NATUS MEDICAL INC
Form 10-K
March 14, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2011**

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) 802 0400

(Registrant s telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value per share	The NASDAQ Stock Market LLC
	(Nasdaq Global Select Market)

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

As of June 30, 2011, the last business day of Registrant s most recently completed second fiscal quarter, there were 29,130,586 shares of Registrant s common stock outstanding, and the aggregate market value of such shares held by non-affiliates of Registrant (based upon the closing sale price of such shares on the Nasdaq Global Select Market on June 30, 2011) was $330,253,865. Shares of Registrant s common stock held by each executive officer and director and by each entity that owns 5% or more of Registrant s outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 7, 2012, the registrant had 29,444,772 shares of its common stock 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 2012 Annual Meeting of Stockholders.

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NATUS MEDICAL INCORPORATED

ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1. Business

This Annual Report on Form 10-K 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 effectiveness and advantages of our products, factors relating to demand for and economic advantages of our products, our plan to develop and acquire additional technologies, products or businesses, our marketing, technology enhancement, and product development strategies, and our ability to complete all of our backlog orders.

Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results to differ materially from those that we predicted in the forward-looking statements. Investors should carefully review the information contained under the caption Risk Factors contained in Item 1A for a description of risks and uncertainties that could cause actual results to differ from those that we predicted. 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, except as required by Federal Securities laws.

Natus®, AABR®, ABaer®, ALGO®, AOAE®, AuDX®, Balance Manager®, Balance Master®, Biliband®, Bio-logic®, Ceegraph®, CHAMP®, Cochlea Scan®, Cool Cap®, Ear Couplers®, Echo Screen®, Embla®, Embletta®, Enterprise®, EquiTest®, Fischer-Zoth®, Flexicoupler®, Gumdrop®, Keypoint®, Keypoint AU®, Keypoint EU®, Keypoint JP®, MASTER®, Medix®, MedixI.C.S.A®, Navigator®, Neatnick®, neoBLUE®, Neuromax®, NeuroWorks®, Oxydome®, REMbrandt®, REMlogic®, Sandman®, Sleeprite®, Sleepscan®, Smart Scale®, Tootsweet®, Traveler®, Warmette® and VAC PAC®, Xact Trace®, are registered trademarks of Natus Medical Incorporated and its subsidiaries. Accuscreen , Bili Lite Pad , Bili-Lite , Biomark , Circumstraint , Coherence , Deltamed , inVision , Medix MediLED , MiniMuffs , NATUS NatalCare , Neometrics Smartpack are non-registered trademarks of Natus and its subsidiaries. Solutions for Newborn CareSM is a non-registered service mark of Natus.

Overview

Natus is a leading provider of healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and balance and mobility disorders. Product offerings include computerized neurodiagnostic systems for audiology, neurology, polysomnography, and neonatology, as well as newborn care products such as hearing screening systems, phototherapy devices for the treatment of newborn jaundice, head-cooling products for the treatment of brain injury in newborns, incubators to control the newborn s environment, and software systems for managing and tracking disorders and diseases for public health laboratories.

We have completed a number of acquisitions since 2003, consisting of either the purchase of a company, substantially all of the assets of a company, or individual products or product lines. Our significant acquisitions are as follows: Neometrics in 2003; Fischer-Zoth in 2004; Bio-logic, Deltamed, and Olympic in 2006; Xltek in 2007; Sonamed, Schwarzer Neurology, and Neurocom in 2008, Hawaii Medical and Alpine Biomed in 2009, Medix in 2010, and Embla in 2011.

Product Families

We categorize our products into the following product families:

Hearing Includes products for newborn hearing screening and diagnostic hearing assessment.

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Neurology Includes products for diagnostic electroencephalography (EEG), diagnostic sleep analysis, or polysomnography (PSG), electromyography (EMG), intra-operative monitoring (IOM), newborn brain monitoring, and assessment of balance and mobility disorders.

Newborn Care Includes thermoregulation devices and products for the treatment of brain injury and jaundice in newborns.

Our principal product offerings within these product families are presented in the table on the following page.

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Our Product Offerings

Hearing

Newborn Hearing Screening

Overview

Hearing impairment is the most common treatable chronic disorder in newborns, affecting as many as five babies out of every 1,000 newborns. It is estimated that 20,000 hearing-impaired babies are born in the United States (U.S.) every year, and as many as 60,000 more in the rest of the developed world. Until the introduction of universal newborn hearing screening programs, screening was generally performed only on those newborns that had identifiable risk factors for hearing impairment. 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. Undetected hearing impairment often results in the failure to learn, process spoken language, and speak. If hearing impairment is not detected prior to discharge from the hospital it is often not detected until the child is 18 months of age or older. 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 early and who received appropriate treatment had significantly better language skills and vocabularies than those children whose hearing loss was detected later.

Newborn Hearing Screening Techniques

The two traditional technologies used to screen newborns and infants for hearing impairment are auditory brainstem response and otoacoustic emissions.

Auditory brainstem response (ABR). ABR technology is the most accurate and comprehensive method for screening and diagnosing hearing impairment. ABR technology is based on detecting the brain s electric impulses resulting from a specific auditory stimulus. ABR screening devices, used for newborn hearing screening, detect and analyze the brainwave response resulting from audible click stimuli presented to the infant s ears. Automated Auditory Brainstem Response (AABR) devices were developed to automatically analyze the ABR waveform resulting from the auditory stimuli with computerized detection algorithms and statistical analysis. These devices can be used by any level of hospital personnel with a minimal amount of training and will deliver a clinically valid and accurate screen. The detection algorithms indicate a PASS or REFER result that requires no interpretation, thereby reducing staffing requirements, test times, and total hearing screening program costs. A REFER test result indicates that the patient should be referred to an Audiologist or Ear, Nose and Throat Physician (ENT) for further diagnostic evaluation.

Otoacoustic emission (OAE). OAEs are sounds created by the active biomechanical processes within the sensory cells of the cochlea. They occur both spontaneously and in response to acoustic stimuli. OAE screening uses a probe placed in the ear canal to deliver auditory stimuli and to measure the response of the sensory cells with a sensitive microphone. OAE screening devices have technology that allows them to discriminate between randomly occurring OAEs, OAEs created by interfering room noise present in the test environment, and the OAEs that are a response to specific test stimuli. Automated OAE screening devices are capable of filtering non-specific OAEs in order to detect and analyze the OAEs that lead to an accurate screen of the infant s hearing. While a PASS test result indicates a proper functioning cochlea, a REFER test result indicates that the OAEs are absent or small compared to normal data. A REFER test result indicates that the patient should be referred to an Audiologist or ENT for further diagnostic evaluation. OAE technology is unable to detect hearing disorders affecting the neural pathways, such as auditory neuropathy. Estimates of the incidence rate of auditory neuropathy among hearing impaired newborns vary widely, but are thought to be in the range of 5% to 15%.

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Newborn Hearing Screening Product Lines

Our newborn hearing screening product lines consist of the ALGO, ABaer, AuDX, and Echo-Screen newborn hearing screeners. These hearing screening products utilize proprietary signal detection technologies to provide accurate and non-invasive hearing screening for newborns and are designed to detect hearing loss at 35 dB nHL or higher. Each of these devices is designed to generate a PASS or REFER result.

ALGO 5 and 3i Newborn Hearing Screeners. These AABR devices deliver thousands of soft audible clicks to the newborn s ears through sound cables and disposable earphones connected to the instrument. Each click elicits an identifiable brain wave, which is detected by disposable electrodes placed on the head of the child and analyzed by the screening device. These devices use our proprietary AABR signal detection algorithm.

ABaer Newborn Hearing Screener. The ABaer, which is a PC-based newborn hearing screening device, offers a combination of AABR, OAE, and diagnostic ABR technologies in one system. The automatic ABR technology utilizes our patented Point Optimized Variance Ratio (POVR) signal detection algorithm developed by the House Ear Institute. Like our ALGO newborn hearing screeners, this device delivers thousands of soft audible clicks to the newborn s ears through sound cables and disposable earphones. Each click elicits an identifiable brain wave, which is detected by disposable electrodes placed on the head of the child and analyzed by the screening device. The ABaer OAE software is the same technology used in our AuDX product and the diagnostic ABR software is the same technology used in our Navigator diagnostic hearing assessment product.

AuDX and Echo-Screen. Our AuDX product is a hand-held OAE screening device that can be used for newborn hearing screening, as well as for patients of all ages, from children through adults. Our Echo-Screen product is a hand-held combination AABR and OAE device for newborn screening that can also used for children through adults in OAE-only mode. These devices record and analyze OAEs generated by the cochlea through sound cables and disposable ear probes inserted into the patient s ear canal. OAE technology is unable to detect hearing disorders affecting the neural pathways, such as auditory neuropathy.

Hearing Screening Supply Products

For infection control, accuracy, and ease of use, the supply products used with our newborn hearing screening devices are designed as single-use, disposable products. Each screening supply product is designed for a specific hearing screening technology.

