NATUS MEDICAL INC
Form 10-K
March 01, 2019
Table of Contents

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

FORM 10-K

ý Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2018
OR
.. Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to .
Commission
file number:
000–33001

NATUS MEDICAL INCORPORATED
(Exact name of Registrant as specified in its charter)

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

6701 Koll Center Parkway, Suite 120, Pleasanton, CA 94566
(Address of principal executive offices) (Zip Code)
(925) 223-6700
(Registrant's telephone number, including area code)
Securities Registered Pursuant to Section 12(b) of the Act:

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

Securities Registered Pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý 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 ý
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 ý 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 ý No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. ý

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 the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ý Accelerated filer ¨

Non-accelerated filer ¨ 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 ý

As of June 30, 2018, the last business day of Registrant's most recently completed second fiscal quarter, there were 33,590,337 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 29, 2018) was $1,158,866,627. 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 February 20, 2019, the registrant had 33,777,388 shares of its common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the Registrant's Definitive Proxy Statement for the 2019 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K, to be filed with the Securities and Exchange Commission, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

NATUS MEDICAL INCORPORATED
ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

Table of Contents

PART I

ITEM 1. Business

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 about Natus Medical Incorporated ("Natus," "we," "us," or "the 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 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, our ability to complete all of our backlog orders, and the anticipated timing and effect of the implementation of our new organizational structure.

Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause our 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" and other trademarks of ours appearing in this report are our property.

Overview

Natus is a leading provider of neurology, newborn care, and hearing and balance assessment healthcare products and services used for the screening, diagnosis, detection, treatment, monitoring and tracking of common medical ailments in newborn care, hearing impairment, neurological dysfunction and neurosurgical treatments, epilepsy, sleep disorders, neuromuscular diseases and balance and mobility disorders.

On January 15, 2019, Natus announced the implementation of a new organizational structure designed to improve operational performance and make it a stronger, more profitable company.

Natus intends to consolidate its three business units, Neuro, Newborn Care and Otometrics into "One Natus." This initiative is designed to create a single, unified company with globally led operational teams in Sales & Marketing, Manufacturing, R&D, Quality, and General and Administrative functions. The new structure is expected to provide for increased transparency, efficiency and cross-functional collaboration across common technologies, processes and customer channels.

Natus expects to transition to the new structure with further implementation stages continuing throughout 2019.

The description of Natus' strategic business units that is contained in this Annual Report describes such strategic business units as they existed during the fiscal year ended December 31, 2018.

Product Families

We are organized into three strategic business units, each with multiple product families:

Neuro—Includes products and services that provide diagnostic, therapeutic and surgical solutions in neurodiagnostics, neurocritical care and neurosurgery. Neuro's comprehensive neurodiagnostic solutions include electroencephalography ("EEG") and long term monitoring ("LTM"), Intensive Care Unit ("ICU") monitoring, electromyography ("EMG"), sleep analysis or polysomnography ("PSG"), and intra-operative monitoring ("IOM"). These solutions enhance the diagnosis of neurological conditions such as epilepsy, sleep disorders and neuromuscular diseases.

Our neurocritical care solutions include management of traumatic brain injury by continuous monitoring of intracranial pressure ("ICP") and cerebrospinal fluid ("CSF") drainage. Our neurosurgical solutions provide options that promote dural healing in the cranium as well as treatment solutions for procedures involving hydrocephalus. We acquired our neurocritical care and neurosurgical product lines from Integra LifeSciences in October 2017 ("Integra Asset Acquisition").

Newborn Care—Includes products and services for newborn care including hearing screening, brain injury, ROP vision screening, thermoregulation, jaundice management, and various disposable newborn care supplies, 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.

Otometrics—Includes products for hearing and diagnostics and hearing aid fitting, including computer-based audiological, otoneurologic and vestibular instrumentation and sound rooms for hearing and balance care professionals. Otometrics has a complete product and brand portfolio known for its sophisticated design technology in the hearing and balance assessment markets. We acquired the Otometrics business in January 2017.

Table of Contents

Neuro

Our Neuro business unit represents a comprehensive line of neurodiagnostic, neurocritical care, and neurosurgical products that are used by healthcare practitioners in the diagnosis and monitoring of neurological disorders of the central and peripheral nervous system. The environments in which these products are used include outpatient private practice facilities and inpatient hospital environments, including diagnostic procedures and monitoring of patients during admissions, surgery, while under sedation, in post-operative care, and in intensive care units. Our Neuro products and services include:

Neurodiagnostic

Electroencephalography—Equipment, supplies and services used to monitor and visually display the electrical activity generated by 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—Equipment and supplies used to measure electrical activity in nerves, muscles, and critical pathways includes EMG, nerve conduction and evoked potential functionality.
- Polysomnography—Equipment and supplies used to measure a variety of respiratory and physiologic functions to assist in the diagnosis and monitoring of sleep disorders, such as insomnia and obstructive sleep apnea, a condition that causes a person to stop breathing intermittently during sleep.
- Intraoperative monitoring—Equipment and supplies used to monitor the functional integrity of certain neural structures (i.e. nerves, spinal cord and parts of the brain) during surgery. The goal of IOM is to provide real time guidance to the surgeon and anesthesiologist which will reduce the risk to the patient during surgery.

Neurocritical Care

- Intracranial pressure monitoring—Equipment and catheters used to monitor pressure in the cranium/brain and catheters to drain cerebrospinal fluid from the brain to aid in hydrocephalus and traumatic brain injury cases.

Neurosurgery

- Shunts and Dural grafts—Shunts are used to manage the drainage of cerebrospinal fluid from the brain to maintain appropriate levels of CSF when treating hydrocephalus. Dural grafts are used in procedures to repair or substitute a patient's dura mater in the brain.

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, 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. Long-term inpatient monitoring of EEG and behavior (LTM) is used to determine complex treatment plans, and for patients with seizures that do not respond to conventional therapeutic approaches, surgical solutions may be appropriate. Patients suffering from severe head trauma and other acute conditions that may affect the brain are monitored in ICUs. In addition, research facilities use EEG equipment to conduct research on humans and laboratory animals.

Global Neuro-Diagnostic Services ("GND"), which we acquired in early 2015, has historically provided in-home ambulatory EEG monitoring. In January 2019, as part of the implementation of our new "One Natus" organizational structure and our enhanced focus on our more profitable medical device businesses, we announced our plans to wind down GND operations during the first quarter of 2019.

Diagnostic Electroencephalograph Monitoring Product Lines

Our EEG diagnostic monitoring product lines for neurology consist of signal amplifiers, workstations to capture and store synchronized video and EEG 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.

Table of Contents

- NeuroWorks; NicoletOne. Our 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 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 that are used to generate compressed 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. The headbox connects electrodes attached to the patient's head to our EEG monitoring systems. Our proprietary amplifier products are sold for a wide variety of applications under the following brand names: Xltek, Trex, EEG32U, EMU40EX, Brain Monitor, Quantum, Nicolet v32 and v44 models.
- 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.
- Supplies. We also manufacture and market a full line of proprietary EEG electrodes and other supplies used in the electroencephalography field.

