

NATUS MEDICAL INC  
Form 10-K  
March 17, 2014  
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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, 2013**

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**  
(State or other jurisdiction of

**77 0154833**  
(I.R.S. Employer

incorporation or organization)

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:

## Edgar Filing: NATUS MEDICAL INC - Form 10-K

**Title of each class**  
Common Stock, \$0.001 par value per share

**Name of each exchange on which registered**  
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

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

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

Indicate by check mark 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  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.

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

Non-accelerated filer

Smaller reporting company

(Do not check if a 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

As of June 30, 2013, the last business day of Registrant's most recently completed second fiscal quarter, there were 30,751,056 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, 2013) was \$419,751,914. 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 14, 2014, the registrant had 31,904,463 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 2014 Annual Meeting of Stockholders.

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**NATUS MEDICAL INCORPORATED**

**ANNUAL REPORT ON FORM 10-K**

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*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® Aura®, Balance Manager®, Balance Master®, Balance Shape®, Biliband®, Bio-logic®, Bo-JECT®, Brain Atlas®, Ceegraph®, CHAMP®, Clarity System®, Cochlea Scan®, Cool Cap®, CoolCare®, Comet®, Dantec®, Ear Couplers®, Ear Muffin®, EC2®, Echo Screen®, Embla US®, Embletta®, Enterprise®, EquiTest®, Fass®, Fischer-Zoth®, Flexicoupler®, Grass®, Grass Technologies®, Gumdrop®, Halo Ear Muffin®, Hawaii Medical®, Keypoint®, Keypoint AU®, Keypoint EU®, Keypoint JP®, MASTER®, Medelec®, Medix®, MedixI.C.S.A®, Navigator®, Neatnick®, neoBLUE®, Neurocom®, Neuromax®, Neurotrac®, NeuroWorks®, Nicolet®, NicoletElite®, Oxydome®, Panorama®, Pocket®, Polyview®, REMbrandt®, REMlogic®, Sandman®, Scout®, Sleeprite®, Sleepscan®, Sleptrek®, Smart Scale®, Sonamed®, Sonara®, Sonara TEK®, Stellate Notta®, STETHODOP®, SZAC®, TECA®, Tootsweet®, Traveler®, Treetip®, Twin®, VAC PAC®, VERSALAB®, Warmette®, Xact Trace®, Xltek® are registered trademarks of Natus Medical Incorporated and its subsidiaries. Accuscreen®, Bili Lite Pad®, Bili-Lite®, Biomark®, Circumstraint®, Coherence®, Deltamed®, inVision®, Medix MediLED®, MiniMuffs®, NatalC®, Neometrics® and 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 newborn care and neurology 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 Families**

We offer two product families:

**Neurology** Includes products for diagnostic electroencephalography (EEG), electromyography (EMG), diagnostic sleep analysis or polysomnography (PSG), intra-operative monitoring (IOM), and transcranial doppler ultrasound technology.

**Newborn Care** Includes products for newborn care including hearing screening, brain injury, thermoregulation, jaundice management, and various disposable products, as well as products for diagnostic hearing assessment for children through adult populations, and products to diagnose and assist in treating balance and mobility disorders.

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### **Neurology**

Our diagnostic and monitoring systems and supplies for the neurology markets represent a comprehensive line of products that are used by healthcare practitioners in the diagnosis and monitoring of neurological disorders of the central and peripheral nervous system, including monitoring of patients during surgery, while under sedation, in post-operative care, and in intensive care units. Our neurology products include:

***Electroencephalography or EEG*** Equipment and supplies used to monitor and visually display the electrical activity generated by nerve cells in the brain and other key physiological signals for both diagnosis and monitoring of neurological disorders in the hospital, research laboratory, clinician office and patient's home.

***Electromyography or EMG*** Equipment and supplies used to measure electrical activity in nerves, muscles, the brain and spinal cord and includes EMG, nerve conduction and evoked potential functionality.

***Polysomnography or PSG*** Equipment and supplies used to measure 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.

***Intraoperative Monitoring or IOM*** Products and supplies that assist surgeons and neurophysiologists in preserving the functional integrity of a patient's nervous system during and after complex surgical procedures.

***Transcranial Doppler*** Products that assist clinicians in evaluating the integrity of blood flow in the brain for both preventive monitoring and diagnosis as well as to assist treatment in acute conditions such as stroke and vasospasm.

### ***Diagnostic EEG and Long-term Monitoring***

We design, manufacture, and market a full line of instruments and supplies 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) as well as other physiological signals needed to support clinical findings. Routine clinical 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, neurophysiologists and epileptologists review and interpret the results.

Routine outpatient clinical EEG testing is performed in hospital neurology laboratories, private physician offices, and in ambulatory settings such as the patient's home, 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 monitoring of EEGs and behavior is used to determine if surgical solutions are appropriate. Patients suffering from severe head trauma and other acute conditions that may affect the brain are monitored in intensive care units. In addition, research facilities use EEG equipment to conduct research on humans and laboratory animals.

### **Diagnostic Electroencephalograph Monitoring Product Lines**

Our EEG diagnostic monitoring product lines for neurology consist of signal amplifiers, workstations to capture and store data, and proprietary software. These products are typically used in concert, as part of an EEG system by the neurology/neurophysiology department of a hospital or clinic to assist in the diagnosis and monitoring of neurological conditions.

***NeuroWorks; Ceegraph; Coherence; Harmonie; NicoletOne.*** Our EEG Systems include a broad range of products, from software licenses and ambulatory monitoring systems to advanced laboratory



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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; NicoletOne Trends.*** 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. NicoletOne Trends provides a comprehensive set of EEG analysis algorithms such as spike and seizure detection, total band power analysis, alpha-delta variability, and spectrogram. These algorithms are used to generate trends of large amounts of data to assist in the clinical evaluation and data review process.

***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, Schwarzer EEG, Nicolet v32 and v44 models and Nicolet Wireless 32 and 64 channel amplifiers.

***Nicolet Cortical Stimulator.*** This product is our proprietary device that provides cortical stimulation to the brain during functional brain mapping either before or during surgery to help the surgeon protect the eloquent parts of the brain. The device can be used as a standalone unit or with the fully integrated NicoletOne software that supports control of the device from the software, automated mapping and comprehensive report generation.

***Digital Video; SmartPack; Universal Reader.*** 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 data compression process, and Universal Reader that is a thin-client software application installed on a physician's review station that permits fast and easy data analysis in a graphical format.

### ***Electrodiagnostic Monitoring***

Our electrodiagnostic systems include EMG, nerve conduction ( NCS ), and often evoked potential (brain electrical activity) functionality. EMG and NCS involve the measurement of electrical activity of muscles and nerves both at rest and during contraction. Measurements may or may not involve the use of stimulation depending on the required test. 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. EMG is also used for clinical applications of botox to relieve muscle spasm and pain. We market both the clinical system and the needles used for these procedures.

In addition to EMG and NCS functionality, many of our Electrodiagnostic systems also include Evoked Potential functionality ( EP ). Evoked potentials are elicited by the brain in response to a stimulus. These evoked potentials can come from the sensory pathways (such as hearing and visual) or from the motor pathways. An examination tests the integrity of these pathways including the associated area of the brain. Sophisticated amplifiers are required to recognize and average evoked potential EMG and NCS signals.

### **Electrodiagnostic Product Lines**

***Dantec Keypoint.*** The Dantec Keypoint EMG and EP family of products feature amplifiers, stimulators, and strong signal quality. The Keypoint is used for advanced neurodiagnostic applications

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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 device that provides muscle and nerve localization information to assist with botox injections. In conjunction with the Bo-ject hypodermic needle and electrodes, it delivers a precise dose of the agent.

**Nicolet EDX family.** A hardware platform of amplifiers, base control units, stimulators and hand-held probes that are sold with two versions of Nicolet brand proprietary software (Viking and Synergy). These mid to high end systems have full functionality, strong signal quality, and flexibility.

**Nicolet VikingSelect and Synergy Plinth.** These are products for the high-end market that use proprietary Viking or Synergy hardware and software.

**Nicolet VikingQuest.** An EMG system for the mid-range market. The device runs on our proprietary Viking software.

**Nicolet Synergy PIU.** An EMG system for the low-end market focused on ease of use and portability. The PIU uses our proprietary Synergy software.

**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 and as trolley-based or portable.

**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.

**Supplies.** We also manufacture and market a full line of proprietary EMG needles.

### ***Diagnostic Polysomnography Monitoring***

Increasing public awareness of sleep disorders has made sleep medicine a 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 full polysomnographic sleep study entails whole-night recordings of brain electrical activity, muscle movement, airflow, respiratory effort, oxygen levels, electrical activity of the heart, and other parameters. In some studies patients are fitted with treatment devices using Continuous Positive Airway Pressure technology ( CPAP ) during the sleep study and the proper settings for the treatment devices are determined during the latter part of the study.

### **Diagnostic PSG Monitoring Product Lines**

We market dedicated diagnostic PSG monitoring products that can be used individually or as part of a networked system for overnight sleep studies to assist in the diagnosis of sleep disorders. Some of our EEG systems described above can also be configured to perform diagnostic PSG monitoring. 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; NicoletOne.*** Our diagnostic PSG systems capture and store all data digitally. 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.

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***Proprietary Amplifiers.*** Our data acquisition systems incorporate recent developments in superior amplifiers for sleep analysis and are sold under brand names such as Embla and Embletta Gold, Xltek Trex and Connex, Schwarzer, and Nicolet. 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 for patient scheduling, inventory control, staff scheduling, data management, business reports and billing interfaces. Enterprise may be used in conjunction with many Natus PSG products.