ABR Screening Supply Kits. Each ABR screen is carried out with single-use earphones and electrodes, which are alcohol and latex-free. The adhesives used in these supply products are specially formulated for use on the sensitive skin of newborns. To meet the needs of our customers we offer a variety of packaging options.

OAE Supply Products. Each OAE screen is carried out with single-use ear tips that are supplied in a variety of sizes and packaging options.

Diagnostic Hearing Assessment

Overview

We design and manufacture a variety of products used to screen for or diagnose hearing loss, or to identify abnormalities affecting the peripheral and central auditory nervous systems in patients of all ages. The technology used in most of these systems is either electrodiagnostic in nature or measures a response from the cochlea known as an OAE.

Electrodiagnostic systems record electrical activity generated in the central nervous system. An electrodiagnostic testing device delivers acoustic stimuli to the ears while electrodes placed on the scalp record the brain s electrical response. The most common auditory test performed with electrodiagnostic equipment is

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the ABR test. This test, which records brainwaves that correspond to responses from the inner ear and brainstem, is used to screen for and define hearing loss characteristics, particularly for patients who cannot reliably respond to standard behavioral tests of hearing, either verbally or through motor response. A technician with minimal training can operate an instrument that performs an automated ABR screening test. More advanced ABR testing techniques that either define the nature of the hearing loss or that screen for other auditory abnormalities such as an acoustic tumor, require the expertise of a trained clinician, usually an audiologist or an ENT physician, an understanding of the technology being used, and the ability to interpret complex waveforms that represent the brain s electrical activity.

In the follow up evaluation of newborns diagnosed with hearing impairment, the clinician can distinguish between hearing impairments caused by mechanical or sensory dysfunction of the ear versus auditory neuropathy. Recent studies confirm the importance of making this distinction, as appropriate treatments for these impairments differ. One study showed that for patients diagnosed with auditory neuropathy, approximately 15% reported some benefit from hearing aids for language learning, while improvement in speech comprehension and language acquisition was reported in 85% of patients who received cochlear implants.

Diagnostic Hearing Assessment Product Lines

Our diagnostic hearing assessment products consist of the Navigator Pro system, the Scout Sport portable diagnostic device, and the AuDX PRO.

Navigator PRO. Our Navigator PRO for hearing assessment consists of a base system that is augmented by discrete software applications that are marketed as enhancements to the system. The Navigator Pro System is a PC-based, configurable device that utilizes evoked potentials, which are electrical signals recorded from the central nervous system that appear in response to repetitive stimuli, such as a clicking noise. The evoked potentials are used to record and display human physiological data associated with auditory and hearing-related disorders. The Navigator Pro System can be used for patients of all ages, from children to adults, including infants and geriatric patients. The device can be configured with additional proprietary software programs for various applications. These additional software programs include: MASTER, AEP, ABaer, and Scout.

Scout SPORT. The Scout SPORT is a PC-based OAE system. The ultra-portable Scout Sport can be carried from one computer to another to test in different locations. For office-based environments, the Scout Sport can be used with a dedicated notebook computer to create an independent portable system.

AuDX PRO. The AuDX PRO is a hand-held OAE screening device with a large color display that can be used for patients of all ages. The AuDX PRO records and analyzes OAEs generated by the cochlea through sound cables and disposable ear probes inserted into the patient s ear canal.

Diagnostic Hearing Supply Products

For infection control, accuracy, and ease of use, most supply products used with our diagnostic hearing devices and systems are designed as single-use, disposable products. Each screening supply product is designed for a specific diagnostic hearing technology, and is similar in nature to our previously described OAE supply products for use in newborn hearing screening.

Neurology

Our monitoring systems for neurology represent a comprehensive line of products that are used by physicians, nurses and medical technologists to assist in the diagnosis and monitoring of neurological disorders of the central and peripheral nervous system and as an aid in monitoring patients during surgery, while under sedation, or in post-operative care. Our product lines consist of the following:

Electroencephalography or EEG Equipment that monitors and visually displays the electrical activity generated by nerve cells in the brain for both diagnosis and monitoring of neurological disorders in the hospital, laboratory, office or patient s home.

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Electromyography or EMG Equipment that measures electrical activity in nerves, muscles, and the spinal cord.

Polysomnography or PSG Equipment that measures a variety of respiratory and neurological functions to assist in the diagnosis and monitoring of sleep disorders, such as snoring and obstructive sleep apnea, a condition that causes a person to stop breathing intermittently during sleep.

Intra-operative Monitoring or IOM Products that assist surgeons in preserving the functional integrity of a patient s nervous system during and after complex surgical procedures.

Balance and Mobility Systems to diagnose and assist in treating balance disorders in an evidence-based, multidisciplinary approach.

Diagnostic EEG Monitoring

Overview

We design, manufacture, and market a full line of computerized instruments used to help diagnose the presence of seizure disorders and epilepsy, look for causes of confusion, evaluate head injuries, tumors, infections, degenerative diseases, and metabolic disturbances that affect the brain, and assist in surgical planning. This type of testing is also done to diagnose brain death in comatose patients. These systems and instruments work by detecting, amplifying, and recording the brain s electrical impulses (EEGs). Routine EEG recording is done by placing electrodes on a patient s scalp over various areas of the brain to record and detect patterns of activity and specific types of electrical events. EEG technologists perform the tests, and neurologists review and interpret the results.

Routine outpatient EEG testing is performed in both hospital neurology laboratories and private physician offices, providing physicians with a clinical assessment of a patient s condition. For patients with seizures that do not respond to conventional therapeutic approaches, long-term inpatient testing of EEGs and behavior is used to determine if surgical solutions are appropriate.

Diagnostic Electroencephalograph Monitoring Product Lines

Our diagnostic EEG monitoring product lines for neurology consist of devices operating with our proprietary software, augmented by signal amplifiers. These products are typically used in concert, as part of an EEG system by the neurology department of a hospital to assist in the diagnosis of assorted neurological conditions.

NeuroWorks; Ceegraph; Coherence; Harmonie. Our computerized EEG Systems include a broad range of products, from software licenses and ambulatory monitoring systems to advanced laboratory systems with multiple capabilities for EEG, ICU monitoring, long-term epilepsy monitoring of up to 256 channels, and physician review stations with quantitative EEG analysis capabilities.

Stellate/Gotman Spike and Seizure; GridView. Our proprietary Spike and Seizure detection algorithm detects, summarizes, and reports EEG events that save health care professionals time by increasing the
speed and accuracy of interpretation. GridView is a tool that allows the clinician to correlate EEG patterns with electrode contacts on a 3D view of the patient brain using magnetic resonance (MR) or computed tomography (CT) images, thus enabling the visualization and annotation of the brain surface and internal structures involved in the diagnosis of epilepsy.

Proprietary Signal Amplifiers. Our proprietary signal amplifiers function as the interface between the patient and the computer, and are also known as the headbox. The headbox connects electrodes attached to the patient s head to our EEG monitoring systems. Our proprietary headbox products are sold for a wide variety of applications under the following brand names: Xltek, Trex, EEG32, EMU128, EMU40, Brain Monitor, and Schwarzer epas. Recent innovations in electronics technology and advanced

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internet-protocol data transmission enable certain of our amplifiers to record and transmit up to 32 channels of digital data using Ethernet communication.

Several additional options are available to enhance our EEG products, including a digital video option, which provides synchronized video recording of a patient s behavior while recording electrical activity from the brain, our patented SmartPack software option, which is an innovative data compression process that reduces the size of data files by as much as 60%, and our Universal Reader which is a physician s review station that permits fast and easy data analysis in a graphical format.

Diagnostic Electromyography Monitoring

Overview

Electromyography (EMG) involves the measurement of electrical activity of muscles both at rest and during contraction. Measuring the electrical activity in muscles and nerves can help diagnose diseases of the peripheral nervous or musculature system. An electromyogram is done to determine if there is any disease present that damages muscle tissue, nerves, or the junctions between nerve and muscle (neuromuscular junctions). An electromyogram can also be used to diagnose the cause of weakness, paralysis, and muscle twitching and is also used as a primary diagnosis for carpal tunnel syndrome, which is the most frequently encountered peripheral compressive neuropathy.

Diagnostic EMG Product Lines

Xltek NeuroMax. A dedicated EMG device focused entirely on signal quality and clinical efficiency. The device gathers neurophysiological data that is saved to a fully customizable report, allowing physicians to care for patients with the most informed advice.

Xltek XCalibur. An EMG system that uses advanced circuit design and digital signal processing to deliver clean signals, making the process of acquiring patient data reliable and quick. The system provides enhanced data acquisition, reporting, and review capabilities.

Dantec Keypoint. The Dantec Keypoint EMG and EP family of products feature superior amplifiers, stimulators, and outstanding signal quality. The Keypoint is used for advanced neurodiagnostic applications such as single fiber EMG, visual and auditory evoked potentials, and in routine nerve conduction studies. The Keypoint system is also available in a portable laptop configuration.