Electrodiagnostic Monitoring

Our electrodiagnostic systems include EMG, nerve conduction ("NCS"), and often evoked potential ("EP") functionality. EMG and NCS involve the measurement of electrical activity of muscles and nerves both at rest and during contraction. Measuring the electrical activity in muscles and nerves can help diagnose diseases of the peripheral, central nervous system or musculature system. An electromyogram is done to determine if there is any disease present that effects 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 EP. Evoked potentials are elicited 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 G-4 and Focus EMG and EP family of products features amplifiers, stimulators, and strong signal quality. The Keypoint is used for advanced neurodiagnostic applications such as single fiber EMG, visual and auditory evoked potentials, and in routine nerve conduction studies. The Keypoint system is also available in a portable laptop configuration.
- Dantec Clavis. The Dantec Clavis device is a hand-held EMG and current stimulation device that provides muscle and nerve localization information to assist with medication and botox injections. In conjunction with the Bo-ject hypodermic needle and electrodes, physicians can better localize the site of the injection.
- Nicolet EDX family. A hardware platform of amplifiers, base control units, stimulators and hand-held probes that are sold with Nicolet brand proprietary software. These mid to high end systems have full functionality, strong signal quality, and flexibility. They include EMG, NCS, EP's, IOM and advanced data analysis features.
- Nicolet VikingQuest. An EMG system for the mid-range market. The device runs on our proprietary software.

Natus Neurology UltraPro. This is a low to mid-level product that offers high quality data collection using the Dantec Keypoint amplifiers and the proprietary Natus EMG software.

- Supplies. We also manufacture and market a full line of proprietary EMG needles and other supplies used in the electrodiagnostic field.

Diagnostic Polysomnography Monitoring

Table of Contents

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 a whole-night recording 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 Positive Airway Pressure technology ("PAP") during the sleep study and the proper settings for the treatment devices are determined. In many cases, the sleep study is performed in the patient's home.

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. Additionally we offer products that are specifically designed to be used in the patient's home. 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 PSG analysis capabilities.

- Embla REMlogic, Sandman; and Xltek SleepWorks. 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.
- 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 MPR, Xltek Trex and SleepWorks, NDx and SDx. 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 Embla 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.
- PMSD. PastuerMatic Sterile Dryers are used in hospital and clinic sleep laboratories to provide non-chemical sterilization of products used in sleep therapy. An environmentally friendly approach to disinfection, the PMSD products offer cost effective sterilization for sleep labs of all sizes.
- Supplies. We also market a broad line of supplies, disposable products and accessories for the PSG laboratory including the XactTrace respiratory monitoring belts.

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's nervous system, and/or to provide functional guidance to the surgeon and anesthesiologist during surgery.

Diagnostic IOM Product Lines

- Xltek Protektor. The Protektor system is an IOM system that provides medical professionals with all information necessary to make immediate and critical surgical decisions. The system combines flexibility with multi-modality allowing full coverage of IOM techniques. The Protektor comes in 16 or 32 channel options.
- Nicolet EDX. These combo 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.

Neurocritical Care Products

Intracranial pressure and temperature provide insight into the health of the brain, especially in patients experiencing a traumatic brain injury, other traumatic, ischemic or hemorrhagic incidents, or a major neurosurgical procedure. A small hole is drilled into the brain to allow insertion of a catheter that contains a pressure/temperature or pressure transducer that allows continuous monitoring of brain temperature and/or pressure.

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Camino ICP Monitor. The Camino ICP Monitor is a compact, portable device that provides tools for continuously determining and monitoring intracranial pressure and intracranial temperature. It has a touch screen interface, physiological alarms, and can output data to either a patient bedside monitor or to remote media types via a USB drive. These systems are used in the intensive care unit (ICU) environment.

Table of Contents

- Camino Catheters. Camino catheters use either fiber optic or strain gauge technology to measure either pressure and temperature or just pressure. Camino catheters measure their respective values at the tip of the catheter which eliminates the need for a fluid-filled system that uses an external transducer to measure pressure. The Camino Flex Ventricular Intracranial Pressure Monitoring Kit has a catheter that allows both the measurement of ICP and CSF drainage.

Neurosurgical Products

During brain surgery, the dura of the brain may need to be repaired or replaced. A dural graft is used to serve as a dural substitute for the surgical repair of dural defects. Moreover, brain surgery is performed to place shunts in the brain to help drain excess CSF either externally or into the body for reabsorption to help treat hydrocephalus.

- DURAFORM. DURAFORM Dural Graft Implant is an absorbable collagen matrix to provide a soft, conforming, and easy to use dural substitute. This product is used in the operating room to provide repair of the dura mater and promote dural healing.
- Shunts. Shunts are used in the operating room to provide solutions for hydrocephalus.

Newborn Care

Our newborn care business unit represents a line of products and services that are used by healthcare practitioners in the diagnosis and treatment of common medical ailments in newborn care, as well as other products used in newborn through adult populations, including hearing diagnostics and balance & mobility systems. Our products are organized in nine modalities and include:

- Newborn Hearing Screening—Products used to screen hearing in newborns.
- 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.
- 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.
- Newborn Brain Injury—Products used to diagnose the severity of brain injury, monitor the effectiveness of drug therapies, detect seizure activity and monitor general neurological status.
- Eye Imaging—Systems and products used in the advanced science and practice of neonatal and pediatric retinal imaging.
- Essentials—Products used in the everyday operation of neonatal intensive care unit (“NICU”) and well-baby nursery department within the hospital environment.
- NICVIEW—Live streaming video for families with babies in the NICU that enables family members and approved friends to see the new baby, 24/7, from anywhere in the world - from any device, within a secured environment.

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.

Newborn Hearing Screening Techniques

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

Table of Contents

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.

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.

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 30 or 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.
- Echo-Screen. Our hand-held Echo-Screen products provide a choice or combination of proprietary ABR and OAE technologies that can also be used for children through adults. The Echo-Screen III device is a compact, multi-modality handheld hearing screener that is tightly integrated with audible Lite Hearing Screening Data Management.

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. Echo-Screen and ABaer offer the choice of either an earphone or use of ear tips for perform ABR screening.
- 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.

Peloton Screening Services

Peloton Screening Services is a nationwide service offering that provides hearing screening services to hospital-based customers. The core platform of the program meets the objectives of today's healthcare environment by aligning with family centered care principals and Joint Committee on Infant Hearing (JCIH) recommendations. Peloton compliments our newborn hearing screening product lines and provides all aspects of a comprehensive service program: equipment, supplies, professional oversight by nurses or audiologists, screening personnel, case management, quality review & oversight, and state data management reporting.

Thermoregulation

Incubators offer a controlled, consistent microenvironment for thermoregulation and humidification within a closed system to maintain skin integrity and body temperature.

Thermoregulation products

- Incubators. Our NatalCare incubators, including those used for transporting infants, provide high thermal performance with a double wall design, 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.

