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

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2001**

OR

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities 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 of incorporation or organization)	**(I.R.S. Employer Identification Number)**

1501 Industrial Road, San Carlos, California 94070
(Address of principal executive offices, including zip code)

(650) 801–0400
(Registrant's Telephone Number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act: None

Securities Registered Pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the Form 10-K or any amendment to this Form 10-K. ☒

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based on the closing sale price of the Registrant's common stock on March 20, 2002, as reported on the Nasdaq National Market, was approximately $67,923,975. Shares of common stock held by each executive officer and director and by each person who may be deemed to be an affiliate of the Registrant have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes. As of March 20, 2002, the Registrant had 15,930,986 shares of its common stock, $0.001 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant has incorporated by reference into Part III of this Form 10-K portions of its Proxy Statement for the 2002 Annual Meeting of Stockholders.

NATUS MEDICAL INCORPORATED

ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1. Business

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 about Natus Medical Incorporated ("Natus®," "we," "us" or "our company"). These statements include, among other things, statements concerning our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. The words "may," "will," "continue," "estimate," "project," "intend," "believe," "expect," "anticipate" and other similar expressions generally identify forward-looking statements. Forward-looking statements in this Item 1 include, but are not limited to, statements regarding the following: the effectiveness and advantages of our products, acceptance of universal newborn hearing and jaundice screening, incidence of newborn jaundice and hearing loss, bidding and selection processes, future results of clinical trials, our marketing, technology enhancement and product development strategies, including additional applications for our CO-Stat® product, our intention to enter into agreements with group purchasing organizations, future third party reimbursement for our products, factors relating to demand for and economic advantages of our products, the effect of Medicare reform legislation, implementation of newborn hearing screening and jaundice management, future manufacturing quality and cost, hiring of additional personnel, quality of materials from suppliers, future availability of components and materials and related production delays, the proprietary nature of our products, including infringement and enforcement of proprietary rights, future competition and our ability to compete, our compliance with regulatory requirements and laws, sufficiency of our facilities, resolution and effect of legal proceedings and our dividend policy.

You are cautioned not to place undue reliance on forward-looking statements. Forward-looking statements are not guarantees of future performance. The forward-looking statements are subject to substantial risks and uncertainties that could cause our future business, financial condition, or results of operations to differ materially from our historical results or currently anticipated results. Investors should carefully review the information contained under the caption "Factors that may affect our business, financial condition, and future operating results," contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in, or incorporated by reference into, this report. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements. These forward-looking statements are made in reliance upon the safe harbor provision of The Private Securities Litigation Reform Act of 1995.

Overview

We are primarily focused on developing, manufacturing and marketing screening products for the identification and monitoring of common medical disorders that may occur during the time from conception to a baby's first birthday. This period is critical to a child's development. By allowing for early detection and treatment, we believe our products can improve clinical outcomes, help reduce costs and minimize the probability of unnecessary retesting or hospital readmission. We design our products to deliver accurate results in a rapid and reliable manner. In addition, our products address the policies and guidelines for standard medical practices adopted by the American Academy of Pediatrics.

We have two primary product lines that have been cleared for marketing by the Food and Drug Administration: the ALGO ® Newborn Hearing Screener, a product line for hearing screening, and the CO-Stat End-Tidal Breath Analyzer, a product line for the management of newborn jaundice. Both of our current product lines are comprised of hardware units and single-use disposable components.

Our ALGO products use automated auditory brainstem response technology to enable simple, nonnvasive and accurate screening for hearing impairment in newborns. The ALGO screener delivers sound stimuli to a newborn's ears and analyzes the resulting brain wave responses to produce a "Pass" or "Refer" result. The procedure can be performed within hours after birth. In addition, our ALGO products meet the American

Academy of Pediatrics' guidelines without requiring a trained clinician to conduct the screening or interpret the results. We currently sell our ALGO products in the United States, Europe, Japan, the United Arab Emirates, Australia, New Zealand and elsewhere.

Our CO-Stat products enable physicians, within hours after birth, to assess the likelihood that serious newborn jaundice will not occur, thereby allowing physicians to keep newborns with higher risk of developing serious newborn jaundice in the hospital or under observation and to discharge those newborns with a lower risk. In the majority of cases, serious jaundice is the result of an abnormally high rate of hemolysis. Our CO-Stat analyzers accurately and non-invasively measure the rate of hemolysis by detecting the level of carbon monoxide in exhaled breath. In addition, we are currently investigating the use of the CO-Stat for monitoring and analysis of other conditions, including pregnancy induced hypertension. We began commercially marketing our CO-Stat products in January 2001.

Clinical Background

Hearing Impairment

Overview

Approximately 4.0 million babies are born each year in the United States, and hearing impairment affects up to five per every 1,000 of those newborns. Until the introduction of universal newborn hearing screening programs, screening was generally performed only on those newborns who had risk factors for hearing impairment, including a family history of hearing impairment, infection prior to birth, low birth weight, skull or facial anomalies or bacterial meningitis. However, screening only those newborns with risk factors for hearing impairment overlooks approximately half of newborns with some level of hearing impairment.

Early identification of hearing impairment and early intervention has been shown to improve language development significantly. Babies identified at birth as deaf or hearing impaired, who begin immediate therapy, can learn and progress at a rate comparable to children with normal hearing, regardless of the severity of hearing loss. However, undetected hearing impairment often results in the failure to learn, process spoken language and speak. A 1997 study conducted at the University of Colorado, Boulder evaluated the impact of hearing impairment on language and speech. All of the children evaluated in the study were born with a hearing impairment but differed by the age at which the hearing impairment was detected. The study concluded that those children whose hearing loss was detected and who received treatment early had significantly better language skills and vocabularies than those children whose hearing loss was detected later.

Newborn Hearing Screening

Newborn hearing screening has been performed in the United States since 1964 but has been generally limited to babies with risk factors for hearing impairment. We believe the lack of accurate, low cost screening devices and the subjective nature of other currently used tests has limited the willingness of governments and physicians to adopt hearing screening as a standard of care for all newborns. In recent years, the clinical evidence in support of early detection for hearing impairment combined with the introduction of new screening technology has increased support for universal newborn hearing screening programs. In 1993, the National Institutes of Health and, in 1994, the Joint Committee on Infant Hearing endorsed universal newborn hearing screening. The combined clinical benefit and cost savings encouraged additional highly populated states to adopt mandates for universal newborn hearing screening as early as 1997.

In the United States, 36 states and the District of Columbia have universal newborn hearing screening mandates in place and legislation is pending in another four states. The majority of the mandates currently allow for implementation over a two to three-year period. An additional 10 states have voluntary programs in place. We define states that voluntarily comply to be states without mandated universal newborn screening but in which we estimate at least 50% of newborns are screened. In these states, the state health departments may purchase and distribute hearing screening equipment even though screening is not mandated. We estimate that

approximately 92% of births in the United States in 2001 occurred in states that currently have mandates or voluntary programs in place. Due in part to the implementation periods in states with mandates, only 65% of newborns born in the United States were screened for hearing loss in 2001.

Recognizing that only 50% of children with hearing impairment have a risk factor, the American Academy of Pediatrics stated that selectively screening babies at high risk was inadequate, and it has recommended that all babies be screened for hearing impairment. In 1999, the American Academy of Pediatrics' Task Force on Newborn and Infant Hearing published guidelines for universal newborn hearing screening programs. These guidelines are intended to establish the standard of care and provide that:

- at least 95% of all newborns should be screened;
- the screening method used must have the ability to detect all infants with a hearing impairment of at least 35 decibels in the better ear;
- the screening method should not refer more than 4% of all children tested for further evaluation;
- no more than 3% of children with normal hearing who are screened should receive results that indicate they have a hearing impairment, a screening error known as a false positive result; and
- no child whose hearing is impaired should receive a normal result, a screening error known as a false negative result.

Because positive results are referred to an audiologist or physician for additional testing and evaluation, the cost of a newborn screening program is reduced by limiting the number of further evaluations stemming from false positive results. In addition, false positive results can cause unnecessary emotional trauma for parents.

In order to meet the standard of care guidelines set forth by the American Academy of Pediatrics, a hearing screening program needs to employ a screening method that focuses on two parameters: sensitivity and specificity. Sensitivity is the capacity to detect the disease or disorder in those infants with the disease or disorder. A sensitivity of 100% indicates that no newborns with a hearing impairment receive results indicating the absence of a hearing impairment. Specificity is the capacity to detect those infants without the disease or disorder. A specificity of 100% indicates that no newborns who actually have normal hearing receive results suggesting the presence of a hearing impairment.

Screening Techniques

Traditional methods of screening for hearing impairment include subjective behavioral tests and more expensive objective diagnostic processes. We believe widespread acceptance of screening newborns for hearing impairment requires a relatively inexpensive screening method that produces sensitive, specific and reliable results. The two traditional technologies used to screen newborns for hearing impairment are auditory brainstem response and otoacoustic emissions.

Auditory brainstem response. Auditory brainstem response technology is the most accurate and comprehensive method for characterizing hearing impairment in adults and infants. Auditory brainstem response technology uses sensors placed on the head to measure the response of the brain and auditory nerves to sounds delivered through earphones. Hearing impairment is evaluated by monitoring the brain's response to varying the frequency and volume of the sounds. Trained clinicians must operate the auditory brainstem response screening equipment, and the screening results must be interpreted by an audiologist or trained physician. Auditory brainstem response technology is primarily used to assess the degree of hearing impairment in adults and children and is not widely used for newborn screening due to the high cost, lengthy procedure time and unavailability of trained specialists in many neonatal nurseries. Enhanced auditory brainstem response devices automate portions of the screening process, such as providing pre-determined parameter menus, to make these devices easier to use or the results easier to interpret. The user has discretion to set some or all of the screening

parameters and, as a result, many enhanced auditory brainstem response devices require substantial user training. A physician, audiologist or other trained specialist may also be required to review a pass or refer result because these products permit discretion in setting screening parameters.

Otoacoustic emissions. Otoacoustic emissions screening is a method of detecting hearing impairment in adults and children. Otoacoustic emissions are sounds created by the active biomechanical processes within the sensory cells of normal ears. Since otoacoustic emissions are present in normal ears, an absence of otoacoustic emissions is a sign of irregular function of these sensory cells, which could result in hearing impairment. Otoacoustic emissions screening uses a probe placed in the ear to deliver auditory stimulus and measures the response of the sensory cells with a sensitive microphone. Otoacoustic emissions screening does not evaluate the function of the entire hearing pathway because it does not assess the neural pathways. Therefore, otoacoustic emissions technology can fail to detect disorders affecting the neural pathways. An individual otoacoustic emissions screening is relatively inexpensive. However, a number of clinical studies have documented that otoacoustic emissions screening can result in an excessive number of false positive results, which require retesting. For example, a study conducted by researchers at the University of Michigan, reported in the December 2000 American Journal of Audiology, concluded that otoacoustic emissions screening of newborns had an 11% to 35% false referral rate, far in excess of the recommendations of the American Academy of Pediatrics. For otoacoustic emissions screening, these false positive results occur because in the first days after birth newborns commonly have fluid in their ears from the birth process, which can impair the ability to accurately assess hearing impairment with one screening.

ALGO Automated auditory brainstem response. In order to address the limitations of other screening techniques, our ALGO product family utilizes automated auditory brainstem response to provide accurate and non-invasive hearing screening for newborns. The ALGO screener, like traditional and enhanced auditory brainstem response devices, utilizes a number of sensors placed on the head to measure the response of the brain and auditory nerves to sounds delivered through earphones. However, unlike traditional auditory brainstem response devices and most enhanced auditory brainstem response devices, our ALGO screener does not require a trained clinician to conduct the screening or an audiologist or physician to interpret the results. The ALGO screener uses algorithms to perform the screening and draw a conclusion as to whether a baby needs to be referred to an audiologist for further evaluation.

Hemolysis and Jaundice

Overview

Babies are generally born with a quantity of red blood cells necessary for fetal life but in excess of their needs as newborns. These excess red blood cells are normally broken down by the body in a process known as hemolysis. The two products of hemolysis are a yellow pigment called bilirubin and a proportional amount of carbon monoxide. Abnormal rates of hemolysis cause abnormal levels of carbon monoxide and bilirubin. An abnormal rate of hemolysis may also be an indicator of a number of other disorders including anemia, infection and some genetic disorders.

High amounts of bilirubin in the body can cause a yellowing of the skin and eyes called jaundice. The high level of bilirubin can result either from too much bilirubin being produced by hemolysis or from the body's failure to excrete the bilirubin. Extremely high levels of bilirubin, or hyperbilirubinemia, are toxic and may cause irreversible brain damage and potentially result in death.

The American Academy of Pediatrics Committee on Fetus and Newborns estimates that each year 60% of the four million newborns in the United States become jaundiced. According to the Journal of the American Medical Association, neonatal jaundice is the single largest cause for hospital readmission of newborns in the United States and accounts for 50% of readmissions. A study of 391 readmitted newborns at nine New York hospitals, reported in the Journal of Perinatal Medicine in 1999, found that of the readmissions, 65% in the first

week of life and 39% overall were due to hyperbilirubinemia. Hyperbilirubinemia occurs in approximately 6% to 10% of newborns. Because of the serious consequences of hyperbilirubinemia, the American Academy of Pediatrics recommends that all newborns be closely monitored for jaundice and has called for the physician to determine the presence or absence of an abnormal rate of hemolysis to establish the appropriate treatment for the newborn. In a 1996 study we commissioned, the Churchill Madison Group estimated that annual inpatient hospital charges for neonatal jaundice were approximately $1.3 billion. By identifying those infants with high rates of hemolysis before they are discharged, fewer newborns would need to be readmitted and treatment could begin earlier.

Depending on its cause, jaundice can be treated by helping the newborn to excrete the bilirubin or to reduce bilirubin production. In the early stages, jaundice can be treated with blue light, known as phototherapy, hydration and frequent feedings. Dangerous or toxic levels of bilirubin are treated by blood exchange transfusion, which is a high-risk procedure for newborns. If a physician can assess the levels of bilirubin being created and excreted by a newborn, the physician can tailor the treatment appropriately, reduce the number of invasive tests required to monitor the levels of bilirubin, evaluate the long-term effects of the jaundice and determine the appropriate term of hospitalization. In full term infants, the level of bilirubin in their blood is highest at approximately 72 hours after birth. However, infants are being discharged from the hospital before 72 hours after birth due to cost considerations. The National Hospital Discharge Survey estimated that for 1998 approximately 73% of all newborns in the United States were discharged before 72 hours after birth. In addition, it estimated that 24% of all newborns in the United States were discharged before 48 hours after birth. Thus, some infants may develop a potentially dangerous elevation in bilirubin levels after discharge. An article in the February 22, 2001 New England Journal of Medicine reported that early discharge and a reluctance to treat jaundice aggressively has led to an increase in the reports of brain damage caused by severe hyperbilirubinemia. In May 2001, the Joint Commission on Accreditation of Healthcare Organizations, a healthcare accrediting body in the United States, issued an alert emphasizing the need for hospitals to review current policies and procedures relating to hyperbilirubinemia in newborns and suggesting steps to prevent its occurrence in the future. In June 2001, the Center for Disease Control's Morbidity and Mortality Weekly Report published four case studies of kernicterus, a form of hyperbilirubinemia which is preventable. The Center for Disease Control's report stated that early detection of hyperbilirubinemia is critical to prevent the irreversible effects of kernicterus.

Our CO-Stat analyzer measures a baby's exhaled carbon monoxide to indicate the rate at which bilirubin is being produced and may assist the clinician in determining the cause of neonatal jaundice. If the rate of red blood cell break down, or hemolysis, is normal or low, the baby is not producing excessive levels of bilirubin and may be a candidate for early discharge. If the rate of hemolysis is high, this may be an indication of potentially serious disorders and increases the likelihood of neonatal jaundice. If the baby is producing high levels of bilirubin and does not develop jaundice in the first few days, the baby is assumed to be eliminating bilirubin efficiently but the underlying cause of the hemolysis may require treatment. If the baby develops jaundice, monitoring the rate of hemolysis with our CO-Stat product can help determine if jaundice is caused by excessive bilirubin production or inadequate bilirubin excretion.

Screening Techniques

Current means of identifying newborns with high or increasing bilirubin levels include visual observation, blood tests to assess bilirubin levels, antibody tests and the use of devices that measure the amount of yellow in the skin.

Total Serum Bilirubin Test. The total serum bilirubin test is a blood test that measures the total amount of bilirubin in the blood but does not differentiate between increased bilirubin production or decreased bilirubin elimination. As a result, the test does not give the clinician the information necessary to determine the cause of the increased bilirubin level and the most appropriate treatment for the newborn.