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.

### ***Intraoperative Monitoring***

Intraoperative monitoring ( IOM ) is the use of electrophysiological methods such as EEG, EMG, and evoked potentials to monitor the functional integrity of certain neural structures (i.e. nerves, spinal cord and parts of the brain) during surgery. The purpose of IOM is to reduce the risk to the patient of damage by the surgeon to the nervous system, and/or to provide functional guidance to the surgeon and anesthesiologist during surgery.

### **Diagnostic IOM Product Lines**

***Protector.*** 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.

***Nicolet Endeavor.*** A dedicated IOM system that offers complete flexibility in work flow and test protocols.

***Nicolet EDX, Synergy Plinth, Viking Select.*** These systems are used in IOM applications where a smaller number of channels is sufficient. This approach is primarily followed in international markets that utilize the integrated system approach that allows for the use of the system in EMG clinical applications as well as in IOM applications.

### ***Transcranial Doppler***

Transcranial Doppler is the use of Doppler ultrasound technology to measure blood flow parameters such as velocity in key vascular structures in the brain. A Doppler probe is held against a specific location on the head and the device displays the information in both visual and auditory formats. This technology is used as preventative screening, diagnosis, and monitoring of various diseases and brain injuries such as stroke, embolism, reduced blood flow during surgery, and vasospasm.

### **Transcranial Doppler Products**

***Sonara and Sonara tek.*** The Sonara is an embedded system that is a self-contained unit that includes cpu, data display screen and speakers. It uses proprietary software with a touch screen menu. Sonara tek is a small portable device used with a laptop. Both models enable the uploading of images to the hospital information system.

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### **Newborn Care**

Our newborn care products represent a comprehensive line of products that are used by healthcare practitioners in the diagnosis and treatment of common medical ailments in newborn care, and other products used in newborn through adult populations. Our newborn care products include:

***Newborn Hearing Screening*** Products used to screen the hearing in the newborn.

***Newborn Brain Injury*** Products used to diagnose the severity of brain injury, monitor the effectiveness of drug therapies, and treat brain injury.

***Thermoregulation*** Products used to control the newborn environment including incubators and warmers.

***Jaundice Management*** Products used to treat jaundice, the single largest cause for hospital readmission of newborns in the U.S.

***Other Newborn Care Products*** Single use disposable products such as pacifiers, phototherapy masks, and x-ray shields, and newborn screening data management systems.

***Diagnostic Hearing Assessment*** 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.

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

### ***Newborn Hearing Screening***

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 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



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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 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%.

### **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 be 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.

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***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.

### ***Newborn Brain Injury***

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. Recently it has 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 in single channel, two-channel or three-channel modes 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.

### **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 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



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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***

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.

### **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 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***

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.

### **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.

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**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.

### ***Diagnostic Hearing Assessment***

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 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

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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.

### **Balance and Mobility**

Balance is an ability to maintain the line of gravity of the body within the base of support with minimal postural sway. Maintaining balance requires coordination of input from multiple sensory systems including the vestibular (i.e. inner ear), somatosensory (i.e. touch, temperature, body position), and visual systems. 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, psychiatry, 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.

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**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.

**VSR and VSR Sport.** 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 designed specifically for the athletic market 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 needed to make objective return-to-play decisions without relying on subjective evaluation.

**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.

**Segment and Geographic Information**

We operate in one reportable segment, which we have presented as the aggregation of our neurology and newborn care product families. Within this reportable segment we are organized on the basis of the healthcare products and services we provide which are used for the screening, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction, epilepsy, sleep 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.

**Revenue by Product Family and Product Category**

For the years ended December 31, 2013, 2012 and 2011, revenue from our product families as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2013	2012	2011
Neurology	65%	56%	43%
Newborn Care	35%	44%	57%
Total	100%	100%	100%

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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, 2013, 2012 and 2011 is as follows:

	Year Ended December 31,		
	2013	2012	2011
Devices and Systems	60%	60%	63%
Supplies and Services	40%	39%	35%
Other	0%	1%	2%
Total	100%	100%	100%

In 2013, 2012 and 2011, 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, 2013, our backlog was approximately \$12.3 million, compared to \$10.7 million at December 31, 2012 and \$8.2 million at December 31, 2011.

**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](http://www.natus.com);

Print and direct mail advertising campaigns; and

Sponsorship of and participation in clinical education seminars and workshops.

A key element of our marketing strategy involves 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.

**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

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products under private label and distribution arrangements.

Domestic revenue as a percent of total revenue was 58%, 56%, and 56% in 2013, 2012 and 2011, 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.

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International revenue as a percent of total revenue was 42%, 44%, and 44% in 2013, 2012 and 2011, 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. Our seasonality results from the purchasing habits of our hospital-based customers, whose purchases are often governed by calendar year budgets.

### ***Group Purchasing Organizations***

More than 90% of the hospitals in the U.S. are members of group purchasing organizations (GPOs), which negotiate volume purchase agreements for member hospitals, group practices, and other clinics. Direct purchases by GPO members accounted for approximately 7%, 10% and 12% of our revenue in 2013, 2012 and 2011, 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.

### ***Customer Service and Support***

We generally provide a one-year warranty on our 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 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, third-party vendors on a contract basis, and our distribution partners.

### **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.

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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 \$32.1 million or 9.3% of total revenue in 2013, \$30.0 million or 10.3% of total revenue in 2012, and \$25.6 million or 11% of total revenue in 2011.

## **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.

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.

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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.

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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 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.

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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.

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;

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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.

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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, 2013, we had approximately 943 full time employees worldwide. In Argentina, some of our production employees are represented by labor unions and our employees in Germany have established a works council. 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 17, 2014:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
James B. Hawkins	58	President and Chief Executive Officer
Jonathan Kennedy	43	Senior Vice President and Chief Financial Officer
Austin F. Noll, III	47	Vice President and General Manager, Neurology SBU
Kenneth M. Traverso	53	Vice President and General Manager, Newborn Care SBU
Ajay A. Bhave	57	Vice President of Global Engineering
D. Christopher Chung, M.D.	50	Vice President Medical Affairs, Quality & Regulatory

*James B. Hawkins* has served as President and Chief Executive Officer, and as a member of the Board of Directors, since joining Natus in April 2004, and as President from April 2004 through January 2011 and from June 2013 to present. In addition, he currently serves as a director of the Digirad Corporation and at IRIDEX Corporation. Prior to joining Natus, Mr. Hawkins was President, Chief Executive Officer and a Director of Invivo Corporation, a developer and manufacturer of multi-parameter vital sign monitoring equipment, and its predecessor, from August 1985 through January 2004. Mr. Hawkins also served as Secretary of Invivo from July 1986 until January 2004. He earned his undergraduate degree in Business Commerce from Santa Clara University and holds a Masters of Business Administration degree from San Francisco State University

*Jonathan Kennedy* joined Natus in April 2013 as Senior Vice President and Chief Financial Officer. Mr. Kennedy was previously employed by Intersil Corporation, where he served as Senior Vice President and Chief Financial Officer from April 2009 to March 2013, Interim Chief Financial Officer from December 2008 to April 2009, Corporate Controller from April 2005 to December 2008, and Director of Finance from June 2004 to April 2005. Prior to that time Mr. Kennedy served as Director of Finance and Information Technology of Alcon,

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Inc. from July 2000 to June 2004 and held various finance and information technology positions at Autonomous Technologies and Harris Corporation. He received a Bachelor of Science degree in Business Administration and a Masters in Science in Accounting from University of Central Florida. Mr. Kennedy is a certified public accountant.

*Austin F. Noll, III* joined Natus in August 2012 as Vice President and General Manager, Neurology Strategic Business Unit. Mr. Noll has over 24 years experience in the medical device industry. Mr. Noll previously served as President & CEO of Simpirica Spine, a California-based start-up company that developed and is commercializing a device for spinal stabilization. Prior to joining Simpirica Spine, Mr. Noll was President & CEO of NeoGuide Systems, a medical robotics company acquired by Intuitive Surgical in 2009. Prior to joining NeoGuide Systems, Mr. Noll held various positions at Medtronic over a 13-year period, where he served as the Vice President and General Manager of the Powered Surgical Solutions and the Neurosurgery businesses. Before Medtronic, he held sales positions at C.R. Bard and Baxter Healthcare. He received a Bachelor of Science degree in Business Administration from Miami University and a Master's in Business Administration from the University of Michigan.

*Kenneth M. Traverso* has served as our Vice President and General Manager, Newborn Care Strategic Business Unit since December 2012. He served as Vice President Marketing and Sales from April 2002 to December 2012. 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.

*Ajay A. Bhave* joined Natus in August 2011 as Vice President of Global Engineering. Mr. Bhave has over 28 years experience as an Engineering & Technology and Operations leader. Mr. Bhave most recently served as the Global Advanced Manufacturing Technology leader for probes used in high end diagnostic ultrasound equipment at General Electric Healthcare, a division of General Electric. From 1990 to 2011, Mr. Bhave held various positions of responsibilities, starting as an acoustic design engineer with subsequent senior management positions in engineering & technology, supply chain management and plant operations, both at the local as well as global level at General Electric Healthcare. From 1988 to 1990, Mr. Bhave was a senior engineer responsible for medical probes development at Staveley Sensors Inc., based out of Hartford, CT. From 1984 to 1998, Mr. Bhave was a senior engineer responsible for design and applications development of ultrasound probes used for non-destructive testing (NDT) in the Nuclear and Oil & Gas industry. Mr. Bhave has a Master's degree in Mechanical Engineering from the University of Lowell, Massachusetts.