Dantec Clavis. The Dantec Clavis device is a hand-held EMG and current stimulation (STIM) device that provides muscle and nerve localization information to assist with botulinum toxin injections (i.e. Botox). In conjunction with the Bo-ject hypodermic needle and electrodes, it delivers a precise dose of the agent.

Schwarzer Topas. The Topas system offers a wide range of sophisticated EMG and evoked potential (EP) examination protocols, as well as an attractive and functional design. The Topas system can be configured as a two or four channel system, as trolley-based or portable version, depending on the needs of the hospital or private practice.

Diagnostic Polysomnography Monitoring

Overview

Increasing public awareness of sleep disorders has made sleep medicine a rapidly growing specialty. Polysomnography (PSG), which involves the analysis of respiratory patterns, brain electrical activity and other physiological data, has proven critical for the diagnosis and treatment of sleep-related diseases such as apnea, insomnia, and narcolepsy. A sleep study entails whole-night recordings of brain electrical activity, muscle movement, airflow, respiratory effort, oxygen levels, electrical activity of the heart (ECG or EKG), and other parameters. These

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recordings typically result in over 1,000 pages of data that are reviewed, analyzed, and scored by a technician, and summarized in a report for the physician. We market configured laboratory systems, portable systems, and ambulatory recorders for home monitoring.

Diagnostic PSG Monitoring Product Lines

Our diagnostic PSG monitoring products can be used individually or as part of a networked system for overnight sleep studies to assist in the diagnosis of sleep disorders. These products include software licenses, ambulatory monitoring systems, and laboratory systems that combine multiple capabilities, including EEG monitoring, physician review stations, and quantitative EEG analysis capabilities.

Embla REMlogic, Sandman and REMbrandt; Sleepscan; SleepWorks; Coherence; Harmonie. Our diagnostic PSG systems capture and store all data digitally and provide time-saving features and software for acquiring and analyzing the data. The systems enable users to specify rules and personal preferences to be used during analysis, summarizing the results graphically and incorporating them in detailed reports. Software packages include customized analysis, tools and interfaces with third party equipment.

Proprietary Amplifiers. Our data acquisition systems incorporate recent developments in superior amplifiers for sleep analysis. Sold under the brand names Embla N7000, S4500, SD32 and Embletta Gold, Xltek Trex and Connex, Schwarzer epas duo 44 and comlab PSG, our amplifiers are used in both hospitals and stand-alone clinics. In addition to exceptional signal quality, headboxes include various tools such as built-in oximeters, and controls to allow the user to start and stop a study or perform electrode impedance testing either at the patient s bedside or from the monitoring room.

Practice Management Software. Our Enterprise Practice Management Software provides a solution for institutions as well as private labs and physicians to patient scheduling, inventory control, staff scheduling, data management, business reports and billing interfaces. Enterprise may be used across the entire Natus PSG family of Software solutions.

We also market a broad line of disposable products and accessories for the PSG laboratory. The Airflow Pressure Transducer uses pressure changes as an indicator of patient airflow levels, as contrasted to other monitoring devices that use temperature to indicate these levels. This product detects shallow breathing in situations where temperature related transducers might remain substantially unchanged. The Embla XactTrace RIP belts provide industry standard signal acquisition of respiration while its associated algorithm provides passive backup to airflow acquisition devices. This reduces the number of unattended portable studies which have to be repeated due to the loss of airflow signal.

Intra Operative Monitoring

Overview

Intra-operative monitoring (IOM) is the use of electrophysiological methods such as EMG and EEG to monitor the functional integrity of neural structures (i.e. brain, nerves, spinal cord) during surgery. The most common applications are in neurosurgery such as spinal surgery, some brain surgeries, ENT procedures, and peripheral nerve surgery. IOM is used to localize neural structures and test the function of these structures for early detection of intra-operative injury, allowing for immediate corrective measures.

Intra-operative Monitoring Products

Protektor. The Protector system is an IOM system that provides medical professionals with all information necessary to make immediate and critical surgical decisions. The system combines flexibility with multi-modality allowing full coverage of IOM techniques. The Protektor is available in a 16 or 32 channel configuration.

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Balance and Mobility

Overview

Balance disorders impact a large percentage of the population in all age ranges from children to adults. Common complaints include dizziness, vertigo, or an inability to walk or drive a vehicle, which can all lead to the curtailment of daily life activities. These symptoms are exacerbated in elderly patients and can result in falls, orthopedic injuries, and sometimes death.

Balance problems are difficult to diagnose and treat because they can be caused by a combination of diseases or movement dysfunctions. Healthcare professionals who take a traditional clinical approach to the examination and treatment of balance problems typically explore one component of the balance system at a time. This approach often requires patients to consult multiple specialists, leading to patient dissatisfaction and increased health care costs, frequently without achieving an optimal outcome.

We believe the most effective strategy for diagnosing and treating balance disorders is an evidence-based, multidisciplinary approach applying a broad range of patient information. Our Balance Manager systems are designed to facilitate the assessment and management of complex balance problems in the context of the total patient to support this process. These systems are used in a broad spectrum of medical disciplines including otolaryngology, neurology, physiatry, orthopedics/sports medicine, geriatrics, and physical rehabilitation.

Balance and Mobility Products

Our principal balance and mobility products are sold under the Neurocom brand:

EquiTest. Proprietary protocols in the EquiTest family of devices objectively quantify and differentiate among sensory, motor, and central adaptive impairments to balance control. This approach is commonly referred to as computerized dynamic posturography (CDP). CDP is complementary to clinical tests designed to localize and categorize pathological mechanisms of balance disorders in that it can identify and differentiate the functional impairments associated with the identified disorders.

Balance Master. A family of devices providing objective assessment and retraining of the sensory and voluntary motor control of balance. With visual biofeedback on either a stable or dynamic support surface and in a stable or dynamic visual environment, the clinician can both assess and retrain patients performing tasks ranging from essential daily living activities through high-level athletic skills. The objective data captured by the device supports the design of effective treatment and/or training programs focused on the specific sensory and motor components underlying a patient s functional limitations.

inVision. Our inVision device incorporates a set of proprietary diagnostic tests that quantify a patient s ability to maintain visual acuity and stable gaze while actively moving the head. The objective information enables the clinician to assess the patient s ability to live and move safely in a dynamic world and to participate in daily-life functions such as driving, walking through a grocery store, or actively engaging in family activities.

VSR and VSR Scout. The VSR provides objective assessment of sensory and voluntary motor control of balance with visual biofeedback. The VSR system is ideal for use in the rehabilitation balance program model. The VSR SPORT is primarily used as part of a concussion management program. It is portable, easy-to use and offers athletic trainers, sports medicine practitioners, and other sport professionals the data they need to make objective return-to-play decisions without relying on subjective evaluation.

Newborn Care

Newborn Care Products

We manufacture a wide variety of products used in the medical care of newborns. These product lines include products to diagnose and treat newborn brain injury, as well as phototherapy lights to treat newborn

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jaundice. We also sell a variety of newborn care products to meet the needs of clinicians in the nursery and the Neonatal Intensive Care Unit (NICU). With our recent acquisition of Medix, we now offer a full range of thermoregulation devices use for the care of newborns.

Newborn Brain Injury

Overview

For many years, newborn infants admitted to the NICU of a hospital have routinely been monitored for heart activity, temperature, respiration, oxygen saturation, and blood pressure. Only recently has it also been considered important to monitor brain activity using continuous EEG. A cerebral function monitor, utilizing amplitude-integrated EEGs (aEEGs), is a device for monitoring background neurological activity.

Neurological Assessment and Treatment Options

Early diagnosis of brain injury in newborns, when combined with early intervention, has been shown to reduce the severity of these brain injuries and in some cases, save the patient s life. These brain injuries, which can occur in as many as three out of every 1,000 newborns, are caused by conditions such as hypoxic ischemic encephalopathy (HIE), subclinical seizures, or neurological disorders. Diagnosing these conditions shortly after birth is imperative, as patients who undergo therapy within six hours after birth show a greater potential for improved outcomes. We believe that diagnoses utilizing aEEG technology can have a marked and positive impact upon the outcomes of some newborns suffering from brain injury.

Newborn Brain Injury Diagnostic Products

Our newborn brain injury diagnostic products record and display parameters that the neonatologist uses to diagnose neurological disorders or brain injury in the newborn. These devices continuously monitor and record brain activity, aiding in the detection and treatment of HIE and seizures. The devices also monitor the effects of drugs and other therapies on brain activity and improve the accuracy of newborn neurological assessments. They are used with electrodes attached to the head of the newborn to acquire an EEG signal that is then filtered, compressed, and displayed graphically on the device or as a hardcopy printout. The monitors have touch screens for easy navigation and onscreen keyboards for data entry at the bedside.

Olympic Brainz Monitor. The Olympic Brainz Monitor (OBM) is our latest generation Cerebral Function Monitor (CFM). The device can be used as a single channel, two-channel or three-channel device to continuously monitor and record brain activity. The OBM displays up to three channels of both aEEG and EEG data. Sophisticated networking, archiving and viewing functions facilitate consultation among medical professionals. Continuous impedance and corresponding EEG signals are also displayed, aiding better clinical management of the newborn.