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 that phototherapy is the standard of care for the treatment of hyperbilirubinemia. The guidelines further recommend that all nurseries

Table of Contents

have the necessary equipment to provide intensive phototherapy, and specifically recommend the use of the "blue" light as incorporated into our neoBLUE products.

Jaundice Management Products

- neoBLUE Product Family. This product line consists of our neoBLUE, neoBLUE Mini, neoBLUE Cozy, neoBLUE Compact 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.
- Medix MediLED Product Family. 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.

Newborn Brain Injury

For many years, newborn infants admitted to the NICU of a hospital have been routinely monitored for heart activity, temperature, respiration, oxygen saturation, and blood pressure. Recently it has also been considered important to monitor brain activity. A cerebral function monitor, utilizing amplitude-integrated EEGs ("aEEGs"), is a device for monitoring background neurological activity. Our simplified aEEG devices introduced over ten years ago, allow neonatologists and nurses to set-up and interpret basic neurological traces without neurology oversight.

Newborn Brain Injury Products

Our newborn brain injury products record and display parameters that the neonatologist uses to assess and monitor neurological status 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 is our latest generation Cerebral Function Monitor. The device can be used in single-channel, two-channel or three-channel modes to continuously monitor and record brain activity.

Eye Imaging

Our RetCam devices incorporate a camera combined with proprietary imaging software that are used to diagnose and monitor a range of ophthalmic maladies in premature infants. RetCam specializes in NICU ophthalmic imaging used in the detection of retinopathy of prematurity (ROP) and Retinoblastoma (RB) in newborns. ROP and RB are diseases of the retina that much be detected very early after birth and treated immediately, so the RetCam diagnostic camera is a fundamental tool in preventing vision loss and total blindness in infants.

Eye Imaging Products

RetCam images enable physicians to assist in the evaluation of pediatric ocular disease which have preserved the vision in thousands of infants. Each of the RetCam systems deliver objective and interpretable detail, allow image comparison over time, enable remote consultations, and provide reliable and defensible medico-legal documentation.

- RetCam 3. Full-featured imaging system with a range of interchangeable lenses, Fluorescein Angiography module option.
- RetCam Shuttle. Laptop-based system with a smaller cart and dual wheel casters for improved transportability.
- RetCam Portable. Laptop-based version in a case for maximum portability.

Essentials

The Newborn Care Essentials products include such items as: Biliband® eye protectors, GumDrop® pacifiers, MiniMuffs® noise attenuators, NeatNick® heal lancets, Olympic® Circumstraint, Olympic® Papoose Boards, Olympic® Smart Scales, OraSwab, Save the Gonads® x-ray protection devices and SugarPlum® glucose lancets.

NICVIEW

Table of Contents

The video streaming solution NICVIEW offers parents and families secured access to a live video stream of their baby. For hospitals, the system offers a step into family centered care.

Balance and Mobility

We have historically offered a number of balance and mobility products under our Neurocom brand, including our EquiTest, Balance Master, VSR, and VSR Sport, and inVision product lines. In January 2019, as part of the implementation of our new “One Natus” organizational structure and our enhanced focus on our more profitable medical device businesses, we announced that we would immediately discontinue sales of new products under our Neurocom brand. We will continue to support Neurocom customers with technical support and service and we believe we will continue as a leader in the balance diagnostic market with our Otometrics' branded balance products.

Otometrics

Otometrics provides hearing diagnostic, hearing aid fitting and balance instrumentation and software solutions to hearing and balance care professionals worldwide. For more than 50 years, Otometrics has been helping hearing and balance care professionals succeed in improving the quality of life for their clients and patients by delivering expert knowledge, reliable solutions and services and trusted partnerships.

Otometrics develops, manufactures and markets computer-based audiological, otoneurologic and vestibular instrumentation in more than 80 countries. The Otometrics solutions portfolio covers key application areas within hearing assessment, hearing screening, hearing instrument fitting and balance assessment. Many of the Otometrics hearing and balance care solutions have set precedent within the hearing care industry and are used by thousands of clinicians around the world.

As an independent provider of hearing care diagnostic solutions, Otometrics works closely with leading hearing aid manufacturers to develop new solutions within hearing assessment and hearing aid fitting.

Hearing Assessment

From otoacoustic emissions (OAE) and immittance screening to advanced audiological testing and 3D digital ear scanning, Otometrics offers a wide range of flexible devices and PC-based solutions that are designed to screen, test and assess patients of all ages. Otometrics hearing assessment solutions offer functionality to support basic audiometric testing to advanced tinnitus and pediatric hearing assessment. Hearing care solutions by Otometrics help streamline the hearing screening and assessment process making it easier and convenient for the professional and the patient. Otometrics also manufacturers and markets a broad line of supplies and disposable products and accessories for hearing assessment.

Hearing Instrument Fitting and Verification

Otometrics' fitting solutions help professionals manage the entire hearing aid fitting process - from fitting and verifying the hearing aid to patient counseling and follow up. Used by thousands of hearing aid dispensers, audiologists and clinicians around the world, Otometrics fitting solutions support otoscopy, audiometry, hearing aid testing and programming, fitting and verification with wireless design and binaural fitting capability. Otometrics fitting solutions are PC-based, Noah-compatible and supported by integrated audiometric software that helps to streamline the fitting process for greater efficiency and patient satisfaction. Otometrics also manufacturers and markets a broad line of supplies and disposable products and accessories for hearing instrument fitting and verification.

3D Digital Ear Scanning

Otometrics hearing assessment solutions include the breakthrough 3D digital ear scanning solutions Otoscan® that gives hearing care professionals innovative ways to attract and convert more clients while delivering customized hearing care in an efficient way. Otoscan® enables hearing care professionals to make digital impressions for custom in-the-ear pieces such as earmolds and hearing aids. The scanner solution applies breakthrough technology to

transform images of the ear into 3D digital files that are uploaded to the cloud service, Otocloud™, for immediate use in production of custom products, delivering significant efficiency and quality gains in the production of hearing aids. Otocloud™ is a web-based portal supported by a dedicated Microsoft Azure server domain.

Audiometric Sound Rooms

Otometrics manufacturers and markets a wide range of sound room solutions specifically designed for audiometric testing. Otometrics Genie sound rooms are built to deliver a quality audiometry testing environment while providing efficiency for staff and comfort for patients. Certified staff help in the planning, choice and installation of each sound room so it becomes an integrated part of the clinic, equipment and workflow. Otometrics Genie sound rooms deliver unique features such as the

Table of Contents

Cam-Lock assembly system, high performance/low profile floor, window in the door, and excellent attenuation and acoustic capabilities to ensure acoustic performance, efficient workflow and maximum testing comfort.

Balance Assessment

Professionals who evaluate patients with balance disorders use Otometrics' vestibular diagnostic and ENG/VNG (electronystagmography/videonystamography) systems and services. These solutions are used by audiologists, otolaryngologists, otologists and neurologists for identifying auditory and vestibular abnormalities. Otometrics balance care solutions are compact and include the world's first portable, gold standard video head impulse test (“vHIT”) and offer modular functionality to support vHIT, video frenzel, positional, oculomotor and SHIMP (suppression head impulse) testing. Otometrics also manufacturers and markets a broad line of supplies, disposable face cushions, and accessories for balance assessment.