*D. Christopher Chung, M.D.*, has served as our Vice President Medical Affairs, Quality and Regulatory since June 2011. From June 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 2010, 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 May 1986 to July 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 board certified in Pediatrics and is a Fellow of the American Academy of Pediatrics.

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**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](http://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](http://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.

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.

Previously we have assumed, and may in the future enter into, 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 used a significant portion of our existing cash resources, in addition to borrowing under our credit facility, to complete the acquisition of the Nicolet business from CareFusion in 2012. This usage of cash had a short term adverse impact on our liquidity, and forced us to place more reliance on cash flow from operations for our liquidity. For future acquisitions where existing cash resources are used to fund the acquisition, if our cash flow from operations is not sufficient for our needs, our business could be adversely impacted.

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

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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 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; Embla and Neometrics in New York; Nicolet in Wisconsin; Xltek 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 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.

**If we are not able to maintain effective internal control over financial reporting in the future, the accuracy and timeliness of our financial reporting may be adversely affected.**

## Edgar Filing: NATUS MEDICAL INC - Form 10-K

We reported a material weakness in our internal control over financial reporting for the year ended December 31, 2012. We remediated this material weakness in 2013 and had no material weaknesses as of December 31, 2013. A material weakness is defined under the standards issued by the Public Company Accounting Oversight Board as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected and corrected on a timely basis.

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The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures quarterly. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If other material weaknesses are identified in the future or we are not able to comply with the requirements of Section 404 in a timely manner, our reported financial results could be materially misstated or could be restated, we could receive an adverse opinion regarding our controls from our accounting firm and we could be subject to investigations or sanctions by regulatory authorities, which would require additional financial and management resources, and the market price of our stock could decline.

### **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. 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 recently implemented the rollout of a world-wide, single-platform enterprise resource planning ( ERP ) application including customer relationship management, product lifecycle management, demand management, consolidation and financial statement generation, and business intelligence. In 2012 we implemented this application in our North American operations, exclusive of the operations of Nicolet. We faced unexpected challenges in preparing our financial statements on a timely basis for the third and fourth quarters of 2012, and the first quarter of 2013 that were resolved only by devoting additional resources to the close. We may experience difficulties in the implementation of the ERP in our operations outside of North America, a portion of which will occur in early 2014, and we may fail to gain the efficiencies the implementation is designed to produce within the anticipated timeframe. We will continue to incur additional costs associated with stabilization and ongoing development of the new platform. 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. Until we have completed this world wide implementation, we will be dependent on multiple platforms.

### **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

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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 Neurology reporting unit.

**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

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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 to the implementation of health care reform, our business may be adversely affected.

**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 federal, 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 7%, 10% and 12% of our total revenue during 2013, 2012 and 2011, respectively. Certain other 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.



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### **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 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;



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

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

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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, 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. Our contracts with our distributors or sub-distributors do not assure us significant minimum purchase volume. If a contract with a distributor or sub-distributor is terminated for cause or by us for convenience, the distributor or sub-distributor will have no obligation to purchase products from us. 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.

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**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 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 or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective.

Delays in receipt of, or failure to receive, clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could adversely impact our operating results. If the FDA finds that we have failed to comply with these requirements, the Agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

Fines, injunctions and civil penalties;

Recall or seizure of our products;

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Issuance of public notices or warnings;

Imposition of operating restrictions, partial suspension, or total shutdown of production;

Refusal of our requests for Section 510(k) clearance or premarket approval of new products;

Withdrawal of Section 510(k) clearance or premarket approvals already granted; or

Criminal prosecution.

Domestic regulation of our products and manufacturing operations, other than that which is administered by the FDA, includes the Environmental Protection Act, the Occupational Safety and Health Act, and state and local counterparts to these Acts.

**Our business would be harmed if the FDA determines that we have failed to comply with applicable regulations governing the manufacture of our products and/or we do not pass an inspection**

We and our suppliers are required to demonstrate and maintain compliance with the FDA's Quality System Regulation. The Quality System Regulation sets forth the FDA's requirements for good manufacturing practices of medical devices and includes requirements for, among other things, the design, testing, production processes, controls, quality assurance, labeling, packaging, storage and shipping of such products. In addition, we and our suppliers must engage in extensive recordkeeping and reporting and must make available our manufacturing facility and records for periodic unscheduled inspections by federal, state and foreign agencies, including the FDA. We cannot assure you that we and our suppliers are or will continue to be in full compliance with the Quality System Regulation, and that we will not encounter any manufacturing difficulties.

Failure of our third party suppliers and manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including, among other things, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or recalls of products and manufacturing restrictions, any of which could harm our business.

**Our Olympic Cool-Cap product is subject to greater products liability exposure and FDA regulation**

The FDA classifies medical devices into one of three classes depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety and effectiveness. Devices deemed to pose lower risk are placed in either Class I or Class II. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life supporting or implantable devices, or a device deemed to not be substantially equivalent to a previously cleared 510(k) device are placed in Class III, and generally require premarket approval from the FDA before they may be marketed.

Our Olympic Cool-Cap is a Class III minimally invasive medical device, and as such we may be subject to an increased product liability risk relative to our other Class I and Class II non-invasive products. In addition, this type of product is subject to greater FDA oversight than our other products and there is greater risk that sales of the product could be interrupted due to the premarket approval processes of the FDA and other regulatory bodies.

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

We are prohibited by the FDA from promoting or advertising our medical device products for uses not within the scope of our clearances or approvals, or from making unsupported promotional claims about the benefits of our products. If the FDA determines that our claims are outside the scope of our clearances, or are unsupported, it could require us to revise our promotional claims or take enforcement action against us. If we were subject to such an action by the FDA, our sales could be delayed, our revenue could decline, and our



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reputation among clinicians could be harmed. Likewise, if we acquire new products, either through the purchase of products, technology assets, or businesses, that are subsequently deemed to have inadequate supporting data, we may be required to (i) obtain adequate data, which could be costly and impede our ability to market these products, or (ii) modify the labeling on these products, which could impair their marketability, as described above.

### **If we deliver products with defects, we may incur costs to repair and, possibly, recall that product and market acceptance of our products may decrease.**

The manufacturing and marketing of our products involve an inherent risk of our delivering a defective product or products that do not otherwise perform as we expect. We may incur substantial expense to repair any such products and may determine to recall such a product, even if not required to do so under applicable regulations. Any such recall would be time consuming and expensive. Product defects or recalls may adversely affect our customers' acceptance of the recalled and other of our products. As an example, in the second quarter of 2010 we discontinued selling the Sonamed Clarity newborn hearing screening product line and incurred costs associated with sales concessions awarded customers who traded in a Clarity device for one of our existing newborn hearing screening devices and the write-down of inventory. We also recorded an impairment charge to write-off the carrying value of the Sonamed and Clarity tradenames.

### **If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.**

We do not provide healthcare services, control the referral of patients for healthcare services, nor bill Medicare, Medicaid or other third-party payors; however, due to the breadth of many healthcare laws and regulations, we could be subject to healthcare fraud regulation and enforcement by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include: (i) the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers, and/or (iii) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

### **Our operating results would suffer if we were subject to a protracted infringement claim**

The medical technology industry is characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. We expect that medical screening and diagnostic products may become increasingly subject to third-party infringement claims as the number of

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competitors in our industry grows and the functionality of products overlap. Third parties such as individuals, educational institutions, or other medical device companies may claim that we infringe their intellectual property rights. Any claims, with or without merit, could have any of the following negative consequences:

Result in costly litigation and damage awards;

Divert our management's attention and resources;

Cause product shipment delays or suspensions; or

Require us to seek to enter into royalty or licensing agreements.

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

We may also find it necessary to bring infringement actions against third parties to seek to protect our intellectual property rights. Litigation of this nature, even if successful, is often expensive and disruptive of our management's attention, and in any event may not lead to a successful result relative to the resources dedicated to any such litigation.

### **We license intellectual property rights from third parties and would be adversely affected if our licensors do not appropriately defend their proprietary rights or if we breach any of the agreements under which we license commercialization rights to products or technology from others**

We license rights from third parties for products and technology that are important to our business. If our licensors are unsuccessful in asserting and defending their proprietary rights, including patent rights and trade secrets, we may lose the competitive advantages we have through selling products that we license from third parties. Additionally, if it is found that our licensors infringe on the proprietary rights of others, we may be prohibited from marketing our existing products that incorporate those proprietary rights. Under our licenses, we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach a license agreement, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license.

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

The sale and use of our products could lead to the filing of a product liability claim by someone claiming to have been injured using one of our products or claiming that one of our products failed to perform properly. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business reputation or financial condition. Our product liability insurance may not protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing any coverage in the future.

### **We have experienced seasonality in the sale of our products**

We experience seasonality in our revenue. For example, our sales typically decline from our fourth fiscal quarter to our first fiscal quarter, due to patterns in the capital budgeting and purchasing cycles of our customers, many of which are government agencies, and the compensation arrangements of our direct sales employees, as those arrangements are tied to calendar-year sales plans. We may also experience declining sales in the third fiscal quarter due to summer holiday and vacation schedules. We anticipate that we will continue to experience these seasonal fluctuations, which may lead to fluctuations in our quarterly operating results. We believe that you should not rely on our results of operations for interim periods as an indication of our expected results in any future period.