Brainz BRM3. The Brainz BRM3 is a bedside monitor that collects and measures electrical activity from both the right and left hemispheres of the brain. The monitor presents a simplified 2-channel EEG display, along with the option to view three channels of time-compressed amplified EEG s (aEEG), providing practitioners with the ability to monitor infants with a wider variety of neurological concerns when compared to single-channel EEG. Outside the U.S. the BRM3 is sold with an optional spike and event detection algorithm called Recognize.

Olympic CFM-6000. The Olympic CFM-6000 is a single-channel aEEG/EEG system that allows the neonatologist to diagnose neurological disorders or brain injury in the newborn. It helps determine the need for further neurological examination or transport to a tertiary-care center.

Newborn Brain Injury Treatment

Olympic Cool-Cap System. The Olympic Cool-Cap is the only FDA-approved device for the treatment of moderate to moderately-severe HIE. A four-year clinical trial for the Cool-Cap was

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completed in 2003, and the FDA approved the product in December 2006. The clinical trial validated the benefit of selective head cooling as a means of reducing the temperature of the brain to diminish the severity of brain injury resulting from HIE in newborns. The device conforms to the clinical trial protocol and is designed to assist the clinician in safely administering treatment, thereby preventing or significantly reducing the severity of neurological injury associated with HIE. The Olympic Cool-Cap brain cooling system uses a single-patient, disposable, cooling cap to continuously circulate sterile water to the patient during the 72-hour treatment period.

Thermoregulation Products

Overview

Incubators offer a controlled, consistent microenvironment for thermoregulation and humidification within a closed system to maintain skin integrity and body temperature. This controlled microenvironment reduces noise and light, supporting developmental care while still providing access for clinical staff and family. Closed incubators are used for premature or sick babies who need a thermal and developmental environment to thrive and grow in the NICU. Transport incubators are designed to offer a controlled environment during transport either intra-hospital from one care area to another within a hospital building or inter-hospital between hospitals. Open infant warmers are the preferred device for labor and delivery rooms and NICU admission.

We currently offer the following thermoregulation products:

Medix Incubators. Medix incubators provide high thermal performance with a double wall design. The NatalCare line of incubators includes easy to use control panels and features such as improved weighing functionality with automatic centering and an electronic tilting mechanism. The easy to clean, smooth design, and choice of options make these customizable incubators appropriate for different use environments.

Medix Open Warmers. Medix open warmers include a full range of options including Apgar timers and resuscitation systems. Available with an attached bed or in free-standing configurations, the warmers feature a microprocessor controlled display module with easy to read display. The heater module has lateral movement capabilities to facilitate X-ray procedures while maintaining heat delivery.

Medix Transport Incubators. Medix transport incubators are light in weight and easy to clean. They incorporate long lasting batteries and a choice of carts to meet the needs of different care environments.

Jaundice Management

Overview

The American Academy of Pediatrics estimates that each year 60% of the approximately four million newborns in the U.S. 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 U.S., and accounts for 50% of readmissions. 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 2004, the American Academy of Pediatrics issued new guidelines for the treatment of jaundice in newborns. The guidelines recommend phototherapy as the standard of care for the treatment of hyperbilirubinemia in infants born at 35 weeks or more of gestation. The guidelines further highlight the need for intense phototherapy, and specifically recommend the use of the blue light treatment incorporated into our neoBLUE products.

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Jaundice Management Products

neoBLUE Product Family. This product line consists of our neoBLUE, neoBLUE Mini, neoBLUE Cozy, and neoBLUE blanket devices, which utilize light emitting diodes (LEDs) to generate a high-intensity, narrow spectrum of blue light that is clinically proven to be most effective in the treatment of newborn jaundice. Our neoBLUE phototherapy devices emit significantly less ultraviolet light and heat than conventional phototherapy devices, reducing the risk of skin damage and dehydration for infants undergoing treatment. Because of the high intensity of these lights, the treatment time associated with phototherapy is reduced.

Bili-Lite Product Family. These devices utilize fluorescent light bulbs for the treatment of hyperbilirubinemia. The Bili-Bassinet provides intensive phototherapy from both under and over the baby for maximum surface area coverage. The Bili-Lite pad is a product designed for both hospital and home-based phototherapy.

Medix MediLED Product Family. This product line from Medix includes a full-size, free-standing LED phototherapy system and a MediLED mini light to be used on top of an incubator or attached to the Medix radiant warmer. The MediLED incorporates an array of blue and white LEDs, while the mini system utilizes blue super LEDs that provide high intensity phototherapy.

Other Newborn Care Product Lines

Medical Devices. These products include devices such as: photometers, radiometers, patient warming lamps, neonatal heatshields, pediatric scales, blanket warming cabinets, exam lights, oxygen hoods, restraining boards, and our newborn circumstraint.

Hawaii Medical Products. These single-use disposable products are sold into the NICU and nursery in hospitals. The Hawaii Medical line includes Gumdrop pacifiers, TootSweet sucrose solution, and NeatNick heel lancets, among a range of positioning devices, electrodes, and other newborn care products.

Disposable Supplies. These products include other disposable supplies such as neonatal noise attenuators, phototherapy eye masks, and x-ray shields for reproductive organs.

Newborn Screening Data Management Product Line. Our suite of newborn screening data management products consists of proprietary software that collects, tracks, manages, and reports newborn screening data to regional government health laboratories and national disease control centers. While all states have laws and/or regulations requiring newborn screening for metabolic disorders, the laws and regulations vary widely in the extent of screening required. Some states use tandem mass spectrometry in their newborn metabolic screening programs, which increases the number of treatable disorders that can be detected. Revenue from installation and upgrades of our newborn screening data management systems is classified as devices and systems revenue, and revenue from maintenance contracts on the systems is classified as supplies and services revenue.

Segment and Geographic Information

We operate in one reportable segment in which we provide healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and balance and mobility disorders.

Our end-user customer base includes hospitals, clinics, laboratories, physicians, nurses, audiologists, and governmental agencies. Most of our international sales are to distributors, who in turn, resell our products to end users or sub-distributors.

Information regarding our sales and long-lived assets in the U.S. and in countries outside the U.S. is contained in *Note 16 Segment, Customer and Geographic Information* of our consolidated financial statements included in this report and is incorporated in this section by this reference.

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Revenue by Product Family and Product Category

For the years ended December 31, 2011, 2010 and 2009, revenue from our four product families as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2011	2010	2009
Neurology	46%	45%	39%
Hearing	26%	32%	40%
Newborn Care	24%	19%	16%
Other	4%	4%	5%
Total	100%	100%	100%

We also look at revenue as either being generated from sales of Devices and Systems, which are generally non-recurring, or related Supplies and Services, which are generally recurring. The products that are attributable to these categories are described above. Revenue from Devices and Systems, and Supplies and Services, as a percent of total revenue for the years ending December 31, 2011, 2010 and 2009 is as follows:

	Year Ended December 31,		
	2011	2010	2009
Devices and Systems	64%	62%	58%
Supplies and Services	34%	37%	40%
Other	2%	1%	2%
Total	100%	100%	100%

In 2011, 2010 and 2009, sales to no single end-user customer comprised more than 10% of our revenue, and revenue from services was less than 10% of our revenue.

Backlog

As of December 31, 2011, our backlog was approximately $8.2 million, compared to $6.0 million at December 31, 2010 and $8.9 million at December 31, 2009.

Marketing and Sales

Marketing

Our marketing strategy differentiates our products by their level of quality, performance, and customer benefit. We educate customers and potential customers worldwide about our products through several traditional methods, including, but not limited to:

Trade conference exhibits;

Direct presentations to healthcare professionals;

Publications in professional journals and trade magazines;

The Internet via our website, *www.natus.com;*

Print and direct mail advertising campaigns; and

Sponsorship of and participation in clinical education seminars and workshops.

Educational efforts directed at government agencies, physicians, and clinicians about the benefits of universal screening in terms of patient outcomes and long-term treatment costs are a key element of our marketing strategy.

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Domestic Direct and Distributor Sales

We sell our products in the United States primarily through a direct sales organization. We believe this direct sales organization allows us to maintain a higher level of customer service and satisfaction than would otherwise be possible by other distribution methods. We also sell certain products under private label and distribution arrangements.

Domestic revenue as a percent of total revenue was 56%, 58%, and 66% in 2011, 2010 and 2009, respectively.

International Direct and Distributor Sales

We sell some of our products outside the U.S. through direct sales channels in Canada and in the French and German speaking regions of Europe, in Denmark, and in parts of Latin America; we sell other products in those regions and into more than 100 other countries through a distributor sales channel.

International revenue as a percent of total revenue was 44%, 42%, and 34% in 2011, 2010 and 2009, respectively.