The Coombs Test. The Coombs test is another frequently administered blood test that determines whether an antibody is affixed to the baby's red blood cells. Antibodies on red blood cells are often associated with a high rate of hemolysis in newborns. However, other conditions may result in the presence of the antibodies, and the antibodies' absence does not rule out a high rate of hemolysis or excessive levels of bilirubin. In addition, the Coombs test does not measure the rate of hemolysis. Even given these limitations, the Coombs test remains the most frequently used indicator of high levels of hemolysis and, in developed countries, it is currently administered to 50% to 60% of newborns prior to hospital discharge.

Skin Tone Assessment. In recent years, a number of devices have been introduced to monitor changes in bilirubin levels by measuring the amount of yellow in the skin. They are convenient because they do not require a blood sample. However, the reliability of tests performed with these devices is complicated by the variations in skin pigmentation, the baby's age and birth weight. As with the blood sampling methods, measuring the amount of yellow in the skin does not identify the factors contributing to the elevated bilirubin level.

Natus CO-Stat Analyzer. In order to address the limitations of other means of analyzing hemolysis, our CO-Stat analyzer measures a baby's exhaled carbon monoxide to assess the rate of hemolysis accurately. Hemolysis produces bilirubin and carbon monoxide in equal amounts, so that the rate of bilirubin production can be estimated by an analysis of the carbon monoxide in a newborn's exhaled breath, while correcting for the carbon monoxide existing in the screening environment. Our CO-Stat analyzer can be used by a clinician with minimal training to conduct the hemolysis monitoring. The physician can use the results of our CO-Stat analysis, which measures the level of exhaled carbon monoxide, to assess the rate of hemolysis. An assessment of how rapidly a newborn is producing bilirubin can help to identify those newborns who are more likely to develop jaundice after discharge from the hospital. If a newborn develops jaundice, knowing how rapidly a newborn is producing bilirubin can also help physicians determine whether jaundice stems from excessive bilirubin production or failure to excrete bilirubin adequately.

Our Products

Our products include the ALGO®, MiniMuff® and CO-Stat product lines. The ALGO screeners and single use disposable supplies are designed to objectively test newborn hearing shortly after birth and prior to discharge. We also make the MiniMuff, a single use protective ear cover, which reduces the level of noise newborns hear in neonatal intensive care units. The CO-Stat analyzer and disposable supplies are designed to provide a measure of the rate of hemolysis in order to assess the cause of elevation in the level of bilirubin. The following table provides a list of our current products.

Hearing Products	*Description*	*Approved Markets*
ALGO 3™ Screener	Newborn hearing screening station	United States, Europe, Australia and New Zealand
ALGO 2e Color™ Screener	Newborn hearing screening station	United States, Europe, Japan, Australia, New Zealand and Canada
ALGO Portable™ Screener	Portable newborn hearing screening station	United States, Europe, Japan, Australia, New Zealand and Canada
ALGO Disposable Kit: EarCoupler® Ear Phones Jelly Button® Sensors	Single use disposables including ear phones and electrodes	United States, Europe, Japan, Australia, New Zealand and Canada
MiniMuff Neonatal Noise Attenuator	Single use disposable ear cover to reduce noise	United States, Europe (no approval required), Australia and New Zealand
Jaundice/Hemolysis Products		
CO-Stat End Tidal Breath Analyzer™	Newborn screening station to analyze the rate of hemolysis	United States and Europe
CO-Stat Disposable Kit: Sample Tubing and Filters	Single use disposables including tubing and filter unit for patient sampling	United States and Europe

Hearing Products

ALGO Product Family

Our ALGO product family utilizes automated auditory brainstem response technology to provide accurate and non-invasive hearing screening for newborns. The ALGO screener delivers thousands of soft clicking sounds to the newborn's ears through sound cables and disposable ear phones connected to the instrument. Each click elicits a series of identifiable brain waves, which are detected by disposable sensors placed on the baby's forehead and shoulder and at the nape of the neck. This methodology will detect hearing loss at 35 decibels or better. The ALGO screener automatically extracts the infant's brainwave responses from the background noise and noise caused by muscle activity. These brainwave responses are then compared to a template based on the brainwave responses of infants with normal hearing. The ALGO screener displays a "Pass" message when it collects sufficient data to establish that the baby's responses are consistent with the responses of a normal hearing child to a 99.96% level of statistical confidence. If a determination cannot be reached after 15,000 clicks, the ALGO screener displays a "Refer" message, indicating that the infant should be referred for more detailed evaluation, including repeating the hearing screening by an audiologist or other specialist. Once the results of the second hearing screening are available, if the results still "Refer" the specialist will conduct additional tests to determine the type and severity of the hearing impairment. While the per test disposable costs of otoacoustic

emissions screening may be lower than the per screening costs of our ALGO disposable supplies, we believe that by using automated auditory brainstem response technology our ALGO products have a number of advantages that include:

- ***Accuracy***. Tests using automated auditory brainstem response have the highest documented specificity and sensitivity for newborn hearing screening of devices not requiring a specially trained audiologist, although the ALGO screener does not determine the cause of the hearing impairment.

- ***Compliant with standard of care guidelines***. Our ALGO screener meets the requirements of the American Academy of Pediatrics for universal newborn hearing impairment for low initial refer rates, minimizing parental anxiety and the cost of rescreening.

- ***Immediate crib-side results***. Our screening tests can be conducted within hours after birth. Middle ear fluid and ear canal debris, which are often still present in the first 12 to 24 hours of after birth, do not significantly affect the results of our test.

- ***Ease of use***. Our test does not require an audiologist or physician to conduct the screening or interpret the results.

- ***Objective results***. Our test produces objective "Pass" or "Refer" results, which do not require interpretation by an audiologist or other trained clinician. The "Refer" result provides indications that the baby's brainwave is not consistent with a normal hearing child but does not quantify the severity of the hearing impairment.

- ***Rapid results***. ALGO hearing screenings can be performed and results can be obtained prior to discharge from the hospital.

The ALGO Newborn Hearing screener line was first introduced in 1985. We acquired the ALGO Newborn hearing screener product line in 1987, and we have since introduced six new versions of the ALGO and currently market the ALGO 3, the ALGO 2e Color and the ALGO Portable.

ALGO 3 Screener. In October 2001, we introduced the ALGO 3 Newborn Hearing Screener. The ALGO 3 incorporates a laptop computer containing our circuit boards and uses commercially available operating system software. This system uses our proprietary software to conduct simultaneous screening of both ears and also conducts tests at 35 decibels. The ALGO 3 uses our software to store results from every test automatically, which facilitates prompt follow-up and tracking of patient results. Users can print daily, weekly or monthly reports, create backup files and integrate screening results into statewide databases. The ALGO 3 also is designed to allow for future software and hardware upgrades. We applied for 6 new patents relating to the ALGO 3 and the disposable supplies used with it, one of which has been granted. The ALGO 3 uses an enhanced software program that makes it faster and easier to use. For example, the ALGO 3 lowered the initial refer rate of the already efficient ALGO 2e Color by an additional 50%. The current list price of the ALGO 3 is $18,500.

ALGO 2e Color Screener. In December 1998, we introduced the ALGO 2e Color. The ALGO 2e Color is similar in configuration, but not in feature and functionality, to the ALGO 3. This system uses its software to conduct simultaneous screening of both ears and conducts tests at 35 decibels. It uses software to store results from every test automatically, which facilitates prompt follow-up and tracking of patient results. The current list price of the ALGO 2e Color is $17,500.

ALGO Portable Screener. In June 1998, we introduced the ALGO Portable, which is compact and weighs less than five pounds. The ALGO Portable screener provides the flexibility to screen newborns in the newborn nursery, doctor's office, clinic or home. The ALGO Portable comes with an attachable printer and is sold primarily in Europe and in Japan and to low-volume birthing centers and hospitals. The current list price of the ALGO Portable is $10,900.

ALGO Disposable Kit. For infection control and accuracy, each hearing impairment test conducted with the ALGO is carried out with the ALGO disposable kit that includes single use earphones, which we call Ear Couplers, and electrodes, which we call Jelly Button Sensors. All of our screening supplies are alcohol and latex-free, and our adhesives are specially formulated for newborns. The current list price of our ALGO disposable kit is $9.75 per kit.

Currently some hospitals use our ALGO products to screen only those newborns with risk factors for hearing loss while other hospitals use our ALGO products in their universal newborn screening programs.

MiniMuff Neonatal Noise Attenuators

In 1995, we introduced our MiniMuff neonatal noise attenuators, which are disposable earmuffs designed to decrease noise exposure for babies in neonatal intensive care units. The MiniMuff fits securely over a baby's ear and reduces sound levels by at least seven decibels, representing a reduction of sound pressure by more than 50%. Our MiniMuff products are sold in the United States and meet health care infection control standards through a single use design. They adhere to the baby's head with a non-toxic adhesive and are designed for a single use on a single patient for one day. The current list price of our MiniMuff product is $5.00.

Hemolysis Products

CO-Stat Product Family

Our CO-Stat products measure a baby's exhaled carbon monoxide to indicate the rate at which bilirubin is being produced and may assist the clinician in determining the cause of neonatal jaundice. In order to conduct a complete assessment of a newborn's risk of jaundice, the clinician must measure the rate at which bilirubin is being produced, the level of bilirubin in the blood or skin and the rate at which the baby is excreting bilirubin. No currently available laboratory test or medical instrument is capable of assessing each of these clinical indicators. We believe our CO-Stat analyzer is the only commercially available device that enables clinicians to measure the rate at which bilirubin is produced. We believe that our CO-Stat products have a number of advantages, which include:

- ***Accuracy***. We believe our CO-Stat analyzer produces reliable results because it separates environmental carbon monoxide from carbon monoxide in exhaled breath.
- ***Address standard of care guidelines***. Our CO-Stat products can be used to address the guidelines of the American Academy of Pediatrics, which recommend the monitoring of the rate of hemolysis in newborns.
- ***Immediate crib-side results***. Screening procedures using the CO-Stat analyzer can be conducted in less than 10 minutes and within hours after birth.
- ***Non-invasive***. No invasive probes or needles are used to conduct hemolysis screening with the CO-Stat analyzer.
- ***Objective results***. The CO-Stat test results are not affected by variations in skin tone or the after effects of the birth process on skin color.
- ***Ease of use***. Our CO-Stat test can be administered by nurses or other hospital staff with minimal training. Operators can learn to use our CO-Stat products with one hour of training. If sampling is inadequate, the CO-Stat products will not provide any test results and will advise the clinician that the test is inadequate to provide results.
- ***Important clinical data provided***. The CO-Stat analyzer indexes the rate at which the baby is producing new bilirubin to aid physicians in determining the cause of newborn jaundice and selecting appropriate therapies. However, in order to determine if the baby is at risk of jaundice caused by the baby's inability to excrete bilirubin, the physician must conduct another test to measure the level of bilirubin in the baby's blood.

By measuring and subtracting the environmental carbon monoxide during the screening procedure, CO-Stat isolates trace levels of carbon monoxide produced primarily through the breakdown of red blood cells. This information helps physicians distinguish between the jaundice stemming from bilirubin production rather than the body's failure to excrete bilirubin. The CO-Stat assists clinicians to assess bilirubin production, but does not determine the level of bilirubin.

CO-Stat End Tidal Breath Analyzer. Our CO-Stat End Tidal Breath Analyzer is a patient-side device used for the non-invasive, quantitative measurement of respiratory rate, carbon dioxide concentration and carbon monoxide concentration in the breath. We believe that the CO-Stat analyzer is the only commercially available product that can detect the rate of hemolysis in newborns. We received Food and Drug Administration clearance for use of our CO-Stat products to monitor hemolysis in March 1998. We began to commercially market our CO-Stat products in January 2001. The current list price of our CO-Stat End Tidal Breath Analyzer is $19,500.

CO-Stat Disposables. A small plastic tube containing filters attaches to the CO-Stat analyzer and is placed at the opening of the baby's nostril. To ensure proper infection control and accuracy of the test, the tube and filters used to sample the baby's breath and environmental carbon monoxide are disposed of after a single use. The sampling of environmental carbon monoxide alters the tube and filters so that they cannot be reused for another test. The current list price of our CO-Stat disposables is $14.00 per disposable.

Product Milestones

We conducted a two-year study of the CO-Stat analyzer at ten sites with 1,300 newborns to evaluate the ability of the carbon monoxide analysis alone and in combination with blood-based bilirubin testing to identify newborns who are at risk for developing hyperbilirubinemia. Principal clinical investigators in the United States included researchers from Stanford University, University Hospital of Cleveland, Women & Infants' Hospital in Providence, Rhode Island, the University of Pennsylvania and William Beaumont Hospital in Royal Oak, Michigan. Investigators from hospitals in Israel, Hong Kong and Japan also participated. Based on the data gathered during the study, the investigators concluded that a high rate of hemolysis is an important contributing factor in the majority of cases of hyperbilirubinemia. In addition, the investigators concluded that the CO-Stat enables clinicians to rule out excessive rates of hemolysis and thereby identify those babies who potentially may be discharged early because they are not likely to develop hyperbilirubinemia. The study also concluded that the preferred means of conducting pre-symptomatic jaundice monitoring is assessing bilirubin production and elimination concurrently. The CO-Stat assists clinicians to assess bilirubin production, but does not determine the level of bilirubin in the blood or bilirubin elimination.

In addition, the University of Chicago conducted a clinical study of approximately 560 babies to assess the cost-effectiveness and clinical reliability of the CO-Stat as compared to the Coombs test. We paid for the collection of the data for the study but did not have any influence over the results. The principal investigators presented the results of the study in March 2001 at the California Association of Neonatologists Annual Meeting. The principal investigators concluded that the Coombs test is not as accurate as the CO-Stat for the identification of hemolysis in newborns. In addition, the principal investigators concluded that the cost of the Coombs test is approximately 1.5 times more per infant for identification and evaluation of hemolysis as compared to the CO-Stat.

We have initiated clinical trials with the CO-Stat designed to evaluate the rate of carbon monoxide production as an indicator for pre-eclampsia and pre-term labor. In addition, we commenced a separate small trial for use of the CO-Stat in the management of sickle cell disorder. These trials are in their early phases and results are not expected until 2003, or beyond. We cannot predict the results of these trials.

Customers

Our customers include neonatologists, physicians, audiologists, hospitals and government agencies. We have sold approximately 3,900 ALGO screeners worldwide. We believe that there are more than 4,000 birthing

and children's hospitals in the United States. Our ALGO products have been installed in at least 2,000 of these facilities. To date, our CO-Stat sales have not been significant.

We sold disposable supplies to conduct approximately 2.0 million hearing screenings in 2001 and approximately 1.7 million hearing screenings in 2000. While the majority of our sales have been to customers in the United States, we have also sold ALGO screeners in 22 countries, including Austria, Australia, Belgium, Germany, Japan, New Zealand and the United Kingdom. From time to time we participate in bidding and other selection processes for country or statewide hearing screening programs. For example, we are currently participating in the National Health Service's selection process in the United Kingdom for newborn hearing screening equipment vendors for England and, potentially, Scotland and Wales. The selection process is expected to be finalized in mid-2002. We cannot assure you that we will be one of the vendors selected by the National Health Service, or if we are selected, of the significance or timing of revenues associated with an award.

We intend to sell our existing ALGO products more extensively within our existing customer sites and sell new products, such as the CO-Stat, as we expand our product offerings. We began to commercially market our CO-Stat analyzer in January 2001. We will also continue to pursue state and hospital system sales as appropriate. In 2001, 2000 and 1999, no single end customer comprised more than 10% of our revenues. Nippon Eurotec, our Japanese distributor, accounted for 11% of our revenues in 2000. We acquired Nippon Eurotec's distribution operations for our products effective July 2001.

Marketing and Sales

Our ALGO products have been commercially available since 1985, and we began selling our MiniMuff products in 1995. We began marketing our CO-Stat products for commercial use in January 2001. We are using similar methods to sell our CO-Stat products as we currently use to sell our ALGO products.

Marketing

Our marketing strategy is to attempt to distinguish our products by their level of sensitivity, specificity and reliability, ease of use and pre-discharge testing advantages. Our marketing staff consisted of 17 persons as of December 31, 2001. We attempt to educate customers and potential customers about our products through:

- participation in physician group and health care agency conferences;
- efforts by our clinical educators;
- publications in professional journals;
- our web site;
- print and direct mail advertising;
- participation in seminars; and
- electronic mail notification to customers about new products.

