MASIMO CORP
Form 10-K
February 17, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 3, 2015

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-33642

Masimo Corporation
(Exact name of registrant as specified in its charter)

Delaware	33-0368882
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
52 Discovery, Irvine, California	92618
(Address of Principal Executive Offices)	(Zip Code)

(949) 297-7000
(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, par value $0.001	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

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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 filing 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 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 is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 (Check one).

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 28, 2014, the last business day of the registrant’s most recently completed second fiscal quarter, as reported on the NASDAQ Global Select Market, was approximately $730.9 million. Shares of stock held by officers, directors and 5 percent or more stockholders 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.

At January 31, 2015, the registrant had 52,613,110 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant’s proxy statement for the registrant’s 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Form 10-K, contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. The forward-looking statements are contained principally in Item 1—"Business," Item 1A—"Risk Factors" and Item 7—"Management's Discussion Analysis of Financial Condition and Results of Operations" but appear throughout this Form 10-K. Examples of forward-looking statements include, but are not limited to, any projection or expectation of earnings, revenue or other financial items; the plans, strategies and objectives of management for future operations; factors that may affect our operating results, including accounting and tax estimates; our success in pending litigation; new products or services; the demand for our products; our ability to consummate acquisitions and successfully integrate them into our operations; future capital expenditures; effects of current or future economic conditions or performance; industry trends and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "opportunity," "plan," "potential," "predicts," "seek," "should," "will," or "v expressions and variations or negatives of these words. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which is subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause our actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed under Item 1A—"Risk Factors" in this Form 10-K. Furthermore, such forward-looking statements speak only as of the date of this Form 10-K. We undertake no obligation to update or revise publicly any forward-looking statements to reflect events or circumstances after the date of such statements for any reason, except as otherwise required by law.

PART I

ITEM 1. BUSINESS

Overview

We are a global medical technology company that develops, manufactures and markets a variety of noninvasive monitoring technologies. We provide our products directly and through distributors and original equipment manufacturers (OEM) partners to hospitals, emergency medical service (EMS) providers, physician offices, veterinarians, long term care facilities and consumers. Our mission is to improve patient outcomes and reduce the cost of care by taking noninvasive monitoring to new sites and applications. We were incorporated in California in May 1989 and reincorporated in Delaware in May 1996.

Our core business is measure-through-motion and low-perfusion pulse oximetry monitoring, known as Masimo Signal Extraction Technology® (SET®) pulse oximetry. Our product offerings have expanded significantly over the years to also include noninvasive optical blood constituent monitoring, optical organ oximetry monitoring, electrical brain function monitoring, acoustic respiration monitoring and optical gas monitoring. In addition, we have developed the Root® patient monitoring and connectivity platform, the Radical-7® bedside and portable patient monitor and the Radius-7™ wearable wireless patient monitor. We have also developed the Patient SafetyNet™ remote patient surveillance monitoring system, which currently allows up to 80 patients to be monitored simultaneously through a central station or remotely by care providers through their pagers or smart phones.

Our solutions and related products are based upon our proprietary Masimo SET® and rainbow® algorithms. These technologies are incorporated into a variety of product platforms depending on our customers' specifications. In addition, we provide our technologies to OEMs in a form factor that is easy to integrate into their patient monitors, defibrillators and infant incubators. Our technology is supported by a substantial intellectual property portfolio that we have built through internal development and, to a lesser extent, acquisitions and license agreements. We have also exclusively licensed from Cercacor Laboratories, Inc. (Cercacor) the right to OEM rainbow® technologies and to incorporate rainbow® technology into our products intended to be used by professional caregivers, including, but not

limited to, hospital caregivers and alternate care facility caregivers.

Conventional Pulse Oximetry

Pulse oximetry enables the noninvasive measurement of the oxygen saturation level of arterial blood, which delivers oxygen to the body's tissues. Pulse oximetry also enables the measurement of pulse rate, which when measured by electrocardiogram (ECG), is called heart rate. Pulse oximeters use sensors attached to an extremity, typically the fingertip. These sensors contain two light emitting diodes that transmit red and infrared light from one side of the extremity through the tissue to a photodetector on the other side of the extremity. The photodetector in the sensor measures the amount of red and infrared light absorbed by

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the tissue. A microprocessor then analyzes the changes in light-absorption to provide a continuous, real-time measurement of the amount of oxygen in the patient's arterial blood. Pulse oximeters typically give audio and visual alerts, or alarms, when the patient's arterial blood oxygen saturation level or pulse rate falls outside of a user-designated range. As a result, clinicians have the opportunity to assess patients who may need immediate treatment to prevent the serious clinical consequences of hypoxemia, or low oxygen saturation levels, and hyperoxemia, or high oxygen levels.

As one of the most common measurements taken in and out of hospitals around the world, pulse oximetry has gained widespread clinical acceptance as a standard patient vital sign measurement because it can give clinicians an early warning of low arterial blood oxygen saturation levels, known as hypoxemia. Early detection is critical because hypoxemia can lead to a lack of oxygen in the body's tissues, which can result in organ damage or death. Pulse oximeters are used primarily in critical care settings, including surgery, recovery rooms, intensive care units (ICUs), emergency departments and alternative care settings, such as long-term care facilities and for home monitoring of patients with chronic conditions.

Clinicians also use pulse oximeters to estimate whether there is too much oxygen in the blood, a condition called hyperoxemia. In premature babies, hyperoxemia can lead to permanent eye damage or blindness. By ensuring that oxygen saturation levels in babies remain within clinically accepted limits, clinicians believe they can lower the incidence of hyperoxemia. In adults, to prevent hyperoxemia, clinicians use pulse oximetry monitoring to guide the administration of oxygen to maintain normal saturation levels.

Conventional pulse oximetry is subject to technological limitations that reduce its effectiveness and the quality of patient care. In particular, when using conventional pulse oximetry, oxygen saturation measurements can be distorted by motion artifact, or patient movement, and low perfusion, or low arterial blood flow at the measurement site. Motion artifact can cause conventional pulse oximeters to inaccurately measure the arterial blood oxygen saturation level, due mainly to the movement and recognition of venous blood. Venous blood may cause falsely low oxygen saturation readings. Low perfusion can also cause conventional pulse oximeters to report inaccurate measurements, or in some cases, no measurement at all. Conventional pulse oximeters cannot distinguish oxygenated hemoglobin, or the component of red blood cells carrying oxygen, from dyshemoglobins, which are hemoglobin bound with carboxyhemoglobin or methemoglobin and are therefore incapable of carrying oxygen. In addition, conventional pulse oximetry readings can also be impacted by bright light and electrical interference from the presence of electrical surgical equipment.

Independent research has shown that over 70% of the alarms outside the operating room are false when using conventional pulse oximetry. In addition, in the operating room, conventional pulse oximeters can fail to give measurements due to weak physiological signals, or low perfusion, in up to 9% of all cases studied. Manufacturers of conventional pulse oximeters have attempted to address some of these limitations with varying degrees of success. Some competing devices have attempted to minimize the observed effects of motion artifact by repeating the last measurement before motion artifact is detected, until a new, clean signal is detected and a new measurement can be displayed, known as freezing values. Other competing devices increase the averaging time during motion, known as long-averaging, in an attempt to reduce the observed effect of motion on their measurements. Still other competing devices extend the audible alarm notification delay, which reduces the awareness of inaccurate measurements. These competing solutions, commonly referred to as "motion tolerant" or "alarm management" techniques, mask the limitations of conventional pulse oximetry. Several published studies have demonstrated that these also contribute to increased occurrences of undetected true alarms, or events where hypoxemia occurs, but is not detected by the pulse oximeter.

Conventional pulse oximetry technology also has several practical limitations. Because the technology cannot consistently measure oxygen saturation levels of arterial blood in the presence of motion artifact or low perfusion, conventional pulse oximetry is limited in non-critical care settings of the hospital, such as general care areas, where the hospital staff-to-patient ratio is significantly lower and the staff has lower tolerance for false alarms. In order for pulse oximetry to become a standard patient monitoring device in these settings, these limitations must be overcome.

In addition, two-wavelength pulse oximeters cannot distinguish oxygenated hemoglobin from dyshemoglobin, including the most prevalent forms of carboxyhemoglobin and methemoglobin. As a result of these dyshemoglobins, pulse oximeters will report falsely high oxygen levels when they are present in the blood.

Masimo SET® Pulse Oximetry

Masimo SET® was designed to overcome the primary limitations of conventional pulse oximetry by maintaining accuracy in the presence of motion artifact, low perfusion and weak signal-to-noise situations. Our Masimo SET® platform, which became available to hospitals in the U.S. in 1998, is the basis of our pulse oximetry products and we believe represented the first significant technological advancement in pulse oximetry since its introduction in the early 1980s. Masimo SET® utilizes five signal processing algorithms, four of which are proprietary, in parallel to deliver high sensitivity and specificity in the measurement of arterial blood oxygen saturation levels. Sensitivity is the ability to detect true events and specificity is the

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ability to reject false alarms. One of our proprietary processing algorithms, Discrete Saturation Transform®, separates the signal from noise in real-time through the use of adaptive filtering and an iterative sampling technique that tests each possible saturation value for validity. Masimo SET® signal processing can therefore identify the venous blood and other noise, isolate them, and extract the arterial signal.

The performance of Masimo SET® pulse oximetry is proven by more than 100 independent studies and thousands of clinical evaluations. We believe that Masimo SET® is trusted by clinicians to safely monitor approximately 100 million patients each year and is used hospital-wide by eight of the top ten hospitals on the U.S. News & World Report Best Hospitals Honor Roll (2013-2014). Compared to conventional pulse oximeters, during patient motion and low perfusion, Masimo SET® provides measurements when other pulse oximeters cannot, dramatically reduces false alarms (specificity), and accurately detects true alarms (sensitivity) that can indicate a deteriorating patient condition. Masimo SET® pulse oximetry has also been shown to improve patient outcomes by helping clinicians reduce retinopathy of prematurity in neonates, screen newborns for critical congenital heart disease (CCHD), reduce ventilator weaning time and arterial blood gas measurements in the ICU, and save lives and costs while reducing rapid response activations and ICU transfers on the general floor.

Our pulse oximetry technology is contained on a circuit board which is placed inside a standalone pulse oximetry monitor, placed inside original equipment manufacturer (OEM) multiparameter monitors, or included as part of an external “Board-in-Cable” solution that is plugged into a port on an OEM or other device. All of these solutions use our proprietary single-patient use or reusable sensors and cables. We sell our products to end-users through our direct sales force and certain distributors, as well as to our OEM partners, for incorporation into their products. In 2013, we also began selling our pulse oximetry products in the consumer market. As of January 3, 2015, we estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET® and rainbow® SET was more than 1.3 million units, excluding handheld devices. Our installed base is the primary driver for the recurring sales of our pulse oximeter and Pulse CO-Oximeter® sensors, most notably, single-patient adhesive sensors.

To complement our Masimo SET® platform, we have developed a wide range of proprietary single-patient use (disposable) and multi-patient (reusable) sensors, cables and other accessories designed specifically to work with Masimo SET® software and hardware. Our single-patient use sensors offer several advantages over reusable sensors, including improved performance, cleanliness, increased comfort and greater reliability. In addition, our neonatal adhesive sensors have been designed to exhibit greater durability compared to competitive sensors. Although our technology platforms operate solely with our proprietary sensor lines, our sensors have the capability to work with certain competitive pulse oximetry monitors through the use of adapter cables.

Adhesive sensors are single-patient use items, but the U.S. Food and Drug Administration (FDA) allows third parties to reprocess pulse oximetry sensors. In response to some hospitals’ requests to implement environmentally friendly or “green” products, we developed the rainbow ReSposable® sensor system. The rainbow ReSposable® sensor, part reusable and part disposable, combines the performance and comfort of single-use adhesive sensors with the economic and “green” advantages of reusable sensors.

Masimo SET® technologies and products offer multiple clinical and financial benefits, including:

- Fewer false alarms and better true alarm detection. Over 100 independent studies demonstrate the advantages of Masimo SET® during challenging conditions in adult, pediatric and neonatal patients.
- Fewer arterial blood gas measurements, faster oxygen weaning time, and lower length of stay in the ICU. Due to the ability of Masimo SET® to monitor patients during challenging conditions, studies have shown that Masimo SET® helps clinicians reduce the need for arterial blood gas, weaning times from the ventilator, and length of stay.
- Lower sensor utilization. Masimo SET® sensors provide enhanced durability for greater sensor longevity, and the underlying performance of Masimo SET® in challenging conditions makes it easier to obtain measurements on digits with low perfusion, which reduces the use of multiple sensors on the same patient.
- Increased detection of critical congenital heart disease through newborn screening. Four studies totaling 118,000 patients have shown that adding Masimo SET® to the standard physical exam helps clinicians to increase the detection of critical congenital heart disease, a potentially fatal disease, before the newborn leaves the hospital. The published evidence for Masimo SET® led the American Academy of Pediatrics and the U.S. Department of Health and Human Services to recommend mandatory screening for all newborns using “motion-tolerant pulse oximeters that

report functional oxygen saturation and have been validated in low perfusion conditions". In 2012, we received FDA 510(k) clearance for Masimo SET® pulse oximeters and neonatal sensors with labeling for screening newborns for CCHD, marking the first time the FDA cleared specific labeling for the use of pulse oximeters, in conjunction with a physical exam, to screen newborns for CCHD.

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- Reduced retinopathy of prematurity in very low birth weight neonates. In a two-phased study of two centers that previously used competing pulse oximetry, both centers simultaneously changed their neonatal oxygen targeting policy, and one of the centers switched to Masimo SET® pulse oximetry. In the first phase of the study, there was no decrease in retinopathy of prematurity at the center using competing pulse oximetry but there was a 58% reduction in significant retinopathy of prematurity and a 40% reduction in the need for laser eye treatment at the center using Masimo SET®. In the second phase of the study, the center still using competing pulse oximetry switched to Masimo SET® and it experienced results similar to the center already using Masimo SET®

Masimo rainbow ® SET® Platform

Since introducing Masimo SET®, we have continued to innovate by introducing breakthrough noninvasive measurements that go beyond arterial blood oxygen saturation and pulse rate. In 2005, we introduced the Masimo rainbow® SET® platform, leveraging our Masimo SET® technology and incorporating licensed rainbow® technology to enable real-time monitoring of additional noninvasive measurements. Our rainbow® SET® platform includes our rainbow® SET® Pulse CO-Oximetry products, which we believe are the first devices cleared by the FDA to noninvasively and continuously monitor multiple blood-based measurements using multiple wavelengths of light, which was previously possible only through intermittent invasive procedures. In addition to monitoring oxygen saturation (SpO_2), pulse rate (PR), perfusion index (PI), Pleth Variability Index (PVI®) and Respiration Rate from Pleth (RRp™), Masimo rainbow® SET Pulse CO-Oximetry has the unique ability to measure and distinguish oxygenated hemoglobins from certain dyshemoglobins, hemoglobins that are incapable of transporting oxygen, and allows for the rapid noninvasive monitoring of hemoglobin (SpHb®), carboxyhemoglobin (SpCO®) and methemoglobin (SpMet®). The Masimo rainbow® SET platform also allows for monitoring of arterial oxygen saturation even under the presence of carboxyhemoglobin and methemoglobin, known as fractional arterial oxygen saturation ($SpfO_2$™). Additionally, the rainbow® SET platform also allows for the calculation of Oxygen Content (SpOC™) and Oxygen Reserve Index (ORI™). Although RRp™, $SpfO_2$™ and ORI™ have received CE Mark, they are not currently available for sale in the U.S.

We have also developed multi-wavelength sensors that have the ability to monitor multiple measurements with a single sensor. We believe that the use of Masimo rainbow® Pulse CO-Oximetry products will become widely adopted for the noninvasive monitoring of these measurements. We also believe that the addition of Acoustic Respiration Rate (RRa®) with our rainbow Acoustic® Monitoring technology for noninvasive and continuous monitoring will strengthen the clinical demand for the rainbow® platform, especially in the growing general floor market.

Products with our MX circuit board contain our Masimo SET® pulse oximetry technology as well as circuitry to support rainbow® measurements. At the time of purchase, or at any time in the future, our customers and our OEMs' customers have the option of purchasing additional rainbow® software measurements, which will allow the customer to expand their patient monitoring systems to monitor incremental measurements with a cost-effective solution. To date, over twenty five companies have released rainbow® SET® equipped products or announced rainbow® integration plans. Companies with released rainbow® SET® products include ATOM Medical, Dräger, Edwards, Fukuda Denshi,GS Corpuls, Philips, Physio-Control, Saadat, Schiller, Welch Allyn and ZOLL. Companies that have announced rainbow® SET integration, but have not yet released products, include CareFusion, and GE Medical Systems.

SpHb®

Hemoglobin is the oxygen-carrying component of red blood cells (RBC). Hemoglobin measurement is one of the most frequent invasive laboratory measurements in the world, and is often measured as part of a complete blood count (CBC), which measures multiple other blood components. A low hemoglobin status is called anemia, which is generally caused by bleeding or the inability of the body to produce red blood cells. As a chronic disorder, anemia can be treated by iron supplements, diet changes or drugs that increase the production of red blood cells. As an acute disorder, anemia due to bleeding requires stoppage of the bleeding before organ dysfunction or death occurs, or a blood transfusion to sustain organ function and life.

SpHb® is available as a continuous monitor or a spot check measurement. Continuous SpHb® monitoring provides real-time visibility into hemoglobin levels and the changes, or lack of changes, in hemoglobin levels, which can

otherwise only be measured through intermittent, invasive blood testing. While SpHb® is not intended to replace invasive hemoglobin tests, when used with other clinical variables, SpHb® may help clinicians identify low hemoglobin and help determine additional test and treatment options.

SpOC™

SpOC™ provides a more complete picture of a patient's oxygenation status by combining noninvasive measurements of both hemoglobin and plasma oxygen levels into a single calculation.

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SpCO®

Carbon monoxide (CO) is a colorless, odorless and tasteless gas that is undetectable by humans and is often unknowingly inhaled from combustion fumes, or during fires by victims and first responders. CO poisoning is the leading cause of accidental poisoning death in the U.S., responsible for up to 50,000 emergency department visits and 500 unintentional deaths annually. CO poisoning, which involves CO binding with hemoglobin cells, thereby preventing them from carrying oxygen, can cause severe neurological damage, permanent heart damage or death in a matter of minutes. Quick diagnosis and treatment of CO poisoning in the emergency department is critical in saving lives and preventing long-term damage, but the condition is often misdiagnosed because symptoms are similar to the flu.