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**An interruption in or breach of security of our information or manufacturing systems, including the occurrence of a cyber incident or a deficiency in our cybersecurity, may result in a loss of business or damage to our reputation.**

We rely on communications, information and manufacturing systems to conduct our business. Any failure, interruption or cyber incident of these systems could result in failures or disruptions in our customer relationship management or product manufacturing. A cyber incident is an intentional attack or an unintentional event that can include gaining unauthorized access to information systems to disrupt operations, corrupt data, or steal confidential information. The occurrence of any failures, interruptions or cyber incidents could result in a loss of customer business or reputation and have a material effect on our business, financial condition, results of operations and cash flows.

**ITEM 1B. Unresolved Staff Comments.**

None.

**ITEM 2. Properties**

Our corporate headquarters are located in San Carlos, California, in facilities covering 26,300 square feet pursuant to a lease that expires in June 2015.

We also utilize the following properties:

**Company-owned Facilities:**

44,900 square feet in Oakville, Ontario, Canada, utilized substantially research and development;

26,000 square feet in Mundelein, Illinois, utilized substantially manufacturing;

116,000 square feet in Buenos Aires, Argentina, utilized substantially for manufacturing;

42,600 square feet in Gort, Ireland, utilized substantially for manufacturing;

6,400 square feet in Old Woking, England, utilized substantially for research and development.

**Leased Facilities:**

Following is a listing of our most significant leased properties; we have a number of smaller facilities under lease in various countries where we operate.

65,000 square feet in Seattle, Washington, pursuant to a lease that expires in December 2014, that is utilized substantially for manufacturing;

65,000 square feet in Middleton, Wisconsin, pursuant to a lease that expires in September 2014 that is utilized for manufacturing;

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100,000 square feet in Middleton, Wisconsin, pursuant to a lease that commences in May 2014 and expires in April 2024 that will be utilized for manufacturing;

19,800 square feet in Skovlunde, Denmark, pursuant to a lease that expires with six-month notice that is utilized for manufacturing;

43,000 square feet in Planegg, Germany, pursuant to a lease that expires in December 2021 that is utilized substantially for manufacturing.

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**ITEM 3. Legal Proceedings**

We may from time to time become a party to various legal proceedings or claims that arise in the ordinary course of business. We are not currently involved in any legal or administrative proceedings that we believe are likely to have a material effect on our business, financial condition, or results of operations, although we cannot be assured of the outcome of such matters.

**ITEM 4. Mine Safety Disclosures**

The disclosure required by this item is not applicable.

**Table of Contents****PART II****ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock trades on the Nasdaq Global Select Market under the symbol "BABY". The following table sets forth, for the periods indicated, the high and low sale price per share of our common stock, as reported on the Nasdaq Global Select Market.

	<b>High</b>	<b>Low</b>
Fiscal Year Ended December 31, 2013:		
Fourth Quarter	\$ 23.03	\$ 13.61
Third Quarter	14.29	11.78
Second Quarter	15.11	12.13
First Quarter	13.78	11.46
Fiscal Year Ended December 31, 2012:		
Fourth Quarter	\$ 13.10	\$ 10.47
Third Quarter	13.36	11.71
Second Quarter	12.31	10.10
First Quarter	11.95	9.88

As of March 14, 2014, there were 31,904,463 shares of our common stock issued and outstanding and held by approximately 35 stockholders of record. We estimate that there are approximately 7,100 beneficial owners of our common stock.

**Dividends**

We have never declared or paid cash dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Based on the terms of our Amended and Restated Credit Agreement with Wells Fargo Bank, National Association ( "Wells Fargo" ), we are prevented from paying dividends without the prior approval of the bank.

**Table of Contents****Stock Performance Graph**

The following information of Part II Item 5 is being furnished and shall not be deemed to be soliciting material or to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor will it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate such information by reference thereto.

The following graph shows a comparison, from January 1, 2008 through December 31, 2013, of cumulative total return for our common stock, the Nasdaq Composite Index and the Standard & Poor's 500 Health Care Equipment Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the Nasdaq Composite Index and the Standard & Poor's 500 Health Care Equipment Index assumes reinvestment of dividends.

		2008	2009	2010	2011	2012	2013
Natus Medical Inc.	Return %		14.21	-4.12	-33.50	18.35	101.61
	Cum \$	100.00	114.21	109.50	72.82	86.18	173.75
NASDAQ Composite-Total Returns	Return %		45.34	18.13	-0.79	17.75	40.17
	Cum \$	100.00	145.34	171.70	170.34	200.57	281.14
S&P 500 Health Care Equipment Index	Return %		28.79	-2.71	-0.80	17.27	27.69
	Cum \$	100.00	128.79	125.30	124.30	145.76	186.12

**ITEM 6. Selected Financial Data**

The following tables set forth certain selected consolidated financial data as of December 31, 2013, 2012, 2011, 2010 and 2009 and for each of the years in the five-year period ended December 31, 2013, and is derived from the Consolidated Financial Statements of Natus Medical Incorporated and its subsidiaries. The Consolidated Financial Statements as of December 31, 2013 and 2012 and for each of the years in the three-year period ended December 31, 2013 are included elsewhere in this report. The selected consolidated balance sheet data as of December 31, 2011, 2010 and 2009 and the consolidated statements of operations data for the years ended December 31, 2010 and 2009 are derived from our Consolidated Financial Statements, which are not included in this report. The selected consolidated financial data set forth below is qualified in its entirety by, and

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should be read in conjunction with, the Consolidated Financial Statements and Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report.

	2013	Year ended December 31,			2009
		2012	2011	2010	
		(in thousands, except per share data)			
<b>Consolidated Statement of Operations Data (a):</b>					
Revenue	\$ 344,112	\$ 292,280	\$ 232,895	\$ 218,412	\$ 166,425
Cost of Revenue	142,081	128,812	101,610	88,608	65,985
Gross profit	202,031	163,468	131,285	129,804	100,440
Operating expenses:					
Marketing and selling	87,151	77,285	63,048	54,838	45,267
Research and development	32,073	29,966	25,580	21,278	16,721
General and administrative (b)	48,528	50,963	32,990	35,754	22,999
Goodwill impairment charge (c)			20,000		
Total operating expense	167,752	158,214	141,618	111,870	84,987
Income (loss) from operations	34,279	5,254	(10,333)	17,934	15,453
Other income (expense), net	(2,716)	(835)	(74)	(190)	1,696
Income (loss) before provision for income taxes	31,563	4,419	(10,407)	17,744	17,149
Provision for income tax expense	8,685	536	772	5,804	5,721
Net income (loss)	\$ 22,878	\$ 3,883	\$ (11,179)	\$ 11,940	\$ 11,428
Earnings (loss) per share:					
Basic	\$ 0.76	\$ 0.13	\$ (0.39)	\$ 0.43	\$ 0.41
Diluted	\$ 0.74	\$ 0.13	\$ (0.39)	\$ 0.41	\$ 0.40
Weighted average shares used in the calculation of earnings (loss) per share:					
Basic	29,993	29,031	28,565	28,092	27,651
Diluted	30,821	29,837	28,565	29,217	28,476
	2013	2012	December 31, 2011	2010	2009
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents, and short-term investments	\$ 56,106	\$ 23,057	\$ 32,816	\$ 29,388	\$ 33,551
Working capital	116,690	70,265	89,497	85,657	75,835
Total assets	426,438	391,853	314,846	325,103	292,256
Long-term debt (including current portion) and short-term borrowings	38,017	32,860	898	1,001	1,163
Total stockholders' equity	306,318	268,752	258,313	264,132	244,413

- (a) Results of operations and financial position of the businesses we have acquired are included from their acquisition dates as follows: Hawaii Medical in July 2009, Alpine Biomed in September 2009, Medix in October 2010, Embla in September 2011, Nicolet in July 2012 and Grass in February 2013.

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- (b) Includes restructuring charges of \$4.7 million, \$8.8 million and \$2.8 million in the years ended December 31, 2013, 2012 and 2011, respectively.
  
- (c) The \$20.0 million goodwill impairment charge in 2011 is related to our Neurology reporting unit.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ( MD&A ) should be read in conjunction with our Consolidated Financial Statements and the accompanying footnotes. MD&A includes the following sections:

**Our Business.** A general description of our business.

**Year 2013 Overview.** A summary of key information concerning the financial results for 2013 and changes from 2012.

**Application of Critical Accounting Policies.** A discussion of the accounting policies that are most important to the portrayal of our financial condition and results of operations and that require critical judgments and estimates.

**Results of Operations.** An analysis of our results of operations for the three years presented in the financial statements.

**Liquidity and Capital Resources.** An analysis of capital resources, sources and uses of cash, investing and financing activities, and contractual obligations.

**Business**

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.

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. Recent significant acquisitions include Nicolet in 2012 and Grass in 2013. We expect to continue to pursue opportunities to acquire other businesses in the future.

**Year 2013 Overview**

In 2013 we completed the purchase of the Grass Technologies Product Group ( Grass ) from Astro-Med Inc. for a cash consideration of \$18.6 million. The Grass product group includes clinically differentiated neurodiagnostic and monitoring products, including a portfolio of electroencephalography (EEG) and polysomnography (PSG) systems for both clinical and research use and related accessories and proprietary electrodes. The addition of Grass products enhanced our existing neurology portfolio and provided new product offerings.