We sell products to our distributors under substantially the same terms as sales through our direct sales channels. Terms of sales to international distributors are generally EXW, reflecting that goods are shipped ex works, in which title and risk of loss are assumed by the distributor at the shipping point. Distributors are generally given exclusive rights in their territories to purchase products from Natus and resell to end users or sub distributors. Our distributors typically perform marketing, sales, and technical support functions in their respective markets. Each distributor may sell Natus products to their customer directly, via other distributors or resellers, or both. We actively train our distributors in product marketing, selling, and technical service techniques.

Seasonality in Revenue

We experience seasonality in our revenue. Our revenue typically drops from our fourth quarter to our first quarter. This seasonality results from the purchasing habits of our hospital-based customers, whose purchases are often governed by calendar year budgets, and the manner in which our direct sales force is compensated, as their compensation is based on annual sales plans that are tied to our December year end.

Group Purchasing Organizations

More than 90% of the hospitals in the U.S. are members of group purchasing organizations (GPO s), which negotiate volume purchase agreements for member hospitals, group practices, and other clinics. Direct purchases by GPO members accounted for approximately 12%, 18% and 24% of our revenue in 2011, 2010 and 2009, respectively. Direct purchases by members of one GPO, Novation, accounted for approximately 2%, 6% and 8% of our revenue in 2011, 2010 and 2009, respectively.

Third-Party Reimbursement

In the U.S., health care providers 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 procedures they perform. Third-party payors can affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement these payors provide for services utilizing our products. For this reason, we are not able to measure a reimbursement success rate for our products.

Customer Service and Support

We provide a one-year warranty on all medical device products. We also sell extended service agreements on our medical device products. Service, repair, and calibration services for our domestic customers are provided

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by Company-owned service centers and our field service specialists. Service for our international customers is provided by a combination of our Company-owned authorized service centers and third-party vendors on a contract basis.

Manufacturing

Other companies manufacture a significant portion of the components used in our products; however, we perform final assembly, testing, and packaging of most of the devices ourselves to control quality and manufacturing efficiency. We also use contract vendors to manufacture some of our disposable supply and medical device products. We perform regular quality audits of these vendors.

We purchase materials and components from qualified suppliers that are subject to our quality specifications and inspections. 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 supplies for use with medical devices. Most of our purchased components are available from more than one supplier.

Our manufacturing, service, and repair facilities are subject to periodic inspection by federal, state, and foreign regulatory authorities. Our quality assurance system is subject to regulation by the FDA and other state government agencies. We are required to conduct our product design, testing, manufacturing, and control activities in conformance with the FDA s quality system regulations and to maintain our documentation of these activities in a prescribed manner. In addition, our production facilities have received ISO 13485 certification. ISO 13485 certification standards for quality operations have been developed to ensure that medical device companies meet 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 allows us to place a CE mark on our products.

Research and Development

We are committed to introducing new products and supporting current product offerings in our markets through a combination of internal as well as external efforts that are consistent with our corporate strategy.

Internal product development capabilities. We believe that product development capabilities are essential to provide our customers with new product offerings. We plan to leverage our core technologies by introducing product line extensions as well as new product offerings.

Partnerships that complement our expertise. We continue to seek strategic partners in order to develop products that may not otherwise be available to us. By taking advantage of our core competencies, we believe that we can bring products to market in an efficient manner and leverage our distribution channels.

New opportunities through technology acquisition. We continue to evaluate new, emerging, and complementary technologies in order to identify new product opportunities. With our knowledge of our current markets we believe that we can effectively develop technologies into successful new products.

Our research and development expenses were $25.6 million or 11% of total revenue in 2011, $21.3 million or 9.7% of total revenue in 2010, and $16.7 million or 10.0% of total revenue in 2009.

Proprietary Rights

We protect our intellectual property through a combination of patent, copyright, trade secret, and trademark laws. We attempt to protect our intellectual property rights by filing patent applications for new features and products we develop. We enter into confidentiality or license agreements with our employees, consultants, and corporate partners, and seek to control access to our intellectual property, distribution channels, documentation, and other proprietary information. However, we believe that these measures afford only limited protection.

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The intellectual rights to some of the original patents for technology incorporated into our products are now in the public domain. However, we do not consider these patents, or any currently viable patent or related group of patents, to be of such importance that their expiration or termination would materially affect our business.

We capitalize the cost of purchased technology and intellectual property, as well as certain costs incurred in obtaining patent rights, and amortize these costs over the estimated economic lives of the related assets.

Competition

We sell our products in competitive and rapidly evolving markets. We face competition from other companies in all of our product lines. Our competitors range from small privately-held companies to multinational corporations and their product offerings vary in scope and breadth. We do not believe that any single competitor is dominant in any of our product lines.

We derive a significant portion of our revenue from the sale of disposable supplies that are used with our medical devices. In the U.S., we sell our supply products in a mature market. Because these products can generate high margins, we expect that our products, particularly our hearing screening supply products, could face increasing competition, including competitors offering lower prices, which could have an adverse effect on our revenue and margins.

We believe the principal factors that will draw clinicians and other buyers to our products, include:

Level of specificity, sensitivity, and reliability of the product;

Time required to obtain results with the product, such as to test for or treat a clinical condition;

Relative ease of use of the product;

Depth and breadth of the products features;

Quality of customer support for the product;

Frequency of product updates;

Extent of third-party reimbursement of the cost of the product or procedure;

Extent to which the products conform to standard of care guidelines; and

Price of the product.

We believe that our primary competitive strength relates to the functionality and reliability of our products. Different competitors may have competitive advantages in one or more of the categories listed above and they may be able to devote greater resources to the development, promotion, and sale of their products.

Government Regulation

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, the medical devices we sell in the United States, with the exception of some disposable products, must first receive one of the following types of FDA premarket review authorizations under the Food, Drug, and Cosmetics Act, as amended:

Clearance via Section 510(k); or

Premarket approval via Section 515 if the FDA has determined that the medical device in question poses a greater risk of injury.

The FDA s 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining premarket approval via Section 515 is much more costly, lengthy, and uncertain. Premarket approval

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generally takes from one to three years, but can take longer. We cannot be sure that the FDA will ever grant either 510(k) clearance or premarket approval for any product we propose to market in the United States.

The FDA 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 FDA 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 under Section 510(k) must demonstrate that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications.

The FDA 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 its Class III classification. The FDA requires these devices to undergo the premarket approval process via Section 515 in which the manufacturer must prove the safety and effectiveness of the device. A premarket approval application must provide extensive pre-clinical and clinical trial data.

The FDA 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 FDA 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 FDA 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 non-significant 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 non-significant risk determination, the manufacturer may begin the clinical trial.

We received approval for our Olympic Cool-Cap product as a Class III device from the FDA through the premarket approval process. Most of our other products have been cleared by the FDA as Class II devices. Some of our disposable products and newborn care products, such as our neonatal headshields and oxygen delivery systems, have received FDA clearance as Class I devices.

FDA Regulation

Numerous FDA regulatory requirements apply to our products. These requirements include:

- FDA quality system regulations which require manufacturers to create, implement, and follow design, testing, control, documentation, and other quality assurance procedures;
- Medical device reporting regulations, which require that manufacturers report to the FDA certain types of adverse and other events involving their products; and
- FDA general prohibitions against promoting products for unapproved uses.

Class II and III devices may also be subject to special controls applied to them, such as performance standards, post-market surveillance, patient registries, and FDA guidelines that may not apply to Class I devices. We believe we are in compliance with applicable FDA guidelines, but we could be required to change our compliance activities or be subject to other special controls if the FDA changes existing regulations or adopts new requirements.

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We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to adequately comply, the Agency can institute a wide variety of enforcement actions, including:

- Issuance of a Form 483 citation;
- Fines, injunctions, and civil penalties;
- Recall or seizure of our products;
- Issuance of public notices or warnings;
- Imposition of operating restrictions, partial suspension, or total shutdown of production;
- Refusal of our requests for 510(k) clearance or pre-market approval of new products;
- Withdrawal of 510(k) clearance or pre-market approval already granted; or
- Criminal prosecution.

The FDA also has the authority to require us to repair, replace, or refund the cost of any medical device manufactured or distributed by us.

Other 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 such regulations.

Countries outside of the U.S. regulate medical devices in a manner similar to that of the FDA. Our manufacturing facilities are subject to audit and have been certified to be ISO 13485:2003, Medical Device Directive 93/42/EEC, and CMDCAS compliant, which allows us to sell our products in Canada, Europe, and other territories around the world. Our manufacturing facilities in North America are subject to ISO 13485 inspections by our notified body, British Standards Institution Management Systems, and by other notified bodies outside of North America. We plan to seek approval to sell our products in additional countries, while maintaining our current approvals. The time and cost of obtaining new, and maintaining existing, market authorizations from countries outside of North America, and the requirements for licensing products in these countries may differ significantly from FDA requirements.

Employees

On December 31, 2011, we had approximately 835 full time employees worldwide. In Argentina, some of our production employees are represented by labor unions; none of our other employees are so represented. We have not experienced any work stoppages and consider our relations with our employees to be good.

