting or writing of advertisements, signs or warning notices

#### Article Number Nine (Responsibility for notification)

In cases when the lessee has or anticipates the need for repairs to the leased space and partitions that the lessor owns, or other facilities in the building, or in cases when there are locations that require equipment for the prevention of disasters or accidents, immediate notice must be given to the lessor.

#### Article Number Ten (Prohibition of transference of leasing rights)

The lessee is prohibited from transferring the right to leasing of the leased space to a third party. However, in cases where the third party is confirmed as the general successor of the lessee through the transfer of the company's business operations or partnership or due to some other arrangement, and the lessor has approved the agreement in accordance in written form, no such restrictions will be imposed.

#### Article Number Eleven (Prohibition of subletting)

The lessee may not transfer the lease either in part or in full to a third party, may not offer continuous use, or use the space in conjunction with a third party, or

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display the name of any operations in this space other than that of the lessee. However, this restriction does not apply in cases where the lessor has provided consent in writing.

Article Number Twelve (Entering the leased space for inspections)

At times when there is a need for maintenance, cleaning, protection from robbery, protection from fire, rescue, or emergency measures, the lessor or its employees may enter the leased space for such purposes, carry out the inspection and determine the appropriate measure to be taken.

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Article Number Thirteen (Compensation for damages)

In cases when the lessee or its agents, employees, hired workers or others associated with the lessee have, either intentionally or by accident, caused damage to the lessor, other lessees or other third parties, the lessee shall provide full compensation.

Article Number Fourteen (Exemptions)

When due to theft or disasters such as earthquake, fire, or flooding that are beyond the control of the lessor, losses incurred by the lessee shall not be the responsibility of the lessor.

Article Number Fifteen (Deposit)

(1.) In order to provide security for the execution of the duties based on this contract, the lessee will pay a security deposit of 13,156,250 yen to the lessor as outlined below. The deposit will not accrue interest.

(2.) In cases when the lessee is late in making payment of rent or other expenses, or when the lessor has suffered losses in taking responsibility for the financial obligations based on this contract, the lessor may, as a matter of course, appropriate the deposit money as compensation.

(3.) Within 7 days of receiving notice of the appropriation of money in cases such as that described in the previous item, the lessee will supplement the amount that is in arrears until it reaches the amount of the deposit money in item 1 above.

(4.) During the period of this lease, the lessee may not use the deposit money to pay rental fee payments or to fulfill other obligations.

(5.) The lessee is not permitted to transfer the right to claim the return of the deposit money to a third party, or to use it as collateral for its obligations.

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(6.) If the lessee has fulfilled all of the obligations outlined in this agreement, the money used as a security deposit will be returned as outlined in the items below.

1. If the lessor has proposed dissolution of the contract, the money will be returned at the time the lessee has completely vacated the premises.

2. If the lessee has proposed dissolution of the contract, the money will be returned within one month from the day the dissolution of the contract goes into effect. However, this is subject to the condition that the lessee has completely vacated the premises by the end of the period the contract is in force.

3. In every case, whether effective under Article 16, dissolution of the contract; Article 17, immediate dissolution of the contract; or Article 18, completion of contract, the date that these occurred will be taken as the starting point, and the money will be returned within one month from that date. However, in these cases as well, the conditions in the previous item will apply.

4. If less than one full year has passed since entering into this agreement in cases of either dissolution of contract or completion of contract, and if less than one full year has passed since entering into this agreement and the deadline for returning the deposit money has arrived, irrespective of the period set in item 2 for the redemption of the deposit, as a special exemption, the period for redemption of the deposit shall be extended to the date at which one full year has passed since entering into the agreement.

5. Regardless of the period set in item three above for redemption of

the deposit, after the lessee has vacated the premises and the lessor has newly rented said premises, when the new deposit money has been received, at that time the lessee's deposit money will be returned.

#### Article Number Sixteen (Dissolution of contract)

The lessor, at the time when the lessee has performed or fulfilled the activities outlined in each item below and there is no need for notification of some sort, will immediately terminate this agreement, and will demand that the premises be vacated if there is no dispute put forth by the lessee. In a case when the lessor has been subject to damages, compensation for these damages can be demanded from the lessee, and will be granted if the lessee does not dispute the claim.

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1. In cases when the application has been filled in falsely at the time of move-in, or when move-in has been carried out incorrectly
2. In case when the rent or other obligations are two months or more in arrears
3. In cases when the leased space has been used for purposes other than those described in Article 2
4. In cases when the exclusive possession of other lessees has been encroached upon in some exceptional manner, or there is concern that such encroachment has taken place

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5. In cases when trust has been lost in some exceptional manner, or in cases when activities counter to the public welfare have taken place
6. In cases when the leased space has been vacated without permission, or in cases when the leased space has not been used for a period of 30 continuous days without obtaining permission
7. In cases when the lessee or its employees, either intentionally or by accident, have damaged the leased space or building in some exceptional manner, or have caused a fire to break out
8. In cases when due to other obligations, the company's assets have been temporarily seized, temporarily disposed of, or in cases of extortion, or in cases when the company has declared bankruptcy, compensation obligations, or company revivification, or in other cases of declarations of company re-organization or dissolution due to death or incompetence
9. In cases when the activities of the lessee or those occupying the same leased space have caused the police to investigate the presence of stimulants or prostitution, etc.
10. In cases when judged to be associated with violent groups or membership in groups that carry out activities that disrupt the legal order
11. In cases when rough or violent language and actions are used, when there is contentious behavior toward others without provocation, or when there are attempts to disrupt the business, maintenance, or management operations related to the building, when orderly proceedings are disrupted and these activities cause the lessor to doubt the maintenance of good faith in dealings with the lessee
12. In cases when any of the items in this contract or those supplemental to this contract are violated