We believe that educational efforts directed at government agencies and other third party payors about the benefits of universal screening in terms of patient outcomes and long-term treatment costs are a key element of our marketing strategy.

Direct Sales

As of December 31, 2001, 33 persons comprised our domestic sales staff, including 15 clinical educators. An additional 10 persons performed customer sales support and management. Internationally, we had 15 persons dedicated to distribution of our products in Japan and the United Kingdom and a domestic staff of four supporting those persons and other distributors.

In the United States, we sell our products to three groups of potential purchasers:

- *States*. To reduce the cost of special education and state funded rehabilitation programs, many states have mandated universal newborn hearing screening through legislation or provided funding for hearing screening at hospitals. Some of these states purchase hearing screening units directly from us and loan them to hospitals. Georgia, Mississippi, New Mexico, North Carolina, Oklahoma and South Carolina have each purchased ALGO products for hospital placement. No states have mandated hemolysis testing for newborns or purchased equipment from us for this purpose.

- *Hospitals*. Hospitals often purchase products from us directly, either in response to a state mandate requiring universal newborn hearing screening or in conjunction with a voluntary screening program for newborn hearing or jaundice management.

- *Neonatologists, pediatricians and audiologists*. Our sales force often identifies these professionals as the advocate of universal hearing screening programs or newborn jaundice management within the hospital. We focus our sales efforts on these individuals who tend to be knowledgeable about the cost and treatment benefits of universal newborn hearing screening or pre-release hemolysis monitoring as the case may be.

Although we have previously relied exclusively on distributors in Japan, we established a Japanese subsidiary in July 2000 and assumed the activities of our top-tier Japanese distributor in July 2001. We commenced sales to re-distributors in Japan in July 2001. We established a subsidiary in the United Kingdom in December 2000, which acquired our distributor in the United Kingdom in January 2001.

Indirect Sales

In addition to our direct sales force, outside the United States we have relied heavily on indirect sales channels. Revenues from sales through distributors were approximately 14% of revenues in 2001 and 2000, and approximately 10% of revenues in 1999, including sales to sub-distributors in Japan. Our distributors either assist our sales staff or are our sole sales and support representatives in their territories. We have established a network of distributors in Europe, Asia and Australia. Our distributors typically perform marketing, sales and technical support functions in their country or region. Each one may distribute directly to the customer, via other distributors or resellers or both. We actively train our distributors in both product and sales methods.

In addition, approximately 90% of the hospitals in the United States are members of group purchasing organizations, which negotiate large volume purchase prices for member hospitals, group practices and other clinics. We have recently signed agreements with Joint Purchasing Corporation and Healthtrust Purchasing Group and we intend to enter into similar agreements with other group purchasing organizations in the future. These group purchasing organizations are not required to continue to negotiate prices with us, and the members of these organizations are not required to purchase our products. For example, members of Novation, a group purchasing organization, receive specially negotiated prices, volume discounts and other preferential terms on their member's direct purchases from us. Our agreement with Novation requires Novation to promote our products to its members and to inform its members about the special terms we have negotiated. We have agreed
to pay Novation marketing fees for these efforts, which fees are based on a percentage of our net sales to Novation's members. Our agreement with Novation continues until January 31, 2003, but we or Novation may cancel it with notice or agree to extend it for two additional one-year terms. Direct purchases by members of Novation accounted for approximately 25% of our revenues in 2001 and approximately 22% of our revenues in 2000. Novation's members purchase products directly from us under the terms negotiated in the group purchasing agreement, and Novation does not purchase and resell our products to its members. Direct purchases by members of group purchasing organizations accounted for approximately 35% of our revenues in 2001 and approximately 23% of our revenues in 2000.

Customer Service and Support

Our ALGO products and our CO-Stat analyzer are sold with a one-year warranty. We also sell extended warranty agreements for our ALGO products. We provide service to our domestic customer base through our Redding, California service center. This facility is equipped to perform full service, repair, and calibration services to customers on a warranty and fee basis. Service for our international customers is provided either by TriVirix International, Inc., our European contract manufacturer, our Japanese subsidiary or our Redding facility. We have certified TriVirix to perform all levels of service and repair on ALGO products.

Third Party Reimbursement

In the United States, health care providers that purchase products like ours generally rely on third party payors, including private health insurance plans, federal Medicare, state Medicaid and managed care organizations, to reimburse all or part of the cost of the procedure in which the product is used. Our ability to commercialize our products successfully in the United States will depend, in part, on the extent to which reimbursement is available for screenings performed with the ALGO screener or CO-Stat analyzer. Third party payors can affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement these payors, such as insurance companies or health maintenance organizations, provide for testing services. In general, reimbursement for hearing impairment screening and jaundice assessment for newborns is included in the lump sum payment for the newborn's birth and hospitalization. For this reason, we are not able to measure a reimbursement success rate for our products.

The current cost reduction orientation of third party payors makes it difficult for new medical screening and testing devices and tests performed with them to be eligible for reimbursement. Often, it is necessary to convince these payors that the new devices or procedures will establish an overall cost savings compared to the cost of those that are currently reimbursed or long-term treatment for the condition if the screening does not occur early. While we believe that our products possess economic advantages that will be attractive, third party payors may not make reimbursement decisions based upon these advantages. Third party payors are increasingly scrutinizing and challenging the prices charged for medical products and services.

Effective October 1, 1991, the United States' Health Care Finance Administration adopted regulations that provide for the inclusion of capital related costs in the prospective payment system for hospital inpatient services. Under this system most hospitals are reimbursed by Medicare on a per diagnosis basis at fixed rates unrelated to actual costs incurred in making the diagnosis. Under this system of reimbursement, equipment costs generally are not reimbursed separately, but rather are included in a single, fixed rate per patient reimbursement for screening based on approved current procedural terminology codes. Some states, such as California and Florida, reimburse clinicians for hearing screenings conducted with ALGO products as a separate reimbursement group from the birth and initial hospitalization reimbursement group. These regulations are being phased in over a ten-year period. Medicare reform legislation required the Health Care Finance Administration to implement a prospective payment system for outpatient hospital services. This system also provides for a per-patient fixed rate reimbursement for outpatient department capital costs. Although the full implications of these changes cannot be
known, we believe that the regulations will place more pressure on hospitals' operating margins, causing them to limit capital expenditures. These regulations could cause hospitals to decide to defer purchasing equipment like our products as a result of limitations on their capital expenditures. The recent Medicare legislation also requires the Health Care Finance Administration to adopt uniform coverage and administration policies for laboratory tests.

In addition to traditional third party reimbursement, universal newborn hearing screening may be either paid for directly by the state or through private insurance coverage required by state legislation. Thirty-six states and the District of Columbia have passed legislation requiring newborns to be screened for hearing impairment prior to hospital discharge.

In the United States, we have found the state to be the most appropriate level of government to implement universal newborn hearing screening. At the state level, the cost of newborn hearing screening can most directly be weighed against the much higher cost to the state of education and treatment programs required for the hearing impaired. A key element of our reimbursement strategy for the ALGO products has been to promote the adoption of universal newborn hearing screening legislation and equipment purchases at the state level.

States typically implement universal newborn hearing screening in the following manners:

- ***Voluntary.*** Hospitals are not required to provide universal newborn hearing screening, but the majority of newborns are screened. In some cases, the state may also purchase the equipment and disposables directly and provide them to hospitals. As of December 31, 2001, the states with voluntary programs are Alabama, Alaska, Arizona, Delaware, Idaho, Iowa, Michigan, Minnesota, North Dakota and South Dakota.

- ***Mandate with equipment purchase.*** The state has mandated universal newborn hearing screening, and the state purchases or subsidizes equipment and disposables for birthing facilities. As of December 31, 2001, the states that have adopted this type of program are Georgia, Illinois, Kentucky, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina and Wyoming.

- ***Mandate with state reimbursement.*** The state has mandated universal newborn hearing screening and reimburses hospitals on a per-test basis for Medicaid patients. As of December 31, 2001, the states that have adopted this type of program are Arkansas, California, Florida, Maryland, Massachusetts, Missouri, Nebraska and Rhode Island.

- ***Mandate without state reimbursement.*** The state has mandated universal newborn hearing screening and requires third party reimbursement, usually as a part of the newborn birth process amount. As of December 31, 2001, the states that have adopted this type of requirement are Colorado, Connecticut, Hawaii, Indiana, Kansas, Louisiana, Maine, Montana, New Hampshire, New Jersey, New York, Oregon, Texas, Utah, Virginia, West Virginia and Wisconsin.

We have sold our ALGO products to customers in each of the 50 states. We help our customers understand the applicable regulations in their state and provide them with copies of published public policies. We also provide hospitals with local references so that customers may learn more about reimbursement in their states.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis or a region-by-region basis. In addition, reimbursement systems in international markets may include both private and government sponsored insurance.

There are currently no states that have passed legislation related to universal newborn hemolysis monitoring.

Manufacturing

A significant portion of the components of our products are manufactured for us by other companies. However, we perform final assembly, testing and packaging of the ALGO 3, the ALGO 2e Color and the CO-Stat analyzer ourselves to control quality and manufacturing efficiency. In order to reduce costs and to add additional capacity, in the future we may move some labor intensive operations to less costly manufacturing locations or outsourcing processes. For example, we entered into an agreement with TriVirix in December 1998 for the manufacture of our ALGO Portable product.

We use contract vendors to manufacture our disposable products, and we perform regular quality audits of these vendors. We expect to hire additional personnel to assemble our CO-Stat products. We will also need to enhance our manufacturing operations to increase our capacity for these products.

We purchase materials and components from qualified suppliers that are subject to our stringent quality specifications and inspections by us. We conduct quality audits of our key suppliers, several of which are experienced in the supply of components to manufacturers of finished medical devices or disposables for use with these medical devices. Most of our purchased components are available from more than one supplier. For those components for which relatively few alternate supply sources exist, we are currently trying to locate additional suppliers that meet our quality standards as well as specific regulatory compliance standards.

Currently, only one Natus approved supply source exists for the adhesive used in our ALGO disposables and our MiniMuff product. The adhesive, called hydrogel, is manufactured by a supplier that also sells the product to a variety of other medical device manufacturers. We are in the process of identifying other sources of hydrogel for ongoing supply, but, in the meantime, our disposables manufacturer has scheduled long term delivery of hydrogel for our products in an amount that we believe will be sufficient to allow us time to locate and qualify a new supplier should our current supplier fail to fulfill our needs. Other formulations of hydrogel exist. However, if a new adhesive is incorporated into our products, then those products may require new regulatory clearance by the Food and Drug Administration, as well as by similar regulatory agencies outside the United States. In addition, we have used a single source to obtain electrochemical sensors for our CO-Stat analyzer. Other sources of supply exist for this component, but we could experience a delay in production of our CO-Stat analyzers if we were unable to obtain a sufficient quantity from our current vendor.

Our manufacturing facility and service and repair facility are subject to periodic inspection by United States, state and foreign regulatory authorities. Our quality assurance system is subject to regulation of both the Food and Drug Administration and the State of California. We are required to conduct our product design, testing, manufacturing and control activities in conformance with the Food and Drug Administration's quality system regulations and to maintain our documentation of these activities in a prescribed manner. Our manufacturing and service and repair facilities are registered and/or licensed by the Food and Drug Administration and the California Department of Health Services, Food and Drug Branch. We have passed all quality system regulations inspections of our facilities conducted by the Food and Drug Administration and the State of California. In addition, our facility has received ISO 9001/EN46001 certification. ISO 9001/EN46001 certification standards for quality operations have been developed to ensure that companies know the standards of quality on a worldwide basis. We have also received the EC Certificate pursuant to the European Union Medical Device Directive 93/42/EEC, which allowed us to place a CE mark on our products after assembling appropriate documentation.

We entered into a manufacturing agreement with TriVirix to serve as our European manufacturing, service and distribution center. We qualified TriVirix's Belfast, Northern Ireland facility to produce the ALGO Portable in April 1999. TriVirix is also a Food and Drug Administration registered manufacturing facility with a full quality system in place in accordance with the Food and Drug Administration's Quality System Regulation and ISO 9002. TriVirix currently supplies all of our ALGO Portable units and has begun to supply a portion of our preamplifier and printed circuit board needs.

Research and Development

We believe that strong product development capabilities are essential to our strategy of enhancing our core technology and developing additional test applications for our current products.

We believe our CO-Stat analyzer may have additional applications for testing of other diseases and common conditions. For example, we believe the CO-Stat may be used to detect pregnancy induced hypertension in its early stages. Exhaled carbon monoxide may be a clinical indicator for disorders such as sudden infant death syndrome, pneumonia, asthma, infection, pre-eclampsia, pre-term labor and blood disorders. We have initiated clinical trials with the CO-Stat designed to evaluate the rate of carbon monoxide production as an indicator for pre-eclampsia and pre-term labor. We commenced a separate trial to test the use of the CO-Stat in the management of sickle cell disorder. However, there are no current commercial uses for our CO-Stat analyzer in

diagnosing or monitoring any of these conditions. We cannot be sure we will ever market a device to monitor or screen for these or any other disorders and cannot predict the results of clinical trials.

Our research and development expenses were $4.3 million in 2001, $3.5 million in 2000 and $2.5 million in 1999. As of December 31, 2001, we had 18 people engaged in research and development activities.

Proprietary Rights

Our products rely on our internally developed intellectual property and other proprietary rights. We rely on a combination of patent, copyright, trademark and trade secret laws, confidentiality procedures and contractual provisions to protect our intellectual property and other proprietary rights. However, we believe that these measures afford only limited protection and do not provide significant barriers to competition. We have eight United States patents, which expire at various times from 2007 to 2017, five patent applications pending before the United States Patent and Trademark Office and eight 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 application granted in Japan and seven patent applications pending in Japan and four patent applications pending in Hong Kong. Our patents and patent applications address various aspects of our current products and those in development including, but not limited to, the earphones used with our ALGO Hearing Screeners, the method by which our CO-Stat analyzer measures end tidal carbon monoxide and the filters used with our CO-Stat analyzer. 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 the subject matter of that patent is in the public domain. Our ALGO screeners and CO-Stat analyzers use our proprietary software to produce their results, which we license under shrink wrap licenses that are included as part of the product packaging. Shrink wrap licenses are not negotiated with or signed by individual customers and purport to take effect upon the opening of the product package or use of the screening equipment. We also generally enter into confidentiality agreements with our employees and technical consultants. Despite our efforts to protect our proprietary rights, unauthorized parties may attempt to copy aspects of our products or improperly obtain and use information that we regard as proprietary. Monitoring unauthorized use of our products is difficult and we are unable to determine the extent to which unauthorized use of our products exists. In addition, the laws of some foreign countries do not protect our proprietary rights as fully as do the laws of the United States. Our means of protecting our proprietary rights may be inadequate and 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 intellectual property rights.

We are not aware that our products employ technologies that infringe any valid proprietary rights of third parties and no assertions of infringement have been made by any third parties. However, the medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. As the number of entrants into our market increases, the possibility of an infringement claim against us grows. While we attempt to ensure that our products do not infringe other parties' patents and proprietary rights, our competitors may assert that our products and the methods we employ now or in the future may be covered by U.S. patents held by these competitors. In addition, our competitors may assert that the products and the methods we employ now or in the future infringe their other proprietary rights. Any infringement claims, with or without merit, could be time consuming to defend or result in costly litigation or damage awards. Any claim could divert management's attention and resources or cause a significant disruption in our revenues while we redesign products if we are found to infringe. A claim also could cause product shipment delays or cessation or require us to enter into royalty or licensing agreements. These royalty or licensing agreements may not be available on terms acceptable to us, if at all.

Competition

We compete in intensely competitive and rapidly evolving markets. We face competition primarily from medical device companies that manufacture hearing screening products, testing products for determining

bilirubin levels based on skin color and chemicals used to conduct the Coombs test or blood-based bilirubin monitoring tests. We have experienced and expect to continue to experience increased competition from current and potential competitors, many of which have significantly greater financial, technical, marketing and other resources.

Companies offering competitive products vary in scope and breadth. With respect to our hearing impairment screening products, our competitors include:

- ETYMOTIC Research, Kedly, Inc., Nicolet Biomedical/Grason-Stadler, Inc., Madsen Electronics, Otodynamics, Ltd., Starkey Laboratories, Inc. and Welch Allyn, Inc., which sell otoacoustic emissions products;
- Intelligent Hearing Systems and Sonamed Corp., which sell enhanced auditory brainstem response and otoacoustic emissions products, which run a test on the basis of parameters set by the clinician performing the test and continue to conduct the test until parameters are satisfied and produce results that must be interpreted by a trained audiologist or other specialist;
- Bio-logic Systems, which sells enhanced auditory brainstem response and otoacoustic emissions products; and
- SLE Ltd., which sells auditory brainstem response products.