Executive Officers

The following table lists our executive officers and their ages as of March 1, 2011:

Name	Age	Position(s)
James B. Hawkins	56	Chief Executive Officer and Director
John T. Buhler	51	President and Chief Operating Officer
Steven J. Murphy	60	Vice President Finance and Chief Financial Officer
William L. Mince	60	Vice President North American Operations
Kenneth M. Traverso	51	Vice President Marketing and Sales
D. Christopher Chung, M.D.	48	Vice President Medical Affairs, Quality & Regulatory

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James B. Hawkins has served as Chief Executive Officer, and as a member of the Board of Directors, since joining Natus in April 2004, and formerly as President from April 2004 through January 2011. Mr. Hawkins has over 25 years of combined medical device and financial management experience. Prior to joining Natus, he was President and Chief Executive Officer of Nasdaq-traded Invivo Corporation for 19 years. Invivo Corporation, a maker of multi-parameter vital sign monitoring equipment used in hospitals, was acquired in early 2004 by Intermagnetics General Corporation. He earned a Bachelor of Commerce degree, specialized in Management from Santa Clara University and a Masters of Business Administration Finance degree from San Francisco State University. Mr. Hawkins is a Director of Iridex Corp.

John T. Buhler has served as President and Chief Operating Officer since February, 2011. Mr. Buhler was employed by Avantis Medical Systems as President and Chief Executive officer from January 2011 to February 2011. He held various positions at SenoRx from May 2008 through July 2010, including President and Chief Executive Officer from March 2010 through July 2010, President and Chief Operating Officer from October 2009 to March 2010, Senior Vice President and Chief Commercial Officer from April 2009 to October 2009, Vice President of Global Sales and Business Development from October 2008 until April 2009, and Vice President of International Sales and Business Development from May 2008 until October 2008. From August 2005 to May 2008, Mr. Buhler served as President and Chief Executive Officer at Ultrasonix Medical Corporation, a privately held manufacturer of diagnostic ultrasound imaging equipment. From 1998 to 2005, Mr. Buhler held various positions at General Electric, last serving as Vice President and General Manager of GE s Ultrasound Performance Technologies Division in Shanghai, China.

Steven J. Murphy has served as Chief Financial Officer since February 2006, Vice President Finance since June 2003, and joined Natus in September 2002 as Director of Finance. From February 2002 through September 2002, Mr. Murphy was interim Controller at Travel Nurse International, a temporary staffing firm that was acquired by Medical Staffing Network in December 2002. From October 1998 through January 2002, Mr. Murphy was Controller of AdvisorTech Corporation, an international software development company providing IT-based solutions in the field of investments, where he was responsible for financial reporting of domestic, Asian and European operations with significant reporting responsibilities to the board of directors and investor groups. From 1996 to 1998 he was Vice President Finance of RWS Group, LLC, an international service company providing management of language-related projects. Mr. Murphy holds a Bachelor of Science degree in Business Administration from California State University, Chico. Mr. Murphy is a certified public accountant.

William L. Mince has served as our Vice President, North American Operations since September 2007 and joined Natus as Vice President Operations in October 2002. From November 2000 to September 2002, Mr. Mince served as President and Founder of My Own Jukebox, an Internet retail company. From July 1998 to October 2000, Mr. Mince was a consultant with the majority of his time spent as Senior Vice President Network Solutions for Premier Retail Network, a media broadcasting company. From July 1997 to June 1998, Mr. Mince served as President and Chief Operating Officer of Ophthalmic Imaging Systems, a publicly-held medical device company. From July 1994 to June 1997, Mr. Mince was Vice President Operations with Premier Retail Network. From May 1988 to June 1994, Mr. Mince was Director of Operations for Nellcor, a medical device company. Mr. Mince holds a Bachelor of Science degree in Business Administration from the University of Redlands and a Masters of Business Administration degree from National University.

Kenneth M. Traverso has served as our Vice President Marketing and Sales since April 2002. From September 2000 to April 2002, he served as our Vice President Sales. 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 Sales, Western Region of Alere Medical, an outpatient chronic disease management company. From May 1995 to January 1998, Mr. Traverso served as Vice President Marketing and Sales of AbTox, Inc., a low temperature sterilization company. From August 1990 to May 1995, Mr. Traverso served in various capacities at Natus, including Vice President Sales. From September 1984 to July 1990 Mr. Traverso served various positions at Nellcor, a medical device company, including Regional Sales Manager, Western Region. Mr. Traverso holds a Bachelor of Science degree in Administration & Marketing from San Francisco State University.

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D. Christopher Chung, M.D., has served as our Vice President Medical Affairs, Quality and Regulatory since June 2011. From February 2003 until June 2011, Dr. Chung also served as our Vice President R&D and Engineering. Dr. Chung served as our Medical Director from October 2000 to February 2003. From 2000 to 2006, Dr. Chung served as a Pediatric Hospitalist at the California Pacific Medical Center in San Francisco. From June 1997 to June 2000, Dr. Chung trained as a pediatric resident at Boston Children s Hospital and Harvard Medical School. From 1986 to 1993, Dr. Chung worked as an Engineer at Nellcor, a medical device company. Dr. Chung holds a Bachelor of Arts degree in Computer Mathematics from the University of Pennsylvania and a Doctor of Medicine degree from the Medical College of Pennsylvania-Hahnemann University School of Medicine. He is a Fellow of the American Academy of Pediatrics.

Other Information

Natus was incorporated in California in May 1987 and reincorporated in Delaware in August 2000.

We maintain corporate offices at 1501 Industrial Road, San Carlos, California 94070. Our telephone number is (650) 802-0400. We maintain a corporate website at www.natus.com. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. This information may also be obtained from the SEC s on-line database, which is located at www.sec.gov. Our common stock is traded on the Nasdaq Stock Market under the symbol BABY .

ITEM 1A. Risk Factors

We have completed a number of acquisitions and expect to complete additional acquisitions in the future. There are numerous risks associated with acquisitions and we may not achieve the expected benefit of any of our acquisitions

Our acquisitions of products, technology assets, or businesses may have a negative impact on our business if we fail to achieve the anticipated financial, strategic, and other benefits of acquisitions or investments, and our operating results may suffer because of this.

Our significant acquisitions are as follows: Neometrics in 2003; Fischer-Zoth in 2004; Bio-logic, Deltamed, and Olympic in 2006; Xltek in 2007; Sonamed, Schwarzer Neurology, and Neurocom in 2008; Hawaii Medical and Alpine Biomed in 2009, Medix in 2010, and Embla in 2011.

We expect to continue to pursue opportunities to acquire other businesses in the future. The acquisitions that we have completed may not result in improved operating results for us, or in our achieving a financial condition superior to that which we would have achieved had we not completed them. Our results of operations may be adversely impacted by costs associated with our acquisitions, including one-time charges associated with restructurings. Further, our acquisitions could fail to produce the benefits that we anticipate, or could have other adverse effects that we currently do not foresee. In addition, some of the assumptions that we have relied upon, such as achievement of operating synergies, may not be realized. In this event, one or more of the acquisitions could result in reduced earnings of Natus as compared to the earnings that would have been achieved by Natus if the acquisition had not occurred.

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We have assumed contingent obligations associated with earnout provisions in some of our acquisitions. We believe these provisions help us to negotiate mutually agreeable purchase terms between us and the sellers. However, a disagreement between us and a seller about the terms of an earnout provision could result in our paying more for an acquisition than we intended. For example, such disagreements arose in connection with our acquisitions of Alpine Biomed and Schwarzer Neurology. Although we resolved these disputes under terms that were not unfavorable to us, we cannot be assured of such outcomes in the future.

We have incurred indebtedness to fund some of our acquisitions. The use of debt to fund our acquisitions may have an adverse impact on our liquidity and cause us to place more reliance on cash flow from operations for our liquidity. If our cash flow from operations is not sufficient for our needs, our business could be adversely affected. If we are required to seek additional external financing to support our need for cash to fund future acquisitions, we may not have access to financing on terms that are acceptable to us, or at all. Alternatively, we may feel compelled to access additional financing on terms that are dilutive to existing holders of our common stock or that include covenants that restrict our business, or both. If the recent lack of liquidity in credit markets persists into the future, our ability to obtain debt financing for future acquisitions may be impaired.

If we fail to successfully manage the combined operations of Natus and the businesses we have acquired, we may not realize the potential benefits of our acquisitions. Our corporate headquarters are located in San Carlos, California. We also have the following operating divisions: Olympic in Washington; Neurocom in Oregon; Bio-logic in Illinois; Neometrics in New York; Xltek and Stellate in Canada; Medix in Argentina; Alpine Biomed in Denmark; Fischer-Zoth, Schwarzer Neurology, IT-Med, and Alpine Biomed Germany (collectively Natus Europe) in Germany; and Deltamed and Alpine Biomed France (collectively Natus France) in France. If we fail to manage these disparate operations effectively, our results of operations could be harmed, employee morale could decline, key employees could leave, and customers could cancel existing orders or choose not to place new ones. In addition, we may not achieve the synergies or other benefits of these and future acquisitions that we anticipate. We may encounter the following additional difficulties and delays involved in integrating and managing these operations, and the operations of companies we may acquire:

- Failure of customers to continue using the products and services of the combined company;
- Failure to successfully develop the acquired technology into the desired products or enhancements;
- Assumption of unknown liabilities;
- Failure to understand products or technologies with which we have limited previous experience;
- Failure to compete effectively in new markets;
- Decreased liquidity, restrictive bank covenants, and incremental financing costs associated with debt we may incur to complete future acquisitions; and
- Diversion of the attention of management from other ongoing business concerns.