CO levels in the blood can be measured using a laboratory CO-Oximeter, which requires a patient or a patient's blood sample to be transported to a hospital with laboratory CO-Oximetry capability. Additional delays occur if a patient needs hyperbaric oxygen therapy, which often requires transfer to yet another medical center with hyperbaric capability. Outside the hospital, laboratory measurements of carboxyhemoglobin are not considered feasible. Historically, this meant that CO levels in the blood could not be assessed in environments in which it would be very useful, such as in the home of a patient or in the medical evaluation of first responders exposed at the scene of a fire. We believe that the greatest opportunity for SpCO® monitoring is in the EMS, fire and hospital emergency department settings. In a 2013 study, elevated SpCO® was used to help indicate a need for invasive testing in emergency department patients with headaches. This study found that 23% of the cases that were ultimately diagnosed with CO poisoning were only diagnosed after elevated SpCO® levels had been tested. While SpCO® is not intended to replace invasive carboxyhemoglobin tests, when used with other clinical variables, SpCO® may help clinicians identify elevated CO levels and help determine additional test and treatment options. Multiple leading emergency first responder associations, including the National Association of Emergency Medical Technicians, the National Association of EMS Educators, the International Association of Fire Fighters and the International Association of Fire Chiefs, now educate their members that noninvasive CO measurement is appropriate when exposure is suspected or when an individual presents symptoms that could indicate elevated CO levels. In addition, the National Fire Protection Association (NFPA), one of the world's authoritative sources on fire prevention and public safety, has recently released updated Fire Rehabilitation Standard 1584, Standard on the Rehabilitation Process for Members During Emergency Operations and Training Exercises, requiring firefighters exposed to smoke at incident scenes and during training to be accessed for elevated CO levels.

SpMet®

Methemoglobin in the blood leads to a dangerous condition known as methemoglobinemia, which occurs as a reaction to some common drugs used in hospitals and outpatient procedures. Methemoglobinemia reduces the amount of oxygen bound to hemoglobin for delivery to tissues and forces normal hemoglobin to bind more tightly to oxygen, releasing less oxygen to the tissues. Methemoglobinemia is often unrecognized or diagnosed late, increasing risk to the patient. Commonly prescribed drugs can introduce methemoglobin into the blood and cause methemoglobinemia. Some of the 30 drugs that are known to cause methemoglobinemia are benzocaine, a local anesthetic, which is routinely used in procedures ranging from endoscopy to surgery; inhaled nitric oxide, routinely used in the Neonatal Intensive Care Unit; nitroglycerin, used to treat cardiac patients, and dapsone, used to treat infections for immune deficient patients, such as HIV patients. Warnings, cautions and alerts regarding the clinical significance and prevalence of methemoglobinemia have been generated by the FDA, Veterans Administration, Institute for Safe Medication Practices and the National Academy of Clinical Biochemistry. The American Academy of Pediatrics recommends monitoring methemoglobin levels in infants who receive nitric oxide therapy.

While SpMet® is not intended to replace invasive methemoglobin tests, when used with other clinical variables, SpMet® may help clinicians detect methemoglobinemia and help determine additional test and treatment options.

PVI®

Pleth Variability Index (PVI®) calculation is a measure of the dynamic changes in the Perfusion Index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI® is displayed as a percentage. The lower the number, the less variability there is in the PI over a respiratory cycle. PVI® may show changes that reflect physiologic factors such

as vascular tone, circulating blood volume and intrathoracic pressure excursions. When used with other clinical variables, PVI® may help clinicians assess fluid responsiveness, improve fluid management in surgical and intensive care patients who are mechanically ventilated, and help determine other treatment options.

RRp™

Respiration rate is defined as the number of breaths per minute. Changes in respiration rate provide an early warning sign of deterioration in patient condition. A low respiration rate is indicative of respiratory depression and high respiration rate is

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indicative of patient distress. Current methods to monitor respiration rate include end tidal CO_2 monitoring, which requires a nasal cannula to be inserted in the patient's nose and therefore has low patient compliance, and impedance monitoring, which is considered unreliable. RRp™ is a breakthrough measurement that allows clinicians to noninvasively and continuously measure and monitor respiration rate using a standard Masimo SET® pulse oximetry or rainbow® Pulse CO-Oximeter sensor®. The RRp™ measurement is determined by the variations in the plethysmograph waveform due to respiration, although the measurement is not possible in all patients or many conditions and may not immediately indicate changes in respiration rate. RRp™ is not currently available for sale in the U.S.

RRa®

Our sound-based monitoring technology, rainbow Acoustic Monitoring™ (RAM™), enables RRa® continuous and noninvasive monitoring of respiration rate. For patients requiring accurate and sensitive respiration rate monitoring, we believe that RRa® has been shown to better detect pauses in breathing than respiration rate measurements from other capnography technologies. The RRa® measurement also provides an important visual indication of breathing through the displayed acoustic waveform. Multiple clinical studies have shown that the noninvasive measurement of RRa® provides as good or better accuracy to monitor respiration rate as end tidal CO_2 monitoring, and can reliably detect respiratory pause episodes, defined as a cessation of breathing for 30 seconds or more. When used with other clinical variables, RRa® may help clinicians assess respiratory depression and respiratory distress earlier and more often to help determine treatment options and potentially enable earlier interventions.

$SpfO_2$™

Prior to our debut of $SpfO_2$™ in October 2012, pulse oximeters could only measure and display functional oxygen saturation (SpO_2). Therefore, when patients had elevated carboxyhemoglobin (from CO poisoning) and/or elevated methemoglobin (negative reaction to more than 30 common drugs used in hospitals, like caines, nitrates, and dapsone), the displayed functional oxygen saturation overestimated the actual oxygen saturation value. $SpfO_2$™, or fractional oxygen saturation, allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to functional oxygen saturation, and may also allow earlier interventions and more timely therapeutic decisions. $SpfO_2$™ is not currently available for sale in the U.S.

ORI™

In October 2014, we announced CE Mark clearance and limited market release of Oxygen Reserve Index (ORI™). ORI™ provides real-time visibility to oxygenation status in moderate hyperoxic range, which we define as a patient's oxygen "reserve". ORI™ can be trended and has optional alarms to notify clinicians of changes in a patient's oxygen reserve. When this technology is used with oxygen saturation (SpO_2) monitoring, ORI™ may extend the continuous and noninvasive visibility of a patient's oxygen status into ranges previously unmonitored in this fashion. ORI™ may also be of value in patients receiving supplemental oxygen, such as those in surgery, under conscious sedation, or in the ICU, as ORI™ it is represented as an "index" parameter with a unit-less scale between 0.00 and 1.00. Furthermore, ORI™ may provide an advance warning of an impending hypoxic state, or an indication of an unintended hyperoxic state, when evaluated in conjunction with the partial pressure of oxygen (PaO_2). In this way, ORI™ may enable proactive interventions to avoid hypoxia and unintended hyperoxia. ORI™ is not currently available for sale in the U.S.

Noninvasive Measurements and Technologies

Following the introduction of our rainbow® SET® platform, we have continued to expand our technology offerings by introducing additional noninvasive measurements and technologies to create new market opportunities in both the hospital and non-hospital care settings.

SedLine® Brain Function Monitoring

Brain function monitoring is most commonly used during surgery to help clinicians avoid over-and under-titration of anesthesia and sedation. SedLine® brain function monitoring technology measures the brain's electrical activity by detecting EEG signals. In contrast to whole scalp EEG monitoring, which is used for diagnostic purposes, this form of EEG monitoring is often referred to as processed EEG monitoring, or brain function monitoring. Brain function monitors display the patient's EEG waveforms, but these are difficult for clinicians to interpret, so the EEG signals are processed and displayed as a single index that gives a continuous, quantitative indication of the patient's depth of

anesthesia and sedation. Our SedLine® brain function monitoring technology can now be delivered through the Masimo Open Connect™ (MOC-9)™ connectivity port within our Root® patient monitoring and connectivity platform that integrates our breakthrough rainbow® and SET® measurements with multiple additional parameters, such as SedLine®. In addition, our SedLine® brain function monitoring technology also displays raw EEG waveforms, the Patient State Index (PSI) and the Density Spectral Array view.

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Capnography and Gas Monitoring

We offer a portfolio of capnography and gas monitoring products ranging from external “plug-in-and-measure” capnography and gas analyzers, integrated modules, and handheld capnograph and capnometer devices. These products have the ability to measure multiple expired gases, such as carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2) and other anesthetic agents. In the case of capnography, respiration rate is also calculated from the CO_2 waveform. These measurements are possible through either mainstream monitoring, which samples gases from a ventilated patient’s breathing circuit, or sidestream monitoring, which samples gases from a breathing circuit in mechanically ventilated patients or through a cannula or mask in spontaneously breathing patients. These capnography and gas measurements are standard-of-care in many hospital environments, such as operating rooms, procedural sedation and ICUs.

O3™

O_3™ regional oximetry, also known as tissue oximetry and cerebral oximetry, uses near-infrared spectroscopy (NIRS) to provide for continuous measurement of tissue oxygen saturation (rSo2) to help detect regional hypoxemia that pulse oximetry alone can miss. In addition, our Root® monitor and O_3™ sensors can automate the differential analysis of regional to central oxygen saturation. O_3™ monitoring is as simple as applying O_3™ regional oximetry sensors to the forehead and connecting the O_3™ MOC-9™ module to any Root® monitor through one of its three MOC-9™ ports. O_3™ regional oximetry is currently intended for use in subjects larger than 40 kg (88 lbs) and has received the CE Mark, but is not currently available for sale in the U.S.

Patient SafetyNet™

Our patient surveillance, remote monitoring and clinician notification solution, Patient SafetyNet™, allows for monitoring of the oxygen saturation, pulse rate, perfusion index, hemoglobin, methemoglobin, and respiration rate of up to 80 patients simultaneously. Patient SafetyNet™ offers a rich user interface with trending, real-time waveform capability at the central station and remote notification via pager or smart phones. Patient SafetyNet™ also features the Adaptive Connectivity Engine™, which enables two-way, HL7-based connectivity to clinical/hospital information systems. The Adaptive Connectivity Engine™ significantly reduces the time and complexity to integrate and validate custom HL7 implementations, and demonstrates our commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture.

In a landmark study published in 2010 by Dartmouth-Hitchcock Medical Center, clinicians using Masimo SET® and Patient SafetyNet™ identified patient distress earlier, which decreased rapid response team activations, ICU transfers and ICU days. Hospitals and other care centers may determine that they can reduce their costs by moving less critically ill patients from the ICU to the general care areas where these patients can be continuously and accurately monitored in a more cost effective manner. We believe that the advanced performance of the Masimo SET® platform coupled with reliable, cost effective and easy-to-use wireless remote monitoring will allow hospitals to create continuous surveillance solutions on general care floors where patients are at risk of avoidable adverse events and where direct patient observation by skilled clinicians is cost prohibitive.

Halo Index™

Halo Index™ is a dynamic indicator that facilitates continuous global trending and assessment of multiple physiological measurements to quantify changes in patient status with a single number displayed on our Patient SafetyNet™ screen. This may allow clinicians to identify patient risk that was otherwise not apparent and may also help clinicians, in the presence of individual parameter alarms, to assess that a patient’s risk remains low, allowing them to focus on other higher risk patients. Halo Index™ has received CE Mark, but is not currently available for sale in the U.S.

Third-Party Device Connectivity

Despite medical technology advances, the lack of device communication and integration creates risks to patient safety in hospitals around the world. Without device interoperability, critical patient information can go unnoticed - leaving clinicians unaware and patients at risk. Existing approaches for device interoperability require separate hardware, software and/or network infrastructure, which can clutter the patient room, increase complexity, burden IT management and increase costs. To address these challenges, we introduced Iris™ connectivity in our Root® patient monitoring and connectivity platform. Iris™ connectivity enables multiple standalone third-party devices such as intravenous pumps, ventilators, hospital beds and other patient monitors to connect through Root®, enabling display,

notification and documentation to the electronic medical record through Masimo Patient SafetyNet™.

Masimo's addition of Iris™ connectivity in Root® and Patient SafetyNet™ provides multiple advantages to hospitals, including the following:

- Allows standalone device information to be remotely viewed with Patient SafetyNet™, transmitted through notification systems or sent to electronic health record systems to facilitate better patient care and meaningful use.

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- Designed to leverage existing network infrastructures and reduce costs while enhancing clinical workflows and decision support to improve patient safety, wherever the clinician is located.
- Flexible and cost-effective platform, avoiding installation of costly, separate systems.
- Brings all the data together to facilitate assessment and decision support.

Our Strategy

Since inception, our mission has been to develop noninvasive monitoring solutions that improve patient outcomes and reduce the cost of patient care. We intend to continue to grow our business and improve our market position by pursuing the following strategies:

- Continue to Expand our Market Share in Pulse Oximetry. We grew our product revenue to $556.8 million in 2014 from $406.5 million in 2011, representing a three year compound annual growth rate of 11.1%. This growth can be attributed to strong, independent clinical evidence that demonstrates the benefits of our technology, the increased access to pulse oximetry customers through our agreements with group purchasing organizations (GPOs), our expanding list of OEM partners and the continued expansion of our worldwide direct sales force. We supplement our direct sales to hospitals and other low acuity healthcare facilities through various U.S. and international distributors. Combined sales through our direct and distributor sales channels increased to $472.7 million, or 84.9% of product revenue in 2014, from $342.9 million, or 84.4% of product revenue in 2011.
- Expand the Pulse Oximetry Market to Other Patient Care Settings. We believe the ability to continuously and accurately monitor patients outside of critical care settings, including the general, medical and surgical floors of the hospital, are currently unmet medical needs and have the potential to significantly improve patient care and increase the size of the pulse oximetry market. We believe the ability of Masimo SET® to accurately monitor and address the limitations of conventional pulse oximetry has enabled, and will continue to enable, us to expand into non-critical care settings and therefore, significantly expand the market for our products. To further support our expansion into the general care areas, we market Patient SafetyNet,™ which enables continuous monitoring of up to 80 patients' oxygen saturation, pulse rate and with rainbow® SET®, noninvasive hemoglobin and respiration rate.
- Expand the Use of rainbow® Technology in Hospital Settings. We believe the noninvasive measurement of rainbow® Pulse CO-Oximetry (SpHb®, SpCO®, SpMet®, PVI®, SpfO$_2$,™ SPOC,™ and ORI),™ rainbow Acoustic Monitoring™ (RRa®), and the Halo Index,™ as well as future measurements, will provide an excellent opportunity to leverage existing customer relationships into new opportunities to improve patient care and, at the same time, expand our product revenue opportunities through a greater ability to convert non-Masimo hospitals to Masimo hospitals due to our expanded rainbow® measurement capabilities.
- Expand the Use of rainbow® Technology in the Non-Hospital Setting. We believe the noninvasive measurement of hemoglobin creates a significant opportunity in markets such as the physician office and emergency departments, and the noninvasive measurement of carboxyhemoglobin creates a significant opportunity in the fire/alternate care market.
- Utilize our Customer Base and OEM Relationships to Market our Masimo rainbow® SET® Products Incorporating Licensed rainbow® Technology. We are currently selling our rainbow® SET® products through our direct sales force and distributors. We include our MX circuit boards in our pulse oximeters and sell them to our OEM partners, equipped with circuitry to support rainbow® Pulse CO-Oximetry measurements that can be activated at time of sale or through a subsequent software upgrade. We believe that, over time, the clinical need of these measurements along with our installed customer base will help drive the adoption of our rainbow® Pulse CO-Oximetry products.
- Continue to Innovate and Maintain Our Technology Leadership Position. We invented and pioneered what we believe is the first pulse oximeter to accurately measure arterial blood oxygen saturation level and pulse rate in the presence of motion artifact and low perfusion. In addition, we launched our rainbow® SET® platform that enabled what we believe is the first noninvasive monitoring of carboxyhemoglobin, methemoglobin and hemoglobin, as well as PVI®, all of which were previously only available with invasive and/or complicated testing. With our introduction of RRa® with rainbow Acoustic Monitoring™ technology, we believe we have launched the first platform to enable noninvasive and continuous respiration monitoring through an easy-to-use single patient adhesive acoustic sensor. We plan to continue to innovate and develop new technologies and products, internally and through our collaboration with Cercacor, from whom we currently license certain rainbow® technologies.

Our future growth strategy is also closely tied to our focus on international expansion opportunities. Since 2007, we have been expanding our sales and marketing presence in Europe, Asia, Canada and Latin America. We have accomplished this by both additional staffing and adding or expanding sales offices in many of these territories. By centralizing a portion of our international operations in Neuchatel, Switzerland, including sales management, marketing, customer support, planning, logistics and administrative functions, we believe we have developed a more efficient and scalable international organization

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that is capable of being even more responsive to the business needs of our international customers under one centralized management structure.

Operating Segment and Geographic Information

We operate in one business segment, using one measurement of profitability to manage our business. Sales and other financial information by geographic area is provided in Note 16 to our consolidated financial statements that are included in this Annual Report on Form 10-K.

Our Products and Markets

We develop, manufacture and market patient monitoring technologies that incorporate a monitor or circuit board and sensors, including proprietary single-patient use, reusable and rainbow ReSposable® sensors and patient cables. In addition, we offer remote alarm/monitoring solutions, software and connectivity solutions.

The following chart summarizes our principal product components and principal markets and methods of distribution:

Patient Monitoring Solutions:

Circuit Boards and Modules (e.g., MX-1®, MX-3®, MX-5, MS-2011, MS-2040, uSpO2®, SedLine®, ISA,™ and IRMA)™	• Signal processing apparatus for all Masimo technology platforms • Mainstream and sidestream capnography and gas monitors	• Incorporated and sold to OEM partners who incorporate our circuit boards into their patient monitoring systems
Monitors and Devices (e.g., Radical-7®, Pronto, Pronto-7®, Rad-57®, Root®, Radius-7,™ and EMMA)™	• Bedside, handheld and wireless monitoring devices that incorporate Masimo SET® with and without licensed Masimo rainbow® SET® technology • Compact and self-contained capnometer which monitors CO_2 concentration	• Sold directly to end-users and through distributors and in some cases to our OEM partners who sell to end-users
Patient Monitoring and Connectivity Platforms (e.g., Root®, Radius-7)™	• Multi-specialty measurement monitor with connected and wireless capabilities • Ability to connect third-party devices such as IV pumps, ventilators, beds, and other patient monitors to the electronic health record	• Sold directly to end-users and through distributors
Sensors (e.g., SET®, rainbow® Pulse CO-Oximetry, rainbow Acoustic™ Sensors,™ and SedLine®)	• Extensive line of both single-patient, reusable and rainbow ReSposable® sensors • Patient cables, as well as adapter cables that enable the use of our sensors on certain competitive monitors	• Sold directly to end-users and through distributors and to OEM partners who sell to end-users
Line Filters, and Mainstream Adapters	• Line of disposables to measure	

(e.g., capnography and gas disposables)	mainstream and sidestream capnography and gas parameters	• Sold directly to end-users and through distributors and to OEM partners who sell to end-users
Remote Alarm and Monitoring Solutions (e.g., Patient SafetyNet™	• Network-linked, wired or wireless, multiple patient floor monitoring solutions • Standalone wireless alarm notification solutions	• Sold directly to end-users

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Proprietary Measurements (e.g., SpHb®, SpCO®, SpMet®, PVI®, RRa®, ORI™, 3D Alarms, Adaptive Threshold Alarm and Halo Index™)	• Rainbow® measurements and other proprietary features sold to installed monitors	• Sold directly to end-users and through OEM partners who sell to end-users
Connectivity (e.g., Root®, Patient SafetyNet™)	• Software and hardware enabling third-party devices to connect through Patient SafetyNet™ to clinicians and for documentation to the electronic health record	• Sold directly to end-users
Consumer Monitoring Solutions:		
Devices (e.g., iSpO$_2$®, MightySat™)	• Pulse oximeter cable and sensor for use with an iPhone, iPad, iPod touch, and select Android smart phones	• Sold directly to consumers through on-line websites

Circuit Boards

Masimo SET® MS Circuit Boards. Our Masimo SET® MS circuit boards perform all signal processing and other pulse oximetry functions incorporating the Masimo SET® platform. Our MS circuit boards are included in our proprietary monitors for direct sale or sold to our OEM partners for incorporation into their monitors. Once incorporated into a pulse oximeter, the MS circuit boards perform all data acquisition processing and report the pulse oximetry levels to the host monitor. The circuit boards and related software interface directly with our proprietary sensors to calculate arterial blood oxygen saturation level and pulse rate. Our latest generation boards include the MS-2003, MS-2011, MS-2013 and MS-2040, with a typical power consumption of less than 45 milliwatts.