With respect to our CO-Stat products, our competitors include:

- Johnson & Johnson and Roche, which sell laboratory equipment and chemicals used to conduct the Coombs test or to measure bilirubin levels in the blood; and
- Chromatics Color Sciences, Minolta and SpectRx, which sell equipment to measure the yellowness of the skin.

We believe the principal factors that will draw clinicians and other buyers to a newborn testing product, including hearing testing and hemolysis monitoring products, include:

- the level of specificity, sensitivity and reliability of the product;
- the time required to run tests with the product;
- the relative ease of use of the product;
- the depth and breadth of the product's features;
- the quality of customer support for the product;
- the frequency of product updates;
- the extent to which third party reimbursement for the purchase of the product or the screening is available;
- the extent to which the products conform to standards of care guidelines; and
- the price of the product.

We believe that we compete favorably on these factors. However, we expect competition in the newborn screening to increase significantly as new companies enter the market and current competitors expand their product lines and services. For example, Bio-logic recently received Food and Drug Administration approval to sell its disposable products for use with versions of our ALGO hearing screener other than the ALGO 3. Many of these potential competitors are likely to enjoy substantial competitive advantages, including greater resources that can be devoted to the development, promotion and sale of their products. In addition, these potential competitors may have more established sales channels, greater product development experience or greater name recognition.

Government Regulation

Food and Drug Administration's Premarket Clearance and Approval Requirements

Unless an exemption applies, the Food and Drug Administration must either clear or approve in advance each medical device that we wish to market in the United States, pursuant to the Federal Food, Drug, and Cosmetics Act of 1938, as amended. Unless an exemption applies, each medical device that we wish to market in the United States must receive in advance from the Food and Drug Administration either:

- clearance pursuant to Section 510(k) of the Food, Drug, and Cosmetics Act; or
- premarket approval pursuant to 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 three to 12 months, but can take longer. The process of obtaining premarket approval is much more costly, uncertain and may take from one to three years or even longer. We cannot be sure that 510(k) clearance or premarket approval will be obtained for products we propose to market.

The Food and Drug Administration decides whether a device must undergo either the 510(k) clearance or premarket approval process based upon statutory criteria. These criteria include the level of risk that the agency perceives to be associated with the device and a determination of whether the product is a type of device that is substantially equivalent to devices that are already legally marketed. The Food and Drug Administration places devices deemed to pose relatively less risk in either class I or class II, which requires the manufacturer to submit a premarket notification requesting 510(k) clearance, unless an exemption applies. The premarket notification must demonstrate that the proposed device is substantially equivalent in intended use and in safety and effectiveness to an existing legally marketed device that is a class I, class II, preamendment class III device or any of those for which the Food and Drug Administration has not yet called for submission of a premarket approval. The Food and Drug Administration has classified our ALGO and CO-Stat products as class II devices.

After a device receives 510(k) clearance, any modification made to the device requires the manufacturer to determine whether the modification could significantly affect its safety or effectiveness. If it does not, the manufacturer's decision must be documented. For example, when we developed our ALGO Portable product, we determined that the ALGO Portable was compliant with the 510(k) clearance for the ALGO I and that the modifications to the ALGO Portable did not significantly affect its safety or effectiveness. If the modification could significantly affect the device's safety and effectiveness, then the modification requires at least a new 510(k) clearance or, in rare instances, could require a premarket approval. The Food and Drug Administration requires each manufacturer to make this determination, but the Food and Drug Administration can review any manufacturer's decision. If the Food and Drug Administration disagrees with a manufacturer's decision, the agency may retroactively require the manufacturer to seek 510(k) clearance or premarket approval. The Food and Drug Administration also can require the manufacturer to cease marketing the modified device or recall the modified device or both until 510(k) clearance or premarket approval is obtained.

The Food and Drug Administration places devices deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed to be not substantially equivalent to a predicate device, in class III. The Food and Drug Administration requires these devices to undergo the premarket approval process in which the manufacturer must prove the safety and effectiveness of the device to the Food and Drug Administration's satisfaction. A premarket approval application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. After any premarket approval, a new premarket approval or premarket approval supplement may be required in the event of significant modifications to the device, its labeling or its manufacturing process.

The Food and Drug Administration may require results of clinical trials in support of a 510(k) submission and generally requires clinical trial results for a premarket approval application. In order to conduct a clinical

trial on a significant risk device, the Food and Drug Administration requires manufacturers to apply for and obtain in advance an investigational device exemption. The investigational device exemption application must be supported by appropriate data, such as animal and laboratory testing results. If the Food and Drug Administration and the Institutional Review Boards at the clinical trial sites approve the investigational device exemption application for a significant risk device, the manufacturer may begin the clinical trial. An investigational device exemption approval provides for a specified clinical protocol, including the number of patients and study sites. If the manufacturer deems the product a nonsignificant risk device, the product will be eligible for more abbreviated investigational device exemption requirements. If the Institutional Review Boards at the clinical trial sites concur with the nonsignificant risk determination, the manufacturer may begin the clinical trial.

The following chart shows the U.S. regulatory status of the products we currently sell and our regulatory status in Europe and other countries:

Natus Product	FDA 510(k)	CE Mark	Japan (Shonin)	Australia and New Zealand	Canada
ALGO 3	October 2001	October 2001		January 2002	
ALGO Portable	June 1998	July 1999	December 2000	January 2001	December 2000
ALGO 2e Color	December 1998	July 1999	September 1997	June 2000	December 2000
CO-Stat	March 1998	July 1999			
MiniMuff	February 1995	January 2001		June 2000	

Pervasive and Continuing Food and Drug Administration Regulation

Numerous Food and Drug Administration regulatory requirements apply to our marketed devices. These requirements include:

- the Food and Drug Administration's quality system regulation which requires manufacturers to create, implement and follow numerous elaborate design, testing, control, documentation and other quality assurance procedures;
- medical device reporting regulations, which require that manufacturers report to the Food and Drug Administration certain types of adverse and other events involving their products; and
- the Food and Drug Administration's general prohibition against promoting products for unapproved uses.

Class II devices may also be subject to special controls applied to them, such as performance standards, post-market surveillance, patient registries and Food and Drug Administration guidelines that may not apply to class I devices. Our products are currently subject to Food and Drug Administration guidelines for 510(k) cleared devices and are not subject to any other form of special controls, such as a requirement to conduct a screening in a laboratory within a medical facility. We believe we are in compliance with the applicable Food and Drug Administration guidelines, but we could be required to change our compliance activities or be subject to other special controls if the Food and Drug Administration changes its existing regulations or adopts new requirements.

We are subject to inspection and market surveillance by the Food and Drug Administration to determine compliance with regulatory requirements. If the Food and Drug Administration finds that we have failed to adequately comply, 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;
- 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 approval already granted; and
- criminal prosecution.

The Food and Drug Administration also has the authority to require repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

Other United States Regulations

We also must comply with numerous additional federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, biohazards, fire hazard control and hazardous substance disposal. We believe we are currently in compliance with applicable safety and quality regulations and the environmental protection, biohazard and hazardous substance disposal regulations. We cannot be sure that we will not be required to incur significant costs to comply with these laws and regulations in the future or that these laws or regulations will not hurt our business and results of operations. Unanticipated changes in existing regulatory requirements or adoption of new requirements could hurt our business, results of operations and financial condition.

Foreign Regulation

Our products are also 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, in the foreign countries in which we sell or plan to sell our products. Our ALGO products carry a CE Mark for sale in Europe and our ALGO 3, ALGO 2E Color and ALGO Portable are listed with TGA for sale in Australia and New Zealand. Our ALGO Portable and ALGO 2E Color have been approved for sale in Japan and Canada. Our manufacturing facility has been audited and certified to be ISO900l/EN46001 compliant, which allows us to sell our products in Europe. Our manufacturing facility is subject to CE Mark and ISO 9001 inspection by TÜV Rheinland. We plan to seek approval to sell our products in additional 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 Food and Drug Administration requirements.

Employees

As of December 31, 2001, we had 146 full time employees, including 18 in research and development, 62 in sales and related customer support services, 17 in marketing, 27 in manufacturing and 22 in finance and administration. None of our employees are represented by a labor union. We have not experienced any work stoppages and consider our relations with our employees to be good.

Executive Officers and Directors

The following table lists our executive officers and their ages as of December 31, 2001:

Name	Age	Position(s)
Tim C. Johnson	44	Chief Executive Officer, President, Chief Operating Officer and Director
William New, Jr., M.D., Ph.D.	59	Chairman, Chief Technology Officer and Director
William H. Lawrenson	54	Vice President, Finance, Chief Financial Officer and Assistant Secretary
Lucille A. Ferus	44	Vice President, Engineering
Bryan P. Flaherty, Ph.D.	38	Vice President, Research and Development
Mark E. Foster	53	Vice President, General Counsel and Secretary
Wade Hampton	46	Vice President, International
Kenneth M. Traverso	41	Vice President, Sales
Thomas M. Waugh	57	Vice President, Operations

Tim C. Johnson has served as our chief executive officer since July 1999, our president since March 1996, our chief operating officer since October 1995 and our secretary from April 1992 to March 2002. Mr. Johnson also was our controller from July 1990 to June 1991 and served as director of finance and administration from July 1991 to March 1992. In April 1992 Mr. Johnson was named vice president of finance and chief financial officer and served in that capacity until December 1997. Prior to joining our company, Mr. Johnson served in various capacities at Cray Research, Inc. and was previously an auditor with Coopers & Lybrand. Mr. Johnson holds a Bachelor of Science degree in Accounting from the University of Minnesota and a Masters of Business Administration degree from Stanford University.

William New, Jr., M.D., Ph.D., one of our co-founders, has served as our chairman, chief technology officer and director since 1987. Dr. New also served as our chief executive officer from 1992 to July 1999. Dr. New served as a member of the clinical anesthesia faculty at Stanford University Medical Center from 1975 to August 2000. Dr. New served as the chairman of the Board of Visitors of the Duke University Medical Center from 1994 to 1998. Dr. New was a co-founder and the chairman of Nellcor Incorporated. Dr. New holds a Bachelor of Science degree and a Masters of Science degree in Engineering from Stanford University, a Doctor of Medicine degree from Duke University and a Doctorate degree in Physiology from the University of California at Los Angeles.

William H. Lawrenson has served as our vice president of finance and chief financial officer since December 1997. Mr. Lawrenson also has served as our assistant secretary since July 2000. Since July 1995, Mr. Lawrenson has also served as president of Saratoga Knowledge Systems, Inc., which he and his wife own. Mr. Lawrenson served as a consultant to IDG Interactive Services, Inc., a wholly owned subsidiary of International Data Group, Inc., a publishing company, from September 1996 to December 1997. From September 1995 to September 1996, Mr. Lawrenson was a vice president and chief operating officer of IDG Interactive Services. From December 1984 to March 1995, Mr. Lawrenson served in various capacities at Dialog Information Services, Inc., an information services company, the most recent of which was as vice president of business development, and he also served as vice president of finance and administration. Mr. Lawrenson is a certified public accountant and a South African chartered accountant. Mr. Lawrenson was educated at the University of Port Elizabeth, South Africa.

Lucille A. Ferus has served as our vice president of engineering since December 1997. Ms. Ferus served as our director of software operations from October 1996 to December 1997. From May 1991 to October 1996, Ms. Ferus served as an engineering manager at Ventritex Corporation, a medical device company. Ms. Ferus was a software engineer at Nellcor from June 1986 to April 1991. From April 1983 to May 1986, Ms. Ferus served as a computer science engineer at Thoratec Laboratories Corporation, a medical device company. Ms. Ferus served

as design engineer at Picker/Cambridge Medical from February 1981 to April 1983 and as a project engineer at the Howmedica division of Pfizer, Inc. from January 1979 to February 1981. Ms. Ferus holds a Bachelor of Science degree in Electrical Engineering and a Master of Science degree in Bioengineering from Fairleigh Dickenson University.

Bryan P. Flaherty, Ph.D. has served as our vice president of research and development since February 2000. Dr. Flaherty was our director of research and development from July 1998 to February 2000. Dr. Flaherty served as our manager of advanced product engineering from November 1996 to July 1998. From June 1994 to November 1996, Dr. Flaherty served as a senior development engineer of Vital Insite, Inc., a medical monitoring technology company. From September 1993 to June 1994, Dr. Flaherty served as a consultant at Failure Analysis Associates, an engineering consulting company. From September 1992 to September 1993, Dr. Flaherty served as a staff engineer at Rush Medical College, and from September 1989 to September 1992, he served as a staff engineer at Hines VA Rehabilitation Research and Development Center. Dr. Flaherty holds a Bachelor of Science degree in Mechanical Engineering from the University of California at Davis and Master of Science and Doctorate degrees in Bioengineering from the University of Illinois, Chicago.

Mark E. Foster has served as our vice president, general counsel and secretary since March 2002. From 1987 to March 2002, Mr. Foster practiced international corporate law as a principal with the Law Offices of Mark Foster. Mr. Foster served as the lawyer and lobbyist in Japan for the United States Electronics Industry Office, a joint effort of the Electronics Industries Association and the American Electronics Association, from 1986 to 1989. During part of the Reagan Administration, Mr. Foster served as special counsel to the United States Embassy in Tokyo, Japan as a trade negotiator. Mr. Foster holds a Bachelor of Arts degree in Humanities from Alma College and a Doctor of Jurisprudence degree from the University of California Hastings College of Law.

Wade Hampton has served as our vice president, international since November 2001. From September 1999 to October 2001, Mr. Hampton served as vice president of international at Coherent Medical Group, a manufacturer of medical lasers. From July 1997 to August 1999, Mr. Hampton served in various senior management positions with Andros, Inc., a medical products original equipment manufacturer, most recently as president of the medical products division. From October 1994 to July 1997, Mr. Hampton held various positions with SpaceLabs Medical, a supplier of patient monitoring equipment and clinical information systems, most recently as an area director of sales in Latin America. Mr. Hampton holds a Bachelor of Science degree in Business Administration from the University of Florida.

Kenneth M. Traverso has served as our vice president of sales since September 2000. From October 1999 to July 2000, Mr. Traverso served as president of DinnerNow.com Inc., an internet aggregator for the restaurant industry. From January 1998 to September 1999, Mr. Traverso served as vice president of sales, western region of Alere Medical, an outpatient chronic disease management company. From May 1995 to January 1998, Mr. Traverso served as vice president of marketing and sales of AbTox, Inc., a low temperature sterilization company. From August 1990 to May 1995, Mr. Traverso served in various capacities at our company, the most recent of which was vice president of sales. Mr. Traverso holds a Bachelor of Science degree in Administration & Marketing from San Francisco State University.

Thomas Waugh has served as our vice president of operations since January 2000. Prior to joining our company, Mr. Waugh was vice president of operations of Surface/Interface, Inc., a semiconductor equipment manufacturer from September 1999 to January 2000. From April 1999 to September 1999, Mr. Waugh worked as an independent consultant. From January 1998 to April 1999, Mr. Waugh served as vice president of manufacturing of VidaMed, Inc., a medical device company. From May 1997 to January 1998, Mr. Waugh served as vice president of operations of ChemTrak, Inc., a medical diagnostics company, and from November 1996 to May 1997, he served as consultant to Tissue Technologies, Inc., a medical laser company. From February 1992 to November 1996, Mr. Waugh served as vice president of operations at American Dental Technologies, Inc. Mr. Waugh holds a Bachelor of Science degree in Electrical Engineering from the University of Colorado, Boulder and a Masters of Science degree in Electrical Engineering from Stanford University.

ITEM 2. Properties

Our principal offices are located in a leased 26,000 square foot facility in San Carlos, California and house substantially all of our manufacturing, research and development and related customer support services employees, as well as all marketing, administration and finance employees. Our lease on the San Carlos facility expires in December 2003. In addition, we lease a 1,000 square foot service and support center in Redding, California, on a month-to-month basis, small facilities in Tokyo, Japan to support our sales efforts in Japan, the lease for which expires in June 2003 and a small office and warehouse facility outside London, England, the lease for which expires in October 2002. We expect that our current leased facilities will be sufficient for our needs over the next 12 months, except that we intend to lease approximately 15,000 square feet of office space for domestic expansion and enter into a longer term lease for our existing service and support center in Redding, California.

ITEM 3. Legal Proceedings

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

ITEM 4. Submission of Matters to a Vote of Security Holders

No stockholder votes took place during the fourth quarter of the year ended December 31, 2001.