Our reported operating results may suffer because of impairment charges incurred to write down the carrying amount of intangible assets, including goodwill, generated as a result of the acquisitions.

Our growth in recent years has depended substantially on the completion of acquisitions and we may not be able to complete acquisitions of this nature or of a relative size in the future to support a similar level of growth

The acquisitions that we have completed have been the primary source of our growth in revenue in recent years. We expend considerable effort in seeking to identify attractive acquisition candidates and, upon doing so, to convince the potential target to consider a sale to us and,

ultimately, to negotiate mutually agreeable acquisition terms. If we are not successful in these efforts in the future, our growth rate will not increase at a rate corresponding to that which we have achieved in recent years. Further, as we grow larger it will be necessary to

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complete the acquisition of larger companies and product lines to support a growth similar to that which we have achieved in the past. The market for attractive acquisitions is competitive and others with greater financial resources than we have may be better positioned than we are to acquire desirable targets. Further, we may not be able to negotiate acquisition terms with target companies that will allow us to achieve positive financial returns from the transaction.

Adverse economic conditions in markets in which we operate may harm our business

Unfavorable changes in U.S. and international economic environments may adversely affect our business and financial results. Economic conditions in the countries in which we operate and sell products worsened and global financial markets subsequently experienced significant volatility and declines throughout much of 2009. Although these conditions improved somewhat in 2010, unfavorable conditions continue to impact the U.S. and European economies. We are unable to foresee when, or if, these factors might return to historical levels. During challenging economic times, and in tight credit markets, our customers may delay or reduce capital expenditures. This could result in reductions in sales of our products, longer sales cycles, difficulties in collection of accounts receivable, slower adoption of new technologies, and increased price competition, all of which could impact our results of operations and financial condition. In addition, we expect these factors will cause us to be more cautious in evaluating potential acquisition opportunities, which could hinder our ability to grow through acquisition while these conditions persist.

We have initiated changes to our information systems that could disrupt our business and our financial results.

We plan to continuously improve our information systems to support the form, functionality, and scale of our business. These types of transitions frequently prove disruptive to the underlying business of an enterprise and may cause us to incur higher costs than we anticipate. Failure to manage a smooth transition to the new systems and the ongoing operations and support of the new systems could materially harm our business operations.

For example, we are currently in the process of implementing the rollout of world-wide, single-platform enterprise resource planning (ERP) solution including customer relationship management, product lifecycle management, demand management, and business intelligence. Until we have completed this world-wide implementation, we will be dependent on multiple platforms. We may experience difficulties in implementing the ERP and we may fail to gain the efficiencies the implementation is designed to produce. The implementation could also be disruptive to our operations, including the ability to timely ship and track product orders to customers, project inventory requirements, manage our supply chain and otherwise adequately service our customers**.**

Future changes in technology or market conditions could result in adjustments to our recorded asset balance for intangible assets, including goodwill, resulting in additional charges that could significantly impact our operating results

Our balance sheet includes significant intangible assets, including goodwill and other acquired intangible assets. The determination of related estimated useful lives and whether these assets are impaired involves significant judgment. Our ability to accurately predict future cash flows related to these intangible assets might be hindered by events over which we have no control. Due to the highly competitive nature of the medical device industry, new technologies could impair the value of our intangible assets if they create market conditions that adversely affect the competitiveness of our products. Further, declines in our market capitalization may be an indicator that our intangible assets or goodwill carrying values exceed their fair values which could lead to potential impairment charges that could impact our operating results. For example, in 2011 we recorded a $20 million goodwill impairment charge related to our European reporting unit.

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

If we fail to protect our intellectual property rights or if our intellectual property rights do not adequately cover the technology we employ, other medical device companies could sell products with features similar to ours, and this could reduce demand for our products. We protect our intellectual property through a combination of patent, copyright, trade secret and trademark laws. 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. 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. Failing to enforce our intellectual property rights could also result in the loss of those rights.

If health care providers are not adequately reimbursed for procedures conducted with our devices or supplies, or if reimbursement policies change adversely, we may not be successful marketing and selling our products or technologies

Clinicians, hospitals, and government agencies are unlikely to purchase our products if they are not adequately reimbursed for the procedures conducted with our devices or supplies. Unless a sufficient amount of conclusive, peer-reviewed clinical data about our products has been published, third-party payors, including insurance companies and government agencies, may refuse to provide reimbursement. Furthermore, even if reimbursement is provided, it may not be adequate to fully compensate the clinicians or hospitals. Some third-party payors may impose restrictions on the procedures for which they will provide reimbursement. If health care providers cannot obtain sufficient reimbursement from third-party payors for our products or the screenings conducted with our products, we may not achieve significant market acceptance of our products. Acceptance of our products in international markets will depend upon the availability of adequate reimbursement or funding within prevailing healthcare payment systems. Reimbursement, funding, and healthcare payment systems vary significantly by country. We may not obtain approvals for reimbursement in a timely manner or at all.

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, particularly those in countries and regions outside the U.S. 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. In a managed care system, the cost of our products may not be incorporated into the overall payment for patient care or there may not be adequate reimbursement for our products separate from reimbursement for other procedures.

Healthcare reforms, changes in healthcare policies, and changes to third-party reimbursements for our products may affect demand for our products

In March 2010 the U. S. government signed into law the *Patient Protection and Affordable Care Act* and the *Health Care & Education Reconciliation Act*. These laws are intended to, among other things, curb rising healthcare costs, including those that could significantly affect reimbursement for our products. The policies supporting these laws include: basing reimbursement policies and rates on clinical outcomes; the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the U.S. Presidential administration or Congress.

There are numerous steps required to implement these laws. Because of the unsettled nature of these reforms, we cannot predict what additional healthcare reforms will be implemented at the federal or state level, or the effect that any future legislation or regulation will have on our business. There is also considerable uncertainty of the impact of these reforms on the medical device market as a whole. If we fail to effectively react

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to the implementation of health care reform, our business may be adversely affected. In addition, if the excise tax on the sale of medical devices is imposed as enacted, this could increase our costs and have an adverse effect on our results of operations, financial position, and cash flows.

If we fail in our efforts to educate clinicians, government agency personnel, and third-party payors on the effectiveness of our products, we may not achieve future sales growth

It is critical to the success of our sales efforts that we educate a sufficient number of clinicians, hospital administrators, and government agencies about our products and the costs and benefits of their use. The commercial success of our products depends upon clinician, government agency, and other third-party payer confidence in the economic and clinical benefits of our products as well as their comfort with the efficacy, reliability, sensitivity and specificity of our products. We believe that clinicians will not use our products unless they determine, based on published peer-reviewed journal articles and experience, that our products provide an accurate and cost-effective alternative to other means of testing or treatment. Our customers may choose to use competitive products, which may be less expensive or may provide faster results than our devices. Clinicians are traditionally slow to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. If clinicians, government agencies and hospital administrators do not adopt our products, we may not maintain profitability. Factors that may adversely affect the medical community s acceptance of our products include:

Publication of clinical study results that demonstrate a lack of efficacy or cost-effectiveness of our products;

Changing governmental and physician group guidelines;

Actual or perceived performance, quality, price, and total cost of ownership deficiencies of our products relative to other competitive products;

Our ability to maintain and enhance our existing relationships and to form new relationships with leading physicians, physician organizations, hospitals, state laboratory personnel, and third-party payers;

Changes in state and third-party payer reimbursement policies for our products; and

Repeal of laws requiring universal newborn hearing screening and metabolic screening.

Sales through group purchasing organizations and sales to high volume purchasers may reduce our average selling prices, which could reduce our operating margins

We have entered, and expect in the future to enter into agreements with customers who purchase high volumes of our products. Our agreements with these customers may contain discounts from our normal selling prices and other special pricing considerations, which could cause our operating margins to decline. In addition, we have entered into agreements to sell our products to members of GPOs, which negotiate volume purchase prices for medical devices and supplies for member hospitals, group practices and other clinics. While we make sales directly to GPO members, the GPO members receive volume discounts from our normal selling price and may receive other special pricing considerations from us. Sales to members of all GPOs accounted for approximately 12%, 18% and 24% of our total revenue during 2011, 2010 and 2009, respectively, and sales to members of one GPO, Novation, accounted for approximately 2%, 6% and 8% of our total revenue in 2011, 2010 and 2009, respectively. Other of our existing customers may be members of GPOs with which we do not have agreements. Our sales efforts through GPOs may conflict with our direct sales efforts to our existing customers. If we enter into agreements with new GPOs and some of our existing customers begin purchasing our products through those GPOs, our operating margins could decline.