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#### Article Number Seventeen (Notice of immediate contract dissolution)

In cases when unavoidable circumstances arise during the term of this lease and this contract is to be dissolved, either the lessor or the lessee may provide the other party with six months' prior notice in accordance with this document and dissolve this contract. However, the lessee may, in lieu of notice, pay to the lessor a dissolution fee in the amount of six months' rental fees and thereby obtain immediate dissolution of the contract. In addition, in cases when the lessee vacates the premises without giving notice in accordance with this document, or in cases when due to debts of the lessee this contract is dissolved, the lessee must bear the responsibility for payment of the same contract dissolution fees.

#### Article Number Eighteen (Cancellation of contract)

In cases when due to natural disasters, earthquakes or other events that cannot be controlled, the building is damaged or destroyed either in part or as a whole,

making it impossible to use the leased space, this contract will be ended as a matter of course.

Article Number Nineteen (Restoration to original condition)

(1.) In cases when this contract is ended (including dissolution and termination of the contract) the lessee must, by the deadline set by the lessor, restore the partitioning of rooms installed in the space, and other facilities and fixtures installed by the lessee; in cases when there are damaged or dirty places, the lessee must restore the leased space to its original condition when returning the premises to the lessor.

(2.) In cases when the leased space has not been restored to its original condition by the time of the deadline set by the lessor, the lessor may take measures to restore the space to its original condition at the lessee's expense.

Article Number Twenty (Measures regarding leftover equipment and goods after the property is vacated)

In cases when there are materials and goods remaining inside the leased space after the contract has ended and the premises have been vacated, the lessor may dispose of these items as it deems fit, and the lessee is without recourse to dispute these actions.

Article Number Twenty-one (Compensation for damages due to late evacuation)

In cases when the lessee has not vacated the premises at the time this contract is ended, the lessee is responsible to pay damages to the lessor equal to double the rental fees due for each day following the ending of the contract until the premises are evacuated, as well as the various expenditures described in Article 6.

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Article Number Twenty-two (Right to demand purchase of incidental fixtures)

Upon vacating the premises, and for that reason, irrespective of category, the lessee shall not demand compensation from the lessor for redecoration of the leased space or partitions between rooms, or for the purchase of other incidental fixtures and facilities. Nor shall compensation be demanded for necessary expenses incurred in connection with these renovations, nor money for moving expenses, removal fees or money for the purchase of rights.

Article Number Twenty-three (Regulations inside the building)

The lessee agrees to abide by the rules of the building management established elsewhere by the lessor.

Article Number Twenty-four (Confirmation of representatives and examination of this contract)

The representatives appointed by the lessor and lessee shall examine all of the articles contained in this document, and announce that they, the lessor and lessee, agree to adhere to the articles they have examined that constitute this contract.

Article Number Twenty-five (Items not covered in regulations/items of responsibility)

In cases when there is doubt about items that are not covered in this document or with regard to the interpretation of these articles, the lessee and lessor shall meet in good faith for discussion in order to clarify that interpretation.

Article Number Twenty-six (Jurisdiction over this agreement)

The lessor and lessee agree that any disputes arising in connection with this contract shall fall under the jurisdiction of the first competent court in the lessor's area of residence.

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Article Number Twenty-seven (Items of special agreement)

(1.) With regard to the monthly rental fees and management fees, the lessee shall bear responsibility for any additional consumption tax.

(2.) Address and information for electronic transfer of rental fees, management fees, and consumption taxes.

Bank name: Fuji Ginko (Fuji Bank) Mita branch

Account number:

Name of client: Sanwa Radiator, Ltd.

In addition, the lessee shall be responsible to pay for the electronic transfer fees.

Upon approval of this contract, two copies of the original contract shall be made up, signed with personal seals affixed to it, and the lessee and lessor shall each keep one copy of this document on file.

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Lessor (landlord)

President, Eiji Watanabe

Sanwa Radiator, Co. Ltd.

24-21 Shiba 3-chome, Minato-ku, Tokyo

(seal affixed)

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Lessee (occupant)

President, Hiroshi Kasamatsu

Natus Japan, Co. Ltd.

3-22 Tora-no-mon, 2 Chome, Minato-ku, Tokyo

(seal affixed)

Representative

Kensetsu Daijin (1) No. 5907

Manager, Tomomi Mori

Sanwa Builds Co., Ltd.

Ueno Realtor Division

Hirokoji Kaikan 6F Ueno

Ueno 1-19-10 Daito-ku, Tokyo

(seal affixed)

Representative for trade in housing development and buildings

Registration number: Tokyo 99499

Tomomi Mori

(seal affixed)

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Announcement of lease agreement

Address: 24-21 Shiba 3-chome, Minato-ku, Tokyo

Building name: Sanwa Building

Type of construction: Steel girders, with steel supported concrete construction, a six-story building

Space being leased: second floor, 347.96 m<sup>2</sup> (105 x 25 tsubo)

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