PART II

ITEM 5. Market for Common Equity and Related Stockholder Matters

Our common stock has been traded on the Nasdaq National Market under the symbol "BABY" since our initial public offering in July 2001. The following table sets forth, for the periods indicated, the high and low closing prices reported on the Nasdaq National Market.

	High	Low
Fiscal Year Ended December 31, 2001:		
Fourth Quarter	$ 8.91	$3.90
Third Quarter (from July 20, 2001)	15.50	7.10

As of March 20, 2002, there were 15,930,986 shares of our common stock issued and outstanding and held by approximately 200 stockholders of record. We estimate that there are approximately 1,100 beneficial owners of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

ITEM 6. Selected Consolidated Financial Data

Our selected consolidated financial data is presented below as of December 31, 2001, 2000, 1999, 1998 and 1997 and for each of the years in the five-year period ended December 31, 2001, and is derived from the consolidated financial statements of Natus Medical Incorporated and its subsidiaries. The consolidated financial statements as of December 31, 2001 and 2000 and for each of the years in the three-year period ended December 31, 2001 are included elsewhere in this report. The selected consolidated balance sheet data as of December 31, 1999, 1998 and 1997 and the consolidated statements of operations data for the years ended December 31, 1998 and 1997 are derived from our consolidated financial statements which are not included in this report. The selected consolidated financial data set forth below is qualified in its entirety by, and should be read in conjunction with, the Consolidated Financial Statements and Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

	Year ended December 31,				
	2001	2000	1999	1998	1997
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenues	$27,401	$ 24,633	$ 19,783	$ 15,884	$ 10,031
Cost of revenues*	10,843	8,745	6,624	5,577	3,612
Gross profit	16,558	15,888	13,159	10,307	6,419
Operating expenses:					
Marketing and selling	12,476	8,984	7,684	6,275	4,259
Research and development	4,318	3,458	2,457	2,711	1,602
General and administrative	3,563	2,586	2,384	1,638	1,231
Amortization of deferred stock compensation*	958	611	—	—	—
Total operating expenses	21,315	15,639	12,525	10,624	7,092
(Loss) income from operations	(4,757)	249	634	(317)	(673)
Other income, net	942	32	20	118	97
(Loss) income before provision for income taxes	(3,815)	281	654	(199)	(576)
Provision for income taxes	68	46	10	—	—
Net (loss) income	(3,883)	235	644	(199)	(576)
Accretion of redeemable convertible preferred stock	763	1,384	2,085	1,389	1,292
Net loss available to common stockholders	$(4,646)	$ (1,149)	$ (1,441)	$ (1,588)	$ (1,868)
Basic and diluted net loss per share	$ (0.62)	$ (1.62)	$ (2.56)	$ (3.63)	$ (7.62)
Shares used in computing basic and diluted net loss per share	7,540	710	562	438	245
*Amortization of deferred stock compensation included in:					
Cost of revenues	$ 139	$ 184	$ —	$ —	$ —
Marketing and selling	$ 507	$ 157	$ —	$ —	$ —
Research and development	84	105	—	—	—
General and administrative	367	349	—	—	—
Operating expenses	$ 958	$ 611	$ —	$ —	$ —

	December 31,				
	2001	2000	1999	1998	1997
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$53,086	$ 983	$ 2,376	$ 1,943	$ 2,823
Working capital	58,642	4,065	3,814	3,206	3,730
Total assets	64,935	10,718	8,699	7,418	6,330
Long-term debt, net of current portion	—	—	—	150	—
Convertible preferred stock	—	25,226	23,842	21,154	19,765
Total stockholders' equity (deficit)	61,029	(18,283)	(18,226)	(16,851)	(15,363)

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, among other things, statements concerning our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. The words "may," "will," "continue," "estimate," "project," "intend," "believe," "expect," "anticipate," and other similar expressions generally identify forward-looking statements. Forward-looking statements in this Item 7 include, but are not limited to, statements regarding the following: the future composition of our revenues and future revenues from international operations, acceptance of our products and the products of our competitors, fluctuation of our operating results and gross margins, expansion opportunities relating to international markets, future increases in marketing and selling expenses, future operating results, warranty allowances, impact of our application of resources, increased spending relating to our products, impact of and trends relating to trade-ins, sufficiency of future resources such as employees, future investments for information system upgrades, investment in and development of new products and enhancement of existing products, future liquidity and capital requirements, sufficiency of cash and cash equivalents and availability of funds, effect of and exposure to foreign currency exchange rates, market risk exposure, increase in size and number of locations of our customer support organization, development of additional infrastructure and future hiring, cost-effectiveness of our products, third-party reimbursement, consolidation of our industry and consequences intellectual property disputes.

You are cautioned not to place undue reliance on forward-looking statements. Forward-looking statements are not guarantees of future performance. The forward-looking statements are subject to substantial risks and uncertainties that could cause our future business, financial condition, or results of operations to differ materially from our historical results or currently anticipated results. Investors should carefully review the information contained under the caption "Factors that may affect our business, financial condition, and future operating results," beginning on page 35 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 discussion and analysis also should be read in conjunction with "Selected Consolidated Financial Data" and our Consolidated Financial Statements and Notes thereto included elsewhere in this report. All forward-looking statements included in this document are based on information available to us on the date hereof, and the we assume no obligation to update any such forward-looking statements. These forward-looking statements are made in reliance upon the safe harbor provision of The Private Securities Litigation Reform Act of 1995.

Overview

We develop, manufacture and market 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 2001, 2000 and 1999. 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 83%, 86% and 90% of our revenues during 2001, 2000 and 1999, 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 distribution operations in Japan in July 2001,

when we acquired the business operations 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 indirect and through distributors and have been characterized by lower gross margins due to the discount the distributors receive from our list prices.

Our significant accounting policies are more fully described in Note 1 to the consolidated financial statements included in this report. The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities in the consolidated financial statements. These estimates include allowances for potentially uncollectible accounts receivable, warranty costs, and a valuation allowance for deferred tax assets. Our actual results could differ materially from these estimates.

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. Advance payments from customers are recorded as deferred revenues until shipment of the related product. We do provide for trade-ins of our own or competitive equipment. Trade-ins are recorded as a reduction of revenue at the time of shipping the replacement equipment, and therefore impact the margins associated with those sales. We expect trade-ins to increase soon after a major product introduction when our customers upgrade their existing equipment to newer models.

We 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. 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.

Our net income or loss can be markedly impacted by the decisions of management regarding the level of resources applied to our business. Management, and our board of directors, makes these decisions on the basis of sales forecasts, expected customer orders, economic conditions and other factors. These costs are primarily personnel and facilities costs that are relatively fixed in the short-term and directly impact net income. In January 2001, we reorganized and expanded our domestic sales force to commercially launch and focus on our CO-Stat products. We increased spending on the marketing of our CO-Stat products in 2001 and expect to maintain these spending levels in 2002. 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. In addition, we have increased international expenses by acquiring the operations of our United Kingdom distributor in January 2001, our Japanese distributor in July 2001 and increasing our support staff. We increased the number of persons dedicated to the sales and marketing of our products internationally to 19 as of December 31, 2001 from two in 2000. Because we have not previously sold or marketed our products internationally through direct efforts, we cannot be certain that our planned resources will be sufficient to support our products in those markets.

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 and accretion ceased as of that time. 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.

As of December 31, 2001, we had total federal and state net operating loss carry forwards of approximately $8.0 million and $1.7 million, respectively, available to reduce future taxable income. If not utilized to offset taxable income in future periods, these net operating loss carry forwards will expire in various amounts beginning in 2003 and continuing through 2021. If we continue to have net losses, we may not be able to utilize some or all of our net operating loss carry forwards before they expire. In addition United States income tax law imposes limitations on the amount of net operating loss carry forwards we can use in any given year and on the ability to use net operating loss carry forwards if we experience a more than 50% change in ownership during any three-year period.

Results of Operations

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

	Percent of Revenue		
	Years Ended December 31,		
	2001	2000	1999
Revenues	100.0%	100.0%	100.0%
Cost of revenues*	39.6	35.5	33.5
Gross profit	60.4	64.5	66.5
Operating expenses:			
Marketing and selling	45.5	36.5	38.8
Research and development	15.8	14.0	12.4
General and administrative	13.0	10.5	12.1
Amortization of deferred stock compensation*	3.5	2.5	—
Total operating expenses	77.8	63.5	63.3
(Loss) income from operations	(17.4)	1.0	3.2
Other income, net	3.4	0.1	0.1
(Loss) income before provision for income taxes	(14.0)	1.1	3.3
Provision for income taxes	0.2	0.2	0.1
Net (loss) income	(14.2)	0.9	3.2
Accretion of redeemable convertible preferred stock	2.8	5.6	10.5
Net loss available to common stockholders	(17.0)%	(4.7)%	(7.3)%
*Amortization of deferred stock compensation included in:			
Cost of revenues	0.5%	0.7%	—
Marketing and selling	1.9%	0.7%	—
Research and development	0.3	0.4	—
General and administrative	1.3	1.4	—
Operating expenses	3.5%	2.5%	—

Comparison of 2001 and 2000

Our revenues increased $2.8 million, or 11%, to $27.4 million in 2001 from $24.6 million in 2000. This increase was primarily attributable to increased quantities of disposable supplies sold. Revenues from disposable supplies increased $2.6 million, or 18%, to $17.6 million in 2001 from $15.0 million in 2000. As a percent of revenues, revenues from sales of disposables increased to 64% in 2001 from 61% in 2000. No end customer accounted for more than 10% of our revenues in either 2001 or 2000. Sales to our Japanese distributor, Nippon Eurotec, accounted for 11% of our revenues in 2000.

Revenues from sales outside the United States increased $1.4 million, or 42%, to $4.7 million in 2001 from $3.3 million in 2000. This increase was due primarily to higher quantities of our products sold in Japan, the United Kingdom and other countries as well as increases in realized selling prices associated with our subsidiaries now acting as distributors in those countries. Japanese sales were $3.4 million in 2001 and $2.7 million in 2000.

Our cost of revenues increased $2.1 million, or 24%, to $10.8 million in 2001 from $8.7 million in 2000. The increase in the cost of revenues in dollars was primarily due to the increased volume of screening equipment and disposable supplies sold during 2001 and increases in manufacturing costs. Cost of revenues included amortization of $139,000 of deferred stock compensation in 2001 and $184,000 in 2000. As a percent of revenues, the cost of revenues increased to 40% in 2001 from 36% in 2000.

Gross profit increased $670,000, or 4%, to $16.6 million in 2001 from $15.9 million in 2000. Gross profit as a percentage of revenues decreased to 60% in 2001 from 65% in 2000. The increase in cost of revenues and the decrease in gross profit as a percentage of revenues was attributable to increased fixed costs related to the hiring of additional employees, increased consulting costs and increased manufacturing costs, particularly those associated with early production runs of our ALGO 3 product. We experienced a reduction in the effective selling price of our ALGO 3 equipment due to an increase in the number of units sold in connection with trade-ins. Trade-ins reduced margins by up to $5,000 per unit, and are typically more frequent at the commencement of a new model cycle. We expect the trends relating to trade-ins to continue in 2002, but with a reduced impact as the year progresses.

Our marketing and selling expenses increased $3.5 million, or 39%, to $12.5 million in 2001 from $9.0 million in 2000. The dollar increase in marketing and selling expenses was primarily attributable to the hiring of additional marketing and selling personnel, increases in commissions due to increased sales and the expansion of our sales efforts, particularly in connection with an increase in our domestic field staff and the acquisition of our distributors in Japan and the United Kingdom during 2001. We expect that marketing and selling expenses will continue to increase in the future.

Our research and development expenses increased $860,000, or 25%, to $4.3 million in 2001 from $3.5 million in 2000. This increase in research and development expenses was primarily attributable to the hiring of additional engineers and consultants.

Our general and administrative expenses increased $977,000, or 38%, to $3.6 million in 2001 from $2.6 million in 2000. The dollar increase in general and administrative expenses was primarily attributable to the hiring of additional personnel, as well as increased legal, accounting and other consulting fees and insurance costs. Payroll, consulting and manufacturing costs in 2001 increased 28% over 2000, a rate greater than our increase in revenue. Many of the increased costs were costs associated with being a public company.

We recorded aggregate amortization of $795,000 of deferred stock compensation in 2000, of which $184,000 was included in cost of revenues and $1.1 million of deferred stock compensation in 2001, of which $139,000 was included in cost of revenues.

Our other income (expense), net increased $910,000 or 2,844%, to $942,000 in 2001 from $32,000 in 2000. The increase was primarily due to higher interest earned on increased average cash and short-term investment balances in 2001 as a result of our initial public offering.

Comparison of 2000 and 1999

Our revenues increased $4.8 million, or 25%, to $24.6 million in 2000 from $19.8 million in 1999. This increase was primarily attributable to increased quantities of disposable supplies sold. Revenues from disposable supplies increased $4.3 million, or 40%, to $15.0 million in 2000 from $10.7 million in 1999. As a percent of

revenues, revenues from sales of disposable supplies increased from 54% in 1999 to 61% in 2000. No end customer accounted for more than 10% of our revenues in either 1999 or 2000. Sales to our Japanese distributor, Nippon Eurotec, accounted for 11% of our revenues in 2000.

Revenues from indirect sales outside the United States increased $1.3 million, or 68%, to $3.3 million in 2000 from $2.0 million in 1999. This increase was due primarily to higher quantities of our products sold in Japan, the United Kingdom and other countries. Sales to Japan were $2.7 million in 2000 and $1.7 million in 1999. Screening equipment sales increased $600,000 and sales of disposable supplies increased $400,000 in 2000. One factor relating to the increase in revenues in the Japanese market was the commencement of the Japanese Ministry of Health, Labor and Welfare's pilot newborn hearing screening program, which provides for reimbursement of newborn hearing screenings. We expect future sales, if any, related to this pilot program to be one-time screening equipment and disposable supplies purchases. We cannot determine whether such programs will continue to purchase disposable supplies or screening equipment from us. Pilot programs have also been initiated in the United Kingdom and proposed in other countries.

Our cost of revenues increased $2.1 million, or 32%, to $8.7 million in 2000 from $6.6 million in 1999. The increase in the cost of revenues in absolute dollars was primarily due to the increased volume of screening equipment and disposable supplies sold during 2000. Cost of revenues included amortization of $184,000 of deferred stock compensation in 2000 but did not include any amortization of deferred stock compensation in 1999. As a percent of revenues, the cost of revenues increased to 36% in 2000 from 34% in 1999. The increase in cost of revenues as a percent of revenues was attributable to the higher percentage of international sales and the lower per unit selling prices associated with those sales. In addition, our cost of revenues in 2000 was impacted by amortization of deferred stock compensation. Excluding amortization of deferred stock compensation, cost of revenues increased to 35% of revenues in 2000 from 34% of revenues in 1999.

Gross profit increased $2.7 million, or 21%, to $15.9 million in 2000 from $13.2 million in 1999. Gross profit as a percentage of revenues decreased to 65% in 2000 from 67% in 1999. The decrease in gross profit as a percentage of revenues was primarily due to a higher percentage of international sales, increased fixed costs of approximately $200,000 related to the addition of employees and consultants dedicated to manufacturing quality control and deferred stock compensation of approximately $200,000.

Our marketing and selling expenses increased $1.3 million, or 17%, to $9.0 million in 2000 from $7.7 million in 1999. The absolute dollar increase in marketing and selling expenses was primarily attributable to the hiring of additional marketing and selling personnel, increases in commissions due to increased sales and the expansion of our sales efforts.

Our research and development expenses increased $1.0 million, or 41%, to $3.5 million in 2000 from $2.5 million in 1999. As a percent of revenues, research and development expenses were 14% in 2000 and 12% in 1999. This increase in research and development expenses was primarily attributable to the hiring of additional engineers and consultants.

Our general and administrative expenses increased $202,000, or 8%, to $2.6 million in 2000 from $2.4 million in 1999. The absolute dollar increase in general and administrative expenses was primarily attributable to the hiring of additional personnel, as well as increased legal, accounting and other consulting fees.

We recorded aggregate amortization of $795,000 of deferred stock compensation in 2000, of which $184,000 was included in cost of revenues. We recorded no amortization of deferred stock compensation in 1999.

Our other income (expense), net increased $12,000 or 60%, to $32,000 in 2000 from $20,000 in 1999. The increase was primarily due to higher interest earned on increased average cash balances in 2000.