Demand for some of our products depends on the capital spending policies of our customers, and changes in these policies could harm our business

A majority of customers for our products are hospitals, physician offices, and clinics. Many factors, including public policy spending provisions, available resources, and economic cycles have a significant effect

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on the capital spending policies of these entities and therefore the amount that they can spend on our equipment products. If budget resources limit the capital spending of our customers, they will be unlikely to either purchase any new equipment from us or upgrade to any of our newer equipment products. Lack of liquidity in credit markets and uncertainty about future economic conditions can have an adverse effect on the spending patterns of our customers. These factors can have a significant adverse effect on the demand for our products.

Our markets are very competitive and in the United States we sell certain of our products in a mature market

We face competition from other companies in all of our product lines. Our competitors range from small privately held companies to multinational corporations and their product offerings vary in scope and breadth. We do not believe that any single competitor is dominant in any of our product lines.

The markets for certain of our products in the U.S., including the newborn hearing screening and EEG monitoring markets, are mature and we are unlikely to see significant growth for such products in the U.S. In the U.S. we derive a significant portion of our revenue from the sale of disposable supplies that are used with our hearing screening devices. Because these disposable supply products can generate high margins, we expect that our products, particularly our hearing screening disposable supply products, could face increasing competition, including competitors offering lower prices, which could have an adverse effect on our revenue and margins.

Our competitors may have certain competitive advantages, which include the ability to devote greater resources to the development, promotion, and sale of their products. Consequently, we may need to increase our efforts, and related expenses for research and development, marketing, and selling to maintain or improve our position.

We expect recurring sales to our existing customers to generate a majority of our revenue in the future, and if our existing customers do not continue to purchase products from us, our revenue may decline.

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

We intend to develop additional products and technologies, including enhancements of existing products, for the screening, detection, treatment, monitoring and tracking of common medical ailments. Developing new products and improving our existing products to meet the needs of current and future customers requires significant investments in research and development. If we fail to successfully sell new products, update our existing products, or timely react to changes in technology, our operating results may decline as our existing products reach the end of their commercial life cycles.

Our plan to expand our international operations will result in increased costs and is subject to numerous risks; if our efforts are not successful, this could harm our business

We have expanded our international operations through acquisitions and plan to expand our international sales and marketing efforts to increase sales of our products in foreign countries. We may not realize corresponding growth in revenue from growth in international unit sales, due to the lower average selling prices we receive on sales outside of the U.S. Even if we are able to successfully expand our international selling efforts, we cannot be certain that we will be able to create or increase demand for our products outside of the U.S. Our international operations are subject to other risks, which include:

Impact of possible recessions in economies outside the U.S.;

Political and economic instability, including instability related to war and terrorist attacks;

Contractual provisions governed by foreign law, such as local law rights to sales commissions by terminated distributors;

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- Decreased healthcare spending by foreign governments that would reduce international demand for our products;
- Continued strengthening of the U.S. dollar relative to foreign currencies that could make our products less competitive because approximately half of our international sales are denominated in U.S. dollars;
- 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;
- Difficulty in obtaining and maintaining foreign regulatory approval;
- Attitudes by clinicians, and cost reimbursement policies, towards use of disposable supplies that are potentially unfavorable to our business.
- Complying with U.S. regulations that apply to international operations, including trade laws, the U.S. Foreign Corrupt Practices Act, and anti-boycott laws, as well as international laws such as the U.K. Bribery Act;
- Loss of business through government tenders that are held annually in many cases; and
- Potentially negative consequences from changes in tax laws, including legislative changes concerning taxation of income earned outside of the U.S.

In particular, our international sales could be adversely affected by a strengthening of the U.S. dollar relative to other foreign currencies, which makes our products more costly to international customers for sales denominated in U.S. dollars.

Our operating results may suffer because of our exposure to foreign currency exchange rate fluctuations

Substantially all of our sales contracts with our U.S. based customers provide for payment in U.S. dollars. With the exception of our Canadian operations, substantially all of the revenue and expenses of our foreign subsidiaries are denominated in the applicable foreign currency. To date we have executed only limited foreign currency contracts to hedge these currency risks. Our future revenue and expenses may be subject to volatility due to exchange rate fluctuations that could result in foreign exchange gains and losses associated with foreign currency transactions and the translation of assets and liabilities denominated in foreign currencies.

Substantially all our sales from our U.S. operations to our international distributors provide for payment in U.S. dollars. A strengthening of the U.S. dollar relative to other foreign currencies could increase the effective cost of our products to our international distributors as their functional currency is typically not the U.S. dollar. This could have a potential adverse effect on our ability to increase or maintain average selling prices of our products to our foreign-based customers.

If guidelines mandating universal newborn hearing screening do not continue to develop in foreign countries and governments do not mandate testing of all newborns as we anticipate, or if those guidelines have a long phase-in period, our sales of newborn hearing screening products may not achieve the revenue growth we have achieved in the past

We estimate that approximately 95% of the children born in the U.S. are currently being tested for hearing impairment prior to discharge from the hospital. To date, there has been only limited adoption of newborn hearing screening prior to hospital discharge by foreign governments, and when newborn hearing screening programs are enacted by foreign governments there can be a phase-in period spanning several years. The widespread adoption of guidelines depends, in part, on our ability to educate foreign government agencies,

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neonatologists, pediatricians, third-party payors, and hospital administrators about the benefits of universal newborn hearing screening as well as the use of our products to perform the screening and monitoring. Our revenue from our newborn hearing screening product lines may not grow if foreign governments do not require universal newborn hearing screening prior to hospital discharge, if physicians or hospitals are slow to comply with those guidelines, or if governments provide for a lengthy phase-in period for compliance.

Because we rely on distributors or sub-distributors to sell our products in most of our markets outside of the U.S., our revenue could decline if our existing distributors reduce the volume of purchases from us, or if our relationship with any of these distributors is terminated

We currently rely on our distributors or sub-distributors for a majority of our sales outside the U.S. Some distributors also assist us with regulatory approvals and education of clinicians and government agencies. We intend to continue our efforts to increase our sales in Europe, Japan, and other developed countries. 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 to market our products effectively or provide timely and cost-effective customer support and service. Even if we are successful in selling our products through new distributors, the rate of growth of our revenue could be harmed if our existing distributors do not continue to sell a large dollar volume of our products. None of our existing distributors are obligated to continue selling our products.

We may be subject to foreign laws governing our relationships with our international distributors. These laws may require us to make payments to our distributors if we terminate our relationship for any reason, including for cause. Some countries require termination payments under local law or legislation that may supersede our contractual relationship with the distributor. Any required payments would adversely affect our operating results.

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. We have relatively few sources of supply for some of the components used in our products and in some cases we rely entirely on sole-source suppliers. In addition, the lead-time involved in the manufacturing of some of these components can be lengthy and unpredictable. If our suppliers become unwilling or unable to supply us with components meeting our requirements, it might be difficult to establish additional or replacement suppliers in a timely manner, or at all. This would cause our product sales to be disrupted and our revenue and operating results to suffer.

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

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

Our products and technologies are complex, and we depend substantially on the continued service of our senior management team. The loss of any of our key employees could adversely affect our business and slow our product development process. Our future success also will depend, in part, on the continued service of our key management personnel, software engineers, and other research and development employees, and our ability to identify, hire, and retain additional personnel, including customer service, marketing, and sales staff. Demand for

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these skilled employees in our industry is very competitive due to the limited number of people available with the necessary technical skills and understanding of our product technologies. We may be unable to attract and retain personnel necessary for the development of our business.

Our ability to market and sell products depends upon receipt of domestic and foreign regulatory approval of our products and manufacturing operations. Our failure to obtain or maintain regulatory approvals and compliance could negatively affect our business

Our products and manufacturing operations are subject to extensive regulation in the United States by the FDA and by similar regulatory agencies in other countries. Our products are classified as medical devices. Medical devices are subject to extensive regulation by the FDA pursuant to regulations that are wide ranging and govern, among other things: design and development; manufacturing and testing; labeling; storage and record keeping; advertising, promotion, marketing, sales distribution and export; and surveillance and reporting of deaths or serious injuries.

Unless an exemption applies, each medical device that we propose to market in the U.S. must first receive one of the following types of FDA premarket review authorizations:

Clearance via Section 510(k) of the Food, Drug, and Cosmetics Act of 1938, as amended; or

Premarket approval via Section 515 of the Food, Drug, and Cosmetics Act if the FDA has determined that the medical device in question poses a greater risk of injury.

The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The premarket approval application process is much more costly, lengthy and uncertain than the 510(k) process, and must be supported by extensive data from preclinical studies and human clinical trials. The FDA may not grant either 510(k) clearance or premarket approval for any product we propose to market. Further, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a premarket approval application. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer s decision. If the FDA requires us to seek 510(k) clearance or premarket approval for modification of a previously cleared product for which we have concluded that new clearances o