Our consolidated revenue increased \$51.8 million for the year ended December 31, 2013 compared to 2012. Grass, acquired in February 2013, contributed to \$12.8 million of incremental revenue in 2013. Nicolet, acquired in July 2012, contributed \$41.7 million of incremental revenue in 2013. We experienced revenue declines across other business units in the United States, Europe, South America, and Canada in 2013.

We incurred \$4.7 million of restructuring charges in 2013 as we took additional steps to improve efficiencies in operations and eliminate redundant costs from our recent acquisitions.

**Application of Critical Accounting Policies**

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

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

***Revenue recognition***

Revenue, net of discounts, is recognized from sales of medical devices and supplies, including sales to distributors, when the following conditions have been met: a purchase order has been received, title has transferred, the selling price is fixed or determinable, and collection of the resulting receivable is reasonably assured. Terms of sale for most domestic sales are FOB origin, reflecting that title and risk of loss are assumed by the purchaser at the shipping point; however, terms of sale for some domestic customers are FOB destination, reflecting that title and risk of loss are assumed by the purchaser upon delivery. Terms of sales to international distributors are generally shipped ex works, in which title and risk of loss are passed to the distributor at the shipping point.

We previously accounted for arrangements with multiple deliverables under ASC Topic 605, where revenue was allocated to the deliverables based on vendor specific objective evidence ( VSOE ). In October 2009 the FASB issued ASU 2009-13, *Multiple Deliverable Revenue Arrangements*, which amends ASC Topic 605, and we prospectively adopted the provisions of ASU 2009-13 on January 1, 2010. Under the revenue recognition rules for tangible products as amended by ASU 2009-13, we now allocate revenue from arrangements with multiple deliverables to each of the deliverables based upon their relative selling prices as determined by a selling-price hierarchy. A deliverable in an arrangement qualifies as a separate unit of accounting if the delivered item has value to the customer on a stand-alone basis. The principal deliverables in our multiple deliverable arrangements that qualify as separate units of accounting consist of (i) sales of medical devices and supplies, (ii) installation services, (iii) extended service and maintenance agreements, and (iv) upgrades to embedded software.

The new rules establish a hierarchy to determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor-specific objective evidence of fair value ( VSOE ), (ii) third-party evidence of selling price ( TPE ), and (iii) best estimate of the selling price ( ESP ). VSOE of fair value is defined as the price charged when the same element is sold separately, or if the element has not yet been sold separately, the price for the element established by management having the relevant authority when it is probable that the price will not change before the introduction of the element into the marketplace. We have established VSOE for substantially all of the undelivered elements in our multiple element arrangements and ESPs on delivered elements. In the future we may rely on ESPs, reflecting our best estimates of what the selling prices of elements would be if they were sold regularly on a stand-alone basis, to establish the amount of revenue to allocate to the undelivered elements. TPE generally does not exist for our products because of their uniqueness.

For products shipped under FOB origin or ex-works terms, delivery is generally considered to have occurred when shipped. Undelivered elements in our sales arrangements, which are not considered to be essential to the functionality of a product, generally include installation or training services that are performed after the related products have been delivered. Revenue related to undelivered installation services is deferred until such time as installation is complete at the customer's site. Revenue related to training services is recognized when the service is provided. Fair value for installation or training services is based on the price charged when the service is sold separately. The fair value of installation and training services is based upon billable hourly rates and the estimated time to complete the service.

Revenue from extended service and maintenance agreements, for both medical devices and data management systems, is recognized ratably over the service period. Freight charges billed to customers are included in revenue and freight-related expenses are charged to cost of revenue. Advance payments from customers are recorded as deferred revenue and recognized as revenue as otherwise described above. We generally do not provide rights of return on products.

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***Inventory is carried at the lower of cost or market value***

We may be exposed to a number of factors that could result in portions of our inventory becoming either obsolete or being held in quantities that exceed anticipated usage. These factors include, but are not limited to: technological changes in our markets, competitive pressures in products and prices, and our own introduction of new product lines.

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

***Carrying value of intangible assets and goodwill***

We amortize intangible assets with finite lives over their useful lives; any future changes that would limit their useful lives or any determination that these assets are carried at amounts greater than their estimated fair value could result in additional charges. We carry goodwill and any other intangible assets with indefinite lives at original cost but do not amortize them. Any future determination that these assets are carried at amounts greater than their estimated fair value could result in additional charges, which could significantly impact our operating results.

We test our intangible assets with finite lives for impairment whenever changes in circumstances indicate the carrying value of these assets may be impaired. Impairment indicators include, but are not limited to, net book value as compared to market capitalization, significant negative industry and economic trends, and significant underperformance relative to historical and projected future operating results. Impairment is considered to have occurred when the estimated undiscounted future cash flows related to the asset are less than its carrying value. Estimates of future cash flows involve consideration of many factors including the marketability of new products, product acceptance and lifecycle, competition, appropriate discount rates, and operating margins.

Goodwill and indefinite-lived intangible assets are tested for impairment at least annually as of October 1st; this assessment is also performed whenever there is a change in circumstances that indicates the carrying value of these assets may be impaired.

As of October 1, 2012, Natus performed its impairment testing based on five reporting units, Natus U.S., Natus Canada, Natus Europe, Medix, and Nicolet. The reporting unit structure was driven by a combination of legal entity status and geographic proximity, as a result of a series of strategic acquisitions. Each business unit functioned through its individual management team and measured its performance against its individual annual budget. This reporting unit structure was not based upon similar economic characteristics including product mix.

As of January 1, 2013, the Company completed and launched its internal realignment into two strategic business units, Neurology and Newborn Care. We believe that these are the applicable reporting units for these analyses based upon economic characteristics including customer base, sales force, vendor base, product mix, manufacturing/subassembly process, product distribution processes, regulatory environment and related inventory characteristics. The Company performed an impairment test under the old structure at the annual test date of October 1, 2012. Effective with first quarter of 2013, the Company transitioned to the new strategic business unit reporting structure.

The determination of whether any potential impairment of goodwill exists is based upon a two-step process. In the first step, the fair value of the reporting unit is compared to the reporting unit's carrying value, including goodwill, to determine if there is a potential impairment. If the fair value of the reporting unit exceeds the carrying amount, the goodwill of the reporting unit is considered not impaired and no further analysis or action is

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required. If the first step indicates that the carrying value exceeds the fair value, a second step is performed to determine the amount of the goodwill impairment loss, if any.

In step two of the impairment test, the implied fair value of a reporting unit's goodwill is compared to the carrying amount of that goodwill. The implied fair value of the goodwill is determined in the same manner as the amount of goodwill recognized in a business combination is determined. That is, the fair value of a reporting unit is allocated to all the assets and liabilities of that reporting unit, including unrecognized intangible assets as if the reporting unit had been acquired in a business combination and the fair value of the reporting unit was the price paid to acquire the reporting unit. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of that goodwill.

To determine the estimated fair value of reporting units, two valuation methodologies are utilized: (i) discounted cash flow analyses, and (ii) guideline publicly-traded companies. The valuations indicated by these methodologies are averaged, with the greatest weight placed on discounted cash flow analyses. Discounted cash flow analyses are dependent upon a number of quantitative and qualitative factors including estimates of forecasted revenue, profitability, earnings before interest, taxes, depreciation and amortization (i.e. EBITDA) and terminal values. The discount rates applied in the discounted cash flow analyses also have an impact on the estimates of fair value, as use of a higher rate will result in a lower estimate of fair value. The estimated total fair value of reporting units is reconciled to the Company's market capitalization.

As of the October 1, 2013 testing date, we determined that goodwill was not impaired; however, we determined that certain trade names were impaired and we recorded an impairment charge of \$1.5 million.

Key assumptions used to determine the fair value were: (i) expected cash flow for the period from October 1, 2013 to December 31, 2022; and (ii) discount rates for the respective reporting units which were 14% and were based on management's best estimate of the after-tax weighted average cost of capital for each reporting unit.

Because the fair values of our reporting units significantly exceeded their book value as of October 1, 2013, we did not perform sensitivity analysis as part of the annual impairment test.

Future changes in the judgments and estimates underlying our analysis of goodwill for possible impairment, including expected future cash flows and discount rate, could result in a significantly different estimate of the fair value of the reporting units and could result in additional impairment of goodwill.

***Liability for product warranties***

Our medical device products are generally covered by a standard one-year product warranty. A liability has been established for the expected cost of servicing our medical device products during this service period. We base the liability on actual warranty costs incurred to service those products. On new products, additions to the reserve are based on a combination of factors including the percentage of service department labor applied to warranty repairs, actual service department costs, and other judgments, such as the degree to which the product incorporates new technology. As warranty costs are incurred, the reserve is reduced.

The estimates we use in projecting future product warranty costs may prove to be incorrect. Any future determination that our product warranty reserves are understated could result in increases to our cost of sales and reductions in our operating profits and results of operations.

***Share-based compensation***

We record the fair value of share-based compensation awards as expenses in the consolidated statement of operations. In order to determine the fair value of stock options on the date of grant, we apply the Black-Scholes

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option-pricing model. Inherent in this model are assumptions related to expected dividend yield, risk-free interest rate, expected stock-price volatility, expected term, and forfeiture rate. While the risk-free interest rate and dividend yield are less subjective assumptions, typically based on factual data derived from public sources, expected stock-price volatility, expected life, and forfeiture rate assumptions require a greater level of judgment which makes them critical accounting estimates. If we used different assumptions, we would have recorded different amounts of share-based compensation.

