

NATUS MEDICAL INC
Form 10-K/A
May 22, 2008
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 1)

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2007

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 Incorporation or Organization)

77-0154833
(I.R.S. Employer Identification No.)

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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: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.001 par value

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 filing requirements for the past 90 days.

Yes No

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

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer (Do not check if a smaller reporting company)

Smaller reporting company

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

As of June 30, 2007, the last business day of the registrant's most recently completed second fiscal quarter, there were 21,636,590 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 Market on July 2, 2007) was \$240,110,035. Shares of Registrant's common stock held by each executive officer and director and by each entity that owns 5% or more of Registrant's outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

On March 7, 2008, the Registrant had 21,768,855 shares of its common stock outstanding.

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Explanatory Note

This Amendment No. 1 on Form 10-K/A (this Amendment) amends our Annual Report on Form 10-K for the year ended December 31, 2007, originally filed with the Securities and Exchange Commission on March 14, 2008 (the Original Filing). This Amendment is being filed to revise information in Items 1, 7, 11 and 12, which are amended and restated in their entirety as contained in this Amendment. Item 1 is being revised to replace the Natus Medical Product Families chart with a corrected version. Item 11 is being revised to correct disclosure of (1) the values of stock and option awards we granted to our named executive officers, as set forth in the summary compensation table and grants of plan based awards table, (2) salary information for one of our executive officers, as set forth in the summary compensation table, and (3) the number of shares subject to outstanding options held by one of our directors, the amount paid prior to October 2007 as an annual retainer to the Chairman of the Company's Compensation Committee and to correct the grant date fair value of the options granted to our non-employee directors in 2007, as set forth in the director compensation table. Item 12 is being revised to add footnote disclosure that one of our executive officers and one of our directors have pledged their shares.

This Amendment continues to speak as of the date of the Original Filing, as we have not updated the disclosures contained in the Original Filing to reflect any events that occurred at a later date, other than the updating of the exhibits to include updated Certifications of our Chief Executive Officer and Chief Financial Officer.

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ITEM 1. Business.

This Annual Report on Form 10-K/A 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, and our marketing, technology enhancement, and product development strategies.

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.

Natus[®], AABR[®], ABAer[®], ALGO[®], AuDX[®], Biliband[®], Bio-logic[®], Ceegraph[®], CHAMP[®], Cool-Cap[®], Ear Couplers[®], Flexicoupler[®], MASTER[®], Navigator[®], neoBLUE[®], Oxydome[®], Sleepscan[®], Smart Scale[®], Traveler[®], Warmette[®] and VAC-PAC[®] are registered trademarks of Natus Medical Incorporated. Accuscreen[®], Bili-Lite Pad[®], Bili-Lite[®], Billi-Bassinets[®], Bili-Mask[®], Bili-Meter[®], Circumstraint[®], EchoLink[®], MiniMuffs[®], Neometrics[®], Papoose Board[®], Smartpack[®] and Warm-Lamp[®] are non-registered trademarks of Natus. Solutions for Newborn Care[®] is a non-registered service mark of Natus. Deltamed[®] and Coherence[®] are registered trademarks of Deltamed SA. Fischer-Zoth[®], AOA[®], Cochlea-Scan[®] and Echo-Screen[®] are registered trademarks of Fischer-Zoth GmbH. Sleeprite[®] is a registered trademark of Excel Tech Ltd. Neuromax[®] and Xltek[®] are non-registered trademarks of Excel Tech Ltd.

Overview

Natus is a provider of healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments such as hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and certain newborn conditions. We develop, manufacture, and market advanced neurodiagnostic and newborn care products to healthcare professionals in over 80 countries. Our product offerings include computerized neurodiagnostic systems for audiology, neurology, polysomnography, and neonatology, as well as newborn care products such as hearing screening systems, phototherapy devices for the treatment of newborn jaundice, head-cooling products for the treatment of brain injury in newborns, and software systems for managing and tracking disorders and diseases for public health laboratories.