Liquidity and Capital Resources

As of December 31, 2001, we had cash, cash equivalents and short-term investments of $53.1 million, stockholders' equity of $61.0 million and working capital of $58.6 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 $4.6 million for 2001, compared to net cash provided by operating activities of $375,000 for 2000 and $1.3 million for 1999. Cash used in operating activities for 2001 resulted primarily from the net loss during the period and an increase in inventories and a decrease in accrued liabilities, offset in part by non-cash items such as deferred stock compensation and depreciation and amortization. Increases in inventories and accounts receivable primarily are associated with the needs of our newly acquired, wholly owned, foreign operations in the United Kingdom and Japan. Net cash provided by operating activities for 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 provided by operating activities for 1999 resulted primarily from net income.

Net cash used in investing activities was $23.5 million for 2001, $762,000 for 2000 and $1.4 million for 1999. Net cash used in investing activities during 2001 was primarily for investment of cash received as a result of our initial public offering and for the purchase of new computers, equipment and furniture as we expanded operations. Net cash used in investing activities for 2000 and 1999 was primarily for the purchase of new computers, equipment and furniture as we expanded operations and purchase of a note receivable in 1999. We intend to invest approximately $500,000 related to information systems upgrades in early 2002.

Net cash provided by financing activities was $57.8 million for 2001. Net cash used by financing activities was $1.0 million for 2000. Net cash provided by financing activities was $519,000 for 1999. The net cash provided by financing activities for 2001 resulted primarily from the proceeds of our initial public offering. The net cash used in financing activities for 2000 resulted primarily from deferred offering costs and repayment of borrowings. The net cash provided by financing activities for 1999 resulted primarily from the proceeds we received from the exercise of warrants to purchase preferred stock and issuance of common stock upon the exercise of stock options.

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

We believe that our current cash and cash equivalent balances 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.

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 17% of our revenues in 2001, approximately 14% of our revenues in 2000 and approximately 10% of our revenues in 1999. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. Prior to our acquisition of the distribution activities of our top-tier distributor in Japan and our acquisition of our distributor in the United Kingdom, our sales generally were denominated in United States dollars. Since that time, our revenues and expenses in these countries have increasingly begun to be denominated in the applicable foreign currency. As our operations in Japan and the United Kingdom increase, we expect that our exposure to foreign currency fluctuations will increase. If the United States dollar uniformly increased or decreased in strength by 10% relative to the currencies in which our sales were denominated, our net loss would have correspondingly increased or decreased by an estimated $400,000 for the year ended December 31, 2001. For purposes of this calculation, we have assumed that the exchange rates would change in the same direction relative to the United States dollar. Changes in exchange rates also may affect the volume of our sales or our foreign currency sales prices compared to those of our foreign competitors and make our products less competitive in those countries.

Our interest income is sensitive to changes in the general level of interest rates in the United States, particularly since the majority of our investments are in short term instruments. However, as substantially all of our short-term investments carry a fixed rate of interest, a hypothetical decrease of 10% in market interest rates would not result in a material decrease in interest income earned on investments held at December 31, 2001 through the date of maturity on those investments.

The fair value of our available-for-sale securities are also sensitive to changes in the general level of interest rates in the United States, and the fair value of our portfolio will fall if market interest rates increase. If market rates were to increase by 10% from levels at December 31, 2001, the fair value of our portfolio would decline by an immaterial amount. Additionally, since we generally have the ability to hold these investments to maturity, these declines in fair value may never be realized.

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of December 31, 2001. Actual results may differ as our analysis of the effects of changes in interest rates does not account for, among other things, sales of securities prior to maturity and repurchase of replacement securities, the change in mix or quality of the investments in the portfolio and changes in the relationship between short-term and long-term interest rates.

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 supercedes Statement of Financial Accounting Standards No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of* and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001. We adopted the provisions of SFAS No. 144 as of January 1, 2002, and do not expect SFAS No. 144 to 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 adopted SFAS No. 142 on January 1, 2002 and, at that time, stopped amortizing goodwill that resulted from business combinations completed prior to June 30, 2001. The adoption of SFAS No. 141 and SFAS No. 142 did not have a material effect on our financial position and 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 became effective for us 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.

Factors that May Affect our Business, Financial Condition and Future Operating 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 $4.6 million in 2001, $1.1 million in 2000 and $1.4 million in 1999. We expect to incur net losses in 2002.

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 97% of our revenues in 2001, approximately 98% of our revenues in 2000 and approximately 98% of our revenues in 1999. 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-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 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 customers defer or cancel purchases of our products, our revenues will be 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

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 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 December 31, 2001, 36 states and the District of Columbia had mandated universal newborn hearing screening, but the phase-in of these guidelines varies widely from six months to four years. To date, there has been only limited adoption of newborn hearing screening prior to hospital discharge by foreign governments. Our 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 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. For instance, we are currently participating in the National Health Service's selection process in the United Kingdom for newborn hearing screening equipment vendors for England and, potentially, Scotland and Wales. The selection process is expected to be finalized in mid-2002. In the event we are not selected as a provider of newborn hearing screening equipment in the process, we will have difficulty selling our hearing screening products in the United Kingdom. Even if we are selected, we cannot be certain of the amount or timing of revenues associated with the award.

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.

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 December 31, 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.

Our sales efforts through group purchasing organizations and 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 25% of our total revenues in 2001 and 22% of our revenues in 2000. Sales to members of group purchasing organizations accounted for approximately 35% of our total revenues in 2001 and 23% of our revenues in 2000. 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 2000, 93% also purchased products from us in 2001. If we fail to sell additional screening products to our existing customers directly or indirectly, we would experience a material decline in revenues.

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 14% of our revenues in 2001 and 2000 and approximately 10% of our revenues in 1999. 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 United States dollar relative to local currencies

Historically, substantially all of our sales contracts have provided for payment in United States dollars. However, our subsidiary in Japan assumed the activities of our top-tier distributor in Japan in July 2001 and our United Kingdom subsidiary acquired our distributor in the United Kingdom in January 2001. Since that time, our revenues and expenses in these countries have increasingly begun to be denominated in the applicable foreign currency. We also expect to begin selling our products in other local currencies as we expand our direct international sales. To date, we have not undertaken any foreign currency hedging transactions, and as a result, our future 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. It also could cause us to incur a loss on the translation of assets denominated in foreign currencies.

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

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

- the impact of possible recessions in economies outside the United States;
- political and economic instability, including instability related to 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 foreign governments;
- greater difficulty in accounts receivable collection and longer collection periods;
- difficulties of staffing and managing foreign operations;
- reduced protection for intellectual property rights in some countries and potentially conflicting intellectual property rights of third parties under the laws of various foreign jurisdictions; and
- difficulty in obtaining foreign regulatory approvals.

Our failure to obtain necessary United States 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 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;
- criminal prosecution; and
- 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 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.

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 versions of our ALGO hearing screeners other than the ALGO 3. 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. We protect our intellectual property through a combination of patent, copyright, trade secret and trademark laws. We have eight issued United States patents, five patent applications pending before the United States Patent and Trademark Office and eight 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, seven patent applications pending in Japan and four patent applications 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.

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 loss carryforwards, which may adversely affect our financial results

As of December 31, 2001, we had total federal and state net operating loss carryforwards of approximately $8.0 million and $1.7 million, respectively, available to reduce future taxable income. These net operating loss carryforwards, if not utilized to offset taxable income in future periods, will expire in various amounts beginning in 2003 through 2021. 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 7A. Quantitative and Qualitative Disclosures About Market Risk

The information required by this Item is set forth in the section entitled “Management’s Discussion and Analysis of Financial Conditions and Results of Operations.”

ITEM 8. Financial Statements and Supplementary Data

The Consolidated Financial Statements and Supplementary Data required by this Item are set forth where indicated in Item 14 of this report.

Quarterly Results of Operations

The following table presents our operating results for each of the eight quarters in the period ending December 31, 2001. The information for each of these quarters is unaudited and has been prepared on the same basis as our audited financial statements appearing elsewhere in this report. In the opinion of our management, all necessary adjustments, consisting only of normal recurring adjustments, have been included to present fairly the unaudited quarterly results when read in conjunction with our audited consolidated financial statements and the related notes appearing elsewhere in this report. These operating results are not necessarily indicative of the results of any future period.

	Quarters Ended							
	Dec. 31, 2001	Sept. 30, 2001	June 30, 2001	Mar. 31, 2001	Dec. 31, 2000	Sept. 30, 2000	June 30, 2000	Mar. 31, 2000
	(in thousands)							
Revenues	$ 7,516	$ 6,324	$ 7,243	$ 6,318	$6,971	$6,653	$6,097	$4,912
Cost of revenues	3,273	2,432	2,710	2,428	2,446	2,391	2,142	1,766
Gross profit	4,243	3,892	4,533	3,890	4,525	4,262	3,955	3,146
Gross margin	56.5%	61.5%	62.6%	61.6%	64.9%	64.1%	64.9%	64.0%
Operating expenses:								
Marketing and selling	3,495	3,010	3,026	2,945	2,344	2,208	2,389	2,043
Research and development	1,105	1,184	1,018	1,011	938	915	862	743
General and administrative	972	855	954	782	645	789	589	563
Amortization of deferred stock compensation	148	238	284	288	182	188	214	27
Total operating expenses	5,720	5,287	5,282	5,026	4,109	4,100	4,054	3,376
(Loss) income from operations	(1,477)	(1,395)	(749)	(1,136)	416	162	(99)	(230)
Other income (expense), net	250	702	(23)	13	4	16	(7)	19
(Loss) income before provision for income taxes	(1,227)	(693)	(772)	(1,123)	420	178	(106)	(211)
Provision for income taxes	67	—	—	1	23	23	—	—
Net (loss) income	(1,294)	(693)	(772)	(1,124)	397	155	(106)	(211)
Accretion of redeemable convertible preferred stock	—	71	346	346	346	346	346	346
Net loss available to common stockholders	$(1,294)	$ (764)	$(1,118)	$(1,470)	$ 51	$ (191)	$ (452)	$ (557)

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

PART III

ITEM 10. Directors and Executive Officers

The information required by this item concerning the our directors is incorporated by reference to the sections captioned "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our Proxy Statement related to the 2002 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K (the "Proxy Statement"). Certain information required by this item concerning executive officers is set forth in Part I of this Report in "Business—Executive Officers."

ITEM 11. Executive Compensation

The information required by this item is incorporated by reference to the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this item is incorporated by reference to the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions

The information required by this item is incorporated by reference to the Proxy Statement.

PART IV

ITEM 14. Exhibits, Financial Statement Schedules, and Reports On Form 8–K

(a)(1) Financial Statements

The following consolidated financial statements are filed as part of this Report:

(a)(2) Financial Statement Schedules

SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS
For the years ended December 31, 2001, 2000 and 1999
(in thousands)

	Balance at Beginning of Period	Additions Charged to Expense	Deductions	Balance at End of Period
Year ended December 31, 2001				
Allowance for doubtful accounts	$ 203	$ 37	$ (1)	$ 239
Accrued warranty costs	$ 548	$ 172	$ (178)	$ 542
Year ended December 31, 2000				
Allowance for doubtful accounts	$ 201	$ 89	$ (87)	$ 203
Accrued warranty costs	$ 487	$ 233	$ (172)	$ 548
Year ended December 31, 1999				
Allowance for doubtful accounts	$ 138	$ 131	$ (68)	$ 201
Accrued warranty costs	$ 500	$ 185	$ (198)	$ 487

(a)(3) Exhibits

Exhibit No.	Exhibit Title
3.1.1	(b) Certificate of Incorporation
3.1.2	(b) Certificate of Amendment to Certificate of Incorporation
3.2	(b) Bylaws of the Registrant
10.1	(b) Form of Indemnification Agreement between the Registrant and each of its directors and officers
10.2	(b) Amended and Restated 1991 Stock Option Plan
10.2.1	(b) Form of Option Agreement under the 1991 Stock Option Plan
10.3	(b) 2000 Stock Option Plan
10.3.1	(b) Form of Option Agreement under the 2000 Stock Option Plan
10.4	(b) 2000 Director Option Plan
10.4.1	(b) Form of Option Agreement under 2000 Director Option Plan
10.5	(b) 2000 Employee Stock Purchase Plan and form of subscription agreement thereunder
10.6	Reserved
10.6.1	Reserved
10.6.2†	(b) Transition Agreement dated as of July 28, 2000 between Registrant, Nippon Eurotec Co. Ltd., Toshibumi Wakayama, Masaaki Kuroiwa and Kenji Tomita
10.7†	(b) Patent License Agreement dated June 30, 1998 between Registrant and The Leland Stanford Junior University
10.8	(b) Lease Agreement dated August 24, 1998 between Registrant and San Carlos Co-Tenancy.
10.9	(b) Promissory Note dated March 24, 1999 between Scott Valley Bank and Tim C. Johnson
10.9.1	(b) Assignment of Deposit Account dated March 24, 1999 between Registrant, Scott Valley Bank and Tim C. Johnson
10.9.2	(b) Security Agreement dated March 26, 1999 between Registrant and Tim C. Johnson
10.10†	(b) Capital Equipment Supplier Agreement dated June 25, 1999 between the Registrant and Novation, LLC
10.11†	(b) Manufacturing Agreement dated December 3, 1998 between Registrant and TriVirix International, Inc. (formerly CMA International, Inc.)
10.12	Reserved
10.13	Reserved
10.14†	(b) Memorandum of Understanding dated December 7, 2000 between Registrant and the Ludlow Company LP
10.15	(b) 2000 Supplemental Stock Option Plan
10.15.1	(b) Form of Option Agreement for 2000 Supplemental Stock Option Plan
10.16	(b) Lease dated March 3, 2000 between W&G Properties Limited, Neonatal Perspectives Limited and Andrew Vincent for the premises located at Unit 9, Northmill, Buckinghamshire, United Kingdom
10.17	Reserved
10.17.1	Reserved

Exhibit No.	Exhibit Title
10.17.2	Reserved
10.17.3	Reserved
10.17.4	Reserved
10.18	(c) Leasing Agreement dated June 11, 2001 between Natus Japan and Sanwa Radiator Co. Ltd. (Japanese to English translation)
21.1	(b) Subsidiaries
23.1	(a) Independent Auditors' Consent
24.1	(a) Power of Attorney (see p. 55)

† Portions of this agreement have been omitted pursuant to a request for confidential treatment and the omitted portions have been filed with the Securities and Exchange Commission.

(a) Filed herewith.

(b) Incorporated by reference to the exhibit bearing the same number filed with the Registrant's Registration Statement on Form S-1 (Registration Statement 333–39891), which the Securities and Exchange Commission declared effective on July 19, 2001.

(c) Incorporated by reference to the exhibit bearing the same number filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

(b) Reports on Form 8-K

We did not file a Current Report on Form 8-K during the three months ended December 31, 2001.

(c) Exhibits

See Item 14(a)(3) above.

(d) Financial Statement Schedules

See Item 14(a)(2) above.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized in the City of San Carlos, California, on March 28, 2002.