Masimo rainbow® SET® MX Circuit Boards. Our next-generation circuit board is the foundation for our Masimo rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring™ platform, utilizing technology licensed from Cercacor. The MX circuit boards offer full functionality of our breakthrough rainbow® technology for noninvasive measurements for total hemoglobin (SpHb®), oxygen content (SpOC™), carboxyhemoglobin (SpCO®), methemoglobin (SpMet®) and acoustic respiration rate (RRa®), in addition to providing Measure-Through-Motion and Low-Perfusion oxygen saturation (SpO2), pulse rate (PR) and perfusion index (PI) measurement capabilities of Masimo SET® pulse oximetry. Customers can choose to buy additional measurements beyond arterial blood oxygen saturation levels and pulse rate at the time of sale or at any time in the future through a field-installed software upgrade.

In September 2014, we announced our new MX-5 OEM circuit board, a technology platform that utilizes approximately half the power of previously available rainbow® circuit boards to deliver breakthrough rainbow® Pulse CO-Oximetry noninvasive measurement performance. In addition to the lower power demands compared to previous rainbow® technology boards, the MX-5 adds dynamic power utilization to scale the MX-5's power draw based upon the combination of parameters being monitored to permit even longer battery runtimes.

uSpO$_2$® Cable/Board. Our SET® technology-in-a-cable contains the low power (MS-2040) technology in a reduced size, allowing it to be embedded into patient cables as part of the sensor connector. This allows for the ability to interface the uSpO$_2$® cable/board to monitoring devices externally via an existing communications port in instances where internal integration of a traditional Masimo SET® technology board is not feasible. The uSpO$_2$® cable/board provides full Masimo SET® Measure-Through-Motion and Low-Perfusion pulse oximetry found in our other products, with a typical power consumption of less than 45 milliwatts.

Monitors / Devices

Radical-7®. The Radical-7® incorporates our MX circuit board, which enables rainbow® SET measurements, and offers three-in-one capability that can be used as:

- a standalone device for bedside monitoring;

- a detachable, battery-operated handheld unit for easy portable monitoring; and
- a monitor interface via SatShare®, a proprietary technology allowing our products to work with certain competitor products, to upgrade existing conventional multiparameter patient monitors to Masimo SET® while displaying rainbow® measurements on the Radical-7® itself.

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The Radical-7® is a wireless, touch screen device, which is on an upgradeable rainbow® SET® platform. With its wide-ranging flexibility, Radical-7® can continuously monitor a patient from the ambulatory environment, to the emergency room, to the operating room, to the general floor and on, until the patient is discharged. Radical-7® delivers the accuracy and reliability of Masimo rainbow® SET® with multi-functionality, ease of use and a convenient upgrade path for existing monitors.

Root®. Root® is a powerful patient monitoring and connectivity platform that integrates our breakthrough rainbow® and SET® measurements with multiple additional specialty measurements through Masimo Open Connect™ (MOC-9™) in an integrated, clinician-centric platform. The first two MOC-9™ technologies for Root® were SedLine® brain function monitoring and Phasein™ capnography. Our third MOC-9™ technology for Root®, O_3™ regional oximetry, provides for continuous and simultaneous measurement of tissue oxygen saturation (rSo2) and SpO2 to help detect regional hypoxemia that pulse oximetry alone can miss. In addition, Iris™ connectivity in Root® enables 3rd party devices such as intravenous pumps and ventilators to connect through Root® and enables display, notification and documentation to the electronic medical record through Masimo Patient SafetyNet.™ In June 2014, we announced FDA clearance for our Root® platform with capnography, wireless communication and Iris™ connectivity for third-party medical devices. O_3™ regional oximetry has received the CE Mark but is not currently available for sale in the U.S. In combination with a Radical-7® handheld monitor, Root® will display alarm information simplifying patient care workflows and potentially helping caregivers make quicker patient assessments.

Radius-7™. In July 2014, we announced CE Mark clearance and limited market release of Radius-7™ for the Root® patient monitoring and connectivity platform. Radius-7™ for the Root® is the first and only wearable, wireless monitor with our rainbow® SET® technology, enabling early identification of clinical deterioration while offering patients continuous monitoring with freedom of movement. With rainbow® SET® noninvasive measurements, Radius-7™ with Root® can alert clinicians at the bedside or remotely, through Masimo Patient SafetyNet,™ of critical changes in a patient's oxygen saturation and pulse rate, even during states of motion and low perfusion, as well as respiration through RRa®. Radius-7™ with Root® obtained FDA 510(k) clearance in December 2014.

SatShare®. Our SatShare® technology enables a conventional monitor to receive continuous measurement updates using Masimo SET® through a simple cable connection from the back of Radical-7® to the sensor input port of the conventional monitor. No software upgrades or new modules are necessary for the upgrade, which can be completed in minutes. SatShare® allows hospitals to standardize the technology and sensors used throughout the hospital while allowing them to gain more accurate monitoring capabilities and additional multi-functionality in a cost-effective manner. This technology has facilitated many hospital-wide conversions of previously installed competitor monitors to Masimo SET®. In addition, Masimo rainbow® SET® measurements such as hemoglobin are available to clinicians on the Radical-7® itself while the device is being used in SatShare® mode.

Pronto®. The Pronto® is a handheld noninvasive multiparameter testing device that uses Masimo rainbow® SET® technology to provide oxygen saturation, pulse rate, perfusion index and spot-checking of hemoglobin levels for both hospitals (i.e., emergency departments) and remote settings such as physician offices.

Pronto-7®. The Pronto-7® is a noninvasive multiparameter device utilizing rainbow 4D™ that provides spot-checking of hemoglobin, oxygen saturation, pulse rate and perfusion index. With a touch screen for easy operation and wireless 802.11 and Bluetooth for printing and communication, the Pronto-7® is well-suited for spot-checking of hemoglobin in clinical and non-clinical settings.

Rad-8®. The Rad-8® is a bedside pulse oximeter featuring Masimo SET® (but without rainbow® capability) with a low cost design and streamlined feature set.

Rad-5®. In addition to the bedside monitors, we have developed handheld pulse oximeters using Masimo SET® (but without rainbow® capability). Our Rad-5® and Rad-5v™ handheld oximeters were the first dedicated handhelds with Masimo SET®.

Rad-57®. The Rad-57® is a fully featured handheld Pulse CO-Oximeter® that provides continuous, noninvasive measurement of hemoglobin, carboxyhemoglobin and methemoglobin in addition to oxygen saturation, pulse rate and perfusion index. Its rugged and lightweight design makes it applicable for use in hospital and field settings, specifically for fire departments and emergency medical service units.

SedLine® MOC-9™ Module. The SedLine® monitor measures brain function on a continuous basis. The SedLine® MOC-9™ module for Root® is an EEG-based brain function monitor that provides information about a patient's response to anesthesia.

O_3™ MOC-9™ Module. The O_3™ MOC-9™ module for Root® uses near-infrared spectroscopy (NIRS) to detect regional hypoxemia by continuously measuring tissue oxygen saturation (rSo2), automating the differential analysis of regional to central oxygen saturation.

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Capnography and Gas Monitoring. Our gas analyzers, IRMA™ and ISA,™ and emergency capnometer (EMMA),™ enable our customers to benefit from CO_2, N_2O, O_2 and anesthetic agent monitoring in many hospital environments.
uSpO_2™ Cable/Board. Our new SET® technology-in-a-cable contains our low power (MS-2040) technology in a reduced size, allowing it to be embedded into patient cables as part of the sensor connector.

Sensors

Sensors and Cables. We have developed one of the broadest lines of single-patient use (disposable), reusable and rainbow ReSposable® sensors and cables. In total, we have over 100 different types of sensors to meet virtually every clinical need. Masimo SET® sensors are uniquely designed to reduce interference from physiological and non-physiological noise. Our proprietary technology platforms operate only with our proprietary sensor lines. However, through the use of adapter cables, we can connect our sensors to certain competitor pulse oximetry monitors. We sell our sensors and cables to end-users directly or through our distributors and OEM partners.
Our single-patient use sensors offer several advantages over reusable sensors, including improved performance, cleanliness, increased comfort and greater reliability. Our reusable sensors are primarily used for short-term, spot-check monitoring. Our rainbow ReSposable® sensors are expected to provide performance advantages for customers currently using reusable and reprocessed sensors.
SofTouch Sensors. We have developed SofTouch sensors, designed with less adhesive or no adhesive at all for compromised skin conditions. These include single-patient sensors for newborns and multi-site reusable sensors for pediatrics and adults.
Trauma and Newborn Sensors. We have developed two specialty sensor lines, specifically designed for trauma and resuscitation situations, as well as for newborns. These sensors contain an identifier which automatically sets the oximeter to monitor with maximum sensitivity and the shortest-averaging mode and allows for quick application, even in wet and slippery environments. Additionally, we introduced low-profile sensors to monitor oxygen saturation in newborns. The newly enhanced low-profile LNCS® and M-LNCS™ Neo, NeoPt and Inf Sensors are smaller and thinner, making them significantly more comfortable for patients and easier to apply for healthcare workers.
Blue Sensors. We believe our Blue Sensors are the first FDA-cleared sensors to accurately monitor arterial blood oxygen saturation levels in cyanotic infants and children with abnormally low oxygen saturation levels.
E1® Ear Sensor. We believe that our E1® Ear Sensor was the first ever, single-patient-use ear sensor that is placed securely in the ear conchae, so clinicians can combine Masimo SET® performance and central monitoring to provide quick access and responsive assessment of oxygenation. The E1® Ear Sensor is designed for field emergency medical services utilization.
TFA-1™ Adhesive Forehead Sensor. We believe our TFA-1™ forehead sensor can combine Masimo SET® performance and central monitoring to provide quick access and responsive assessment of oxygenation, for hospitals desiring forehead monitoring with a disposable sensor.
Rainbow® Sensors. We have developed proprietary, multi-wavelength sensors for use with our rainbow® Pulse CO-Oximetry products. In contrast to traditional sensors that only have the capability to monitor arterial blood oxygen saturation levels and pulse rate, our rainbow® sensors can also monitor carboxyhemoglobin, methemoglobin and hemoglobin. Our licensed rainbow® SET® sensors are the only sensors that are compatible with our licensed rainbow® SET® products. Rainbow® sensors are available in single-patient use, rainbow ReSposable® and reusable spot-check sensor types.
In August 2014, we announced CE Mark regulatory clearance in Japan and limited market release of the rainbow® DCI-mini,™ the first noninvasive hemoglobin (SpHb®) spot-check sensor for infants and small children (weight 3 to 30 kg). Paired with our handheld Pronto® device, the rainbow® DCI-mini™ sensors are designed to help clinicians quickly and easily spot-check hemoglobin levels in infants and small children, which may facilitate the identification of anemia. The rainbow® DCI-mini™ is not currently available for sale in the U.S. or Europe.
Rainbow Acoustic™ Sensors. We believe we were the first to market a continuous respiration rate monitoring technology based on an acoustic sensor placed on the patient's neck. Our rainbow Acoustic™ sensors detect the sounds associated with breathing and convert the sounds into continuous respiration rate using proprietary signal processing that is based on Masimo SET®.

SedLine® Sensor. Used with the SedLine® MOC-9™ module for the Root® patient monitor, the SedLine® sensor is a disposable sensor that collects EEG data for out Sedline® monitor.

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Rainbow® Universal ReSposable SuperSensor.™ This sensor, which is not currently available for sale in the U.S., is the first noninvasive sensor to provide simultaneous monitoring of SpHb®, SpCO®, SpMet®, $SpfO_2$,™ SpOC,™ PI, PVI® and Measure-Through-Motion and Low-Perfusion arterial blood oxygen saturation (SpO_2) and pulse rate (PR).

O_3™ Sensor. Used with the O_3™ MOC-9™ module for the Root® patient monitor, each O_3™ sensor contains four light-emitting diodes and two detectors to continuously measure rSo2.

We offer our customers choices for reducing pollution and waste in our world while also reducing costs, including Masimo Reprocessed Sensors, the only reprocessing solution that maintains new Masimo sensor performance specifications, and rainbow ReSposable® Sensors, offering unprecedented sustainability with a lower carbon footprint and greater waste reduction than reprocessed or new sensors. Rainbow ReSposable® Sensors offer equivalent performance and comfort to single-patient use sensors and a similar sensor price-per-patient to mixed third-party reprocessed and new sensors.

Remote Alarm and Monitoring Solutions

Masimo Patient SafetyNet.™ Patient SafetyNet™ is a remote monitoring and clinician notification system. It instantly routes bedside-generated alarms through a server to a qualified clinician's handheld paging device in real-time. Each system can support up to 80 bedside monitors and can either be integrated into a hospital's existing IT infrastructure or operate as a stand-alone wireless network.

Proprietary Measurements

All of our monitors shipped since January 2006, including Radical-7® and certain future OEM products, which incorporate the MX board will allow purchases of software for rainbow® measurements, as well as other future measurements or features that can be field installed. Our current rainbow® measurements include ORI,™ PI, PR, PVI®, RRp,™ SpHb®, SpO_2, SpCO®, SpMet®, SpOC™ and $SpfO_2$,™ as well as rainbow® Acoustic Monitoring, RRa®

Currently, clinicians monitor multiple clinical measurements on each patient and respond independently to each of the measurements. Halo Index™ is a dynamic indicator that facilitates continuous global trending and assessment of multiple physiological measurements into a simple and comprehensive assessment within a single index to quantify changes in patient status, which is displayed on the Patient SafetyNet™ remote monitoring and notification system. Halo Index™ has received CE Mark, but is not currently available for sale in the U.S. In the future, subject to receipt of regulatory clearance, we expect Halo Index™ will also be available as part of our standalone devices and OEM boards. As more clinical evidence is collected on Halo Index,™ its clinical utility in a variety of care areas and patient types will become more specific.

In October 2014, we announced CE Mark clearance of Eve,™ a Newborn Screening Software Application for Radical-7® Pulse CO-Oximeters®. Eve™ is designed to help clinicians more effectively and efficiently screen newborns for critical congenital heart disease (CCHD). The Eve™ Newborn Screening Software Application in the Radical-7® Pulse CO-Oximeter® automates the screening steps with animated instruction, including sensor application, measurement selection and screening result determination. Eve™ is intended to provide consistent application of the screening protocol to reduce method and operator-induced variability and improve efficiency by automating the data capture and comparison between readings. Eve™ is currently not available for sale in the U.S.

X-Cal™

X-Cal™ preserves system quality, performance and reliability by reducing imitation sensor and cable use and monitoring component life. The technical benefit of X-Cal™ is based on the fact that the Masimo sensors, patient cables and instruments work as an integrated system to provide the physiologic measurements that have advanced the standard of care.

X-Cal™ addresses three common problems experienced by clinicians using an integrated Masimo system, including:

- Patient safety may be compromised by using imitation Masimo sensors and cables because they are not produced with comparable components, do not provide proper shielding from ambient interferences, create electrostatic noise caused by motion, do not have our quality and performance controls, and are not tested or warranted to work within a Masimo system;
- We design our sensors and cables to last well beyond their warranty and customer feedback indicates our sensors and cables last significantly longer than competing products, but cable and sensor reliability may still be compromised when used beyond the life they were reliably designed for, affecting patient care and causing clinicians and

biomedical engineers to spend time troubleshooting intermittent cable and sensor issues; and

- We believe that third-party reprocessed pulse oximetry sensors introduce challenges in the clinical environment due to potential quality issues. Internal Masimo testing indicates that 91% of a leading third-party reprocessor's sensors that were

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tested failed to meet our performance specifications. In fact, most third-party reprocessed sensors do not indicate that they are capable of performing in Measure-Through-Motion or Low-Perfusion conditions or neonatal applications, key performance requirements available with Masimo SET® sensors. Also, no third-party company has attempted to reprocess rainbow® SET® sensors.

Connectivity

Iris™ connectivity in Root® enables third-party devices such as intravenous pumps and ventilators to connect through Root® enabling display, notification and documentation to the electronic medical record through Masimo Patient SafetyNet™.

Consumer Products

The $iSpO_2$® pulse oximeter was designed for use with an iPhone, iPad, iPod touch and select Android smart phones. The $iSpO_2$® uses Masimo SET® for Measure-Through-Motion and Low-Perfusion performance to allow consumers to check their own SpO_2, PR and PI measurements through a pulse oximeter cable and sensor connected to an iPhone, iPad, iPod touch or select Android Smart Phone device. This version is not intended for medical use and is available online in the U.S. for sports and aviation use only. In December 2013, we received the CE Mark on $iSpO_2$® for the Android operating system, enabling functionality on select Android-based phones outside of the U.S. The $iSpO_2$® Rx, the professional version for medical use, also received the CE Mark in December 2013, but is not yet available for sale in the U.S.

Our MightySat™ fingertip pulse oximeter for personal use provides accurate oxygen saturation and pulse rate measurements and is designed for those who want reliable measurements even under extreme conditions. MightySat™ is available in three versions, each of which provides SpO_2, PR, and PI measurements in a compact, battery-powered design with a large color screen that can be rotated for real-time display of the pleth waveform as well as measurements. Optional Bluetooth wireless functionality enables measurement display via a free, downloadable app on iOS and Android mobile devices, as well as the ability to trend and communicate measurements. MightySat™ is also available with optional PVI®, a measure of the dynamic changes in the PI that occur during one or more complete respiratory cycles. MightySat™ is available online and is intended for sports and aviation use only. MightySat™ is not intended for medical use.

Cercacor Laboratories, Inc.

Cercacor is an independent entity spun-off from us to our stockholders in 1998. Joe Kiani and Jack Lasersohn, members of our board of directors, are also members of the board of directors of Cercacor. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Cercacor. We are a party to a cross-licensing agreement with Cercacor, which was amended and restated effective January 1, 2007 (the Cross-Licensing Agreement), which governs each party's rights to certain intellectual property held by the two companies.

The following table outlines our rights under the Cross-Licensing Agreement relating to specific end user markets and the related technology applications of specific measurements.