**Results of Operations**

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

	Percent of Revenue Years Ended December 31,		
	2013	2012	2011
Revenue	100.0%	100.0%	100.0%
Cost of revenue	41.3	44.1	43.6
Gross profit	58.7	55.9	56.4
Operating expenses:			
Marketing and selling	25.3	26.4	27.1
Research and development	9.3	10.3	11.0
General and administrative	14.1	17.4	14.2
Goodwill impairment charge			8.6
Total operating expenses	48.7	54.1	60.8
Income (loss) from operations	10.0	1.8	(4.4)
Other income (expense), net	(0.8)	(2.9)	(0.0)
Income (loss) before provision for income tax	9.2	1.5	(4.5)
Income tax provision	2.5	1.8	0.3
Net income (loss)	6.6%	1.3%	(4.8)%

**Acquisitions**

We completed three significant acquisitions during 2013, 2012 and 2011, and the timing of these acquisitions had an impact on the comparison of our results of operations for the years ended December 31, 2013, 2012 and 2011.

**Comparison of 2013 and 2012****Revenue**

For the year ended December 31, 2013, our consolidated revenue increased by \$51.8 million, or 17.7% to \$344.1 million, compared to \$292.3 million for the year ended December 31, 2012. The increase was attributable to our recent acquisitions. Grass, acquired in February 2013, contributed \$12.8 million of revenue in 2013. Nicolet, acquired in July 2012, contributed \$41.8 million of incremental revenue in 2013. Revenue from our products other than Grass and Nicolet experienced a decrease of \$2.7 million from the prior year, driven by Newborn Care.

Revenue from our neurology products increased \$55.6 million, or 33.1% to \$223.7 million in the year ended December 31, 2013, compared to \$168.1 million in 2012. Revenue from our neurology products, other than



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Grass and Nicolet products, increased by \$1.1 million in 2013 compared to 2012, primarily attributable to an increase in sales of our EEG products. Revenue from our newborn care products decreased by \$3.8 million, or 3% to \$120.4 million in 2013, compared to \$124.2 million in 2012. This decline was primarily attributed to lower sales of newborn and diagnostic hearing, balance monitoring and devices in Europe and North America.

Revenue from neurology devices and systems was \$139.0 million in 2013, representing an increase of 28.6% or \$30.9 million, from \$108.1 million reported in 2012. Grass contributed \$7.6 million of the increase in neurology devices and systems. Nicolet contributed \$23.8 million of incremental revenue to neurology devices and systems. Revenue from newborn care and other devices and systems was \$66.6 million in 2013, representing a decrease of 9% or \$6.6 million, from \$73.2 million reported in 2012. This decline in sales of newborn care devices and systems revenue was comprised of newborn hearing, balance monitoring and distributed product revenue.

Revenue from devices and systems was 59.8% of consolidated revenue in 2013 compared to 62% of total revenue in 2012.

Revenue from neurology supplies and services was \$84.6 million in 2013, representing an increase of 41% or \$24.6 million, from \$60.0 million reported in 2012. Grass contributed \$5.1 million of the increase in neurology supplies and services in 2013. Nicolet contributed incremental revenue of \$18.0 million of the increase in neurology supplies and services. Neurology supplies and services revenue other than Grass and Nicolet increased by \$1.5 million in the year ended December 31, 2013 compared to the year ended December 31, 2012. This increase was primarily attributable to services provided both domestically and internationally. Revenue from newborn care supplies and services was \$53.8 million in 2013, representing an increase of 5.5% or \$2.8 million, from \$51.2 million reported in 2012. This increase was comprised of both domestic newborn care supplies and services revenue.

Revenue from supplies and services was 40.2% of consolidated revenue in 2013 compared to 38% of total revenue in 2012.

No single customer accounted for more than 10% of our revenue in either 2013 or 2012. Revenue from domestic sales increased 22.5% to \$199.6 million in 2013, from \$163.0 million in 2012. Revenue from international sales increased 11.8% to \$144.5 million in 2013, compared to \$129.3 million in 2012. Revenue from domestic sales was 58% of total revenue in 2013 compared to 56% of total revenue in 2012, and revenue from international sales was 42% of total revenue in 2013 compared to 44% of total revenue in 2012.

### **Cost of Revenue and Gross Profit**

Our cost of revenue increased \$13.3 million, or 10.3% to \$142.1 million in 2013, from \$128.8 million in 2012. Of this increase, \$9.9 million was incremental cost from Grass and Nicolet. Gross profit increased \$38.5 million, or 23.6%, to \$202.0 million in 2013 from \$163.5 million in 2012 due to the overall growth in revenue and also as a result of our improved margins associated with product mix. Gross profit as a percentage of revenue was 58.7% in 2013 and 55.9% in 2012. The increase in gross profit as a percentage of revenue was the result of a higher percentage of sales of neurology products which generally carry higher margins than our other products.

### **Operating Costs**

Total operating costs increased \$9.6 million, or 6% to \$167.8 million in 2013, from \$158.2 million in 2012. The operating expense of Grass and the incremental expense of Nicolet contributed to \$17 million in operating costs. We recorded \$4.7 million of restructuring charges in 2013 compared to \$5.2 million in 2012. These amounts were offset by reduced employee compensation costs resulting from the additional restructuring activities implemented in mid 2013.

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Our marketing and selling expenses increased \$9.9 million, or 12.8% to \$87.2 million in 2013, from \$77.3 million in 2012. Marketing and selling expenses as a percent of total revenue decreased to 25.3% in 2013 from 26.4% in 2012. The marketing and selling expenses of Grass and the incremental marketing and selling expenses of Nicolet were \$10.7 million. The remainder of the increase in marketing and selling expenses was primarily related to higher sales commission and sales related costs associated with the increase in our revenue.

Our research and development expenses increased \$2.1 million, or 7% to \$32.1 million in 2013 from \$30.0 million in 2012. Research and development expenses as a percent of total revenue decreased to 9.3% in 2013 from 10.3% in 2012. The research and development expenses of Grass and the incremental research and development expenses of Nicolet were \$4.6 million, offset by lower employee compensation costs resulting from additional cost cutting activities initiated in 2013.

Our general and administrative expenses decreased \$2.4 million, or 4.7% to \$48.5 million in 2013 from \$51.0 million in 2012. General and administrative expenses as a percent of revenue decreased from 17.4% in 2012 to 14.1% in 2013. The general and administrative expense of Grass and the incremental general and administrative expenses of Nicolet resulted in a net reduction of \$(0.4) million. The overall reductions in general and administrative expenses were due to \$7.3 million reduction in severance expenses offset by increased external audit fees of \$1.2 million and increased expenses related to our Oracle implementation of \$1.6 million.

**Other Income (Expense), net**

Other income (expense), net consists of investment income, interest expense, net currency exchange gains and losses, and other miscellaneous income and expense. We reported other income (expense), net of \$(2.7) million in 2013, compared to \$(835,000) in 2012. Investment income of \$32,456 in 2013 was \$23,411 less than the amount reported for 2012. We reported \$1.4 million of foreign currency exchange losses in 2013 versus \$220,305 of foreign exchange losses in 2012. This increase was driven primarily by foreign denominated sales from our Nicolet business in Europe. Interest expense was \$1.7 million in 2013 compared to \$489,000 in 2012 due to increased interest associated with the increase in our term loan from Wells Fargo.

**Provision for Income Tax**

We recorded income tax expense of \$8.7 million and \$536,000 in 2013 and 2012, respectively. Our effective tax rate was 27.5% and 12.1% for the years ended December 31, 2013 and 2012, respectively. The higher income tax expense in 2013 is primarily the result of significantly higher pretax earnings. The higher effective tax rate in 2013 compared with 2012 is primarily due to income tax benefits recorded in 2012 as a result of expiration of the statute of limitations on uncertain tax positions for which no similar benefit was taken in 2013. Other significant items impacting the provision for income taxes in 2013 was the income tax benefits derived from the recognition of the 2012 federal research and development tax credit by enactment of the American Taxpayer Relief Act of 2012 in January 2013.

***Comparison of 2012 and 2011******Revenue***

For the year ended December 31, 2012, our consolidated revenue increased by \$59.4 million, or 25% to \$292.3 million, compared to \$232.9 million for the year ended December 31, 2011. The increase was attributable to our recent acquisitions. Nicolet, acquired in July 2012, contributed \$51.5 million of revenue in 2012. Embla, acquired in September 2011, contributed \$28.8 million of revenue in 2012, compared to \$10.9 million of revenue in 2011, or an increase of \$17.9 million. Revenue from our products other than Nicolet and Embla decreased by \$10 million in 2012, compared to 2011, due in large part to our emphasizing the sale of the newly acquired products that serve the same markets as certain of our Xltek, Bio-logic and Schwarzer products.

Revenue from our neurology products increased \$63.9 million, or 61.3% to \$168.1 million in the year ended December 31, 2012, compared to \$104.2 million in 2011. Revenue from our neurology products, other than Nicolet and Embla products, decreased by \$4.4 million in 2012 compared to 2011. This decline was attributable

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to weak economic conditions in Europe and to our emphasizing the sales of our newly acquired neurology products. Revenue from our newborn care products decreased by \$4.5 million, or 3.5% to \$124.2 million in 2012, compared to \$128.7 million in 2011. This decline was primarily attributed to lower sales of newborn and diagnostic hearing, balance monitoring and supplies.