NATUS MEDICAL INCORPORATED

By /s/ Tim C. Johnson

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

By /s/ William H. Lawrenson

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Tim C. Johnson and William H. Lawrenson and each of them acting individually, as his or her attorney-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report on Form 10-K has been signed on behalf of the Registrant by the following persons and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Tim C. Johnson **(Tim C. Johnson)**	Chief Executive Officer, President, Chief Operating Officer and Director (Principal Executive Officer)	March 28, 2002
/s/ William H. Lawrenson **(William H. Lawrenson)**	Vice President, Finance, Chief Financial Officer and Assistant Secretary (Principal Financial Officer)	March 28, 2002
/s/ William New, Jr. **(William New, Jr., M.D., Ph.D)**	Chairman of the Board of Directors and Chief Technology Officer	March 28, 2002
/s/ James J. Bochnowski **(James J. Bochnowski)**	Director	March 28, 2002
/s/ William M. Moore **(William M. Moore)**	Director	March 28, 2002
/s/ David Nierenberg **(David Nierenberg)**	Director	March 28, 2002

NATUS MEDICAL INCORPORATED

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of
Natus Medical Incorporated:

We have audited the accompanying consolidated balance sheets of Natus Medical Incorporated and subsidiaries (the "Company") as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the consolidated financial statement schedule listed in Item 14(a)(2) in the Annual Report on Form 10-K of the Company. These consolidated financial statements and consolidated financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and consolidated financial statement schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2001 and 2000 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule referenced above, when considered in relation to the basic consolidated financial statements as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ Deloitte & Touche LLP

Deloitte & Touche LLP

San Jose, California
February 5, 2002

NATUS MEDICAL INCORPORATED

CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	December 31,	
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,351	$ 681
Short-term investments	22,735	302
Accounts receivable, net of allowance for doubtful accounts of $239 in 2001 and $203 in 2000	5,209	4,400
Inventories	3,598	2,194
Prepaid expenses and other current assets	655	263
Total current assets	62,548	7,840
Property and equipment, net	1,757	1,308
Convertible notes receivable	—	115
Long-term investment	327	321
Deposits and other assets	303	1,134
Total assets	$ 64,935	$ 10,718
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Liabilities:		
Accounts payable	$ 892	$ 750
Accrued liabilities	2,702	2,694
Deferred revenues	312	331
Total liabilities	3,906	3,775
Commitments and contingencies (Note 8)		
Convertible preferred stock:		
Series A convertible preferred stock, $0.001 par value; 1,241,842 shares authorized; 1,241,841 shares issued and outstanding in 2000; aggregate liquidation value of $3,803 in 2000	—	2,227
Redeemable convertible preferred stock, $0.001 par value; 8,781,412 shares authorized; aggregate liquidation value of $25,178 in 2000 and aggregate redemption value of $22,999 in 2000:		
Series B: 3,967,126 shares authorized; 3,967,120 shares issued and outstanding in 2000	—	12,478
Series C: 3,214,286 shares authorized; 2,490,181 shares issued and outstanding in 2000	—	5,864
Series D: 1,600,000 shares authorized; 1,232,392 shares issued and 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: 15,864,670 in 2001 and 868,034 in 2000	86,007	2,902
Deferred stock compensation	(767)	(1,532)
Accumulated deficit	(24,299)	(19,653)
Accumulated other comprehensive income	88	—
Total stockholders' equity (deficit)	61,029	(18,283)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 64,935	$ 10,718

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

NATUS MEDICAL INCORPORATED

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Years Ended December 31,		
	2001	2000	1999
Revenues	$27,401	$24,633	$19,783
Cost of revenues*	10,843	8,745	6,624
Gross profit	16,558	15,888	13,159
Operating expenses:			
Marketing and selling	12,476	8,984	7,684
Research and development	4,318	3,458	2,457
General and administrative	3,563	2,586	2,384
Amortization of deferred stock compensation*	958	611	—
Total operating expenses	21,315	15,639	12,525
(Loss) income from operations	(4,757)	249	634
Interest income	812	29	35
Interest expense	(39)	(8)	(17)
Other income, net	169	11	2
(Loss) income before provision for income taxes, net	(3,815)	281	654
Provision for income taxes	68	46	10
Net (loss) income	(3,883)	235	644
Accretion of redeemable convertible preferred stock	763	1,384	2,085
Net loss available to common stockholders	$(4,646)	$(1,149)	$(1,441)
Basic and diluted net loss per share	$ (0.62)	$ (1.62)	$ (2.56)
Common shares used in computing basic and diluted net loss per share	7,540	710	562
*Amortization of deferred stock compensation included in:			
Cost of revenues	$ 139	$ 184	$ —
Marketing and selling	507	$ 157	—
Research and development	84	105	—
General and administrative	367	349	—
Operating Expenses	$ 958	$ 611	$ —

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

NATUS MEDICAL INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
AND COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Common Stock		Deferred Stock Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income	Stockholders' Equity (Deficit)	Comprehensive Income (Loss)
	Shares	Amount					
Balances, January 1, 1999	515,632	$ 212	$ —	$ (17,063)	$ —	$ (16,851)	
Accretion to redemption value on Series B, C and D redeemable convertible preferred stock				(1,389)		(1,389)	
Accretion to redemption value of shares issued on exercise of warrants on Series C redeemable convertible preferred stock				(696)		(696)	
Exercise of options	82,057	66				66	
Net income				644		644	$ 644
Comprehensive income							$ 644
Balances, December 31, 1999	597,689	278	—	(18,504)		(18,226)	
Accretion to redemption value on Series B, C and D redeemable convertible preferred stock				(1,384)		(1,384)	
Deferred stock compensation		2,504	(2,327)			177	
Amortization of deferred stock compensation			795			795	
Exercise of stock options	270,345	120				120	
Net income				235		235	$ 235
Comprehensive income							$ 235
Balances, December 31, 2000	868,034	2,902	(1,532)	(19,653)	—	(18,283)	
Accretion to redemption value of Series B, C and D redeemable convertible preferred stock				(763)		(763)	
Initial public offering of common shares, net of issuance cost of $6,799	5,750,000	56,451				56,451	
Conversion of preferred stock to common stock	8,931,534	25,989				25,989	
Deferred stock compensation		332	(332)			—	
Amortization of deferred stock compensation			1,097			1,097	
Exercise of stock options	268,357	134				134	
Employee stock purchase plan	46,745	199				199	
Unrealized gain on available-for-sale short term investments					76	76	$ 76
Foreign currency translation adjustment					12	12	12
Net loss				(3,883)		(3,883)	(3,883)
Comprehensive loss							$ 3,795
Balances, December 31, 2001	15,864,670	$86,007	$ (767)	$ (24,299)	$ 88	$ 61,029	

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

NATUS MEDICAL INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2001	2000	1999
Operating activities:			
Net income (loss)	$ (3,883)	$ 235	$ 644
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	847	655	585
Loss on disposal of property and equipment	7	7	—
Amortization of deferred stock compensation	1,097	795	—
Non cash marketing expense	—	177	—
Writeoff of note receivable	—	—	200
Changes in operating assets and liabilities:			
Accounts receivable	(979)	(1,272)	(321)
Inventories	(1,392)	(941)	(73)
Prepaid expenses and other current assets	(400)	(123)	101
Accounts payable	142	(224)	15
Accrued liabilities and deferred revenues	(67)	1,066	103
Net cash (used in) provided by operating activities	(4,628)	375	1,254
Investing activities:			
Acquisition of property and equipment	(1,046)	(668)	(694)
Deposits and other assets	(72)	(55)	(36)
Purchase of convertible notes receivable	—	(20)	(95)
Purchase of note receivable	—	—	(200)
Purchases of short-term investments	(163,945)	(596)	(569)
Sales of short-term investments	141,589	583	559
Cash paid for acquisition of business	(9)	—	—
Purchase of long-term investment	(6)	(6)	(315)
Net cash used in investing activities	(23,489)	(762)	(1,350)
Financing activities:			
Exercise of warrants on Series C preferred stock	—	—	603
Issuance of common stock	59,156	120	66
Deferred offering costs	(1,383)	(989)	—
Borrowings on bank loans	2,000	—	—
Payments of borrowings	(2,000)	(150)	(150)
Net cash provided by (used in) financing activities	57,773	(1,019)	519
Exchange rate effect on cash and equivalents	14	—	—
Net increase (decrease) in cash and equivalents	29,670	(1,406)	423
Cash and cash equivalents, beginning of year	681	2,087	1,664
Cash and cash equivalents, end of year	$ 30,351	$ 681	$ 2,087
Noncash investing and financing activities:			
Accretion of redeemable convertible preferred stock	$ 763	$ 1,384	$ 2,085
Exercise of warrants, cashless	$ —	$ —	$ 448
Forgiveness of convertible notes receivable and accounts receivable for acquisition of business	$ 189	$ —	$ —
Conversion of convertible preferred stock into common stock	$ 25,989	$ —	$ —
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 39	$ 8	$ 17
Cash paid for income taxes	$ 50	$ 45	$ 7

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

NATUS MEDICAL INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2001, 2000 and 1999

1— ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization

Natus Medical Inc. (the "Company") was incorporated in California in May 1987 and reincorporated in the State of Delaware in August 2000. The Company is primarily focused on developing, manufacturing and marketing products for the identification and monitoring of common medical disorders that may occur during the time from conception to a baby's first birthday. The Company's primary product lines are the ALGO® Newborn Hearing Screener, a product line for hearing screening, and the CO-Stat™ End Tidal Breath Analyzer, a product line for the evaluation of newborn jaundice. Both the ALGO and CO-Stat product lines are comprised of hardware units and single-use disposable components.

On July 28, 2000, the Company created and incorporated a wholly owned subsidiary in Japan. On December 21, 2000, the Company created and incorporated a wholly owned subsidiary in the United Kingdom.

Principles of Consolidation

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

Basis of Presentation

All share and per share amounts in the accompanying consolidated financial statements have been restated to give effect to the two-for-five reverse stock split that occurred on August 15, 2000.

Use of Estimates

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

Revenue Recognition

The Company recognizes revenues, net of discounts, 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. Rights of return are generally not provided. Advance payments from customers are recorded as deferred revenues until shipment of the related product. The Company provides for trade-ins of its own or competitive equipment. Trade-ins are recorded as a reduction of revenue at the time of shipping the replacement equipment. Provisions are made for initial standard warranty obligations of one year, and post-sale training and customer support at the time the related revenue is recognized. Revenues from extended warranty contracts are recognized ratably over the warranty period. Advance payments from customers are recorded as deferred revenue until shipment of the related product.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with a remaining maturity of three months or less to be cash equivalents.

Short-Term Investments

The Company classifies its short-term investments as available–for-sale securities in accordance with the provision of the Statements of Financial Accounting Standard ("SFAS") No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*." Securities classified as available-for-sale are reported at fair market value with the related unrealized gains and losses included, net of tax, in accumulated other comprehensive income. The cost of securities sold is based on the specific identification method. Realized gains and losses and declines in value of securities judged to be other than temporary are included in interest income or expense.

Certain Significant Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents, short-term investments and accounts receivable. Cash and cash equivalents and short-term investments consist of cash in bank accounts and investments in money market funds. To minimize its exposure to credit risk, the Company invests in highly liquid, high investment-grade financial instruments.

The Company sells its products primarily to hospitals and medical institutions. The Company generally does not require its customers to provide collateral or other security to support accounts receivable. The Company maintains allowances for estimated potential bad debt losses. No single customer accounted for more than 10% of accounts receivable at December 31, 2001 and one customer accounted for 14% of accounts receivable at December 31, 2000.

The Company operates in a dynamic industry and, accordingly, can be affected by a variety of factors. For example, management believes that changes in any of the following areas could have a negative effect on the Company in terms of its future financial position, cash flows and results of operations: ability to obtain additional financing; changes in domestic and international economic and/or political conditions or regulations; currency exchange rate fluctuations; fundamental changes in the technology; market acceptance of the Company's products and products under development; changes in the overall demand for products offered by the Company; successful and timely completion of product development efforts; competitive pressures in the form of new product introductions by competitors or price reductions on current products; availability of necessary product components; inventory obsolescence; development of sales channels; litigation or other claims against or by the Company based on intellectual property, patent, product, regulatory or other factors; and the hiring, training and retention of key employees.

Fair Value of Financial Instruments

The Company's financial instruments include cash and cash equivalents, short-term and long-term investments, and accounts receivable. Cash and cash equivalents and short-term investments are reported at their respective fair values on the balance sheet dates. The recorded carrying amount of accounts receivable approximates their fair value due to their short-term maturities.

Inventories

Inventories are stated at the lower of standard cost, which approximates actual cost on a first-in, first-out basis, or market.

Property and Equipment

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over estimated useful lives of three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life. The Company capitalizes the costs associated with acquiring and installing software to be used for internal purposes.

Long-Lived Assets

The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of that asset may not be recoverable. When the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount, an impairment loss would be measured based on the discounted cash flows compared to the carrying amount. No impairment charge has been recorded in any of the years presented.

Long-Term Investment

At December 31, 2001, the Company has a $327,000 interest-bearing certificate of deposit with a bank that matures in April 2004. This investment has been assigned to a bank to guarantee a loan on the primary residence of an officer totaling $250,000 plus accrued interest. The sole collateral for such guarantee is 27,088 shares of the Company's common stock that is owned by the officer. Due to this arrangement, the Company has classified the investment as held-to-maturity. The estimated fair value of the long-term investment, using discounted cash flows is approximately $313,000 and $273,000 at December 31, 2001 and 2000, respectively.

Research and Development Costs

Costs incurred in research and development are charged to operations as incurred. The Company's products include certain software applications that are integral to the operation of the product. The costs to develop such software have not been capitalized as the Company believes its current software development process is essentially completed concurrent with the establishment of technological feasibility of the software.

Foreign Currency Translation

The functional currency for the Company's foreign subsidiaries is the local currency of the country where the subsidiary is located. Accordingly, translation adjustments for the Company's subsidiaries are included as a component of accumulated other comprehensive income (loss). Gains and losses from transactions denominated in currencies other than the functional currencies of its subsidiaries are included in other income and expense.

Stock-Based Compensation

The Company accounts for stock-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board ("APB") No. 25, *Accounting for Stock Issued to Employees*, as interpreted by Financial Accounting Standards Board ("FASB") Interpretation No. 44, "*Accounting for Transactions Involving*

Stock Compensation—an Interpretation of APB Opinion No. 25." The Company accounts for stock-based awards to nonemployees in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation* and Emerging Issues Task Force ("EITF") Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

Comprehensive Income (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 net assets during the period from non-owner sources. The consolidated statement of comprehensive loss has been included with the consolidated statement of stockholders' equity. Accumulated other comprehensive income at December 31, 2001 consisted of unrealized gain on available for sale securities and translation gains on foreign currency transactions.

Net Loss per Common Share

Basic net loss per common share excludes dilution and is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding during the respective period. Diluted net loss per share was the same as basic net loss per share for all periods presented since the effect of any potentially dilutive securities is excluded as they are anti-dilutive. Such outstanding securities consist of the following: at December 31, 2001, options to purchase 1,920,929 shares of common stock; at December 31, 2000, 8,931,534 shares of convertible preferred stock and options to purchase 1,685,513 shares of common stock; and at December 31, 1999, 8,931,534 shares of convertible preferred stock and options to purchase 1,093,630 shares of common stock.

Recently Issued Accounting Standards

In October 2001, the Financial Accounting Standards Board (the "FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets* . SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 is effective for fiscal years beginning after December 15, 2002. The Company adopted the provisions of SFAS No. 144 on January 1, 2002, and does not expect SFAS No. 144 to have a material effect on its financial position or results of operations.

In June 2001, the FASB issued SFAS No. 141, *Business Combinations* and SFAS No. 142, *Goodwill and Other Intangible Assets*. 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 adopted SFAS No. 142 on January 1, 2002 and stopped amortizing goodwill that resulted from business combinations completed prior to June 30, 2001. The adoption of SFAS No. 141 and 142 did not have a material effect on the Company's financial position and results of operations.

In June 1998, the Financial Accounting Standards 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 became effective for the Company in fiscal year 2001. The Company generally 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.

2—SHORT-TERM INVESTMENTS

The following table represents the estimated fair value of the Company's short-term investments classified as available-for-sale securities at December 31, 2001 (in thousands):

	Cost at December 31, 2001	Gross Unrealized Gains	Gross Unrealized Losses	Fair market value at December 31, 2001
U.S. Government agency bonds	$ 22,659	$ 78	$ (2)	$ 22,735

3—INVENTORIES

Inventories consist of (in thousands):

	December 31,	
	2001	2000
Raw materials and subassemblies	$ 2,497	$ 1,017
Finished goods	1,101	1,177
Total	$ 3,598	$ 2,194

4— PROPERTY AND EQUIPMENT

Property and equipment consist of (in thousands):

	December 31,	
	2001	2000
Office furniture and equipment	$ 1,316	$ 1,074
Computer software and hardware	1,451	1,082
Demonstration and loaned equipment	1,231	734
Leasehold improvements	369	228
	4,367	3,118
Accumulated depreciation and amortization	(2,610)	(1,810)
Total	$ 1,757	$ 1,308

5— ACCRUED LIABILITIES

Accrued liabilities consist of (in thousands):

	December 31,	
	2001	2000
Compensation and related benefits	$ 1,315	$ 873
Warranty reserve	542	548
Accrued professional fees	167	551
Other	678	722
Total	$ 2,702	$ 2,694

6— CONVERTIBLE AND REDEEMABLE CONVERTIBLE PREFERRED STOCK

Upon the closing of the Company's initial public offering in July 2001, each outstanding share of preferred stock was converted into common stock on one-for-one basis. In accordance with the preferred stock rights, all preferred stock outstanding automatically converted into the conversion price at the time of the initial public offering.