We have completed a number of acquisitions since 2003, consisting of either the purchase of a company, substantially all of the assets of the company, or individual products or product lines. The businesses we have acquired include Neometrics in 2003, Fischer-Zoth in 2004, and Bio-logic, Deltamed, and Olympic in 2006. On November 29, 2007 we acquired Excel-Tech Ltd. (Xltek), based in Oakville, Ontario, Canada. Xltek develops and markets computer-based electrodiagnostic systems and disposable supplies used by medical practitioners to aid in the detection, diagnosis, and monitoring of neurologic and sleep disorders.

Product Families

We categorize our products into the following product families:

Hearing Includes product lines for Newborn Hearing Screening and Diagnostic Hearing Assessment.

Monitoring Systems for Neurology Includes product lines for Diagnostic Neurologic Analysis (EEG), Diagnostic Sleep Analysis (PSG), Electromyography (EMG), Intra-operative Monitoring (IOM); and Newborn Brain Monitoring (CFM).

Newborn Care Includes products for the treatment of Brain Injury and Jaundice in newborns.

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Our principal product offerings within these product families are presented in the table below:

Our Product Offerings

Hearing

Newborn Hearing Screening

Overview

Hearing impairment is the most common treatable chronic disorder in newborns, affecting as many as five babies out of every 1,000 newborns. It is estimated that 20,000 hearing-impaired babies are born in the United States (U.S.) every year, and as many as 60,000 more in the rest of the developed world. Until the introduction of universal newborn hearing screening programs, screening was generally performed only on those newborns who 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.

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Newborn Hearing Screening in the United States

We estimate that today approximately 95% of the children born in the U.S. are being screened for hearing impairment prior to discharge from the hospital. In 1994, the American Academy of Pediatrics Task Force on Newborn and Infant Hearing first published specific guidelines for universal newborn hearing screening programs. In 2000 and 2007, the Joint Committee on Infant Hearing (JCIH) Position Statements outlined principles, guidelines, and benchmarks for early hearing detection and intervention programs. These principles and guidelines are considered the standard of care today. Because positive results are referred to an audiologist or an Ear, Nose and Throat physician (ENT) for additional testing and evaluation, limiting the number of refers stemming from false positive results reduces the cost of a newborn screening program. In addition, false positive results can cause unnecessary emotional trauma for parents.

The 2007 JCIH Position Statement updated and expanded the definition of targeted hearing loss and recommended a specific protocol for babies admitted to the Neonatal Intensive Care Unit (NICU) for more than 5 days. Additionally, the document expressed increased awareness, not only of the need for diagnostic audiology evaluation for children diagnosed with hearing impairment at birth, but also for surveillance and hearing screening for children at risk of delayed onset and progressive hearing impairment during the first three years of life.

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

Otoacoustic emissions (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 3 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.

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ABaer Newborn Hearing Screener. The ABaer, which is a PC-based newborn hearing screening device, offers a combination of automatic ABR, 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.

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

Hearing Screening Supply Products

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

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

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

Diagnostic Hearing Assessment

Overview

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

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 auditory brainstem response (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.

Diagnostic Hearing Assessment Product Lines

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

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

HINT PRO. Our *Hearing in Noise Test* application uses test sentences, procedures, and headphone norms developed by the House Ear Institute. The system features computerized administration, scoring, report generation, and data storage. The HINT measures the patient's ability to recognize and repeat short sentences presented in quiet or in noise. The speech and noise sources can be spatially separated to measure binaural directional hearing and spatial unmasking. The patient's sentence recognition threshold is measured in quiet and in three noise conditions.

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, newborns through geriatrics. The AuDX records and analyzes OAEs generated by the cochlea through sound cables and disposable ear probes inserted into the patient's ear canal. A REFER test result indicates that the patient should be referred to an Audiologist or ENT for further diagnostic evaluation.

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Cochlea-Scan. The Cochlea-scan is an easy to use handheld device to assess hearing loss. It utilizes Distortion Product Otoacoustic Emissions (DPOAE) technology, which allows the user to quantify hearing loss using physiologic measures instead of relying upon a patient's behavioral response.