	End User Markets	
Measurements	Professional Caregiver and Alternate Care Market	Patient and Pharmacist
Vital Signs[1]	Masimo (owns)	Cercacor (non-exclusive license)
Non-Vital Signs[2]	Masimo (exclusive license)	Cercacor (owns or exclusive license)

(1) Vital Signs measurements include, but are not limited to, SpO_2, peripheral venous oxygen saturation, mixed venous oxygen saturation, fetal oximetry, sudden infant death syndrome, ECG, blood pressure (noninvasive blood pressure, invasive blood pressure and continuous noninvasive blood pressure), temperature, respiration rate, CO_2, pulse rate, cardiac output, EEG, perfusion index, depth of anesthesia, cerebral oximetry, tissue oximetry and/or EMG, and associated features derived from these measurements, such as 3-D alarms, PVI® and other features.

(2)

Non-Vital Signs measurements include the body fluid constituents other than vital signs measurements and include, but are not limited to, carbon monoxide, methemoglobin, blood glucose, hemoglobin and bilirubin.

Our License to Cercacor. We granted Cercacor an exclusive, perpetual and worldwide license, with sublicense rights, to use our Masimo SET® technology, including all improvements, for the monitoring of non-vital signs measurements and to develop and sell devices incorporating Masimo SET® for monitoring non-vital signs measurements in the "Cercacor Market". The Cercacor Market consists of any product market in which a product is intended to be used by a patient or pharmacist rather than a professional medical caregiver regardless of the particular location of the sale, including sales to doctors, hospitals, alternate

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care market professionals or otherwise, provided the product is intended to be recommended, or resold, for use by the patient or pharmacist. We also granted Cercacor a non-exclusive, perpetual and worldwide license, with sublicense rights, to use Masimo SET® for the measurement of vital signs in the Cercacor Market. In exchange, Cercacor pays us a 10% royalty on the amount of vital signs sensors and accessories sold by Cercacor.

Cercacor's License to us. We exclusively license from Cercacor the right to make and distribute products in the "Masimo Market" that utilize rainbow® technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation, and hemoglobin, which includes hematocrit. The Masimo Market consists of any product market where the product is intended to be used by a professional medical caregiver, including hospital caregivers, surgicenter caregivers, paramedic vehicle caregivers, doctors' offices caregivers, alternate care facility caregivers and vehicles where alternative care services are provided. We also have the option to obtain exclusive licenses to make and distribute products in the Masimo Market that utilize rainbow® technology for the monitoring of other non-vital signs measurements, including blood glucose. We have 180 days after proof of feasibility to exercise the above-referenced option to obtain a license for the measurement of blood glucose for an additional $2.5 million and licenses for other non-vital signs measurements for an additional $0.5 million each. During the year ended December 28, 2013, we exercised our right to license five new non-vital sign measurements for $0.5 million each, or $2.5 million. The licenses are exclusive until the later of 20 years from the grant of the applicable license or the expiration of the last patent included in the rainbow® technology related to the applicable measurements. To date, we have developed and commercially released devices that measure carbon monoxide, methemoglobin and hemoglobin using licensed rainbow® technology. We also make and distribute products that monitor respiration rate via rainbow Acoustic Monitoring,™ which is a Masimo-developed rainbow® technology and, therefore, is not required to be licensed from Cercacor.

Our license to rainbow® technology for these measurements in these markets is exclusive on the condition that we continue to pay Cercacor royalties on our products incorporating rainbow® technology, subject to certain minimum aggregate royalty thresholds, and that we use commercially reasonable efforts to develop or market products incorporating the licensed rainbow® technology. The royalty is up to 10% of the rainbow® royalty base, which includes handhelds, tabletop and multiparameter devices. Handheld products incorporating rainbow® technology carry a 10% royalty rate. For other products, only the proportional amount attributable to that portion of our devices used to monitor non-vital signs measurements, rather than to monitoring vital signs measurements, and sensors and accessories for measuring only non-vital sign parameters are included in the 10% rainbow® royalty base. For multiparameter devices, the rainbow® royalty base includes the percentage of the revenue based on the number of rainbow® enabled measurements. For hospital contracts where we place equipment and enter into a sensor contract, we pay a royalty to Cercacor on the total sensor contract revenue based on the ratio of rainbow® enabled devices to total devices. During the year ended January 3, 2015 and going forward, we are subject to certain specific annual minimum aggregate royalty payment obligations of $5.0 million per year.

Change in Control. The Cross-Licensing Agreement provides that, upon a change in control:

- if the surviving or acquiring entity ceases to use "Masimo" as a company name and trademark, all rights to the "Masimo" trademark will be assigned to Cercacor;
- the option to license technology developed by Cercacor for use in blood glucose monitoring will be deemed automatically exercised and a $2.5 million license fee for this technology will become immediately payable to Cercacor; and
- the minimum aggregate annual royalties payable to Cercacor for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, hemoglobin and/or glucose will increase to $15.0 million per year until the exclusivity period of the agreement ends, plus up to $2.0 million for each additional measurement with no maximum ceiling for non-vital sign measurements.

A change in control includes any of the following with respect to us or Cercacor:

- the sale of all or substantially all of either company's assets to a non-affiliated third-party;
- the acquisition by a non-affiliated third-party of 50% or more of the voting power of either company;
- Joe Kiani, our Chief Executive Officer and the Chief Executive Officer of Cercacor, resigns or is terminated from his position with either company; and

- the merger or consolidation of either company with a non-affiliated third-party.

Ownership of Improvements. Any improvements to Masimo SET® or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third-party that relates to non-vital signs monitoring, and any new technology acquired by Cercacor, is and will be owned by Cercacor. Any improvements to the Masimo SET® platform or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third-party that relates to vital signs monitoring, and any new technology acquired by us, is and will be owned by us. However, for both non-vital signs and vital signs monitoring, any improvements to the technology, excluding acquired technology, will be assigned to the other party and will be subject to the

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terms of the licenses granted under the Cross-Licensing Agreement. Any new non-vital signs monitoring technology utilizing Masimo SET® that we develop will be owned by Cercacor and will be subject to the same license and option fees as if it had been developed by Cercacor. Also, we will not be reimbursed by Cercacor for our expenses relating to the development of any such technology.

Cercacor Services Agreement (Services Agreement). We have also entered into a services agreement with Cercacor. Under this Services Agreement, we provide Cercacor with certain accounting, human resources, information technology, legal and other administrative services. For the year ended January 3, 2015, Cercacor paid us $0.2 million for these services. We expect Cercacor to continue to engage us for these services. However, pursuant to the Services Agreement, Cercacor may terminate the agreement by providing us a 30 day notice, and we may terminate with a 180 day notice to Cercacor.

Cercacor's Expenses related to Pronto-7®. In February 2009, in order to accelerate the development of the technology and product development supporting our Pronto-7® device, Cercacor agreed to re-direct a substantial amount of its engineering development activities to focus on this project and we agreed to fund such expenses. Accordingly, from April 2009 through June 2010, we agreed to reimburse Cercacor for all third-party engineering materials and supplies expenses related to Pronto-7® development and 50% of Cercacor's total engineering and engineering-related payroll expenses. Since July 2010, Cercacor has continued to assist us with other product development efforts and charged us accordingly. Beginning in 2012, due to a revised estimate of the support required by us to complete the various Pronto-7® related projects, our board of directors approved an increase in the percentage of Cercacor's total engineering and engineering related payroll expenses funded by us from 50% to 60%. For the year ended January 3, 2015, the total funding for these additional Cercacor expenses was $3.1 million. This arrangement has been discontinued by mutual agreement effective as of January 4, 2015.

Government Regulation

As a global medical technology company, we are subject to significant government regulation, compliance requirements, fees and costs, both in the U.S. and abroad. These regulatory requirements subject our products and our business to numerous risks that are specifically discussed within "Risks Related to Our Regulatory Environment" under Part I, Item 1A—"Risk Factors" within this Annual Report on Form 10-K. A summary of certain critical aspects of our regulatory environment is included below.

Food and Drug Administration (FDA) Premarket Clearance and Approval Requirements

The FDA, along with other federal, state and local authorities, regulates our products and product-related activities. Pursuant to the U.S. Food, Drug, and Cosmetic Act (FDCA) and the regulations promulgated under that Act, the FDA regulates the design, development, clinical trials, testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices. We endeavor to ensure that our products and procedures remain in compliance with all applicable FDA regulations, but the regulations regarding the manufacture and sale of our products are subject to change. We cannot predict the effect, if any, that these changes might have on our business, financial condition and results of operations. Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive from the FDA either 510(k) clearance, by filing a 510(k) pre-market notification, or PMA approval, by filing a pre-market approval application (PMA).

The FDA's 510(k) clearance process usually takes from four to twelve months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain. We cannot be sure that 510(k) clearance or PMA approval will be obtained for any product we propose to market on a timely basis or at all. In addition, if the FDA discovers that an applicant has submitted false or misleading information, the FDA may refuse to review submissions until certain requirements are met pursuant to its Application Integrity Policy.

The FDA decides whether a device must undergo either the 510(k) clearance or PMA approval process based upon statutory criteria. These criteria include the level of risk that the agency perceives is associated with the device and a determination of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II, which generally requires the manufacturer to submit a pre-market notification requesting 510(k) clearance, unless an exemption applies.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls (General Controls) for medical devices, which include compliance with the applicable portions of

the FDA's Quality System Regulation (QSR) facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process.

Class II devices are subject to the FDA's General Controls, the FDA's QSR, including the Design Control regulations, and any other special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and

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clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure. All of our current regulated devices are classified as Class II devices.

Class III devices are those deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or those devices deemed not substantially equivalent to a legally marketed predicate device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the PMA approval process during which the manufacturer must establish the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must be supported by valid scientific evidence, including extensive preclinical (including bench tests and laboratory and animal studies) and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. As part of the PMA application review, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the FDA's QSR. If the FDA approves the PMA, it may place restrictions on the device or the labeling or require additional clinical studies. If the FDA's evaluation of the PMA application or the manufacturing facility is not favorable, the FDA may deny approval of the PMA application or issue a "not approvable" letter. The FDA may also require additional clinical trials, which can delay the PMA approval process by several years. None of our products are currently approved under the PMA process.

To obtain 510(k) clearance, a company must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" in intended use and in technological and performance characteristics to a legally marketed "predicate device" that is either a Class I, Class II or Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials may require an Investigational Device Exemption (IDE) application approved in advance by the FDA for a specified number of patients, unless the proposed study is deemed a non-significant risk study, which is eligible for an exemption from the IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards (IRBs) at the clinical trial sites. Submission of an IDE application does not give assurance that the FDA will issue the IDE. If the IDE application is approved, there can be no assurance the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. The trial must also comply with the FDA's regulations, including the requirement that informed consent be obtained from each subject. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance to market the product in the U.S.

We believe that our OEM partners may be required to obtain 510(k) premarket clearance from the FDA for certain of their products that incorporate Masimo SET® technology, Masimo rainbow® SET® technology, Masimo Board-in-Cable technology or Masimo sensors. In order to facilitate our OEM partners in obtaining 510(k) clearance for their products that incorporate Masimo SET® or Masimo rainbow® SET® boards and sensors, we grant our OEM partners a right to cross-reference the files from our cleared Masimo SET® circuit boards, sensor, cable and notification system 510(k) submissions.

We recently launched iSpO$_2$®, a non-medical use pulse oximeter intended for sports and aviation use. We are marketing this product in accordance with the FDA's current policy and enforcement discretion which indicates that pulse oximeters that are not intended for medical purposes can be marketed directly to consumers without first obtaining 510(k) clearance. We cannot assure you that the FDA will not change its policy regarding the regulation of these products. If the FDA changes its policy, we may be required to seek 510(k) clearance to market this pulse oximeter. We also may be required to cease marketing and/or recall the product until we obtain a new 510(k) clearance.

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User Fees

Pursuant to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the Medical Device User Fee Amendments of 2012 (MDUFA III) and provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA), unless a specific exemption applies, both 510(k) submissions and PMA applications are subject to user fees. The PMA user fees are significantly higher.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, it continues to be subject to the FDA's regulatory authority. FDA regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR and current good manufacturing practices, which requires manufacturers, including third-party manufacturers, to follow stringent design control, testing, change control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process, including requirements for packaging, labeling and record keeping, complaint handling, corrective and preventive actions and internal auditing;
- labeling control and advertising regulations, including FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses or indications;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our future approved devices;
- medical device reporting (MDR), regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of its conditions of approval, governing laws and/or regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

We must also register with the FDA as a medical device manufacturer, list all products placed in commercial distribution and obtain all necessary state permits or licenses to operate our business. As a manufacturer, we are subject to announced and unannounced inspections by the FDA to determine our compliance with the FDA's QSR and other regulations. Our OEM partners also are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements.

If the FDA finds that we or one of our OEM partners have failed to comply with the FDA's QSR, the agency can institute a wide variety of enforcement and other regulatory actions, including:

- an FDA Form 483, which is issued by the FDA at the conclusion of an inspection when an investigator has observed any conditions that may constitute violations of the FDCA and related Acts;
- a public warning letter outlining potential violations of the FDCA;
- fines and civil penalties against us and/or OEM partners;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawal or suspension of clearances and/or approvals of our products or those of our third-party suppliers by the FDA or other regulatory bodies;
- product recall;
- product detention or seizure;
- interruption of production;

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- refusal to provide export certificates, which may be necessary to permit the export of devices from the U.S. to other countries;
- operating restrictions;
- injunctions of future violations (including those agreed to in a consent decree); and
- criminal prosecution.

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

Advertising and Promotion

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission (FTC) and by federal and state regulatory and enforcement authorities, including the FDA, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and various state attorneys general. Although physicians are permitted to use their medical judgment to use medical devices for indications other than those cleared or approved by the FDA, we may not promote our products for such "off-label" uses and can only market our products for cleared or approved uses. Recently, promotional activities for FDA-regulated products of other companies have been the subject of FTC enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. FTC enforcement actions often result in consent decrees that constrain future actions. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

Import and Export Requirements

To import a device, the importer must file an entry notice and bond with the United States Bureau of Customs and Border Protection (CBP). All devices are subject to FDA examination before release from CBP. Any article that appears to be in violation of the FDCA may be refused admission and a notice of detention and hearing may be issued. If the FDA ultimately refuses admission, the CBP may issue a notice for redelivery and assess liquidated damages for up to three times the value of the lot. The CBP also imposes its own regulatory requirements on the import of our products, including inspection and possible sanctions for noncompliance.

Products exported from the United States are subject to foreign countries' import requirements and the exporting requirements of the FDA or European regulating bodies, as applicable. In particular, international sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Foreign countries often require, among other things, an FDA certificate for products for export, also called a Certificate for Foreign Government. To obtain this certificate from the FDA, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities were in compliance with the FDA's QSR regulations at the time of the last FDA inspection. If the FDA determines that our facilities or procedures do not comply with the FDA's QSR regulations, it may refuse to provide such certificates until we resolve the issues to the FDA's satisfaction.

Foreign Regulation Regarding Clearance and Approval

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance and the requirements may differ.

In particular, marketing of medical devices in the European Economic Area (EEA) is subject to compliance with European Medical Device Directives. Under this regime, a medical device may be placed on the market within the EEA if it conforms to certain "essential requirements" and bears the CE Mark. The most fundamental and essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the essential performance(s) intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

Manufacturers must demonstrate that their devices conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. The

classification rules are mainly based on three criteria: the length of time the device is in contact with the body, the degree of invasiveness and the extent to which the device affects the anatomy. Conformity assessment procedures for all but the lowest risk classification of

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device involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Manufacturers usually have some flexibility to select conformity assessment procedures for a particular class of device and to reflect their circumstances, e.g., the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer's quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE Mark. Application of the CE Mark allows the product to be distributed throughout the EEA. We maintain CE Marking on all of our products that require such markings.

Other U.S. and Foreign Regulation

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

The Physician Payment Sunshine Act (Sunshine Act), which was enacted by Congress as part of the Patient Protection and Affordable Care Act (PPACA) on March 23, 2010, requires medical device companies to track and publicly report, with limited exceptions, all payments and transfers of value to physicians and teaching hospitals in the U.S. Implementing regulations for these tracking and reporting obligations were finalized in 2013, and companies are now required to track payments made and to report such payments to the government by March 31 of each year. In addition, in December 2005, the International Electrotechnical Commission published a revised version of its standard for medical electrical equipment, IEC, 60601-1:2005 (3rd edition). In this publication, standards are listed as general requirements concerning basic safety and the essential performance of equipment. These new standards were required to be in place by June 1, 2012 in Europe and by December 31, 2013 in the U.S. for new submissions. Failure to adhere to this regulation will prevent us from using our equipment in our clinical trials.

Medical Device Tax

In March 2010, the U.S. Congress adopted and President Obama signed into law comprehensive health care reform legislation. Among other initiatives, these laws impose significant new taxes on medical device makers in the form of a 2.3% excise tax on U.S. medical device sales, with certain exemptions, beginning on January 1, 2013. For the years ended January 3, 2015 and December 28, 2013, we recorded $6.6 million and $6.3 million, respectively, in medical device taxes that were included in selling, general and administrative expenses.

Conflict Minerals and Supply Chain

We are subject to SEC rules adopted pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act concerning "conflict minerals" (generally tin, tantalum, tungsten and gold) and similar rules are under consideration by the European Union (EU). Certain of these conflict minerals are used in the manufacture of our products. Although the rules are being challenged in court, in their present form they require us to investigate the source of any conflict minerals necessary to the production or functionality of our products. If any such conflict minerals originated in the Democratic Republic of the Congo or adjoining countries (the DRC region), we must undertake comprehensive due diligence to determine whether such minerals financed or benefited armed groups in the DRC region. Since our supply chain is complex, our ongoing compliance with these rules could affect the pricing, sourcing and availability of conflict minerals used in the manufacture of our products.

We are also subject to disclosure requirements regarding abusive labor practices in portions of our supply chain under the California Transparency in Supply Chains Act.

Environmental

Our manufacturing processes involve the use, generation and disposal of solid wastes, hazardous materials and hazardous wastes, including silicone adhesives, solder and solder paste, sealants, epoxies and various solvents such as methyl ethyl ketone, acetone and isopropyl alcohol. As such, we are subject to stringent federal, state and local laws

relating to the protection of the environment, including those governing the use, handling and disposal of hazardous materials and wastes. Products that we sell in Europe are subject to regulation in EU markets under the Restriction of the Use of Hazardous Substances Directive (RoHS). RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in EU member states. In addition, the

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EU's Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products.

Future environmental laws may require us to alter our manufacturing processes, thereby increasing our manufacturing costs. We believe that our products and manufacturing processes at our facilities comply in all material respects with applicable environmental laws and worker health and safety laws; however, the risk of environmental liabilities cannot be completely eliminated.