Segment and Geographic Information

We operate in one reportable segment, which we have presented as the aggregation of our neuro, newborn care, and otometrics 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, and 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 19—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, 2018, 2017 and 2016, revenue from our product families as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2018	2017	2016
Neuro	53 %	48 %	62 %
Newborn Care	23 %	29 %	38 %
Otometrics	24 %	23 %	— %
Total	100 %	100 %	100 %

We also look at revenue as either being generated from sales of Devices and Systems, which are generally non-recurring, or related Supplies and Services, which are generally recurring. The products that are attributable to these categories are described above. Revenue from Devices and Systems, Supplies and Services as a percent of total revenue for the years ending December 31, 2018, 2017 and 2016 is as follows:

	Year Ended December 31,		
	2018	2017	2016
Devices and Systems	72 %	71 %	63 %
Supplies	22 %	22 %	28 %
Services	6 %	7 %	9 %
Total	100 %	100 %	100 %

In 2018, 2017 and 2016, no single end-user customer comprised more than 10% of our revenue.

Backlog

In general, the company does not manufacture its products against a backlog of orders and does not consider backlog to be a significant indicator of the level of future sales activity. Production and inventory levels are based on the level of incoming orders as well as projections of future demand. Therefore, the company believes that backlog information is not meaningful to understanding its overall business and should not be considered a reliable indicator of the company's ability to achieve any particular level of revenue or financial performance.

Marketing and Sales

9

Table of Contents

Marketing

Our marketing strategy differentiates our products by their level of quality, performance, and customer benefit. We educate customers worldwide about our products through trade conferences and direct presentations to healthcare professionals.

Domestic Direct and Distributor Sales

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

For the years ended December 31, 2018, 2017 and 2016, domestic revenue as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2018	2017	2016
Domestic revenue	56.7 %	54.1 %	65.6 %

International Direct and Distributor Sales

We sell some of our products outside the U.S. through direct sales channels in Australia, Canada, China, Denmark, France, Germany, Italy, the Netherlands, New Zealand, Nordics (Finland, Sweden, Norway) Spain, United Kingdom and parts of Latin America; we sell other products in those regions and into more than 100 other countries through a distributor sales channel.

For the years ended December 31, 2018, 2017 and 2016, international revenue as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2018	2017	2016
International revenue	43.3 %	45.9 %	34.4 %

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 “ex works,” where 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 to 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. Demand for our products is historically higher in the second half of the year compared to the first. 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 (“GPO”s), which negotiate volume purchase agreements for member hospitals, group practices, and other clinics.

For the years ended December 31, 2018, 2017 and 2016, revenue from direct purchases by GPO members as a percent of total revenue was approximately as follows:

	Year Ended December 31,		
	2018	2017	2016
Direct purchases by GPO members	13.3 %	14.5 %	12.3 %

Third-Party Reimbursement

In the U.S., healthcare 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. In addition, our Peloton hearing screening service is dependent on third-party payors to reimburse us for services provided.

10

Table of Contents

Customer Service and Support

We generally provide a one-year warranty on our medical device and system products. We also sell extended service agreements on our medical device and system products. Service, repair, and calibration services for our domestic customers are provided by Company-owned service centers and our field service specialists. Service for international customers is provided by a combination of Company-owned facilities and 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 many 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 assessments of these vendors, which include on-site quality audits.

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 local and foreign regulatory authorities. Our quality assurance system is subject to regulation by the U.S. Food and Drug Administration ("FDA") and other 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 International Organization for Standardization ("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 $61.7 million or 11.6% of total revenue in 2018, $51.8 million or 10.3% of total revenue in 2017, and $33.4 million or 8.8% of total revenue in 2016.

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.

We have several registered trademarks and service marks. Our marks are pending or registered trademarks in the United States and several foreign countries. We intend to file for additional trademarks to strengthen our trademark rights, but we cannot be certain that our trademark applications will result in registration or that our trademarks will be enforceable.

Table of Contents

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 and we expect that our products could face increasing competition, including competitors offering lower prices, which could have an adverse effect on our revenue and profit margins.

Integra LifeSciences continues to offer products and services that compete with the neurosurgery product lines we acquired in the Integra Asset Acquisition, and we expect significant competition from Integra LifeSciences as we seek to maintain and expand this business.

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, 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 six 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 FDA 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.

Table of Contents

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. Most of our products have been cleared by the FDA as Class II 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 FDA can institute a wide variety of enforcement actions, including:

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

The FDA also has the authority to require us to repair or replace any misbranded or adulterated 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 13485:2016, Medical Device Directive 93/42/EEC, and MDSAP compliant, which allows us to sell our products in Canada, Europe, and other territories around the world. All of our manufacturing facilities are subject to inspection by our notified bodies or other competent authorities, and in some cases without advance notice. 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.

In 2017, the European Union ("EU")adopted the EU Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and

post-market surveillance requirements. The regulation has a three-year implementation period to May 2020 and will replace the existing directives on medical devices in the EU. After May 2020, medical devices marketed in the EU will require certification according

Table of Contents

to these new requirements, except that devices with valid CE certificates, issued pursuant to the Medical Device Directive before May 2020, may be placed on the market until 2024. Complying with this new regulation will require us to incur significant costs and failure to meet the requirements of the regulation could adversely impact our business in the European Union and other countries that utilize or rely on European Union requirements for medical device registrations.

Employees

On December 31, 2018, we had approximately 1,729 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 we consider our relations with our employees to be good.

Executives

The following table lists our executive officers and their ages as of March 1, 2019:

Name	Age	Position(s)
Jonathan A. Kennedy	48	President and Chief Executive Officer
B. Drew Davies	53	Executive Vice President and Chief Financial Officer
D. Christopher Chung, M.D.	55	Vice President Medical Affairs, Quality & Regulatory
Austin F. Noll, III	52	Executive Vice President and Chief Commercial Officer

Jonathan A. Kennedy has served as Chief Executive Officer, and as a member of the Board of Directors since July 2018. Mr. Kennedy joined Natus as Senior Vice President and Chief Financial Officer in April 2013 and was appointed Executive Vice President and Chief Financial Officer in September 2016. In addition, he currently serves on the Board of Directors for IRadimed Corporation. Before joining Natus, Mr. Kennedy was Senior Vice President and Chief Financial Officer of Intersil Corporation, a global semiconductor manufacturer, since 2009. Prior to that, he was Intersil's Corporate Controller since 2005 and Director of Finance since 2004. Before joining Intersil, Mr. Kennedy held management roles in Finance and Information Technology with Alcon Inc. and Harris Corporation. He holds a Bachelor of Science degree in Business Administration and a Master of Science degree in Accounting from the University of Central Florida. Mr. Kennedy is also a Certified Public Accountant.