Centor. The Centor is a portable Audio-Evoked Potentials (AEP) product that records auditory evoked responses (AERs) in order to perform objective diagnoses as well as hearing-loss screening for adults and neonates. The system records AERs with standard or automatic protocols, including ABR, Middle Latency Audio-Evoked Potentials (MLAEP), ElectroCochleoGraphy (EcochG), Vestibular Evoked Myogenic Potentials (VEMP), as well as pure tone or vocal stimulation.

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.

Monitoring Systems for Neurology

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

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

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

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

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

Diagnostic Electroencephalograph (EEG) Monitoring

Overview

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

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

Diagnostic Electroencephalograph (EEG) Monitoring Product Lines

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

Kortex; Ceegraph VISION; Coherence. Our computerized EEG Systems include a broad range of products, from software licenses and ambulatory monitoring systems to advanced laboratory systems with multiple capabilities for EEG, ICU monitoring, long-term epilepsy monitoring of up to 128 channels, and physician review stations with quantitative EEG analysis capabilities.

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 disposable 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: Netlink EEG, Netlink LTM, Netlink Traveler, Traveler II, Trex, EEG32, EMU128, EMU40, and the Brain Monitor. Recent innovations in electronics technology and advanced internet-protocol data transmission enable certain of our amplifiers to record and transmit up to 32 channels of digital data using Ethernet communication.

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

Diagnostic Polysomnography (PSG) Monitoring

Overview

Increasing public awareness of sleep disorders has made sleep medicine a rapidly growing specialty. The analysis of respiratory patterns, brain electrical activity and other physiological data has proven critical for the diagnosis and treatment of sleep-related diseases such as apnea, insomnia, and narcolepsy. A sleep study entails whole-night recordings of brain electrical activity, muscle movement, airflow, respiratory effort, oxygen levels, electrical activity of the heart (ECG), and other parameters. These recordings typically result in over 1,000 pages of data that are reviewed, analyzed, and scored by a technician, and summarized in a report for the physician. We market configured laboratory systems, portable systems, and ambulatory recorders for home monitoring.

Diagnostic Polysomnography (PSG) Monitoring Product Lines

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

Sleepscan; Connex; SleepWorks; Coherence. Our diagnostic PSG systems capture and store all data digitally and provide time-saving features and software for acquiring and analyzing the data. The systems enable users to specify rules and personal preferences to be used during analysis, summarizing the results graphically and incorporating them in detailed reports. Our Sleepscan customized analysis includes color-coded sleep stages and flow loop analysis. The Coherence system utilizes a Pulse Transit Time device for the detection of respiratory events and arousals.

Sleepscan Netlink. Our Sleepscan Netlink data acquisition system incorporates recent developments in superior amplifiers for sleep analysis. In addition to exceptional signal quality, the Netlink headbox includes a built-in oximeter, and allows the user to start and stop a study or perform electrode impedance testing either at the patient's bedside or from the monitoring room.

We also market a broad line of disposable products and accessories for the polysomnography 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. This method has been documented in industry publications to produce the signature waveform used in identifying a respiratory disorder known as Upper Airway Resistance Syndrome.

Electromyography (EMG)

Overview

An electromyogram (EMG) measures the electrical activity of muscles both at rest and during contraction. Measuring the electrical activity in muscles and nerves can help diagnose diseases that damage muscle tissue or nerves. An EMG 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 EMG can also be used to diagnose the cause of weakness, paralysis, and muscle twitching. It is also used as a primary diagnosis for carpal tunnel syndrome, which is the most frequently encountered peripheral compressive neuropathy.

Diagnostic Electromyography (EMG) Product Lines

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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 take care of patients with the most informed advice.

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's software tools enrich data acquisition, reporting and review capabilities.

Intra-operative Monitoring (IOM)

Overview

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

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Intra-operative Monitoring Products

Protektor. 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 intra-operative monitoring techniques.