Health Care Fraud and Abuse

In the U.S., there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. For example, the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the referral of patients for, or the purchase, order or recommendation of, health care products and services reimbursed by a federal health care program, including Medicare and Medicaid. Recognizing that the federal anti-kickback law is broad and potentially applicable to many commonplace arrangements, Congress and the Office of Inspector General within the Department of Health and Human Services (OIG), have created statutory "exceptions" and regulatory "safe harbors". Exceptions and safe harbors exist for a number of arrangements relevant to our business, including, among other things, payments to bona fide employees, certain discount and rebate arrangements, and certain payment arrangements involving GPOs. Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the law, but the OIG or other government enforcement authorities may examine the practice to determine whether it involves the sorts of abuses that the statute was designed to combat. Violations of this federal law can result in significant penalties, including imprisonment, monetary fines and assessments, and exclusion from Medicare, Medicaid and other federal health care programs. Exclusion of a manufacturer, like us, would preclude any federal health care program from paying for its products. In addition to the federal anti-kickback law, many states have their own laws that parallel and implicate anti-kickback restrictions analogous to the federal anti-kickback law, but may apply regardless of whether any federal health care program business is involved. Federal and state anti-kickback laws may affect our sales, marketing and promotional activities, educational programs, pricing and discount practices and policies, and relationships with health care providers by limiting the kinds of arrangements we may have with hospitals, alternate care market providers, GPOs, physicians and others in a position to purchase or recommend our products.

Federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payers that are false or fraudulent. For example, the Federal Civil False Claims Act (31 U.S.C. § 3729 et seq.) imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and Medicare. Some suits filed under the False Claims Act, known as "qui tam" actions, can be brought by a "whistleblower", or "relator" on behalf of the government and such individuals may share in any amounts paid by the entity to the government in fines or settlement. Manufacturers, like us, can be held liable under false claims laws, even if they do not submit claims to the government, where they are found to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims. A number of states also have false claims laws, and some of these laws may apply to claims for items or services reimbursed under Medicaid and/or commercial insurance. Sanctions under these federal and state laws may include civil monetary penalties, exclusion from government health care programs and imprisonment.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created new federal crimes, including health care fraud and false statements related to health care matters. The health care fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers. The false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of either statute is a

felony and may result in fines, imprisonment and exclusion from government health care programs.

The Foreign Corrupt Practices Act of 1977 and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws or the adoption of new federal or state

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laws or regulations could adversely affect many of the arrangements we have with customers and physicians. Therefore, our risk of being found in violation of these laws is increased by the fact that some of these laws are broad and open to interpretation.

Privacy and Security of Health Information

Numerous federal, state and international laws and regulations, including HIPAA, govern the collection, use and disclosure of patient-identifiable or protected health information (PHI). HIPAA applies to covered entities, which include most healthcare facilities that purchase and use our products. The HIPAA Privacy Rule restricts the use and disclosure of PHI, and requires covered entities and business associates under business associate agreements to safeguard that information and to provide certain rights to individuals with respect to that information. The HIPAA Security Rule establishes detailed requirements for safeguarding PHI transmitted or stored electronically. Although we are not a covered entity, we are sometimes deemed to be a business associate of covered entities due to activities that we perform for or on behalf of covered entities, which sometimes requires covered entities to contractually bind us, as a business associate, to protect the privacy and security of PHI we may encounter during activities such as training customers on the use of our products or investigating product performance.

Enacted in February 2009, the Health Information Technology for Economic and Clinical Health Act (HITECH) made significant amendments to the HIPAA Privacy and Security Rules. Under HIPAA and HITECH, business associates must comply with a number of HIPAA Privacy Rule requirements and all of the HIPAA Security Rule provisions, and business associates are directly subject to HIPAA civil and criminal enforcement and the associated penalties for violation of the Privacy and Security Rule requirements.

The HIPAA standards also apply to the use and disclosure of PHI for research and generally require the covered entity performing the research to obtain the written authorization of the research subject (or an appropriate waiver) before providing that subject's PHI to sponsors like us for purposes related to the research. These covered entities also typically impose contractual limitations on our use and disclosure of the PHI they disclose to us. We may be required to make costly system modifications to comply with the privacy and security requirements that will be imposed on us and our failure to comply may result in liability and adversely affect our business.

Numerous other federal and state laws protect the confidentiality of PHI, including state medical privacy laws and federal and state consumer protection laws. These various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability.

Other countries also have, or are developing, laws governing the collection, use and transmission of health information and these laws could create liability for us or increase our cost of doing business.

Third-Party Reimbursement

Health care providers, including hospitals, that purchase our products generally rely on third-party payers, including the Medicare and Medicaid programs and private payers, such as indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of the products and the procedures in which they are used. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payers. No uniform coverage or reimbursement policy for medical technology exists among all third-party payers, and coverage and reimbursement can differ significantly from payer to payer.

The Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for administering the Medicare program, along with its contractors, establish coverage and reimbursement policies for the Medicare program. Because a large percentage of the hospitals using our products treat elderly or disabled individuals who are Medicare beneficiaries, Medicare's coverage and reimbursement policies are particularly significant to our business. In addition, private payers often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payers will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

In general, Medicare will cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage. For example, several Medicare local

contractors have issued policies that restrict coverage for pulse oximetry in hospital inpatient and outpatient settings to a limited number of conditions, including limiting coverage to patients who (i) exhibit signs of acute respiratory dysfunction, (ii) have chronic lung disease, severe cardiopulmonary disease or neuromuscular disease involving the muscles of respiration, (iii) are under treatment with a medication with known pulmonary toxicity, or (iv) have sustained multiple trauma or complaints of acute chest pain.

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Reimbursement for our products may vary not only by the type of payer involved but also based upon the setting in which the product is furnished and utilized. For example, Medicare payment may be made, in appropriate cases, for patient stays in the hospital inpatient and outpatient settings involving the use of our products. Medicare generally reimburses hospitals based upon prospectively determined amounts. For hospital inpatient stays, the prospective payment generally is determined by the patient's condition and other patient data and procedures performed during the inpatient stay, using a classification system known as Medicare Severity Diagnosis-Related Groups (MS-DRGs). Prospective rates are adjusted for, among other things, regional differences, co-morbidity and complications. Hospitals generally do not receive separate Medicare reimbursement for the specific costs of purchasing our products for use in the inpatient setting. Rather, Medicare reimbursement for these costs is deemed to be included within the prospective payments made to hospitals for the inpatient services in which the products are utilized.

In contrast, some differences may be seen in the reimbursement for use of our products in hospital outpatient departments. In this setting, Medicare payments also are generally made under a prospective payment system based on the ambulatory payment classifications (APCs) under which individual items and procedures are categorized. Hospitals receive the applicable APC payment rate for the procedure regardless of the actual cost for such treatment. Some outpatient services such as oximetry services do not receive separate reimbursement. Rather, their reimbursement is deemed packaged into the APC for an associated procedure, and the payment for that APC does not vary depending on whether the packaged procedure is performed. Some procedures also are paid through Composite APCs, which are APCs that establish a payment rate that applies when a specific combination of services is provided. Reimbursement for certain pulse oximetry monitoring services, including those using our products, may be separately payable when they are the only service provided to the patient on that day, packaged if provided with certain critical care services, or reimbursed through a composite APC when provided in connection with certain other services. Because payments through the Prospective Payment System in both the hospital inpatient and outpatient settings are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, hospitals have incentives to lower their operating costs by utilizing products that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs. If hospitals cannot obtain adequate coverage and reimbursement for our products, or the procedures in which they are used, we cannot be certain that they will purchase our products, despite the clinical benefits and opportunity for cost savings that we believe can be derived from their use.

Our success with rainbow® SET® technologies in U.S. care areas with reimbursable monitoring procedures, such as hospital emergency departments, hospital procedure labs, and the physician office may largely depend on the ability of providers to receive reimbursement for such procedures. While private insurance payers generally follow Medicare coding and payment, we cannot be certain of this and, in many cases, cannot control the coverage or payment rates that private insurance payers put in place. In addition, the PPACA could affect future Medicare payment for services involving the use of our products.

Our success in non-U.S. markets depends largely upon the availability of coverage and reimbursement from the third-party payers through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payer government managed systems as well as systems in which private payers and government managed systems exist side-by-side. Our ability to achieve market acceptance or significant sales volume in international markets we enter will be dependent in large part on the availability of reimbursement for procedures performed using our products under health care payment systems in such markets.

Competition

The medical device industry is highly competitive and many of our competitors have substantially greater financial, technical, marketing and other resources than we do. While we regard any company that sells pulse oximeters as a potential customer, we also recognize that the companies selling pulse oximeters on an OEM basis and/or pulse oximetry sensors are also potential competitors. Our primary competitor, Covidien Ltd. (Covidien), who was recently acquired by Medtronic plc, currently holds a substantial share of the pulse oximetry market. Covidien sells its own brand of Nellcor pulse oximeters to end-users, sells pulse oximetry modules to other monitoring companies on an OEM basis, and licenses to certain OEMs the right to make their pulse oximetry platforms compatible with their sensors. We also face substantial competition from larger medical device companies, including companies that

develop products that compete with our proprietary Masimo SET® and our OEM partners. We believe that a number of companies have announced products that claim to offer Measure-Through-Motion accuracy. Based on those announcements and our investigations, we further believe that many of these products include technology that infringes our intellectual property rights. We have settled claims against some of these companies and intend to vigorously enforce and protect our proprietary rights with respect to the others whom we believe are infringing our technology.

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We believe that the principal competitive factors in the market for pulse oximetry products include:

- accurate monitoring during both patient motion and low perfusion;
- ability to introduce other clinically beneficial measurements related to oxygenation and respiration, such as noninvasive and continuous hemoglobin and acoustic respiration rate;
- competitive pricing, including bundling practices;
- brand recognition and perception of innovation abilities;
- sales and marketing capability;
- access to hospitals which are members of GPOs;
- recent proliferation of integrated delivery networks;
- access to OEM partners; and
- patent protection.

Seasonality

The healthcare business in the United States and overseas is typically subject to quarterly fluctuations in hospital and other alternative care admissions. Historically, our third fiscal quarter revenues have generally experienced a sequential decline from our second fiscal quarter revenues. We believe this is primarily due to the summer vacation season during which people tend to avoid elective procedures. This historical trend did not occur in fiscal year 2014 primarily due, we believe, to the delayed installation of new hospitals contracted in 2013 and higher OEM revenues related to the introduction of RoHs-compliant products in Europe. Another factor affecting the seasonality of our quarterly revenues is the traditional “flu season” that often increases hospital and acute care facility admissions in the first and fourth calendar quarters. Because our non-sales variable operating expenses often do not fluctuate in the same manner as our quarterly product sales, this may cause fluctuations in our quarterly operating income that are disproportionate to fluctuations in our quarterly revenue.

Sales and Marketing

We have sales and marketing employees in the U.S. and abroad. We expect to moderately increase our worldwide sales and sales support organizations as we continue to expand our presence throughout both the U.S. and the world, including Europe, the Middle East, Asia, Latin America, Canada and Australia. We currently sell all of our medical products both directly to hospitals and the alternate care market via our sales force and certain distributors. We sell our non-medical/consumer products through e-commerce Internet sites such as Amazon.com.

The primary focus of our sales representatives is to facilitate the conversion of competitor accounts to our Masimo SET® and rainbow® SET® pulse oximetry products, to expand the use of Masimo SET® and Patient SafetyNet™ on the general floor and to create and expand the use of rainbow® measurements in both critical care and non-critical care areas. In addition to sales representatives, we employ clinical specialists to work with our sales representatives to educate end-users on the benefits of Masimo SET® and assist with the introduction and implementation of our technology and products to their sites. Our sales and marketing strategy for pulse oximetry has been and will continue to be focused on building end-user awareness of the clinical and cost-saving benefits of our Masimo SET® platform. More recently, we have expanded this communication and educational role to include our Masimo rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring™ products, including hemoglobin, carboxyhemoglobin, methemoglobin, PVI®, acoustic respiration rate and Halo Index.™ During 2014, we continued to build a dedicated worldwide blood management sales force whose primary focus is working with hospitals to identify new opportunities to deploy our SpHb® technology.

For the year ended January 3, 2015, two just-in-time distributors, Owens & Minor and Cardinal Health, represented approximately 14% and 11%, respectively, of our total revenue. These were the only two customers that represented 10% or more of our revenue for the year ended January 3, 2015. Importantly, these two distributors take and fulfill orders from our direct customers, many of whom have signed long-term sensor purchase agreements with us. As a result, in the event a specific just-in-time distributor is unable to fulfill these orders, the orders would be redirected to other distributors or fulfilled directly by us.

Additionally, we sell certain of our products through our OEM partners who both incorporate our boards into their monitors and resell our sensors to their customers’ installed base of Masimo SET® products. Our OEM agreements allow us to expand the availability of Masimo SET® through the sales and distribution channels of each OEM partner.

To facilitate clinician awareness of Masimo SET® installations, all of our OEM partners have agreed to place the Masimo SET® logo prominently on their instruments.

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In order to facilitate our U.S. direct sales to hospitals, we have signed contracts with what we believe to be the five largest national GPOs in the U.S., based on the total volume of negotiated purchases. In return for the GPOs putting our products on contract, we have agreed to pay the GPOs a percentage of our revenue from their member hospitals. In 2014 and 2013, revenue from the sale of our pulse oximetry products to hospitals that are associated with GPOs amounted to $309.9 million and $287.9 million, respectively.

Our marketing efforts are designed to build end-user awareness through digital and print advertising, direct mail and trade shows. In addition, we distribute published clinical studies, provide product education for doctors, nurses, biomedical engineers and respiratory therapists and assist with product evaluations.

Intellectual Property

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect our intellectual property.

We have developed a patent portfolio internally, and, to a lesser extent, through acquisitions and licensing, that covers many aspects of our product offerings. As of January 3, 2015, we had 468 issued patents and 234 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. Our issued U.S. patents have expiration dates (not including any patent term extensions) from 2015 to 2033. Additionally, as of January 3, 2015, we owned 61 U.S. registered trademarks and 194 foreign registered trademarks, as well as trade names that we use in conjunction with the sale of our products. Our trademarks are perpetually renewable.

Under the Cross-Licensing Agreement, we and Cercacor have agreed to allocate proprietary ownership of technology developed based on the functionality of the technology. We will have proprietary ownership, including ownership of all patents, copyrights and trade secrets, of all technology related to the noninvasive monitoring of vital signs measurements, and Cercacor will have proprietary ownership of all technology related to the noninvasive monitoring of non-vital signs measurements. We also rely upon trade secrets, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with consultants, vendors and employees, although we cannot be certain that the agreements will not be breached or that we will have adequate remedies for any breach.

There are risks related to our intellectual property rights. For further detail on these risks, see “Risks Related to Our Intellectual Property” under Item 1A—“Risk Factors” in this on Form 10-K.

Research and Product Development

We believe that ongoing research and development efforts are essential to our success. Our research and development efforts focus primarily on continuing to enhance our technical expertise in pulse oximetry, expanding our noninvasive monitoring of other measurements and developing remote alarm and monitoring solutions.

Although we and Cercacor each have separate research and development projects, we collaborate with Cercacor on multiple research and development activities related to rainbow® technology and other technologies. Under the Cross-Licensing Agreement, the parties have agreed to allocate proprietary ownership of technology developed by either party based on the functionality of the technology. We will have proprietary rights to all technology related to the noninvasive measurement of vital signs measurements, and Cercacor will have proprietary ownership of all technology related to the noninvasive monitoring of non-vital signs measurements.

Our total research and development expenditures for fiscal year 2014 were $56.6 million, which included $3.1 million related to expenses incurred by Cercacor pursuant to the Cross-Licensing Agreement. In fiscal year 2013, our total research and development expenditures were $55.6 million, which included $3.9 million related to expenses incurred by Cercacor. We expect our research and development expenses to increase moderately in fiscal year 2015 and beyond as we expand our research and development staff, enhance our existing products and technologies and develop new products for market introduction.

Manufacturing

Our strategy is to manufacture products in-house when it is efficient and cost-effective for us to do so. We currently manufacture our bedside and handheld pulse oximeters, our full line of disposable and reusable sensors and most of our patient cables in-house. We maintain an approximate 15,000 square foot manufacturing area in our facility in Irvine, California, and an approximate 149,000 square foot manufacturing facility in Mexicali, Mexico, both of which

are International Organization for Standardization (ISO) 13485:2012 certified. We also maintain an approximate 90,000 square foot facility in Hudson, New

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Hampshire, a portion of which is used to manufacture advanced light emitting diodes and other advanced component-level technologies. In addition, we maintain an ISO Certified facility approximating 13,000 square feet in Danderyd, Sweden, a portion of which is used to manufacture ultra-compact mainstream and sidestream capnography and gas monitoring technologies. We will continue to utilize third-party contract manufacturers for products and subassemblies that can be more efficiently manufactured by these parties, such as our circuit boards. We monitor our third-party manufacturers and perform inspections and product tests at various steps in the manufacturing cycle to ensure compliance with our specifications. We also do full functional testing of our circuit boards.

For raw materials, we and our contract manufacturers rely on sole source suppliers for some components, including digital signal processor chips and analog to digital converter chips. We and our contract manufacturers have taken steps to minimize the impact of a shortage or stoppage of shipments of digital signal processor chips or analog to digital converter chips, including maintaining a safety stock of inventory and designing software that may be easily ported to another digital signal processor chip. We believe that our sources of supply for components and raw materials are adequate. In the event of a delay or disruption in the supply of sole source components, we believe that we and our contract manufacturers will be able to locate additional sources of these sole source components on commercially reasonable terms and without experiencing material disruption in our business or operations.

We have agreements with certain major suppliers and each agreement provides for varying terms with respect to contract expiration, termination and pricing. Most of these agreements allow for termination upon specified notice, ranging from four to six months, to the non-terminating party. Certain of these agreements with our major suppliers allow for pricing adjustments, each agreement provides for annual pricing negotiation, and one agreement also guarantees Masimo the most favorable pricing offered by the supplier to any of its other customers.

Employees

As of January 3, 2015, we had approximately 1,200 full-time employees and approximately 2,400 dedicated contract employees worldwide.

Address

Our principal executive offices are located at 52 Discovery, Irvine, California 92618, and our telephone number at that address is (949) 297-7000. Our website address is www.masimo.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, proxy statements, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge at www.masimo.com as soon as reasonably practicable after electronically filing such reports with the SEC. Any information contained on, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way a part of, this Annual Report on Form 10-K.

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ITEM 1A. RISK FACTORS

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the following risks come to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our stock could decline, and you could lose all or part of your investment.

Risks Related to Our Revenues

We currently derive substantially all of our revenue from our Masimo SET® platform, Masimo rainbow® SET® platform and related products. If this technology and the related products do not continue to achieve market acceptance, our business, financial condition and results of operations would be adversely affected.

We are dependent upon the success and market acceptance of our proprietary Masimo SET® technology. Currently, our primary product offerings are based on the Masimo SET® platform. Continued market acceptance of products incorporating Masimo SET® will depend upon our ability to continue to provide evidence to the medical community that our products are cost-effective and offer significantly improved performance compared to conventional pulse oximeters. Health care providers that currently have significant investments in competitive pulse oximetry products may be reluctant to purchase our products. If hospitals and other health care providers do not believe our Masimo SET® platform is cost-effective, safe or more accurate or reliable than competitive pulse oximetry products, they may not buy our products in sufficient quantities to enable us to generate revenue growth from the sale of these products. In addition, allegations regarding the safety and effectiveness of our products, whether or not substantiated, may impair or impede the acceptance of our products. If we are unable to achieve additional market acceptance of our core technology or products incorporating Masimo SET®, we will not generate significant revenue growth from the sale of our products, which would adversely affect our business, financial condition and results of operations.