B. Drew Davies joined Natus as Executive Vice President and Chief Financial Officer in October 2018. Mr. Davies most recently served as Executive Vice President and Chief Financial Officer of Extreme Networks since June 2016. Before joining Natus, Mr. Davies served as Vice President and Corporate Controller at Marvell Semiconductor Inc. from December 2015 until May 2016. Prior to that, Mr. Davies was the Senior Vice President, Corporate Controller at Spansion, Inc. from August 2012 to December 2015. Prior to Spansion, Mr. Davies was Corporate Controller at Intersil Corporation from April 2009 to August 2012, and served as Operations Controller from March 2008 to April 2009. Mr. Davies also served as Chief Financial Officer of Nanoconduction, Inc. from March 2007 to March 2008, Director of Finance and Administration for STATSChipPac from September 1999 to March 2007, held various finance roles at Micron Custom Manufacturing Services from November 1992 to September 1999. Mr. Davies holds a Master of Business Administration degree from Santa Clara University and a Bachelor of Science, Business Accounting degree from the University of Idaho.

D. Christopher Chung, joined Natus in 2000 as the Medical Director. He has also served as Vice President of R&D and most recently since 2011 as Vice President Medical Affairs, Quality and Regulatory. From 2000 to 2007, Dr. Chung also served as a Pediatric Hospitalist at the California Pacific Medical Center in San Francisco providing patient care in the Neonatal Intensive Care Unit and Newborn Nursery. From 1997 to 2000, Dr. Chung trained as a pediatric resident at Boston Children's Hospital and Harvard Medical School. From 1986 to 1993, Dr. Chung worked as an R&D engineer Nellcor Incorporated, a medical device company that pioneered the development of pulse oximetry. 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. Dr. Chung has also been awarded nine U.S. Patents in the medical device field.

Austin F. Noll, III joined Natus in August 2012 as the Vice President and General Manager, Neuro. Prior to joining Natus, Mr. Noll served as the President and CEO of Simpirica Spine, a California-based start-up company that developed and commercialized a novel device for spinal stabilization. Prior to joining Simpirica Spine, Mr. Noll served as the President and CEO of NeoGuide Systems, a medical robotics company acquired by Intuitive Surgical. Prior to joining NeoGuide Systems, Mr. Noll held numerous management 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 of Business Administration degree from the University of Michigan.

Other Information

Table of Contents

Natus was incorporated in California in May 1987 and reincorporated in Delaware in August 2000.
We maintain corporate offices at 6701 Koll Center Parkway Suite 120, Pleasanton, California 94566. Our telephone number is (925) 223-6700. We maintain a corporate website at www.natus.com. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.
We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. This information may also be obtained from the SEC's on-line database, which is located at www.sec.gov. Our common stock is traded on the Nasdaq Stock Market under the symbol "BABY".

Item 1A. Risk Factors

Our business results depend on our ability to successfully manage ongoing organizational change and business transformation and achieve cost savings and operating efficiency initiatives.
On January 15, 2019 Natus announced the implementation of a new organizational structure, "One Natus," designed to improve operational performance and make it a stronger, more profitable company. There can be no assurance that we will realize, in full or in part, the anticipated benefits of this new structure. Our financial goals assume a level of increased productivity. If we are unable to deliver these expected improvements, or continue to invest in business growth, or if the volume and nature of change require additional resources, our business operations and financial results could be materially and adversely impacted. Our ability to successfully manage and execute these initiatives and realize expected savings and benefits in the amounts and at the times anticipated is important to our business success. Any failure to do so, which could result from our inability to successfully execute organizational change and business transformation plans, changes in global or regional economic conditions, competition, changes in the industries in which we compete, unanticipated costs or charges, loss of key personnel and other factors described herein, could have a material adverse effect on our businesses, financial condition and results of operations.
Our growth in recent years has depended substantially on the completion of acquisitions and we may not be able to complete acquisitions of the same nature or relative size in the future to support a similar level of growth.
The acquisitions that we have completed have contributed to our growth in recent years. We have expended considerable effort in seeking to identify attractive acquisition candidates, and ultimately, to negotiate mutually agreeable acquisition terms. The market for attractive acquisitions is competitive and others with different strategic objectives or 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 acceptable financial returns from the transaction.
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, beginning in 2012 we 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, and in 2015 we completed the final implementation of the ERP. In 2018 we completed the implementation of the ERP application for our Otometrics and Integra acquisitions. 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 ongoing development and stabilization 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. As we continue to integrate the Otometrics

and Integra operations, we will incur costs which could materially exceed expectations and there can be no assurance that implementation will not disrupt our operations.

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.

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. We

Table of Contents

reported a material weakness in our internal control reporting for the year ended December 31, 2017, which we remediated in 2018. Separately, during the fourth quarter of 2018, in connection with a change in control owner, management identified an existing control that was not designed at a sufficient precision to adequately review our analysis of separate reporting units, which could have resulted in a material misstatement. Although we took steps to remediate these issues in 2018 and believe that material weaknesses were remediated as of December 31, 2018, these measures may not be sufficient to avoid similar weaknesses or other deficiencies in the future. For additional information on the material weakness identified in the fourth quarter of 2018, see the “Management's Report on Internal Control Over Financial Reporting” section of “Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in this Annual Report.

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 independent registered 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.

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.

We are subject to a variety of operational risks inherent in our business which may disrupt our business and negatively impact our results of operations.

We are exposed to many types of operational risks, including business continuity, direct or indirect loss resulting from inadequate or failed internal and external processes, systems or human error, the effects of natural or man-made catastrophic events (such as natural disasters, pandemics, cyber-attacks, acts of terrorism, civil unrest and other catastrophes) or from other external events. Exposure to such events could disrupt our systems and operations significantly, which may result in financial loss and reputational damage.

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.

In 2016 voters in the United Kingdom approved "Brexit," calling for the United Kingdom to withdraw from the European Union by March 29, 2019. The effects of the Brexit vote and the perceptions as to the impact of the withdrawal of the U.K. from the European Union may adversely affect business activity and economic and market conditions in the U.K., the Eurozone, and globally, and have contributed to instability in global financial and foreign exchange markets, including volatility in the value of the pound sterling and the euro. In addition, Brexit could lead to additional political, legal and economic instability in the European Union. Natus has not identified any additional risk factors under Brexit other than those discussed herein. Additionally, we have not identified any trends or potential

changes to critical accounting estimates as a result of Brexit. We will continue to assess risk factors and accounting and reporting considerations. Any of these effects of Brexit, among others, could adversely affect our business, financial condition or future results.

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. Our exposure to the currency fluctuations is enhanced as a result of the Otometrics acquisition. 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

Table of Contents

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.

We are exposed to certain risks as a result of operating in countries with high levels of inflation.

These risks include the risk that the rate of price increases will not keep pace with the cost of inflation, adverse economic conditions may discourage business growth which could affect demand for our services, the devaluation of the currency may exceed the rate of inflation and reported U.S. dollar revenues and profits may decline, and these countries may be deemed “highly inflationary” for U.S. GAAP purposes.