Newborn Care

Newborn Care Products

Natus manufactures a wide variety of products used in the medical care of newborns. These product lines include products to diagnose and treat newborn brain injury, as well as a line of phototherapy lights to treat newborn jaundice. The Company also sells a variety of newborn care products to meet the needs of clinicians in the nursery and Neonatal Intensive Care Unit.

Newborn Brain Injury

Overview

For many years, newborn infants admitted to the neonatal intensive care unit of a hospital have routinely been monitored for heart activity, temperature, respiration, oxygen saturation, and blood pressure. Only recently has it also been considered important to monitor brain activity using continuous electroencephalography (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.

Clinical studies have also shown that recent advancements in two primary technologies can have a marked and positive impact upon newborn brain injury. These technologies are amplitude-integrated EEG and servo-controlled patient cooling.

Newborn Brain Injury Product Line

Olympic CFM-6000 System. The Cerebral Function Monitor (CFM) provides the Neurologist with the technology to diagnose neurological disorders or brain injury in the newborn. The device continuously monitors and records brain activity, aiding in the detection and treatment of HIE and seizures. The device also monitors the effects of drugs and other therapies on brain activity and improves the accuracy of newborn neurological assessments. The Olympic CFM-6000 helps determine the need for further neurological examination or transport to a tertiary-care center. The CFM is used with electrodes attached to the head of the newborn to acquire an aEEG signal that is then filtered, compressed, and displayed graphically on the device or as a hardcopy printout.

Olympic Cool-Cap System. The Olympic Cool-Cap is the only FDA approved device for administering selective head cooling as a treatment for moderate to severe HIE. A four-year clinical trial for the Cool-Cap was completed in 2006, and the FDA gave approval for the product in December 2006. The clinical trial validated the benefit of direct brain cooling in reducing the severity of brain injury resulting from newborn HIE. Both the device and the proprietary software conform to the clinical trial protocol and are designed to assist the clinician in safely administering the treatment, thereby preventing or significantly reducing the severity of neurological injury associated with HIE.

Newborn Brain Injury Supply Products. In addition to disposable electrodes used to perform each aEEG test using the CFM-6000, 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.

Jaundice Management Products

Overview

The American Academy of Pediatrics estimates that each year 60% of the approximately four million newborns in the U.S. become jaundiced. According to the Journal of the American Medical Association, neonatal jaundice is the single largest cause for hospital readmission of newborns in the U.S., and accounts for 50% of readmissions. Because of the serious consequences of hyperbilirubinemia, the American Academy of Pediatrics recommends that all newborns be closely monitored for jaundice and has called for the physician to determine the presence or absence of an abnormal rate of hemolysis to establish the appropriate treatment for the newborn.

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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.

We currently offer the following products that meet guidelines of the American Academy of Pediatrics for the treatment of newborn jaundice:

neoBLUE Product Family. This product line consists of our neoBLUE, neoBLUE Mini, and neoBLUE Cozy 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. The neoBLUE phototherapy devices emit significantly less ultraviolet light and heat than conventional phototherapy devices, reducing the risk of skin damage and dehydration for infants undergoing treatment. Because of the high intensity of these lights, the treatment time associated with phototherapy is reduced.

Bili-Lite Product Family. These devices utilize fluorescent light bulbs for the treatment of hyperbilirubinemia. The Bili-Bassinet provides intensive phototherapy from both under and over the baby for maximum surface area coverage. The Bili-Lite pad is a product designed for home-based phototherapy; because of its design, it does not require the use of eye shields, making it easier for parents to use.

Other Newborn Care Product Lines

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

Disposable Supplies. These products include disposable supplies such as: neonatal noise attenuators, phototherapy eye masks, restraining boards, and x-ray shields for newborn gonads.