Some of our products, including those based on licensed rainbow® technology, are in development or have been recently introduced into the market and may not achieve market acceptance, which could limit our growth and adversely affect our business, financial condition and results of operations.

Products that we have introduced into the market in recent years, including, but not limited to, those based on rainbow® technology, a technology that we license, may not be accepted in the market. If our products do not gain market acceptance or if our customers prefer our competitors' products, our potential revenue growth would be limited, which would adversely affect our business, financial condition and results of operations.

Given that certain rainbow® technology products are relatively new to the marketplace, we do not know to what degree the market will accept these products, if at all. Even if our customers recognize the benefits of our products, we cannot assure you that our customers will purchase them in quantities sufficient for us to be profitable or successful. We are continuing to invest in significant sales and marketing resources to achieve market acceptance of these products with no assurance of success. The degree of market acceptance of these products will depend on a number of factors, including:

- perceived clinical benefits from our products;
- perceived cost effectiveness of our products;
- perceived safety and effectiveness of our products;
- reimbursement available through Centers for Medicare and Medicaid Services (CMS) programs for using some of our products; and
- introduction and acceptance of competing products or technologies.

In general, our recent noninvasive measurement technologies are considered disruptive. These recent technologies have performance levels that we believe are acceptable for many clinical environments but may be insufficient in others. In addition, these technologies may perform better in some patients and settings than others. Over time, we hope to continue to improve the performance of these technologies and, if we do, we expect them to become more useful in more environments and to become more widely adopted. While this is the adoption pattern experienced historically with other new noninvasive measurements, such as oxygen saturation, we are unable to guarantee that such adoption pattern will apply to our recent and future technologies.

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Our ability to commercialize new products, new or improved technologies and additional applications for Masimo SET® and our licensed rainbow® technology are each limited to certain markets by our Cross-Licensing Agreement with Cercacor Laboratories, Inc. (Cercacor), which may impair our growth and adversely affect our business, financial condition and results of operations.

In May 1998, we spun off a newly-formed entity, Cercacor, and provided it rights to use Masimo SET® to commercialize non-vital signs monitoring applications, while we retained the rights to Masimo SET® to commercialize vital signs monitoring applications. On May 2, 1998, we entered into a cross-licensing agreement with Cercacor, which has been amended several times, most recently in an Amended and Restated Cross-Licensing Agreement, effective January 1, 2007 (the Cross-Licensing Agreement). Under the Cross-Licensing Agreement, we granted Cercacor:

- an exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET® owned by us, including all improvements on this technology, for the monitoring of non-vital signs parameters and to develop and sell devices incorporating Masimo SET® for monitoring non-vital signs parameters in any product market in which a product is intended to be used by a patient or pharmacist rather than by a professional medical caregiver, which we refer to as the Cercacor Market; and
- a non-exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET® for measurement of vital signs in the Cercacor Market.

Non-vital sign measurements consist of body fluid constituents other than vital sign measurements, including, but not limited to, carbon monoxide, methemoglobin, blood glucose, hemoglobin and bilirubin. Under the Cross-Licensing Agreement, we are only permitted to sell devices utilizing Masimo SET® for the monitoring of non-vital signs parameters in markets where the product is intended to be used by a professional medical caregiver, including, but not limited to, hospital caregivers and alternate care facility caregivers, rather than by a patient or pharmacist, which we refer to as the Masimo Market. Accordingly, our ability to commercialize new products, new or improved technologies and additional applications for Masimo SET® is limited. In particular, our inability to expand beyond the Masimo Market may impair our growth and adversely affect our business, financial condition and results of operations.

Pursuant to the Cross-Licensing Agreement, we have licensed from Cercacor the right to make and distribute products in the Masimo Market that utilize rainbow® technology for certain noninvasive measurements. As a result, the opportunity to expand the market for our products incorporating rainbow® technology is also limited, which could limit our ability to maintain or increase our revenue and impair our growth.

We face competition from other companies, many of which have substantially greater resources than we do. If we do not successfully develop and commercialize enhanced or new products that remain competitive with products or alternative technologies developed by others, we could lose revenue opportunities and customers, and our ability to grow our business would be impaired, adversely affecting our financial condition and results of operations.

A number of our competitors have substantially greater capital resources, larger customer bases and larger sales forces, have established stronger reputations with specific customers, and have built relationships with Group Purchasing Organizations (GPOs) that are more effective than ours. Our Masimo SET® platform faces additional competition from companies developing products for use with third-party monitoring systems, as well as companies that currently market their own pulse oximetry monitors.

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for Masimo SET® and licensed rainbow® technology. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. In particular, we may not be able to successfully commercialize our products for applications other than arterial blood oxygen saturation and pulse rate monitoring, including respiration rate, hemoglobin, carboxyhemoglobin and methemoglobin monitoring. If we do not successfully adapt our products and applications both within and outside these measurements, we could lose revenue opportunities and customers. Furthermore, one or more of our competitors may develop products that are substantially equivalent to our U.S. Food and Drug Administration (FDA) cleared products, or those of our original equipment

manufacturer (OEM) partners, whereby they may use our products or those of our OEM partners as predicate devices to more quickly obtain FDA clearance of their competing products. Competition could result in reductions in the price of our products and fewer orders for our products, which could, in turn, cause a reduction in our revenues and product gross margins, thereby adversely impacting our business, financial condition and results of operations.

We depend on our domestic and international OEM partners for a portion of our revenue. If they do not devote sufficient resources to the promotion of products that use Masimo SET® and licensed rainbow® technology, our business would be harmed.

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We are, and will continue to be, dependent upon our domestic and international OEM partners for a portion of our revenue through their marketing, selling and distribution of certain of their products that incorporate Masimo SET® and licensed rainbow® technology. Although we expect that our OEM partners will accept and actively market, sell and distribute products that incorporate licensed rainbow® technology, they may not elect, and have no contractual obligation, to do so. Because products that incorporate our technologies may represent a relatively small percentage of business for some of our OEM partners, they may have less incentive to promote these products over other products that do not incorporate these technologies. In addition, some of our OEM partners offer products that compete with ours. Therefore, we cannot guarantee that our OEM partners, or any company that may acquire any of our OEM partners, will vigorously promote products incorporating Masimo SET® and licensed rainbow® technology. The failure of our OEM partners to successfully market, sell or distribute products incorporating these technologies, the termination of OEM agreements, the loss of OEM partners or the inability to enter into future OEM partnership agreements would have a material adverse effect on our business, financial condition and results of operations.

Covidien may seek to avoid paying any royalties to us, which would significantly reduce our royalty revenue and total revenues and adversely affect our business, financial condition and results of operations.

We are party to a settlement agreement with Covidien, who was recently acquired by Medtronic plc. Under the current settlement agreement, we earn royalties on Covidien's total U.S. based pulse oximetry sales. For the years ended January 3, 2015, December 28, 2013 and December 29, 2012, our royalties from the Covidien settlement agreement totaled approximately $29.9 million, $29.8 million and $28.3 million, respectively. Because these royalty payments do not carry any significant cost, they result in significant improvements to our reported gross profit, operating income levels and earnings per share. As a result, an elimination of royalties that we earn under the settlement agreement in the future would have a significant impact on our revenue, gross margins, operating income and earnings per share.

On January 28, 2011, we entered into a second amendment to the settlement agreement with Covidien. As part of this amendment, which became effective on March 15, 2011, Covidien agreed to pay us a royalty at a rate of 7.75% of its U.S. pulse oximetry revenue, as that term is defined in the January 28, 2011 second amendment. Pursuant to the second amendment, in exchange for this royalty payment, we provided Covidien with a covenant not to sue for its current pulse oximetry products, but not for any other technologies that Covidien may add. As of January 3, 2015, Covidien has the right to stop paying us royalties, subject to certain notice requirements, which, if exercised, would have a material adverse impact on our revenue, gross margins, legal expenses, operating income and earnings per share.

If we fail to maintain or develop relationships with GPOs, sales of our products would decline.

Our ability to sell our products to U.S. hospitals depends, in part, on our relationships with GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate beneficial pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors.

These negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, the GPO's affiliated hospitals and other members may be less likely or unlikely to purchase our products. If a GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be prohibited from making sales to members of the GPO for the duration of such contractual arrangement. For the years ended January 3, 2015, December 28, 2013 and December 29, 2012, shipments of our pulse oximetry products to customers that are members of GPOs represented approximately $309.9 million, $287.9 million and $253.7 million, respectively, of our revenue from sales to U.S. hospitals. Our failure to renew our contracts with GPOs may cause us to lose market share and could have a material adverse effect on our business, financial condition and results of operations. In addition, if we are unable to develop new relationships with GPOs, our competitive position would likely suffer and our opportunities to grow our revenues and business would be harmed.

Certain GPOs are creating, coordinating and facilitating regional purchasing coalition (RPC) supply chain networks that include anti-competitive practices such as sole sourcing and bundling. These RPCs circumvent and potentially violate rules of conduct for GPOs and have the effect of reducing product purchasing decisions available to the hospitals that belong to these regional organizations. If the GPOs and RPCs are permitted to continue practices that limit, reduce or eliminate competition, we could lose customers who are no longer able to choose or purchase our

products, resulting in lower sales that could adversely affect our business, financial condition and results of operations.

Inadequate levels of coverage or reimbursement from governmental or other third-party payers for our products, or for procedures using our products, may cause our revenue to decline.

Sales of our products depend in part on the reimbursement and coverage policies of governmental and private health care payers. The ability of our health care provider customers, including hospitals, to obtain adequate coverage and reimbursement for our products or the procedures in which our products are used may impact our customers' purchasing decisions. Therefore,

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our customers' inability to obtain adequate coverage, reimbursement for our products or reimbursement for the procedures in which our products are used would have a material adverse effect on our business.

Third-party payers have adopted, and are continuing to adopt, health care policies intended to curb rising health care costs. These policies include, among others:

- controls on reimbursement for health care services and price controls on medical products and services;
- limitations on coverage and reimbursement for new medical technologies and procedures; and
- the introduction of managed care and prospective payment systems in which health care providers contract to provide comprehensive health care for a fixed reimbursement amount per person or per procedure.

We cannot guarantee a governmental or third-party payer will reimburse, or continue to reimburse, a customer for the cost of our products or the procedures in which our products are used. In fact, some payers have indicated that they are not willing to reimburse for certain of our products or for the procedures in which our products are used. For example, some insurance carriers have issued policies denying coverage for transcutaneous hemoglobin measurement on the grounds that the technology is investigational in the outpatient setting. Other payers are continuing to investigate our products to determine if they will provide reimbursement to our customers. While we are working with these payers to obtain reimbursement, we may not be successful. These trends could lead to pressure to reduce prices for our current and future products and could cause a decrease in the size of the market or a potential increase in competition that could have a material adverse effect on our business, financial condition and results of operations.

Our customers may reduce, delay or cancel purchases due to a variety of factors, such as lower hospital census levels or third-party guidelines, or may require that we reduce the price of our products, which could adversely affect our business, financial condition and results of operations.

Our customers are facing growing levels of uncertainties, such as lower overall hospital census for paying patients and the impact of that lower census on hospital budgets. In addition, although not yet fully understood, the impact of the Patient Protection and Affordable Care Act may force hospitals to reevaluate their entire cost structure, including the amount of capital they allocate to medical device technologies and products. Such developments could have a significant negative impact on our OEM customers, that, due to their traditionally larger capital equipment sales model, could see declines in purchases from their hospital customers. This, in turn, could reduce our board sales to our OEM customers. In addition, certain of our products, including our rainbow® measurements such as carbon monoxide, methemoglobin and hemoglobin, that are sold with upfront license fees and more complex and expensive sensors could also be impacted by hospital budget reductions.

In addition, states and other local regulatory authorities may issue guidelines regarding the appropriate scope and use of our products from time to time. For example, some of our noninvasive monitoring devices may be subject to authorization by individual states as part of Emergency Medical Services (EMS) scope of practice procedures. Although a lack of inclusion into scope of practice procedures does not prohibit usage, it may limit adoption.

Additionally, as a result of the continued consolidation in the health care industry, we may experience decreasing prices for our products due to the potential increased market pricing power of our health care provider customers. If these and other competitive forces drive down the price of our products, and we are not able to counter that pressure with cost reductions to our existing products or the introduction of new higher priced products, our product gross profit margins will decline. This, in turn, could have a material adverse effect on our business, financial condition and results of operations.

The loss of any large customer or distributor, or any cancellation or delay of a significant purchase by a large customer, could reduce our net sales and harm our operating results.

We have a concentration of OEM, distribution and direct customers. If for any reason we were to lose our ability to sell to a specific group or class of customers, or through a distributor, we could experience a significant reduction in revenue which would adversely impact our operating results. Also, we cannot provide any assurance that we will retain our current customers, groups of customers, or distributors, or that we will be able to attract and retain additional customers in the future. For the years ended January 3, 2015, December 28, 2013 and December 29, 2012, we had sales through two just-in-time distributors, which in total represented approximately 25.1%, 23.9% and 25.4%

of our total revenue, respectively. The loss of any large customer or distributor could have a material adverse effect on our business, financial condition and results of operations.

Imitation Masimo sensors and third-party medical device reprocessors that reprocess our single-patient-use sensors may harm our reputation. Also, these imitation and third-party reprocessed sensors, as well as genuine Masimo reprocessed sensors, are sold at lower prices than new Masimo sensors and could cause our revenue to decline, which may adversely affect our business, financial condition and results of operations.

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We are aware that other organizations are manufacturing and selling imitation Masimo sensors. In addition, we are aware that certain medical device reprocessors have been collecting our used single-patient-use sensors from hospitals and then reprocessing, repackaging and reselling those sensors to hospitals. These imitation and third-party reprocessed sensors are sold at lower prices than new Masimo sensors. Our experience with both these imitation sensors and third-party reprocessed sensors is that they provide inferior performance, increased sensor utilization, reduced comfort and a number of monitoring problems. Notwithstanding these limitations, and despite our customers' acknowledged preference for genuine Masimo single-patient-use adhesive sensors due to concerns relating to performance and risk of contamination, some of our customers have indicated a willingness to consider purchasing some of their sensor requirements from these imitation manufacturers and third-party reprocessors in an effort to reduce their overall operating costs. These imitation and reprocessed sensors have led and may continue to lead to confusion with our genuine Masimo products; have reduced and may continue to reduce our revenue; and, in some cases, have harmed and may continue to harm our reputation if customers conclude incorrectly that these imitation or reprocessed sensors are original Masimo sensors. In addition, we have expended a significant amount of time and expense investigating issues caused by imitation and reprocessed sensors, troubleshooting problems stemming from such sensors, educating customers about why imitation and reprocessed sensors do not perform up to our performance level and to their expectations, enforcing our proprietary rights against the imitation manufacturers and reprocessors, and enforcing our contractual rights under our customer contracts.

In response to these imitation sensors and third-party reprocessors, we offer to our customers our own Masimo reprocessed sensors, which we re-manufacture and test to ensure that they meet the same performance specifications as our new Masimo sensors. In addition, we have incorporated X-Cal™ technology into certain products to ensure our customers get the performance they expect by using genuine Masimo sensors. We believe this technology will help ensure that hospitals, clinicians and, ultimately, their patients, receive true Masimo measurement quality and performance, and will curtail some of the harm to us that results when customers experience performance and other problems with imitation and reprocessed sensors. Reprocessed sensors sold by Masimo are generally offered at a lower price and, therefore, may reduce certain customer demand for our new sensors. As a result, increased sales of genuine Masimo reprocessed sensors may result in lower revenues which could negatively impact our business, financial condition and results of operations.

From time to time we may carry out strategic initiatives that are not viewed favorably by our customers, which may reduce demand for our products.

We expect to continue to implement new technologies and take action to protect and enforce our contractual, intellectual property and other rights. For example, beginning in 2013 and continuing through 2014, we have expanded our investment in a new worldwide blood management sales force whose primary focus is to work with hospitals to identify new opportunities for our noninvasive hemoglobin measurement, SpHb®. Although we believe implementing new technologies and making these investments are, and will continue to be, in the long term best interests of Masimo and our stockholders, there are no assurances that the market will perceive their benefits or that these actions will yield favorable results for us, which may result in reduced customer demand for our products, cause our revenue to decline and have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If the patents we own or license, or our other intellectual property rights, do not adequately protect our technologies, we may lose market share to our competitors and be unable to operate our business profitably.

Our success depends significantly on our ability to protect our rights to the technologies used in our products, including Masimo SET® and licensed rainbow® technology. We rely on patent protection, trade secrets and a combination of copyright and trademark laws, as well as nondisclosure, confidentiality and other contractual arrangements, to protect our technology and rights. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or maintain any competitive advantage. In addition, we cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The U.S. Patent and Trademark Office (the PTO) may deny or require a significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with

significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO.

On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act), which includes a number of significant changes to U.S. patent law, was signed into law. The provisions of the Leahy-Smith Act include changes in the way patent applications will be prosecuted, including a transition to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, and may also affect patent litigation. Under a “first-to-file” system, a third party that files a patent application with the PTO before us could be awarded a patent covering an invention of ours even if we made the invention before it was made by the third-party. The PTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act. Many of

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the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-to-file" provisions, only became effective in March 2013. Additionally, the Leahy-Smith Act introduced procedures that may make it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications, and, as a result, our issued patents, and those that may be issued or licensed in the future, may expire or be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related technologies. Furthermore, the Leahy-Smith Act contains new statutory provisions that require the PTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on our business, the cost of prosecuting our licensed and future patent applications, our ability to obtain patents based on our licensed and future patent applications and our ability to enforce or defend our licensed or future issued patents. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our pending and future patent applications and the enforcement or defense of our issued and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

Some of our patents related to our Masimo SET® algorithm technology began to expire in March 2011. Additionally, upon expiration of other issued or licensed patents, we may lose some of our rights to exclude competitors from making, using, selling or importing products using the technology based on the expired patents. While we seek to offset potential losses relating to important expiring patents by securing additional patents on commercially desirable improvements, there can be no assurance that we will be successful in securing such additional patents, or that such additional patents will adequately offset the effect of expiring patents. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. Additionally, there is no assurance that competitors will not be able to design around our patents.

We also rely on contractual rights with the third parties that license technology to us to protect our rights in such licensed technology. In addition, we rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology.

We seek to protect our know-how and other unpatented proprietary technology with confidentiality agreements and intellectual property assignment agreements with our employees, OEM partners, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Common law trademarks provide less protection than registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S. If we fail to apply for intellectual property protection or if we cannot adequately protect our intellectual property rights in these foreign countries, our competitors may be able to compete more effectively against us, which could adversely affect our competitive position, as well as our business, financial condition and results of operations.