Prior to the conversion, the Company had outstanding 1,241,841, 3,967,120, 2,490,181 and 1,232,392 shares of Series A convertible preferred stock and Series B, C and D redeemable convertible preferred stock, respectively. Changes in each class of convertible preferred stock from January 1, 1999 to December 31, 2001 are as follows (in thousands):

	Series A	Series B	Series C	Series D	Warrants for Series C	Total
Balances, January 1, 1999	$ 2,227	$ 11,050	$ 3,168	$ 4,151	$ 558	$ 21,154
Issuance of 344,652 shares of Series C redeemable convertible preferred stock upon exercise of warrants for cash	—	—	713	—	(110)	603
Issuance of 716,961 shares of Series C redeemable convertible preferred stock upon exercise of warrants, cashless—net of shares tendered at $3.50 per share	—	—	448	—	(448)	—
Accretion to redemption value of shares issued on exercise of warrants on Series C redeemable convertible preferred stock	—	—	696	—	—	696
Accretion to redemption value on Series B, C and D redeemable convertible preferred stock	—	714	391	284	—	1,389
Balances, December, 31, 1999	2,227	11,764	5,416	4,435	—	23,842
Accretion to redemption value on Series B, C and D redeemable convertible preferred stock	—	714	448	222	—	1,384
Balances, December 31, 2000	2,227	12,478	5,864	4,657	—	25,226
Accretion to redemption value on Series B, C and D redeemable convertible preferred stock	—	394	247	122	—	763
Conversion of preferred stock to common stock on initial public offering	(2,227)	(12,872)	(6,111)	(4,779)	—	(25,989)
Balances, December 31, 2001	$ —	$ —	—	—	$ —	$ —

7— STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

The Company has 120,000,000 shares of common stock authorized at a par value or $0.001 per share. On July 19, 2001, the Company completed an initial public offering of its shares pursuant to which it issued 5,750,000 common shares for proceeds of approximately $56,451,000, net of issuance costs.

Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized at a par value of $0.001 per share. In accordance with the terms of the certificate of incorporation, the Board of Directors is authorized to provide for the issuance of one or more series of preferred stock, including increases or decreases to the series. The Board of Directors has the authority to set the rights, preferences and terms of such shares. As of December 31, 2001, no shares of preferred stock were issued and outstanding.

Stock Option Plans

Effective August 2000, the Company adopted the 2000 Stock Option Plan (the "2000 Plan") and reserved 1,500,000 shares of common stock for issuance under the 2000 Plan. Each year beginning January 1, 2002, the aggregate number of shares reserved under the 2000 Plan will automatically increase by the lesser of (i) 1,500,000, (ii) 7% of the shares of common stock outstanding at the end of preceding year, or (iii) an amount determined by the Board of Directors. On January 1, 2002, the number of shares reserved under the 2002 Plan increased by 1,110,527 shares. The 2000 Plan provides for the granting of incentive stock options to employees and nonqualified stock options to employees, directors, and consultants.

Under the 2000 Plan, incentive and nonqualified stock options may be issued at not less than the fair market value of the stock at the date of grant, as determined by the Board of Directors. Options issued under the 2000 Plan become exercisable as determined by the Board of Directors and expire no more than ten years after the date of grant. Most options vest ratably over four years. For those optionees who, at the time the option is granted, own stock representing more than 10% of the voting power of all classes of stock of the Company, stock options may be issued at not less than 110% of the fair market value of the stock at the date of grant, and the options expire five years after the date of grant. At December 31, 2001, 1,176,000 shares were available for grant of future options under the 2000 Plan.

The Company also has the 1991 Stock Option Plan (the "1991 Plan") and the 2000 Supplemental Stock Option Plan (the "Supplemental Plan"), which provided for the granting of incentive stock options to employees and nonqualified stock options to employees and consultants. Options outstanding under the 1991 Plan and Supplemental Plan generally were governed by the same terms as those under the 2000 Plan. At the time of the Company's initial public offering, the 1991 Plan and Supplemental Plan was terminated such that no new options may be granted under these plans. Outstanding options at the date of the initial public offering remain outstanding under their original terms.

In addition, effective August 2000, the Company adopted the 2000 Director Option Plan (the "Director Plan"). The Director Plan provides for an initial grant to new nonemployee directors, options to purchase 30,000 shares of common stock. Subsequent to the initial grants, each nonemployee director will be granted an option to purchase 10,000 shares of common stock at the next meeting of the Board of Directors following the annual meeting of stockholders, if on the date of the annual meeting the director has served on the board of directors for six months. The Company reserved a total of 400,000 shares of common stock under the Director Plan, plus an annual increase to be added on the first day of the Company's fiscal year beginning January 1, 2002 equal to the lesser of (i) 100,000 shares, (ii) 0.5% of the shares of common stock outstanding on the last day of the preceding fiscal year, or (iii) an amount determined by the Board of Directors. At December 31, 2001, 310,000 shares were available for grant of future options under the Director Plan. On January 1, 2002, the number of shares reserved under the Director Plan increased by 79,323 shares.

A summary of option activity under various option plans is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 1999 (471,583 shares exercisable at a weighted average exercise price of $0.28 per share)	1,080,991	$ 0.68
Granted (weighted average fair value of $0.73 per share)	135,600	$ 2.25
Exercised	(82,057)	$ 0.80
Cancelled	(40,904)	$ 1.63
Outstanding, December 31, 1999 (668,006 shares exercisable at a weighted average exercise price of $0.58 per share)	1,093,630	$ 0.85
Granted (weighted average fair value of $5.28 per share)	985,820	$ 4.27
Exercised	(270,345)	$ 0.44
Cancelled	(123,592)	$ 3.13
Outstanding, December 31, 2000 (699,317 shares exercisable at a weighted average exercise price of $0.87 per share)	1,685,513	$ 2.73
Granted (weighted average fair value of $6.57 per share)	547,500	$ 6.82
Exercised	(268,357)	$ 0.50
Cancelled	(43,727)	$ 4.91
Outstanding, December 31, 2001 (793,027 shares exercisable at a weighted average exercise price of $2.31 per share)	1,920,929	$ 4.16

The following table summarizes information concerning outstanding and exercisable options outstanding at December 31, 2001:

Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Number Exercisable
$ 0.25	181,933	5.12	181,933
$ 1.00	92,942	6.02	91,126
$ 1.50	411,368	8.29	197,269
$ 1.88	96,474	6.64	83,323
$ 2.25	107,950	7.46	72,902
$ 4.55	54,000	9.80	—
$ 4.90	100,000	9.83	—
$ 5.00	10,800	8.49	3,875
$ 5.69	162,000	9.81	—
$ 6.25	540,942	8.99	150,939
$ 8.13	20,000	9.30	—
$10.00	44,520	7.89	11,660
$11.00	90,000	9.55	—
$14.38	8,000	9.64	—
	1,920,929		793,027

The Company continues to account for its stock-based awards to employees using the intrinsic value method in accordance with APB No. 25 as interpreted by FIN 44, which, among other things, clarifies the definition of an employee for purposes of applying APB 25, the criteria for determining whether a plan qualifies as a non-compensatory plan, and the accounting consequence of various modifications to the terms of a previously fixed stock option award. However, SFAS No. 123 requires the disclosure of pro forma net loss as if the Company had adopted the fair value method. Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of the option pricing models.

For purposes of pro forma disclosures, the estimated fair value of stock-based awards is amortized against pro forma net income over the stock-based awards' vesting period for options and over the offering period for stock purchases under the Company's various stock option plans. If the computed fair values of the Company's awards had been amortized to expense over the related vesting periods, pro forma net loss and net loss per share, basic and diluted, would have been as follows (in thousands):

	Years Ended December 31,		
	2001	2000	1999
Net loss available to common stockholders:			
As reported	$(4,646)	$(1,149)	$(1,441)
Pro forma	$(5,094)	$(1,367)	$(1,544)
Basic and diluted net loss per share:			
As reported	$ (0.62)	$ (1.62)	$ (2.56)
Pro forma	$ (0.68)	$ (1.93)	$ (2.75)

Fair values of the options granted under the stock option plans were estimated at grant dates using a Black-Scholes option pricing model. The Company used the multiple option award approach and the following assumptions:

	Years Ended December 31,		
	2001	2000	1999
Expected life in years—Stock options	5.5 years	5.5 years	5.5 years
Expected life in years—ESPP	0.5 years	—	—
Risk free interest rate—Stock options	4.5%	6.0%	6.0%
Risk free interest rate—ESPP	1.0%	—	—
Expected volatility	118%	88%	(1)
Dividend yield	None	None	None

(1) As the Company was privately held until July 2001, volatility was not applicable until filing its initial Registration Statement on August 19, 2000 as the Company utilized the minimum value method.

Employee Stock Purchase Plan

In August 2000, the Board of Directors approved the adoption of the 2000 Employee Stock Purchase Plan (the "Purchase Plan") and reserved 1,000,000 shares of the Company's common stock for issuance under the Purchase Plan. Each year, beginning January 1, 2002, the aggregate number of shares reserved for issuance under the Purchase Plan will automatically increase by a number of shares equal to the lesser of (i) 650,000, (ii) 4% of the shares of common stock outstanding on the last day of the preceding fiscal year or (iii) an amount determined by the Board of Directors. The Purchase Plan adoption became effective at the time of the initial public offering.

Under the Purchase Plan, eligible employees are allowed to have salary withholdings of up to 15% of their base compensation to purchase shares of common stock at a price equal to 85% of the lower of the market value of the stock at the beginning or end of defined purchase periods. There were 46,745 shares issued under the Purchase Plan in 2001. At December 31, 2001, 953,255 shares were reserved for future issuance under the Purchase Plan. On January 1, 2002, the number of shares reserved under the Purchase Plan increased by 634,587 shares.

Deferred Stock Compensation

In connection with the grant of stock options to employees through December 31, 2001, the Company recorded deferred stock compensation of $2,659,000 for the aggregate differences between the exercise prices of options at their dates of grant and the deemed fair value for accounting purposes of the common shares subject to these options. Such amount is included as a reduction of stockholders' equity and is being amortized on a graded vesting method over the option vesting periods, which are generally four years.

8—LEASES

The Company has entered into noncancelable operating leases for its facilities through December 2003. Minimum lease payments under noncancelable operating leases as of December 31, 2001 are as follows (in thousands):

	Operating Leases
Year Ending December 31,	
2002	656
2003	601
Total minimum lease payments	$ 1,257

Rent expense totaled approximately $745,000, $574,000, $413,000 in 2001, 2000 and 1999, respectively.

9—INCOME TAXES

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2001 and 2000 are as follows (in thousands):

	December 31,	
	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 3,395	$ 2,377
Accruals deductible in different periods	989	974
Capitalized research and development costs for California	254	289
Credit carryforwards	551	397
Stock compensation expense on nonqualified stock options	97	121
Total net deferred tax assets	5,286	4,158
Valuation allowance	(5,286)	(4,158)
Total	$ —	$ —

The Company's amount of income tax recorded differs from the amount using the federal statutory rate as follows (in thousands):

	Years Ended December 31,		
	2001	2000	1999
Federal statutory tax expense (benefit)	$(1,335)	$ 98	$ 229
State tax expense (benefit)	(219)	16	38
Valuation allowance	1,070	(41)	(361)
Stock compensation expense on incentive stock options	447	279	—
Other	105	(306)	104
	$ 68	$ 46	$ 10

At December 31, 2001, the Company had federal net operating loss carryforwards of approximately $8.0 million and state net operating loss carryforwards of approximately $1.7 million available to reduce future taxable income. The federal net operating loss carryforwards expire beginning in 2003 through 2021, and the state net operating loss carryforwards expire through 2009. At December 31, 2000, the Company had research and experimentation credit carryforwards available of approximately $379,000 for federal tax purposes that expire through 2021 and $172,000 for California tax purposes which do not expire over time.

The extent to which the federal and California operating loss and tax credit carryforwards can be used to offset future taxable income may be limited, depending on the extent of ownership changes within any three-year period, as provided in the Tax Reform Act of 1986. Such a limitation could result in the expiration of carryforwards before they are utilized.

10—EMPLOYEE BENEFIT PLAN

The Company has a 401(k) tax-deferred savings plan under which eligible employees may elect to have a portion of their salary deferred and contributed to the plan. Employer matching contributions are determined by the Board of Directors and are discretionary. There was no employer matching contributions in 2001 or 1999. For the year ending December 31, 2000, the Board of Directors approved a dollar-for-dollar employer match of up to $500 per employee on employee contributions, which resulted in the aggregate employer contributions of $46,000 in 2000. Employer contributions vest ratably over four years from date of employment.

11—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 processes as well as type of customers and distribution methods are consistent among all of the Company's devices.

Revenues from customers by geographic area are as follows (in thousands):

	Years Ended December 31,		
	2001	2000	1999
Revenues:			
United States	$ 22,683	$ 21,306	$ 17,804
Japan	3,410	2,703	1,717
All other	1,308	624	262
	$ 27,401	$ 24,633	$ 19,783

At December 31, 2001, the long-lived assets located outside the United States with the Company's foreign subsidiaries totaled approximately $150,000, and the remainder was located within the United States. At December 31, 2000, all of the Company's long-lived assets were located within the United States.

In 2000, sales to a distributor accounted for 11% of revenues. In 2001 and 1999, no sales to a single customer accounted for greater than 10% of revenues.

EXHIBIT INDEX

Exhibit No.	Exhibit Title
3.1.1	(b) Certificate of Incorporation
3.1.2	(b) Certificate of Amendment to Certificate of Incorporation
3.2	(b) Bylaws of the Registrant
10.1	(b) Form of Indemnification Agreement between the Registrant and each of its directors and officers
10.2	(b) Amended and Restated 1991 Stock Option Plan
10.2.1	(b) Form of Option Agreement under the 1991 Stock Option Plan
10.3	(b) 2000 Stock Option Plan
10.3.1	(b) Form of Option Agreement under the 2000 Stock Option Plan
10.4	(b) 2000 Director Option Plan
10.4.1	(b) Form of Option Agreement under 2000 Director Option Plan
10.5	(b) 2000 Employee Stock Purchase Plan and form of subscription agreement thereunder
10.6	Reserved
10.6.1	Reserved
10.6.2†	(b) Transition Agreement dated as of July 28, 2000 between Registrant, Nippon Eurotec Co. Ltd., Toshibumi Wakayama, Masaaki Kuroiwa and Kenji Tomita
10.7†	(b) Patent License Agreement dated June 30, 1998 between Registrant and The Leland Stanford Junior University
10.8	(b) Lease Agreement dated August 24, 1998 between Registrant and San Carlos Co-Tenancy.
10.9	(b) Promissory Note dated March 24, 1999 between Scott Valley Bank and Tim C. Johnson
10.9.1	(b) Assignment of Deposit Account dated March 24, 1999 between Registrant, Scott Valley Bank and Tim C. Johnson
10.9.2	(b) Security Agreement dated March 26, 1999 between Registrant and Tim C. Johnson
10.10†	(b) Capital Equipment Supplier Agreement dated June 25, 1999 between the Registrant and Novation, LLC
10.11†	(b) Manufacturing Agreement dated December 3, 1998 between Registrant and TriVirix International, Inc. (formerly CMA International, Inc.)
10.12	Reserved
10.13	Reserved
10.14†	(b) Memorandum of Understanding dated December 7, 2000 between Registrant and the Ludlow Company LP
10.15	(b) 2000 Supplemental Stock Option Plan
10.15.1	(b) Form of Option Agreement for 2000 Supplemental Stock Option Plan
10.16	(b) Lease dated March 3, 2000 between W&G Properties Limited, Neonatal Perspectives Limited and Andrew Vincent for the premises located at Unit 9, Northmill, Buckinghamshire, United Kingdom
10.17	Reserved
10.17.1	Reserved
10.17.2	Reserved
10.17.3	Reserved

Exhibit No.	Exhibit Title
10.17.4	Reserved
10.18	(c) Leasing Agreement dated June 11, 2001 between Natus Japan and Sanwa Radiator Co. Ltd. (Japanese to English translation)
21.1	(b) Subsidiaries
23.1	(a) Independent Auditors' Consent
24.1	(a) Power of Attorney (see p. 55)

† Portions of this agreement have been omitted pursuant to a request for confidential treatment and the omitted portions have been filed with the Securities and Exchange Commission.

(a) Filed herewith.

(b) Incorporated by reference to the exhibit bearing the same number filed with the Registrant's Registration Statement on Form S-1 (Registration Statement 333-39891), which the Securities and Exchange Commission declared effective on July 19, 2001.

(c) Incorporated by reference to the exhibit bearing the same number filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

Exhibit 23.1

INDEPENDENT AUDITORS' CONSENT

To the Board of Directors and Stockholders of
Natus Medical Incorporated:

We consent to the incorporation by reference in Registration Statement No. 333-65584 of Natus Medical Incorporated and subsidiaries on Form S-8 of our report dated February 5, 2002 appearing in this report on Form 10-K of Natus Medical Incorporated and subsidiaries for the year ended December 31, 2001.

/s/ Deloitte & Touche LLP

San Jose, California
March 25, 2002