Effective July 1, 2018, Argentina's economy is considered to be highly inflationary under U.S. GAAP since it has experienced a rate of general inflation in excess of 100% over the latest three-year period, based upon the cumulative inflation rates published by Center for Audit Quality (CAQ) SEC Regulations Committee and its International Practices Task Force (IPTF). As a result, beginning July 1, 2018, the U.S. dollar is the functional currency for the Company's subsidiary in Argentina, Medix I.C.S.A. Accordingly, all gains and losses resulting from the translation of the Company's Argentinian operations are required to be recorded directly in the statement of operations. Through June 30, 2018, prior to being designated as highly inflationary, currency translation adjustments of Medix's balance sheet are reflected in shareholders' equity as part of Other Comprehensive Income; however subsequent to July 1, 2018, such adjustments are reflected in earnings.

The interest rates on our revolving credit facility are priced using a spread over LIBOR.

LIBOR, the London interbank offered rate, is the basic rate of interest used in lending between banks on the London interbank market and is widely used as a reference for setting the interest rate on loans globally. We typically use LIBOR as a reference rate in our term loans such that the interest due to our creditors pursuant to a term loan extended to us is calculated using LIBOR. Most of our term loan agreements contain a stated minimum value for LIBOR.

The Company’s credit facility permits interest on the outstanding principal balance to be calculated based on LIBOR. On July 27, 2017, the U.K. Financial Conduct Authority (the "FCA") announced that it will no longer require banks to submit rates for the calculation of LIBOR after 2021 and while work on substitutions is ongoing, considerable uncertainty exists around what will replace LIBOR and how it will be implemented. Actions in the meantime, by the FCA, other regulators, or law enforcement agencies are expected to influence the method by which LIBOR is calculated. At this time, it is not possible to predict the effect of any such changes or any other reforms to LIBOR that may be enacted in the U.K. or elsewhere.

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, or disclosure of private patient health information, 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.

In the course of performing our business we obtain, from time to time, confidential patient health information. For example, we may learn patient names and be exposed to confidential patient health information when we provide training on our products to our customers’ staff. Complying with federal and state privacy and security requirements imposes compliance related costs, subjects us to potential regulatory audits, and may restrict our business operations. These various laws may be subject to varying interpretations by courts and government agencies creating potentially complex compliance issues for our business. If we were to violate any of our legal obligations to safeguard any

confidential patient health information or protected health information against improper use and disclosure, we could lose customers and be exposed to liability, and our reputation and business could be harmed. Concerns or allegations about our practices with regard to the privacy or security of personal health information or other privacy-related matters, even if unfounded, could damage our reputation and harm our business.

We are also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may be more onerous than corresponding U.S. laws. These regulations may require that we obtain individual consent before we collect or process any personal data, restrict our use or transfer of personal data, impose technical and organizational measures to ensure the security of personal data, and require that we notify regulatory agencies, individuals or the public about any data security breaches. As we expand our international operations, we may be required to expend significant

Table of Contents

time and resources to put in place additional mechanisms to ensure compliance with multiple data privacy laws. Failure to comply with these laws may result in significant fines and other administrative penalties and harm our business.

The FDA has issued guidance advising manufacturers to take cybersecurity risks into account in product design for connected medical devices and systems, to assure that appropriate safeguards are in place to reduce the risk of unauthorized access or modification to medical devices that contain software and reduce the risk of introducing threats into hospital systems that are connected to such devices. The FDA also issued guidance on post market management of cyber security in medical devices. Compliance with these requirements may require changes in business practices, complicate our operations, and add complexity and additional management and oversight needs. They also may complicate our clinical research activities, as well as product offerings that involve transmission or use of clinical data.

Failure to comply with laws relating to the confidentiality of sensitive personal information or standards related to the transmission of electronic health data may require us to make significant changes to our products, or incur penalties or other liabilities.

State, federal and foreign laws, such as the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), regulate the confidentiality of sensitive personal information and the circumstances under which such information may be released. These measures may govern the disclosure and use of personal and patient medical record information and may require users of such information to implement specified security measures, and to notify individuals in the event of privacy and security breaches. Evolving laws and regulations in this area could restrict the ability of our customers to obtain, use or disseminate patient information, or could require us to incur significant additional costs to re-design our products in a timely manner to reflect these legal requirements, either of which could have an adverse impact on our results of operations. Other health information standards, such as regulations under HIPAA, establish standards regarding electronic health data transmissions and transaction code set rules for specified electronic transactions, for example transactions involving submission of claims to their party payors. These standards also continue to evolve and are often unclear and difficult to apply. In addition, under the federal Health Information Technology for Economic and Clinical Health Act, or HITECH Act, some of our businesses that were previously only indirectly subject to federal HIPAA privacy and security rules became directly subject to such rules because the businesses may be deemed to serve as "business associated" to certain of our customers.

Outside the U.S., we are impacted by the privacy and data security requirements at the international, national and regional level, and on an industry specific basis. We serve customers across the globe. Legal requirements in these countries relating to the collection, storage, handling and transfer of personal data and potentially intellectual property continue to evolve with increasingly strict enforcement regimes. More privacy and security laws and regulations are being adopted, and more are be enforced, with potential for significant financial penalties. In the European Union, increasingly stringent data protection and privacy rules that will have substantial impact on the use of patient data across the healthcare industry became effective in May 2018. The new European Union General Data Protection Regulation ("GDPR") applies uniformly across the European Union and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR also requires companies processing personal data of individuals, including employees, residing in the European Union to comply with European Union privacy and data protection rules. Failure to maintain the confidentiality of sensitive personal information in accordance with the applicable regulatory requirements, or to abide by electronic health data transmission standards, could expose us to breach of contract claims, fines and penalties, costs for remediation and harm to our reputation.

The personal information that we collect may be vulnerable to breach, theft or loss that could adversely affect our reputation, results of operation and financial condition.

In the ordinary course of our business, we collect, process, transmit and retain personal information regarding our employees and their families, vendors and customers, which can include social security numbers, social insurance numbers, banking and tax identification information, health-care information and credit card information. A third-party may be able to circumvent the security and business controls we use to limit access and use of personal information, which could result in a breach of employee, customer, or vendor's privacy. A major breach, theft or loss

of personal information regarding our employees and their families, vendors or customers that is held by us could result in substantial fines and penalties. For example, the European Union adopted a new regulation that became effective May 2018, called the General Data Protection Regulation ("GDPR"), which requires companies to meet certain requirements regarding the handling of personal data. Failure to meet GDPR requirements could result in penalties of up to 4% of worldwide revenue. As a result of legislative and regulatory rules, we may be required to notify the owners of the personal information of any data breaches, which could harm our reputation and financial results, as well as subject us to litigation or actions by regulatory authorities. Furthermore, media or other reports of existing or perceived security vulnerabilities in our systems, even if no breach has been attempted or has occurred, can adversely impact our brand and reputation, and thereby materially impact our business. Significant capital investments and other expenditures could be required to remedy a breach and prevent future problems, including costs associated with additional security technologies, personnel, experts and credit monitoring services for those whose data has been breached. These costs, which could be material, could adversely impact our

Table of Contents

results of operations during the period in which they are incurred. The techniques and sophistication used to conduct cyber-attacks and breaches, as well as the sources and targets of these attacks, change frequently and are often not recognized until such attacks are launched or have been in place for a period of time. Accordingly, our expenditures to prevent future cyber-attacks are breaches may not be successful.