If third parties claim that we infringe their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling certain products.

Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage in the marketplace. We face the risk of claims that we have infringed on third parties' intellectual property rights. Searching for existing intellectual property rights may not reveal important intellectual property and our competitors

may also have filed for patent protection, which is not publicly-available information, or claimed trademark rights that have not been revealed through our availability searches. In addition, many of our employees were previously employed at other medical device companies. We may be subject to claims that our employees have disclosed, or that we have used, trade secrets or other proprietary information of our employees' former employers. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement against us, even those without merit, could:

- increase the cost of our products;
- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;

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- force us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, product candidates and technologies;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third-party's intellectual property on terms that may not be favorable or acceptable to us;
- require us to indemnify third parties pursuant to contracts in which we have agreed to provide indemnification for intellectual property infringement claims;
- divert the attention of our management and other key employees;
- result in our customers or potential customers deferring or limiting their purchase or use of the affected products impacted by the claims until the claims are resolved; and
- otherwise have a material adverse effect on our business, financial condition and results of operations.

In addition, new patents obtained by our competitors could threaten the continued commercialization of our products in the market even after they have already been introduced. Philips Electronics North America Corporation and Shenzhen Mindray Bio-Medical Electronics Co., Ltd. have each filed antitrust and patent infringement counterclaims against us, as further explained in Part I, Item 3 of this Annual Report on Form 10-K.

We believe competitors may currently be violating and may in the future violate our intellectual property rights, and we may bring additional litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert management's attention from implementing our business strategy.

We believe that the success of our business depends, in significant part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets. We were previously involved in significant litigation to protect our patent position and may be required to engage in further litigation. In 2006, we settled a costly, six-year lawsuit against Mallinckrodt, Inc., part of Tyco Healthcare (currently Covidien Ltd.), and one of its subsidiaries, Nellcor Puritan Bennett, Inc., in which we claimed that Covidien was infringing some of our pulse oximetry signal processing patents.

In February 2009, we filed a patent infringement suit against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH (collectively, Philips) related to Philips' FAST pulse oximetry technology and certain of Philips' patient monitors. In each of December 2012 and December 2013, we filed patent infringement and breach of contract suits against Mindray DS USA, Inc., Shenzhen Mindray Bio-Medical Electronics Co, Ltd., and Mindray Medical International Ltd. (collectively, Mindray). These suits are described in Part I, Item 3 of this Annual Report on Form 10-K, and Note 15 to the consolidated financial statements. Both Philips and Mindray are OEM partners of ours. There is no guarantee that we will prevail in these suits or receive any damages or other relief if we do prevail.

Our ongoing and future litigation could result in significant additional costs and further divert the attention of our management and key personnel from our business operations and the implementation of our business strategy and may not be adequate to protect our intellectual property rights.

Risks Related to Our Regulatory Environment

Our failure to obtain and maintain FDA clearances or approvals on a timely basis, or at all, would prevent us from commercializing our current or upgraded products in the United States, which could severely harm our business.

Each medical device that we wish to market in the U.S. generally must first receive 510(k) clearance from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA) by filing a 510(k) pre-market notification, receive clearance through the de novo review process, or obtain pre-market approval by submitting a pre-market approval (PMA) application. Even if regulatory clearance or approval of a product is granted, the clearance or approval may be subject to limitations on the indicated uses for which the product may be marketed. We cannot guarantee that the FDA will grant 510(k) clearance on a timely basis, if at all, for new products or uses that we propose for Masimo SET® or licensed rainbow® technology. The FDA's 510(k) clearance process of our products and uses typically takes between four to twelve months, and may take longer. However, over the past two years, we have experienced a significantly longer 510(k) clearance review process. Our more recent experience and interactions with the FDA, along with information we have received from other medical device manufacturers, suggests that, in some cases, the FDA is requiring applicants to provide much more or different information and data for 510(k) clearance than it had previously; and that the FDA may not rely on approaches that it had previously accepted to support 510(k) clearance,

thereby leading to more review cycles or to decisions that may not be substantially the same as previous equivalent decisions. As a result, we have experienced lengthier FDA 510(k) review periods over the past two years, which has delayed the 510(k) clearance process for our products and uses over this period compared to prior periods.

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In connection with our most recent FDA 510(k) filing for certain improvements to our Pronto-7® product, the FDA expressed concerns and requested additional information regarding the methods we used to validate the SpHb® parameter. We responded to the FDA's request for additional information on March 25, 2014. The FDA responded that the remaining issues would not likely be resolved in the time remaining, so we voluntarily withdrew the application on March 31, 2014. We have since had further discussions with the FDA and believe we have a better understanding of the FDA's expectations on validation methodologies for future 510(k) filings for Pronto-7®. We intend to work with the FDA to address whatever remaining concerns the agency has, but we cannot be sure we will be able to resolve those concerns.

To date, the FDA has regulated pulse oximeters incorporating Masimo SET® and licensed rainbow® technology, patient monitor devices, sensors, cables and other products under the 510(k) process. Although 510(k) clearances have been obtained for such products, if substantial safety or effectiveness problems develop with our devices, we would need to recall our devices. Furthermore, our new products or significantly modified marketed products could be denied 510(k) clearance and be required to undergo the more burdensome PMA process. The process of obtaining PMA is much more costly, lengthy and uncertain than the process for obtaining 510(k) clearance and generally takes one to three years, but may be longer.

We recently launched iSpO$_2$®, a non-medical use pulse oximeter intended for sports and aviation use. We are marketing this product in accordance with the FDA's current policy and enforcement discretion which indicates that pulse oximeters that are not intended for medical purposes can be marketed directly to consumers without first obtaining 510(k) clearance. We cannot assure you that the FDA will not change its policy regarding the regulation of these products. If the FDA changes its policy, we may be required to seek 510(k) clearance to market this pulse oximeter. We also may be required to cease marketing and/or recall the product until we obtain a new 510(k) clearance.

The failure of our OEM partners to obtain required FDA clearances or approvals for products that incorporate our technologies could have a negative impact on our revenue.

Our OEM partners are required to obtain their own FDA clearances for products incorporating Masimo SET® and licensed rainbow® technology to market these products in the U.S. We cannot guarantee that the FDA clearances we have obtained will make it easier for our OEM partners to obtain clearances of products incorporating these technologies, or that the FDA will ever grant clearances on a timely basis, if at all, for any future product incorporating Masimo SET® and licensed rainbow® technology that our OEM partners propose to market.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Our products, along with the manufacturing processes, labeling and promotional activities for our products, are subject to continual review and periodic inspections by the FDA and other regulatory bodies. Among other requirements, we and our suppliers are required to comply with the FDA's Quality System Regulation (QSR), which covers the methods and documentation of the design, control testing, production, component suppliers control, quality assurance, complaint handling, labeling control, packaging, storage and shipping of our products. The FDA enforces the FDA's QSR through announced and unannounced inspections. We are also subject to similar state requirements and licenses.

In 2013, the FDA inspected our facility in Irvine, California and issued an FDA Form 483 listing observations the investigator believed may constitute violations of statutes or regulations administered by the FDA, including observations relating to complaint handling, medical device reporting and corrective and preventative action (CAPA) procedures. In 2014, the FDA also inspected our facility in Mexicali, Mexico and issued a Form 483 listing observations relating to our CAPA procedures, documentation practices associated with our device history records and procedures for employee training. We submitted responses to both Form 483s. In August 2014, we received from a final inspection report the FDA closing out the Mexicali inspection and a warning letter (the Warning Letter) related to the Irvine inspection. We submitted a response (Response Letter) to the Warning Letter on September 5, 2014 and held a regulatory meeting with the FDA on September 19, 2014. At the meeting, in addition to discussing our Response Letter, the FDA raised issues beyond the scope of the Warning Letter in the areas of Good Manufacturing Practices, quality, bioresearch monitoring and labeling/promotion. We have been in communication with the FDA

since the meeting and are working to resolve the issues raised by the FDA. We do not know what further actions, if any, the FDA will take in connection with these issues.

In December 2014, the California Department of Public Health, Food and Drug Branch (Food and Drug Branch) conducted an inspection of our facility in Irvine, California, and issued a Notice of Violation listing observations relating to complaint handling and CAPA procedures that the investigator believed may constitute violations of California statutes or regulations. We responded to the Notice of Violation in January 2015 and are working to resolve the issues raised by the Food and Drug Branch. We do not know what further actions, if any, the Food and Drug Branch will take in connection with these issues.

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Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies or failure to adequately respond to any FDA Form 483 observations could result in, among other things, any of the following items:

- warning letters or untitled letters issued by the FDA;
- fines, civil penalties, in rem forfeiture proceedings, injunctions and criminal prosecution;
- import alerts;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawal or suspension of clearance or approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;
- product recall or seizure;
- orders for physician notification or device repair, replacement or refund;
- interruption of production or inability to export to certain foreign countries; and
- operating restrictions.

If any of these items were to occur, it would harm our reputation and adversely affect our business, financial condition and results of operations.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We currently market and intend to continue to market our products internationally. Outside of the U.S., we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The regulatory registration/licensing process varies among international jurisdictions and may require additional testing. The time required for international registration of new products may differ from that required for obtaining FDA clearance. The foreign registration/licensing process may include all of the risks associated with obtaining FDA clearance in addition to other risks. We may not obtain foreign regulatory registration/licensing on a timely basis, if at all. FDA clearance does not ensure new product registration/licensing by foreign regulatory authorities. Clearance by one foreign regulatory authority does not ensure clearance by any other foreign regulatory authority or by the FDA. If we fail to receive necessary approvals to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, financial condition and results of operations could be adversely affected.

Modifications to our marketed devices may require new regulatory clearances or premarket approvals, or may require us to cease marketing or recall the modified devices until clearances or approvals are obtained.

We have made modifications to our devices in the past and we may make additional modifications in the future. Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly PMA approval. We may not be able to obtain such clearances or approvals in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business, financial condition and results of operations. If the FDA disagrees with our conclusion and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could have an adverse effect on our business, financial condition and results of operations.

Federal regulatory reforms may make it difficult to maintain or attain approval to develop and commercialize our products and technologies.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. However, any future regulatory changes could make it more difficult for us to maintain or attain approval to develop and commercialize our products and technologies.

If our products cause or contribute to a death or serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions, including recall of our products.

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Under the FDA medical device reporting regulations, we are required to report to the FDA any incident in which a product of ours may have caused or contributed to a death or serious injury or in which a product of ours malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union (EU) markets are legally required to report any serious or potentially serious incidents involving devices produced or sold by the manufacturer to the relevant authority in those jurisdictions where any such incident occurred.

The FDA and similar foreign governmental authorities have the authority to require the recall of our commercialized products in the event of material deficiencies or defects in, for example, design, labeling or manufacture. In the case of the FDA, the authority to require a recall generally must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found or they become aware of a safety issue involving a marketed product. A government-mandated or voluntary recall by us or by one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. We may initiate certain voluntary recalls involving our products in the future. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations.

Since our inception, we have initiated eleven field actions related to our products, none of which were material to our operating results. All field actions involving “reportable events” were reported to the FDA and other foreign regulatory agencies within the appropriate regulatory timeframes. Because of our dependence upon patient and physician perceptions, any negative publicity associated with these or any future voluntary recalls could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Off-label promotion of our products or promotional claims deemed false or misleading could subject us to substantial penalties.

We must have adequate substantiation for our product performance claims. Obtaining 510(k) clearance only permits us to promote our products for the uses specifically cleared by the FDA. Use of a device outside its cleared or approved indications is known as “off-label” use. Physicians may use our products off-label because the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. Although we may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. If the FDA determines that we or our OEM partners have promoted our products for off-label use or have made false or misleading or inadequately substantiated promotional claims, it could request that we or our OEM partners modify those promotional materials or take regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our promotional or training materials to constitute promotion of an uncleared or unapproved use, which could also result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In either event, in addition to potential extensive fines and penalties, our reputation could be damaged and adoption of our products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management’s attention and result in substantial damage awards against us.

We may be subject to or otherwise affected by federal and state health care laws, including fraud and abuse and health information privacy and security laws, and could face substantial penalties if we are unable to fully comply with these laws.

Although we do not provide health care services or receive payments directly from Medicare, Medicaid or other third-party payers for our products or the procedures in which our products are used, health care regulation by federal and state governments will impact our business. Health care fraud and abuse laws potentially applicable to our operations include, but are not limited to:

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the Federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the purchase, order or recommendation of an item or service reimbursable under a federal health care program (such as the Medicare or Medicaid programs);

- federal false claims laws which prohibit, among other things, knowingly and willfully presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent;

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- the provisions of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services; and
- state laws analogous to each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental third-party payers, including commercial insurers, and state laws governing the privacy of certain patient identifiable health information (PHI).

Federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payers that are false or fraudulent. For example, the federal Civil False Claims Act imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and Medicare. Some suits filed under the Civil False Claims Act, known as "qui tam" actions, can be brought by a private individual, referred to as a "whistleblower" or "relator," on behalf of the government, and such individuals may share in any amounts paid by the entity to the government in fines or settlement. Such complaints are filed under seal and remain sealed until the applicable court orders otherwise. In recent years, the number of suits brought by private individuals has increased dramatically. Manufacturers, like us, can be held liable under false claims laws, even if they do not submit claims to the government, if they are found to have caused medical care providers to have submitted claims to the government for payment for a service or the use of a device that is not properly covered for government reimbursement. A number of states also have false claims laws, and some of these laws may apply to claims for items or services reimbursed under Medicaid and/or commercial insurance. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs and imprisonment. In particular, when an entity is determined to have violated the federal Civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim.

In April 2011, we were informed by the United States Attorney's Office for the Central District of California, Civil Division, that a qui tam complaint had been filed against us in the U.S. District Court for the Central District of California by three of our former physician office sales representatives. The qui tam complaint alleged, among other things, that our noninvasive hemoglobin products failed to meet their accuracy specifications, and that we misled the FDA and customers regarding the accuracy of the products. In November 2011, the United States declined to intervene in the case, and in October 2013, the District Court granted summary judgment in our favor. The former sales representatives have appealed the District Court's decision. We are unable to predict the final outcome of the qui tam action. A reversal of the District Court's decision in this matter could have a material adverse effect on our financial condition or results of operations in the future.

In the third quarter of 2013, we were notified that the FDA and the United States Attorney's Office for the Central District of California, Criminal Division, are investigating the allegations regarding our noninvasive hemoglobin products. In the second quarter of 2014, we received grand jury subpoenas requesting documents pertaining to, among other things, the testing, marketing and sales of our Pronto® and Pronto-7® products. We and several of our executives, including our CEO, have signed agreements tolling the statute of limitations as to any charges that may be brought. We are fully cooperating with the investigation but cannot predict its outcome. The investigation may be a distraction to management and cause us to incur significant expenses, and could result in criminal, civil or regulatory proceedings against us, our officers and/or other employees.

We have certain arrangements with hospitals that may be affected by health care fraud and abuse laws. For instance, under our standard customer arrangements, we provide hospitals with free pulse oximetry monitoring devices in exchange for their agreement to purchase future pulse oximetry sensor requirements from us. In addition, we occasionally provide our customers with rebates in connection with their annual purchases. While we believe that these arrangements are structured such that we are currently in compliance with applicable federal and state health care laws, one or more of these arrangements may not meet the Federal Anti-Kickback Statute's safe harbor requirements, which may result in increased scrutiny by government authorities that are responsible for enforcing these laws.

There can be no assurance that we will not be found to be in violation of any of such laws or other similar governmental regulations to which we are directly or indirectly subject and, as a result, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion of our products from reimbursement under Medicare, Medicaid and other federal health care programs, and the curtailment or restructuring of our operations. Any penalties could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Further, we are required to comply with federal and state laws governing the transmission, security and privacy of individually identifiable PHI that we may obtain or have access to in connection with the manufacture and sale of our products. We may be

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required to make costly system modifications to comply with the HIPAA privacy and security requirements. In addition, if we do not properly comply with existing or new laws and regulations related to the protection of health information, we could be subject to criminal or civil sanctions, the potential enforcement of which is greater as a result of the Health Information Technology of Economic and Clinical Health Act.

Numerous other federal and state laws protect the confidentiality of PHI, including state medical information privacy laws, state social security number protection laws and state and federal consumer protection laws. In some cases, more protective state privacy and security laws are not preempted by HIPAA and may be subject to interpretation by various governmental authorities and courts, resulting in potentially complex compliance issues for us and our customers.

In addition, state and federal human subject protection laws apply to our receipt of individually identifiable PHI in connection with clinical research. These laws could create liability for us if one of our research collaborators uses or discloses research subject information without authorization and in violation of applicable laws.

We may incur significant costs and potential liabilities in defending our new products and technologies in various legal and other proceedings.

Our breakthrough noninvasive measurement technologies are new and not yet widely understood or accepted. These new technologies may become the subject of various legal and other proceedings. We may incur significant costs in explaining and defending our new products and technologies in these proceedings, often to non-technical audiences. The outcomes of these proceedings are unpredictable and may result in significant liabilities, regardless of the merits of the claims made in the proceedings.

Legislative and regulatory changes in the health care industry could have a negative impact on our financial performance. Furthermore, our business, financial condition, results of operations and cash flows could be significantly and adversely affected by health care reform legislation in the U.S. or if reform programs are adopted in our key markets.

Changes in the health care industry in the U.S. and elsewhere could adversely affect the demand for our products as well as the way in which we conduct our business. In recent years, President Obama signed health care reform legislation into law that required most individuals to have health insurance, established new regulations on health plans, created insurance pooling mechanisms and reduced Medicare spending on services provided by hospitals and other providers. Beginning on January 1, 2013, this legislation also imposed significant new taxes on medical device makers in the form of a 2.3% excise tax on U.S. medical device sales, as well as related compliance and reporting obligations. For the years ended January 3, 2015 and December 28, 2013, we recorded medical device excise taxes of approximately $6.6 million and $6.3 million, respectively.

Moreover, the Physician Payment Sunshine Act (the Sunshine Act), which was enacted by Congress as part of the Patient Protection and Affordable Care Act on March 23, 2010, requires medical device companies to track and publicly report, with limited exceptions, all payments and transfers of value to physicians and teaching hospitals in the U.S. Implementing regulations for these tracking and reporting obligations were finalized in 2013, and companies are now required to track payments made since August 1, 2013. In addition, commencing March 31, 2014, medical device companies are also required to report payments to the government on an annual basis. If we fail to comply with the data collection and reporting obligations imposed by the Sunshine Act, we may be subject to substantial civil monetary penalties.

In general, an expansion in the government’s role in the U.S. health care industry may lower reimbursements for our products, reduce demand for innovative products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly in a material manner. In addition, as a result of the continued focus on health care reform, there is risk that Congress may implement changes in laws and regulations governing health care service providers, including measures to control costs or reductions in reimbursement levels. We cannot predict the effect any future legislation or regulation will have on us or what health care initiatives, if any, will be implemented at the state level. Furthermore, many private payers look to Medicare’s coverage and reimbursement policies in setting their coverage policies and reimbursement amounts such that federal reforms could influence the private sector as well. Finally, many states also may attempt to reform their Medicaid programs such that either coverage for certain items or services may be narrowed or reimbursement for them could be reduced. These health care reforms may

adversely affect our business.