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

Segment and Geographic Information

We operate in one reportable segment in which we provide healthcare products used for the screening, detection, treatment, monitoring and tracking of common medical ailments such as hearing impairment, neurological dysfunction, epilepsy, sleep disorders, and newborn care, including jaundice, brain injury, and metabolic testing. We develop, manufacture, and market advanced neurodiagnostic and newborn care products to healthcare professionals in over 80 countries. Our product offerings include computerized neurodiagnostic systems for audiology, neurology, polysomnography, and neonatology, as well as newborn care products such as hearing screening systems, phototherapy devices for the treatment of newborn jaundice, head-cooling products for the treatment of brain injury in newborns, and software systems for managing and tracking disorders and diseases for public health laboratories.

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

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For the years ended December 31, 2007, 2006 and 2005, revenue from our four product families as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2007	2006	2005
Hearing	53%	61%	77%
Monitoring Systems for Neurology	14%	19%	%
Newborn Care	28%	15%	20%
Other	5%	5%	3%
Total	100%	100%	100%

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We expect that with the acquisition of Xltek, which was effective November 29, 2007, revenue from our Monitoring Systems for Neurology product family will contribute to a greater portion of total revenue in the future.

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, 2007, 2006 and 2005 is as follows:

	Year Ended December 31,		
	2007	2006	2005
Devices and Systems	62%	57%	45%
Supplies and Services	37%	41%	54%
Other	1%	2%	1%

Total 100% 100% 100%

In 2007, 2006 and 2005, 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, 2007, the Company's backlog was approximately \$4.4 million, compared to \$2.9 million at December 31, 2006 and an immaterial amount at December 31, 2005. We anticipate that we will complete all of the backlog orders by the fourth quarter of 2008.

Marketing and Sales

Marketing

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

Trade conference exhibits;

Direct presentations to healthcare professionals;

Publications in professional journals and trade magazines;

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

Print and direct mail advertising campaigns; and

Sponsorship of and participation in clinical education seminars.

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

Domestic Sales

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We sell our products in the United States primarily through a direct sales organization. This direct sales organization is a significant benefit to the Company, we believe, allowing us to maintain a higher level of customer service and satisfaction than would otherwise be possible by another distribution method. Revenue from our direct sales channels as a percent of total revenue was 57%, 64% and 84% in 2007, 2006 and 2005, respectively. The reduction of revenue sold through our direct sales channels as a percent of total revenue in 2007 and 2006 compared to 2005 resulted from an increase in sales of our line of diagnostic hearing products, which are sold through distributors. We gained this product line through our acquisition of Bio-logic in January 2006. We also sell certain products under private label arrangements. Domestic revenue resulting from sales through both of these non-direct sales channels was 10% of total revenue in 2007, 11% of total revenue in 2006 and an immaterial percentage in 2005.

International Sales

We sell our products outside the U.S. primarily through a distributor sales channel, which consists of distributors selling Natus products into more than 80 countries as of December 31, 2007. 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 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.

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Through our acquisition of Deltamed in September 2006, we now sell some of our products in France and Germany through a direct sales organization. We previously had direct sales organizations in Japan and the United Kingdom (U.K.). However, in 2004 we ceased selling through a direct sales force in Japan and began to sell through a distributor, and in February 2006 we ceased selling through a direct sales force in the U.K. and began to sell through a distributor.

Revenue from international sales was approximately 33%, 29% and 36% of our total revenue in 2007, 2006 and 2005, respectively.

Seasonality in Revenue

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

Group Purchasing Organizations

More than 90% of the hospitals in the U.S. are members of group purchasing organizations (GPO s), which negotiate volume purchase prices for member hospitals, group practices, and other clinics. Direct purchases by members of group purchasing organizations accounted for approximately 35%, 31% and 28% of our revenue in 2007, 2006 and 2005, respectively. Direct purchases by members of one GPO, Novation, accounted for approximately 9%, 12% and 15% of our revenue in 2007, 2006 and 2005, respectively. Our revenue recognition policies related to sales to GPO members are described in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, contained in this report.

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. In general, reimbursement for newborn screening is included in the lump-sum payment for the newborn s birth and hospitalization. For this reason, we are not able to measure a reimbursement success rate for our screening products.