Revenue from neurology devices and systems was \$108.1 million in 2012, representing an increase of 42.6% or \$32.3 million, from \$75.8 million reported in 2011. Nicolet and Embla contributed to \$32.6 million of the increase in neurology devices and systems. Revenue from newborn care and other devices and systems was \$73.2 million in 2012, representing a decrease of 5.7% or \$4.4 million, from \$77.6 million reported in 2011. This decline in newborn care devices and systems revenue was comprised of newborn hearing, balance monitoring and distributed product revenue.

Revenue from devices and systems was 62% of consolidated revenue in 2012 compared to 65.9% of total revenue in 2011.

Revenue from neurology supplies and services was \$60.0 million in 2012, representing an increase of 105% or \$31.5 million, from \$28.5 million reported in 2011. Nicolet and Embla contributed to \$36 million of the increase in neurology supplies and services. Neurology supplies and services revenue other than Nicolet and Embla decreased by \$4.5 million in the year ended December 31, 2012 compared to the year ended December 31, 2011. This decline was primarily attributable to weak economic conditions in Europe. Revenue from newborn care supplies and services was \$51.0 million in 2012, no change from the \$51.0 million reported in 2011. This increase was driven by domestic newborn care supplies and services revenue.

Revenue from supplies and services was 38% of consolidated revenue in 2012 compared to 34.1% of total revenue in 2011.

No single customer accounted for more than 10% of our revenue in either 2012 or 2011. Revenue from domestic sales increased 24% to \$163.0 million in 2012, from \$131.3 million in 2011. Revenue from international sales increased 27% to \$129.3 million in 2012, compared to \$101.6 million in 2011. Revenue from domestic sales was 55.9% of total revenue in 2012 compared to 56.4% of total revenue in 2011, and revenue from international sales was 44% of total revenue in 2012 compared to 44% of total revenue in 2011. Freight revenue was 1% of total revenue in 2012 compared to 2% of total revenue in 2011.

**Cost of Revenue and Gross Profit**

Our cost of revenue increased \$27.2 million, or 27%, to \$128.8 million in 2012, from \$101.6 million in 2011. Of this increase, \$27.1 million was attributable to Nicolet and Embla. Gross profit increased \$32.2 million, or 25%, to \$163.5 million in 2012 from \$131.3 million in 2011 also as a result of our increased sales. Gross profit as a percentage of revenue was 55.9% in both 2012 and 56.4% 2011.

**Operating Costs**

Total operating costs increased \$16.6 million, or 12%, to \$158.2 million in 2012, from \$141.6 million in 2011. The operating expense of Nicolet and the incremental expense of Embla contributed to \$28.1 million in operating costs and we recorded \$8.8 million of restructuring charges. These increases were partially offset by reduced employee compensation costs resulting from the restructuring activities implemented early in 2012. In 2011 we recorded a \$20.0 million goodwill impairment charge related to our Neurology reporting unit for which there was no similar charge in 2012.

Our marketing and selling expenses increased \$14.2 million, or 23%, to \$77.3 million in 2012, from \$63.0 million in 2011. Marketing and selling expenses as a percent of total revenue decreased to 26.4% in 2012 from 27.1% in 2011. The marketing and selling expenses of Nicolet and the incremental expenses of Embla were \$12.8 million. The remainder of the increase in marketing and selling expenses was primarily related to higher sales commission and sales related costs associated with the increase in our revenue, \$724,000 of amortization of

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backlog recognized through purchase accounting associated with the Nicolet acquisition, and a \$560,000 impairment charge of certain trade names.

Our research and development expenses increased \$4.4 million, or 17%, to \$30.0 million in 2012 from \$25.6 million in 2011. Research and development expenses as a percent of total revenue decreased to 10.3% in 2012 from 11% in 2011. The research and development expenses of Nicolet and the incremental expense of Embla were \$6.1 million, partially offset by lower employee compensation costs resulting from cost cutting activities initiated early in 2012.

Our general and administrative expenses increased \$18.0 million, or 54%, to \$51 million in 2012 from \$33 million in 2011. General and administrative expenses as a percent of revenue increased from 14.2% in 2011 to 17.4% in 2012. The general and administrative expense of Nicolet and the incremental expense of Embla was \$9.2 million, which amount was partially offset by lower general and administrative costs otherwise achieved due to the effects of our 2012 restructuring efforts. The cost of restructuring activities and direct costs of acquisitions increased by \$6 million and \$2.4 million, respectively, in 2012 compared to 2011.

### **Other Income (Expense), net**

Other income (expense), net consists of investment income, interest expense, net currency exchange gains and losses, and other miscellaneous income and expense. We reported other income (expense), net of \$(835,000) in 2012, compared to \$(74,000) in 2011. Investment income of \$56,000 in 2012 was \$28,000 more than the amount reported for 2011. We reported \$220,305 of foreign currency exchange losses in 2012 versus \$15,000 of foreign exchange gains in 2011. Interest expense was \$489,000 in 2012 compared to \$268,000 in 2011 due primarily to borrowings to fund the Nicolet acquisition.

### **Provision for Income Tax**

We recorded income tax expense of \$536,000 and \$772,000 in 2012 and 2011, respectively. The lower income tax expense in 2012 is primarily the result of the settlement of foreign and U.S. state income tax audits and the expiration of the statute of limitations on uncertain tax positions that were recorded as a component of income tax expense in prior years. Although we reported a pre-tax loss of approximately \$10.4 million in 2011, we recorded income tax expense of \$772,000, as only \$1.6 million of the \$20.0 million goodwill impairment charge is expected to be deductible for tax purposes.

### **Liquidity and Capital Resources**

Liquidity is our ability to generate sufficient cash flows from operating activities to meet our obligations and commitments. In addition, liquidity includes the ability to obtain appropriate financing and to raise capital. Therefore, liquidity cannot be considered separately from capital resources that consist of our current funds and the potential to increase those funds in the future. We plan to use these resources in meeting our commitments and in achieving our business objectives.

As of December 31, 2013, we had cash and cash equivalents of \$56.1 million, stockholders' equity of \$306.3 million, and working capital of \$116.7 million compared with cash and cash equivalents of \$23.1 million, stockholders' equity of \$268.8 million, and working capital of \$70.3 million as of December 31, 2012. The \$46.4 million increase in working capital from December 31, 2012 to December 31, 2013 resulted primarily from a \$33.0 million increase in cash and cash equivalents and refinancing \$11.3 million of short-term borrowings to long-term debt. We believe that our current cash and cash equivalents and any cash generated from operations will be sufficient to meet our ongoing operating and capital requirements for the foreseeable future.

As of December 31, 2013, our foreign subsidiaries held cash and short term investment of approximately \$30.0 million out of the total cash and short term investment of \$56.1 million. We currently intend to permanently reinvest the cash held by our foreign subsidiaries. If, however, a portion of these funds were needed for and distributed to our operations in the United States, we would be subject to additional U.S. income taxes

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and foreign withholding taxes. The amount of taxes due would depend on the amount and manner of repatriation, as well as the location from where the funds are repatriated. If the foreign earnings were repatriated, the cash and short term investments available for other foreign financing activities will be reduced by the foreign taxes paid on the repatriation of earnings in these regions. We do not intend to repatriate the funds for U.S. operations and we have positive cash balances in the U.S. subsidiaries. To add the liquidity of the U.S. operational needs, we have a line of credit with Wells Fargo Bank to support domestic cash needs. We do not foresee to repatriate the foreign funds for the U.S. operations.

At December 31, 2013 we had a \$75 million credit facility consisting of a \$25 million revolving credit line and a \$50 million 5-year term loan with Wells Fargo. The credit facility contains covenants, including covenants relating to liquidity and other financial measurements, and provides for events of default, including failure to pay any interest when due, failure to perform or observe covenants, bankruptcy or insolvency events, and the occurrence of a material adverse effect, and restricts our ability to pay dividends. We have granted Wells Fargo a security interest in substantially all of our assets. We have no other significant credit facilities.

***Comparison of 2013 and 2012***

Cash provided by operations increased by \$17.2 million for the year ended December 31, 2013 to \$36.6 million, compared to \$19.4 million in 2012. The sum of our net income and certain non-cash expense items, such as reserves, depreciation and amortization, goodwill and intangible asset impairment charges, and share based compensation was approximately \$42.7 million in 2013 due to a greater focus on operational efficiency, compared to \$27 million in 2012. The aggregate impact of changes in certain operating assets and liabilities was a cash outflow of \$5.9 million in 2013 compared to a cash outflow of \$7.7 million in 2012.

Cash used in investing activities was \$22.3 million for the year ended December 31, 2013, compared to \$62.5 million in 2012. We used \$1.8 million of cash to acquire property and equipment during the year ended December 31, 2013 and \$2.2 million to acquire property and equipment during the year ended December 31, 2012. We used \$1.9 million of cash to acquire intangible assets during the year ended December 31, 2013 and \$5.0 million to acquire intangible assets during the year ended December 31, 2012. We used \$18.6 million of cash to acquire other businesses during the year ended December 31, 2013 compared with \$55.1 million during the year ended December 31, 2012.