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 (collectively, the "ACA"). The ACA contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers and importers. The Medical Device Excise Tax ("MDET") went into effect on January 1, 2013 but was suspended for the period January 1, 2016 to December 31, 2017 with the signing of The Consolidated Appropriations Act, 2016 (Pub.L. 114-113).

No action by Congress was taken before the moratorium was set to expire on December 31, 2017. Therefore, MDET was reinstated on January 1, 2018. On January 22, 2018 the U.S. government signed funding bill HR 195 to extend an additional two-year moratorium on the MDET. The moratorium was retroactive to January 1, 2018. Unless there is legislative action prior to 2020, the MDET will automatically reinstate in 2020.

Uncertainty surrounding the ACA and the U.S. healthcare system may impact the way our customers spend on medical devices, supplies, and services in the future. If we fail to effectively react to the implementation of healthcare reform, our business may be adversely affected.

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

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

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

Table of Contents

example, some payors are moving toward a managed care system in which providers contract to provide comprehensive healthcare 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.

Our Peloton hearing screening service is dependent on third-party payors to reimburse us for services provided to patients. We have encountered challenges in obtaining reimbursement from third parties and are dedicating resources to the education of third-party payors to the benefits of these services. Our inability to obtain reimbursement for these services, and any adverse changes in reimbursement policies or amounts for either of these services, or other products or services that we provide, could harm our business.

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.

In 2014 and 2016 we received formal communications from the FDA regarding deficiencies in our manufacturing processes in our Seattle facility. As a result, we imposed ship-holds on certain of our products produced there and have discontinued certain other products produced in that facility. We are dedicating substantial resources to the resolution of the conditions identified by the FDA. These actions had an adverse effect on our results of operations in 2016 and 2017.

Our inability to address issues that have been raised by the FDA, or failure of us or our third party suppliers and manufacturers 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.

If we fail in our efforts to educate clinicians, government agency personnel, and third-party payors about 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 a high volume 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,

Table of Contents

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 13.3%, 14.5% and 12.3% of our total revenue during 2018, 2017 and 2016, 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.

Consolidation in the healthcare industry could have an adverse effect on our revenues and results of operations.

Many healthcare industry companies, include our customers and competitors, are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide goods and services to our customers could become more intense. Our customers may try to use their market power to negotiate price concessions and our competitors may utilize their size and broad product lines to offer cheaper alternatives to our products. If we are forced to reduce our prices because of consolidation in the healthcare industry, our revenues would decrease and our consolidated earnings, financial condition, or cash flow would suffer.

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. The market for newborn care products is affected by birthrates, and a declining U.S. birthrate has adversely affected our operating results in recent periods. 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. Our hearing 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.

In October 2017 we completed the acquisition of our neurosurgery business from Integra LifeSciences. We are relying on Integra LifeSciences for certain transition services to support the acquired business and at the same time we are competing with them in the sale of neurosurgery products. Integra LifeSciences may face conflicting interests in performing required services for us and this may result in adverse effects on the acquired business.

We have substantial international operations which are subject to numerous risks; if our international operations are not successful, our business will be adversely affected.

In 2018, approximately 43.3% of our sales were made outside the U.S. We 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 and to political and diplomatic matters such as the BREXIT of the United Kingdom from the European Union;
- Adverse changes in tariffs and trade protection measures;

Table of Contents

- Difficulty in obtaining and maintaining foreign regulatory approval and complying with foreign regulations, including the EU Medical Device Regulation;
- 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;
- 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;
- Changes in capital and exchange controls affecting international trade;
- 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;
- 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.

The recently passed comprehensive U.S. tax reform legislation could materially affect our business and financial condition.

The Tax Cuts and Jobs Act (the “Tax Act”) was signed into law in December 2017. The new law made numerous changes to federal corporate tax law that we expect will impact our effective tax rate in future periods. The changes included in the Tax Act are broad and complex. The final transition impacts of the Tax Act may differ from our current estimates, possibly materially, due to, among other things, changes in interpretations of the Tax Act, any legislative action to address questions that arise because of the Tax Act, any changes in accounting standards for income taxes or related interpretations in response to the Tax Act, or any updates or changes to estimates the Company has utilized to calculate the transition impacts.

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

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

Table of Contents

through new distributors, the rate of growth of our revenue could be harmed if our existing distributors do not continue to sell a large dollar volume of our products. None of our existing distributors are obligated to continue selling our products.

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

If we lose our relationship with any supplier of key product components or our relationship with a supplier deteriorates or key components are not available in sufficient quantities, our manufacturing could be delayed and our business could suffer.

We contract with third parties for the supply of some of the components used in our products and the production of our disposable products. Some of our suppliers are not obligated to continue to supply us. We have relatively few sources of supply for some of the components used in our products and in some cases we rely entirely on sole-source suppliers. In addition, the lead-time involved in the manufacturing of some of these components can be lengthy and unpredictable. If our suppliers become unwilling or unable to supply us with components meeting our requirements, it might be difficult to establish additional or replacement suppliers in a timely manner, or at all. This would cause our product sales to be disrupted and our revenue and operating results to suffer.

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

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

Our products and technologies are complex, and we depend substantially on the continued service of our senior management team. The loss of any of our key employees could adversely affect our business and slow our product development process. The successful implementation of our "One Natus" organizational structure also depends on key employees. Our future success 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

Table of Contents

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 FDA 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;
- 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;
- 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; or
- Foreign governments and regulatory authorities have, and may continue to, propose and implement regulations that apply to our products and operations. For example, in 2017 the European Union adopted the EU Medical Device Regulation, which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements once it is fully implemented in 2020. Penalties for regulatory non-compliance could be severe, including fines and revocation or suspension of a company's business license, mandatory price reductions, and criminal sanctions. Future laws and regulations may have a material adverse effect on our business.

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 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.

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 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

Table of Contents

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 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.

We are currently subject to cases based on third-party patent infringement claims. A successful claim of infringement against us from any current or future claim 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. We are currently subject to one such lawsuit. 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 the second half of our fiscal year to the first half of the fiscal year, 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 anticipate that we will continue to experience seasonal fluctuations, which may lead to fluctuations

Table of Contents

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.

Our stock price may be volatile, which may cause the value of our stock to decline or subject us to a securities class action litigation.

The trading price of our common stock price may be volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- general economic, industry and market conditions;
- actions by institutional or other large stockholders;
- the depth and liquidity of the market for our common stock;
- volume and timing of orders for our products;
- developments generally affecting medical device companies;
- the announcement of new products or product enhancements by us or our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- investor perceptions of us and our business, including changes in market valuations of medical device companies; and
- our results of operations and financial performance.