Customer Service and Support

We provide a one-year warranty on all medical device products. We also sell extended service agreements on our medical device products. Service, repair, and calibration services for our domestic customers is provided by Company-owned service centers and our employee field service specialists. Service for our international customers is provided by a combination of our Company-owned authorized service centers and third-party vendors on a contract basis.

Manufacturing

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

We purchase materials and components from qualified suppliers that are subject to our quality specifications and inspections. We conduct quality audits of our key suppliers, several of which are experienced in the supply of components to manufacturers of finished medical devices, or supplies for use with medical devices. Most of our purchased components are available from more than one supplier.

Our manufacturing, service, and repair facilities are subject to periodic inspection by federal, state, and foreign regulatory authorities. Our quality assurance system is subject to regulation by the FDA and other state government agencies. We are required to conduct our product design, testing, manufacturing, and control activities in conformance with the FDA s quality system regulations and to maintain our documentation of these activities in a prescribed manner. In addition, our production facilities have received ISO 13485 certification. ISO 13485 certification standards for quality operations have been developed to ensure that medical device companies meet the standards of quality on a worldwide basis. We have also received the EC Certificate pursuant to the European Union Medical Device Directive 93/42/EEC, which allowed us to place a CE mark on our products after assembling appropriate documentation.

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.

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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 \$15.6 million or 13.2% of total revenue in 2007, \$10.6 million or 11.8% of total revenue in 2006 and \$4.3 million or 10.0% of total revenue in 2005.

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.

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 affect 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.

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Government Regulation

FDA s Premarket Clearance and Approval Requirements

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

Clearance via Section 510(k); or

Premarket approval via Section 515 if the FDA has determined that the medical device in question poses a greater risk of injury. The FDA s 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining premarket approval via Section 515 is much more costly, lengthy, and uncertain. Premarket approval 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.

The FDA decides whether a device must undergo either the 510(k) clearance or premarket approval process based upon statutory criteria. These criteria include the level of risk that the Agency perceives to be associated with the device and a determination of whether the product is a type of device that is substantially equivalent to devices that are already legally marketed. The FDA places devices deemed to pose relatively less risk in either class I or class II, which requires the manufacturer to submit a premarket notification requesting 510(k) clearance, unless an exemption applies. The premarket notification under Section 510(k) must demonstrate that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications.

The FDA places devices deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed to be not substantially equivalent to a predicate device, in its Class III classification. The FDA requires these devices to undergo the premarket approval process via Section 515 in which the manufacturer must prove the safety and effectiveness of the device. A premarket approval application must provide extensive pre-clinical and clinical trial data.

The FDA may require results of clinical trials in support of a 510(k) submission and generally requires clinical trial results for a premarket approval application. In order to conduct a clinical trial on a significant-risk device, the FDA requires manufacturers to apply for and obtain, in advance, an investigational-device exemption. The investigational-device exemption application must be supported by appropriate data, such as animal and laboratory testing results. If the FDA and the Institutional Review Boards at the clinical trial sites approve the investigational-device exemption application for a significant-risk device, the manufacturer may begin the clinical trial. An investigational-device exemption approval provides for a specified clinical protocol, including the number of patients and study sites. If the manufacturer deems the product a non-significant risk device, the product will be eligible for more abbreviated investigational-device exemption requirements. If the Institutional Review Boards at the clinical trial sites concur with the non-significant risk determination, the manufacturer may begin the clinical trial.

We received approval for our Olympic Cool-Cap product as a Class III device from the FDA through the premarket approval process. Most of our other products in our newborn hearing screening, diagnostic hearing, EEG monitoring, polysomnography, and newborn care product lines have been approved 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 approval as Class I devices.

FDA Regulation

Numerous FDA regulatory requirements apply to our marketed devices. These requirements include:

FDA quality system regulations which require manufacturers to create, implement, and follow design, testing, control, documentation, and other quality assurance procedures;

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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 Class 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 the applicable FDA guidelines, but we could be required to change our compliance activities or be subject to other special controls if the FDA changes its exi