Cash provided by financing activities was \$17.25 million in the year ended December 31, 2013 and \$33.4 million in the year ended December 31, 2012. In 2013 under our short-term borrowing arrangement we borrowed \$18.0 million relating to the funding of the Grass acquisition and \$4.0 million for working capital. During the second quarter of 2013, we borrowed \$35.3 million under our Wells Fargo facility in connection refinancing and used substantially all the proceeds from the new loan agreement to repay \$33.3 of short-term borrowing obligations. We repaid \$18.9 million and \$4.4 million under term loan agreements in the years ended December 31, 2013 and 2012, respectively. We received cash from sales of our stock pursuant to our stock awards plans and our employee stock purchase plan in the amount of \$9.0 million and \$1.9 million in the years ended December 31, 2013 and 2012, respectively. Our after-tax cost of stock-based compensation was an excess tax benefit of \$3.1 million in 2013 and an expense of \$(381,000) in 2012.

***Comparison of 2012 and 2011***

Cash provided by operations decreased by \$3.4 million for the year ended December 31, 2012 to \$19.4 million, compared to \$22.8 million in 2011. The sum of our net income (loss) and certain non-cash expense items, such as reserves, depreciation and amortization, goodwill and intangible asset impairment charges, and share based compensation was approximately \$27 million in 2012, compared to \$29.7 million in 2011. The aggregate impact of changes in certain operating assets and liabilities was a cash outflow of \$7.7 million in 2012 compared to a cash outflow of \$7 million in 2011.

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Cash used in investing activities was \$62.5 million for the year ended December 31, 2012, compared to \$19.4 million in 2011. We used \$7.3 million of cash to acquire property and equipment during the year ended December 31, 2012 and \$4.2 million to acquire property and equipment during the year ended December 31, 2011. We used \$55.1 million of cash to acquire businesses during the year ended December 31, 2012 compared with \$15.1 million during the year ended December 31, 2011. During the year ended December 31, 2012 we capitalized \$5.3 million of internal use software development costs compared with \$666,000 in 2011. In addition, we sold \$1.0 million of marketable securities during the year ended December 31, 2011.

Cash provided by financing activities was \$33.4 million in the year ended December 31, 2012 and \$1.7 million in the year ended December 31, 2011. We borrowed \$31 million relating to the funding of the Nicolet acquisition and \$5.3 million for working capital. We received cash from sales of our stock pursuant to our stock awards plans and our employee stock purchase plan in the amount of \$1.9 million and \$2.3 million in the years ended December 31, 2012 and 2011, respectively. Our after-tax cost of stock-based compensation was \$381,000 and \$160,000 more than the tax benefit we received from those arrangements on the exercise of employee stock options in 2012 and 2011, respectively. These amounts were recorded as a decrease to stockholders' equity. We repaid \$4.4 million and \$3.0 million under term loan agreements in the years ended December 31, 2012 and 2011, respectively.

***Future Liquidity***

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

Amount and timing of revenue;

Extent to which our existing and new products gain market acceptance;

Extent to which we make acquisitions;

Cost and timing of product development efforts and the success of these development efforts;

Cost and timing of marketing and selling activities; and

Availability of borrowings under line of credit arrangements and the availability of other means of financing.

***Contractual Obligations***

In the normal course of business, we enter into obligations and commitments that require future contractual payments. The commitments result primarily from purchase orders placed with contract vendors that manufacture some of the components used in our medical devices and related disposable supply products, purchase orders placed for employee benefits and outside services, as well as commitments for leased office space and equipment, leased vehicles and bank debt. The following table summarizes our contractual obligations and commercial commitments as of December 31, 2013 (in thousands):

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Unconditional purchase obligations	\$ 29,366	\$ 27,957	\$ 1,341	\$ 68	\$
Operating and financing lease obligations	22,377	4,254	7,338	1,993	8,792
Long-term debt (including current portion and interest)	39,288	11,122	28,166		

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Total	\$ 91,031	\$ 43,333	\$ 36,845	\$ 2,061	\$ 8,792
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Purchase obligations are defined as agreements to purchase goods or services that are enforceable and legally binding. Included in the purchase obligations category above are obligations related to purchase orders for

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inventory purchases under our standard terms and conditions and under negotiated agreements with vendors. We expect to receive consideration (products or services) for these purchase obligations. The purchase obligation amounts do not represent all anticipated purchases in the future, but represent only those items for which we are contractually obligated. The table above does not include obligations under employment agreements for services rendered in the ordinary course of business.

We are not able to reasonably estimate the timing of any potential payments for uncertain tax positions under ASC 740, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement 109. As a result, the preceding table excludes any potential future payments related to our ASC 740 liability for uncertain tax positions. See Note 14 of our Consolidated Financial Statements for further discussion on income taxes.

### **Quantitative and Qualitative Disclosures about Market Risk**

We develop products in the U.S, Canada, Europe, and Argentina, and sell those products into more than 100 countries throughout the world. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. Most of our sales in Europe and Asia are denominated in the U.S. Dollar and Euro and with the acquisitions of Xltek in November 2007, Medix in 2010 and Nicolet in 2012, a small portion of our sales are now denominated in Canadian dollar, Argentine peso and British pound. As our sales in currencies other than the U.S. dollar increase, our exposure to foreign currency fluctuations may increase.

In addition, changes in exchange rates also may affect the end-user prices of our products compared to those of our foreign competitors, who may be selling their products based on local currency pricing. These factors may make our products less competitive in some countries.

If the U.S. Dollar uniformly increased or decreased in strength by 10% relative to the currencies in which our sales were denominated, our net income would have correspondingly increased or decreased by an immaterial amount for the year ended December 31, 2013.

Our interest income is sensitive to changes in the general level of interest rates in the U.S. However, because current market conditions have resulted in historically low rates of return on our investments, a hypothetical decrease of 10% in market interest rates would not result in a material decrease in interest income earned on investments held at December 31, 2013.

When able, we invest excess cash in bank money-market funds or discrete short-term investments. The fair value of our short-term investments and cash equivalents ( investments ) is sensitive to changes in the general level of interest rates in the U.S., and the fair value of these investments will fall if market interest rates increase. However, since we generally have the ability to hold the investments to maturity, these declines in fair value may never be realized. If market interest rates were to increase by 10% from levels at December 31, 2013, the fair value of our investments would decline by an immaterial amount.

All of the potential changes noted above are based on sensitivity analyses performed on our financial position as of December 31, 2013. Actual results may differ as our analysis of the effects of changes in interest rates does not account for, among other things, sales of securities prior to maturity and repurchase of replacement securities, the change in mix or quality of the investments in the portfolio, and changes in the relationship between short-term and long-term interest rates.

### **Off-Balance Sheet Arrangements**

Under our bylaws, we have agreed to indemnify our officers and directors for certain events or occurrences arising as a result of the officer or director s serving in such capacity. We have a directors and officers liability insurance policy that limits our exposure and enables us to recover a portion of any future amounts paid resulting

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from the indemnification of our officers and directors. In addition, we enter into indemnification agreements with other parties in the ordinary course of business. In some cases we have obtained liability insurance providing coverage that limits our exposure for these other indemnified matters. We have not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. We believe the estimated fair value of these indemnification agreements is minimal and have not recorded a liability for these agreements as of December 31, 2013. We had no other off-balance sheet arrangements during any of fiscal 2013, 2012 or 2011 that had, or are reasonably likely to have, a material effect on our consolidated financial condition, results of operations, or liquidity.

### **Recent Accounting Pronouncements**

See *Note 1 Organization and Significant Accounting Policies* to the Consolidated Financial Statements contained herein for a full description of recent accounting pronouncements including the respective expected dates of adoption and effects on results of our operations and financial condition.

### **Cautionary Information Regarding Forward Looking Statements**

*This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 about Natus Medical Incorporated. These statements include, among other things, statements concerning our expectations, beliefs, plans, intentions, future operations, financial condition and prospects, and business strategies. The words may, will, continue, estimate, project, intend, believe, expect, anticipate, and other similar expressions generally identify forward-looking statements. Forward-looking statements in this Item 7 include, but are not limited to, statements regarding the following: our ability to capitalize on improving market conditions, the sufficiency of our current cash, cash equivalents and short-term investment balances, and any cash generated from operations to meet our ongoing operating and capital requirements for the foreseeable future, and our intent to acquire additional technologies, products or businesses.*

*Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results predicted in the forward-looking statements as well as our future financial condition and results of operations to differ materially from our historical results or currently anticipated results. Investors should carefully review the information contained under the caption Risk Factors contained in Item 1A of this report for a description of risks and uncertainties. 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.*

### **ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk**

The information required by this Item is set forth in the section entitled *Management's Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures About Market Risk*, and is incorporated by reference in this section.

### **ITEM 8. Financial Statements and Supplementary Data**

The Consolidated Financial Statements and Supplementary Data required by this Item are set forth where indicated in Item 15 of this report.

**Table of Contents****Selected Quarterly Financial Data (Unaudited)**

The following table presents our operating results for each of the eight quarters in the period ended December 31, 2013. The information for each of these quarters is unaudited and has been prepared on the same basis as our audited financial statements appearing elsewhere in this report.

In the opinion of our management, all necessary adjustments, consisting only of normal recurring adjustments, other than the correction discussed in the preceding paragraph, have been included to present fairly the unaudited quarterly results when read in conjunction with our audited Consolidated Financial Statements and the related notes appearing elsewhere in this report. These operating results are not necessarily indicative of the results of any future period.

	Quarters Ended							
	Dec. 31, 2013	Sept. 30, 2013	June 30, 2013	March 31, 2013	Dec. 31, 2012	Sept. 30, 2012	June 30, 2012	March 31, 2012
	(in thousands, except per share)							
Revenue	\$ 90,636	\$ 85,392	\$ 82,250	\$ 85,834	\$ 90,821			