In addition, the stock market in general, and the NASDAQ Stock Market and the market for medical devices in particular, have experienced substantial price and volume volatility that is often seemingly unrelated to the operating performance of particular companies. These broad market fluctuations may cause the trading price of our common stock to decline. In the past, securities class action litigation has often been brought against a company after a period of volatility in the market price of its common stock. We may become involved in this type of litigation in the future. Any securities litigation claims brought against us could result in substantial expense and the diversion of management's attention from our business.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties

Our corporate headquarters are located in Pleasanton, California, in a facility covering 8,200 square feet pursuant to a lease that expires in October 2019.

We also utilize the following properties:

Company-owned Facilities:

- 116,000 square feet in Buenos Aires, Argentina, utilized substantially for manufacturing;
- 44,900 square feet in Oakville, Ontario, Canada, utilized substantially for research and development;
- 42,600 square feet in Gort, Ireland, utilized substantially for manufacturing; and
- 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.

- 124,000 square feet in Middleton, Wisconsin, pursuant to a lease that expires in April 2024, that is primarily utilized for manufacturing;
- 65,000 square feet in Seattle, Washington, pursuant to a lease that expires in December 2020, that is utilized substantially for manufacturing;
- 52,000 square feet in Taastrup, Denmark, pursuant to a lease with the option to terminate with six months-notice beginning January 2022, that is utilized for manufacturing, research and development, marketing and sales, and general and administrative;
- 43,000 square feet in Planegg, Germany, pursuant to a lease that expires in December 2021 that is utilized substantially for sales and marketing and a large portion is subleased to third parties;
- 37,282 square feet in San Diego, California, pursuant to a lease that expires in June 2022, that is utilized substantially for manufacturing;

Table of Contents

- 25,128 square feet in Schaumburg, Illinois, pursuant to a lease that expires in July 2021, that is utilized substantially for marketing and sales; and
- 23,860 square feet in Quebec, Canada, pursuant to a lease that expires in December 2023, that is utilized substantially for manufacturing.

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.

In January 2017, a putative class action lawsuit (Badger v. Natus Medical Incorporation, et al., No. 17-cv-00458-JSW) alleging violations of federal securities laws was filed in the United States District Court for the Northern District of California, naming as defendants the Company and certain officers and a director. In July 2017, plaintiffs filed an amended complaint with a new lead plaintiff (Costabile v. Natus Medical Incorporation, et al., No. 17-cv-00458-JSW) alleging violations of federal securities laws based on allegedly false and misleading statements. The defendants moved to dismiss the Amended Complaint, and in February 2018 the motion to dismiss was granted with leave to amend. The plaintiffs re-filed an amended complaint in April 2018 and Natus responded in May 2018. In December 2018, the Amended Complaint was again dismissed with leave to amend. The Company continues to believe that the plaintiffs' allegations are without merit, and intended to vigorously defend against the claims.

ITEM 4. Mine Safety Disclosures

The disclosure required by this item is not applicable.

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.

	High	Low
Fiscal Year Ended December 31, 2018:		
Fourth Quarter	$36.85	$27.69
Third Quarter	37.90	31.05
Second Quarter	37.95	31.10
First Quarter	39.25	28.00
Fiscal Year Ended December 31, 2017:		
Fourth Quarter	$43.60	$37.10
Third Quarter	39.50	31.65
Second Quarter	41.25	33.28
First Quarter	39.75	33.55

As of February 20, 2019, there were 33,777,388 shares of our common stock issued and outstanding and held by approximately 105 stockholders of record. We estimate that there are approximately 18,758 beneficial owners of our common stock.

Dividends

We have never declared or paid cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future.

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

27

Table of Contents

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, 2014 through December 31, 2018, 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.

		2013	2014	2015	2016	2017	2018
Natus Medical Inc.	Return %		60.18	33.32	(27.58)	9.77	(10.90)
	Cum $	100.00	160.18	213.56	154.67	169.78	151.24
NASDAQ Composite-Total Returns	Return %		14.75	6.96	8.87	29.64	(2.84)
	Cum $	100.00	114.75	122.74	133.62	173.22	168.30
S&P 500 Health Care Equipment Index	Return %		26.28	5.97	6.48	30.90	16.24
	Cum $	100.00	126.28	133.82	142.50	186.53	216.82

Purchases of Equity Securities by the Issuer

The following table provides information regarding repurchases of common stock for the year ended December 31, 2018.

Table of Contents

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
February 1, 2018—February 28, 2018	29,722	$ 31.23	29,722	$ 29,071,782
March 1, 2018—March 31, 2018	118,171	$ 32.19	147,893	$ 25,271,403
June 1, 2018—June 30, 2018	25,652	$ 34.79	173,545	$ 24,378,970
Total	173,545	$ 32.41	173,545	$ 24,378,970

On February 22, 2018, the Board of Directors authorized the repurchase of up to $30 million in common stock with an expiration date of February 26, 2019.

ITEM 6. Selected Financial Data

The following tables set forth certain selected consolidated financial data for each of the years in the five-year period ended December 31, 2018, and is derived from the Consolidated Financial Statements of Natus Medical Incorporated and its subsidiaries. The Consolidated Financial Statements for each of the years in the three-year period ended December 31, 2018 are included elsewhere in this report. The selected consolidated balance sheet data as of December 31, 2016, 2015 and 2014 and the consolidated statements of operations data for the years ended December 31, 2015 and 2014 are derived from our Consolidated Financial Statements, which are not included in this report. The selected consolidated financial data set forth below is qualified in its entirety by, and should be read in conjunction with, the Consolidated Financial Statements and Notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this report.

Table of Contents

	Year ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data (a):					
Revenue	$530,891	$500,970	$381,892	$375,865	$355,834
Cost of revenue	217,952	213,376	144,632	145,492	138,480
Intangibles amortization	8,924	6,380	2,327	2,836	2,967
Gross profit	304,015	281,214	234,933	227,537	214,387
Operating expenses:					
Marketing and selling	136,680	126,166	84,834	87,675	85,729
Research and development	61,482	51,822	33,443	30,434	30,100
General and administrative	70,599	74,424	50,877	46,363	45,444
Intangibles amortization	22,585	19,171	8,983	7,447	3,025
Restructuring	37,231	914	1,536	2,145	4,238
Total operating expense	328,577	272,497	179,673	174,064	168,536
Income from operations	(24,562)	8,717	55,260	53,473	45,851
Other income (expense), net	(7,698)	(3,567)	(357)	(1,064)	158
Income before provision for income tax	(32,260)	5,150	54,903	52,409	46,009
Provision for income tax	(9,325)	25,443	12,309	14,485	13,531
Net income (loss)	$(22,935)	$(20,293)	$42,594	$37,924	$32,478
Earnings per share:					
Basic	$(0.69)	$(0.62)	$1.31	$1.17	$1.03
Diluted	$(0.69)	$(0.62)	$1.29	$1.14	$1.00
Weighted average shares used in the calculation of earnings per share:					
Basic	33,111	32,564	32,460	32,348	31,499
Diluted	33,111	32,564	33,056	33,241	32,568