Consistent with or in addition to Congressional or state reforms, CMS, the federal agency that administers the Medicare and Medicaid programs, could change its current policies that affect coverage and reimbursement for our products. CMS determined in 2007 that certain uses of pulse oximetry monitoring are eligible for separate Medicare payment in the hospital outpatient setting when no separately payable hospital outpatient services are reported on the same date of service. Each year, however, CMS re-examines the reimbursement rates for hospital inpatient and outpatient and physician office settings and could either increase or decrease the reimbursement rate for procedures utilizing our products. We are unable to predict when legislation or regulation that affects our business may be proposed or enacted in the future or what effect any such legislation or

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regulation would have on our business. Any such legislation, regulation or policies that affect the coverage and reimbursement of our current or future products, or the procedures utilizing our current or future products, could cause our sales to decrease and our revenue to decline.

Our success in international markets also may depend upon the eligibility of reimbursement for our products through government-sponsored health care payment systems and other third-party payers. Outside of the U.S., reimbursement systems vary by country. These systems are often subject to the same pressures to curb rising health care costs and control health care expenditures as those in the U.S. In addition, as economies of emerging markets develop, these countries may implement changes in their health care delivery and payment systems. If adequate levels of reimbursement from third-party payers outside of the U.S. are not obtained, sales of our products outside of the U.S. may be adversely affected.

In addition, the requirements or restrictions imposed on us or our products may change, either as a result of administratively adopted policies or regulations or as a result of the enactment of new laws. Our medical devices and business activities are subject to rigorous regulation by the FDA and other federal, state and international governmental authorities. These authorities and members of Congress have been increasing their scrutiny over the medical device industry. In recent years, the U.S. Congress, Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and the Department of Defense have issued subpoenas and other requests for information to medical device manufacturers, primarily related to financial arrangements with health care providers, regulatory compliance and product promotional practices. We anticipate that the government will continue to scrutinize our industry closely, and any new regulations or statutory provisions could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance.

Risks Related to Our Business and Operations

We may experience conflicts of interest with Cercacor with respect to business opportunities and other matters.

Prior to our initial public offering in August 2007, our stockholders owned 99% of the outstanding shares of capital stock of Cercacor and we believe that, as of January 3, 2015, a number of our stockholders, including certain of our directors and executive officers, continued to own shares of Cercacor stock. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Cercacor. Jack Lasersohn, a member of our board of directors, also serves on the board of directors of Cercacor.

Due to the interrelated nature of Cercacor with us, conflicts of interest will arise with respect to transactions involving business dealings between us and Cercacor, potential acquisitions of businesses or products, development of products and technology, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Cercacor. We cannot guarantee that any conflict of interest will be resolved in our favor, or that, with respect to our transactions with Cercacor, we will negotiate terms that are as favorable to us as if such transactions were with another third-party.

We will be required to pay Cercacor for the right to use certain improvements to Masimo SET® that we develop.

Under the Cross-Licensing Agreement, if we develop improvements to Masimo SET® for the noninvasive monitoring of non-vital signs parameters, we would be required to assign these developments to Cercacor and then license the technology back from Cercacor in consideration for royalty obligations to Cercacor. Therefore, any improvement to this technology would be treated as if it had been developed exclusively by Cercacor. In addition, we will not be reimbursed by Cercacor for our expenses relating to the development of any such technology. As a result of these terms, we may not generate any revenue from the further development of Masimo SET® for the monitoring of non-vital signs parameters, which could adversely affect our business, financial condition and results of operations.

We are required to pay royalties to Cercacor for all products sold that contain certain rainbow® technologies, including certain annual minimum royalty payments, and this may impact our reported gross margins if we discontinue consolidating Cercacor within our financial statements.

The Cross-Licensing Agreement requires us to pay Cercacor a royalty for all products that we sell which include its proprietary rainbow® technology. This includes handheld, table-top and multiparameter products that incorporate licensed rainbow® technology. Beginning in 2009, for hospital contracts where we place equipment and enter into a sensor contract, we pay a royalty to Cercacor on the total sensor contract revenue based on the ratio of rainbow®

enabled devices to total devices. The agreement also requires that we make available to Cercacor, at its request, up to 10% of our annual board and sensor production volume at our total manufactured cost. In addition to these specific royalty and product obligations, our Cross-Licensing Agreement requires that we pay Cercacor specific annual minimum royalty payments.

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Currently, we are required to consolidate Cercacor within our financial statements. Accordingly, the royalties that we owe to Cercacor are eliminated in our condensed consolidated financial statements presented within this Annual Report on Form 10-K and our other periodic reports, and the gross profit margins reported in our consolidated financial results do not include the royalty expense that we pay to Cercacor. We are also obligated to include, and have included, Cercacor's engineering and administrative expenses in our reported engineering and administrative expenses. If our financial statements were not consolidated with Cercacor, our reported cost of goods sold would increase and our reported engineering and administrative expenses would decrease. In the future, depending upon the success of rainbow® products and the royalties earned by Cercacor on those revenues, it is possible that the royalty expense will grow at a rate higher than the growth of engineering and administrative expenses. Should this occur, and if we also were no longer required to consolidate Cercacor's financial results within our financial statements, our unconsolidated cost of goods sold could grow at a faster rate than our unconsolidated engineering expenses.

Despite describing and reflecting this Cercacor consolidation requirement within our financial statements, failure to understand or appreciate the significance of our consolidation of Cercacor's financial statements may lead current and prospective investors to draw inaccurate perspectives and conclusions regarding our historical and future financial condition and results of operations.

In the event that the Cross-Licensing Agreement is terminated for any reason, or Cercacor grants a license to rainbow® technology to a third-party, our business would be materially and adversely affected.

Cercacor owns all of the proprietary rights to certain rainbow® technology developed with our proprietary Masimo SET® for products intended to be used in the Cercacor Market, and all rights for any non-vital signs measurement for which we do not exercise an option pursuant to the Cross-Licensing Agreement. In addition, Cercacor has the right to terminate the Cross-Licensing Agreement or grant licenses covering rainbow® technology to third parties if we breach certain terms of the agreement, including any failure to meet our minimum royalty payment obligations or failure to use commercially reasonable efforts to develop or market products incorporating licensed rainbow® technology. If we lose our exclusive license to rainbow® technology, we would lose the ability to prevent others from making, using, selling or importing products using rainbow® technology in our market. As a result, we would likely be subject to increased competition within our market, and Cercacor or competitors who obtain a license to rainbow® technology from Cercacor would be able to offer related products.

We may not be able to commercialize our products incorporating licensed rainbow® technology cost-effectively or successfully.

As a result of the royalties that we must pay to Cercacor, it is generally more expensive for us to make products that incorporate licensed rainbow® technology than products that do not include licensed rainbow® technology. We cannot assure you that we will be able to sell products incorporating licensed rainbow® technology at a price the market is willing to accept. If we cannot commercialize our products incorporating licensed rainbow® technology successfully, we may not be able to generate sufficient product revenue from these products to be profitable, which could adversely affect our business, financial condition and results of operations.

Rights provided to Cercacor in the Cross-Licensing Agreement may impede a change in control of our Company.

Under the Cross-Licensing Agreement, a change in control includes the resignation or termination of Joe Kiani from his position of Chief Executive Officer of either Masimo or Cercacor. A change in control also includes other customary events such as the sale or merger of the Company or Cercacor to a non-affiliated third party or the acquisition of 50% or more of the voting power of the Company or Cercacor by a non-affiliated third party. In the event we undergo a change in control, we are required to immediately pay a $2.5 million fee to exercise an option to license technology developed by Cercacor for use in blood glucose monitoring. Additionally, our per product royalties payable to Cercacor will become subject to specified minimums, and the minimum aggregate annual royalties for licensed rainbow® measurements payable to Cercacor related to carbon monoxide, methemoglobin, fractional arterial oxygen saturation, hemoglobin and blood glucose will increase to $15.0 million, plus up to $2.0 million for other rainbow® measurements. Also, if the surviving or acquiring entity ceases to use "Masimo" as a company name and trademark following a change in control, all rights to the "Masimo" trademark will automatically be assigned to Cercacor. This could delay or discourage transactions involving an actual or potential change in control of us, including transactions in which our stockholders might otherwise receive a premium for their shares over our

then-current trading price. In addition, our requirement to assign all future improvements for non-vital signs to Cercacor could impede a change in control of our company.

We may experience significant fluctuations in our quarterly results in the future, we may not maintain our current levels of profitability, and changes to existing accounting pronouncements or taxation rules may affect how we conduct our business and our results of operations.

Our operating results have fluctuated in the past and are likely to fluctuate in the future. We may experience fluctuations in our quarterly results of operations as a result of:

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- delays or interruptions in manufacturing and shipping of our products;
- varying demand for and market acceptance of our technologies and products;
- delayed acceptance of our new products, negatively impacting the carrying value of our inventory;
- design, technology or other market changes that could negatively impact the carrying value of our inventory;
- the effect of competing technological and market developments resulting in lower selling prices or significant promotional costs;
- changes in the timing of product orders and the volume of sales to our OEM partners;
- actions taken by GPOs;
- delays in hospital conversions to our products and declines in hospital patient census;
- our legal expenses, particularly those related to litigation matters;
- changes in our product or customer mix;
- movements in foreign currency exchange rates;
- market seasonality of our sales due to quarterly fluctuations in hospital and other alternative care admissions;
- our ability to renew existing long-term sensor contract commitments;
- changes in the total dollar amount of annual contract renewal activities;
- changes in the mix and, therefore, the related costs of products that we supply at no upfront costs to our customers as part of their long-term sensor commitments;
- changes in hospital and other alternative care admission levels;
- our inability to efficiently scale operations and establish processes to accommodate business growth;
- unanticipated delays or problems in the introduction of new products, including delays in obtaining clearance or approval from the FDA;
- high levels of returns and repairs; and
- change in reimbursement rates for SpHb®, SpCO® and SpMet® parameters.

In addition, a change in accounting pronouncements or taxation rules or practices, or the interpretation of them by the SEC or other regulatory bodies, can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements or taxation rules and varying interpretations of accounting pronouncements or taxation practice have occurred and may occur in the future. Changes to existing rules, the adoption of new rules, changes in tax laws, or the expiration of existing favorable tax holidays may adversely affect our reported financial results or the way we conduct our business.

If our operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. Our expense levels are based, in part, on our expectations regarding future revenue levels and are relatively fixed in the short term. As a result, if our revenue for a particular period was below our expectations, we would not be able to proportionately reduce our operating expenses for that period. Any revenue shortfall would have a disproportionately negative effect on our operating results for the period. Due to these and other factors, you should not rely on our results for any one quarter as an indication of our future performance.

Our results of operations could vary as a result of the methods, estimates and judgments that we use in applying our accounting policies.

The methods, estimates and judgments that we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates and judgments are, by their nature, subject to substantial risks, uncertainties and assumptions, and factors may arise over time that lead us to change our methods, estimates and judgments. Changes in those methods, estimates and judgments could significantly affect our results of operations. See “Critical Accounting Estimates” contained in Part II, Item 7 of this Annual Report on Form 10-K.

If we lose the services of our key personnel, or if we are unable to attract and retain other key personnel, we may not be able to manage our operations or meet our growth objectives.

We are highly dependent on our senior management, especially Joe Kiani, our Chief Executive Officer, and other key officers. We are also heavily dependent on our engineers and field sales team, including sales representatives and clinical specialists. Our success will depend on our ability to retain our current management, engineers and field sales team, and, in order to manage current operations and growth effectively, to attract and retain qualified personnel in the future, including scientists, clinicians,

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engineers and other highly skilled personnel. As competition for senior management, engineers and field sales personnel is intense, we may not be able to retain our personnel. In addition, some of our key personnel hold stock options with an exercise price that is greater than our recent closing prices, which may minimize the retention value of these options. The loss of the services of members of our key personnel, or the inability to attract and retain qualified personnel in the future, could prevent the implementation and completion of our objectives, including the development and introduction of our products. In general, our key personnel may terminate their employment at any time and for any reason without notice.

Existing or future acquisitions of businesses could negatively affect our business, financial condition and results of operations if we fail to integrate the acquired businesses successfully into our existing operations or if we discover previously undisclosed liabilities.

We have acquired six businesses since our inception and we may acquire additional businesses in the future. Successful acquisitions depend upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. Even if we complete acquisitions, we may experience:

- difficulties in integrating any acquired companies, personnel, products and other assets into our existing business;
- delays in realizing the benefits of the acquired company, products or other assets;
- diversion of our management's time and attention from other business concerns;
- limited or no direct prior experience in new markets or countries we may enter;
- higher costs of integration than we anticipated;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions; and
- changes in the overall financial model as certain acquired companies may have a different revenue, gross profit margin or operating expense profile.

In addition, an acquisition could materially impair our operating results by causing us to incur debt or requiring us to amortize acquisition expenses and acquired assets. We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance and product liabilities that we did not uncover prior to our acquisition of such businesses, which could result in us becoming subject to penalties or other liabilities. Any difficulties in the integration of acquired businesses or unexpected penalties or liabilities in connection with such businesses could have a material adverse effect on our business, financial condition and results of operations.

The risks inherent in operating internationally and the risks of selling and shipping our products and of purchasing our components and products internationally may adversely impact our business, financial condition and results of operations.

We derive a portion of our net sales from international operations. In the years ended January 3, 2015, December 28, 2013 and December 29, 2012 approximately 31.7%, 30.1%, and 29.5%, respectively, of our product revenue was derived from our international operations. In addition, we purchase a portion of our raw materials and components on the international market. The sale and shipping of our products across international borders, as well as the purchase of materials and components from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and we would be exposed to potentially significant penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, manufacturing and sales activities. Any material decrease in our international sales would adversely affect our business, financial condition and results of operations.

In addition, our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include, but are not limited to:

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- a shortage of high-quality sales people and distributors;
-

loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;

- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;

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- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- pricing pressure that we may experience internationally;
- changes in foreign currency exchange rates;
- laws and business practices favoring local companies;
- political instability and actual or anticipated military or political conflicts;
- financial and civil unrest worldwide;
- longer payment cycles; and
- difficulties in enforcing or defending intellectual property rights.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from promising or making improper payments to non-U.S. officials for the purpose of obtaining an advantage to secure or retain business. Because of the predominance of government-sponsored health care systems around the world, many of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could subject us to cash and non-cash penalties, disrupt our operations, involve significant management distraction and result in a material adverse effect on our business, financial condition and results of operations.

Our operations may be adversely impacted by our exposure to risks related to foreign currency exchange rates.

We market our products in certain foreign markets through our subsidiaries and other international distributors. The related sales agreements may provide for payments in a foreign currency. While a majority of our sales are transacted in U.S. Dollars, some of our sales agreements with foreign customers provide for payment in currencies other than the U.S. Dollar. These foreign currency revenues, when converted into U.S. Dollars, can vary depending on average exchange rates during a respective period. For example, during the fiscal year ended January 3, 2015, we estimate that the strengthening of the U.S. Dollar, relative to other foreign currencies, negatively impacted our foreign currency revenues by $4.3 million, of which approximately $3.4 million occurred during the fourth fiscal quarter. Similarly, certain of our foreign sales support subsidiaries transact business in their respective country's local currency, which is also their functional currency. As a result, expenses of these foreign subsidiaries when converted into U.S. Dollars can vary depending on average monthly exchange rates during a respective period. We are also exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables and payables. When converted to U.S. Dollars, these receivables and payables can vary depending on the monthly exchange rates at the end of the period. In addition, certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses based on the currency underlying such intercompany transactions. Accordingly, our operating results are subject to fluctuations in foreign currency exchange rates.

The balance sheets of our foreign subsidiaries whose functional currency is not the U.S. Dollar are translated into U.S. Dollars at the rate of exchange at the balance sheet date and the statements of comprehensive income and cash flows are translated into U.S. Dollars using the average monthly exchange rate during the period. Any foreign exchange gain or loss as a result of translating the balance sheets of our foreign subsidiaries whose functional currency is not the U.S. Dollar is included in equity as a component of accumulated other comprehensive income (loss).

We currently do not hedge our foreign currency exchange rate risk. Should we decide in the future to hedge such exchange rate risk by entering into forward contracts, these contracts may not mitigate the potential adverse impact on our financial results due to the variability of timing and amount of payments under these contracts. In addition, our failure to sufficiently hedge, forecast or otherwise manage such foreign currency risks properly could have a material adverse effect on our business, financial condition and results of operations.

We currently manufacture our products at several locations and any disruption to or expansion of our manufacturing operations could adversely affect our business, financial condition and results of operations.

We rely on our manufacturing facilities in Mexicali, Mexico; Irvine, California; Hudson, New Hampshire; and Danderyd, Sweden. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial time to repair. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since some of our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist or terrorist organizations, epidemics, communication failures, fire, floods and similar events. In the event that one of our facilities was affected by a natural or man-made disaster, we

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would be forced to rely on third-party manufacturers if we could not shift production to our other manufacturing facilities. Furthermore, our insurance for damage to our property and the disruption of our business from casualties may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If we are forced to seek alternative facilities, or if we voluntarily expand one or more of our manufacturing operations to new locations, we may incur additional transition costs and we may experience a disruption in the supply of our products until the new facilities are available and operating.

We also purchase materials and components from international sources. Any disruption in the supply of such materials, including transportation or port delays, could adversely impact our manufacturing operations. Disruptions may also occur as a result of local, regional and worldwide health risks. Such disruptions may include the inability to manufacture and distribute our products due to the direct effects of illness on individuals or due to constraints on supply and distribution that may result from either voluntary or government imposed restrictions.

Any disruption or delay at our manufacturing facilities, any expansion of our operations to additional locations, or any changes in market conditions could create operational hurdles and have an adverse impact on our ability to produce sufficient inventory of our products or may require us to incur additional expenses in order to produce sufficient inventory, depending on changes in product demand. Furthermore, if we are unable to meet the demand of our customers, our customers may cancel orders or purchase products from our competitors, which could adversely affect our business, financial condition and results of operations. Conversely, if product demand decreases, we may be unable to timely adjust our manufacturing cost structure, resulting in excess capacity, which would lower gross product margins. Similarly, if we are unable to forecast demand accurately, we could be required to record charges related to excess or obsolete inventory, which would also lower our gross margin.

Our suppliers may not supply us with a sufficient amount of materials and components or materials and components of adequate quality.

We depend on sole or limited source suppliers for key materials and components of our noninvasive blood constituent patient monitoring solutions, and if we are unable to obtain these components on a timely basis, we will not be able to deliver our noninvasive blood constituent patient monitoring solutions to customers. Also, we cannot guarantee that any of the materials or components that we purchase, if available at all, will be of adequate quality. From time to time, there are industry-wide shortages of several electronic components that we use in our noninvasive blood constituent patient monitoring solutions. We may experience delays in production of our products if we fail to identify alternate vendors for materials and components, or any parts supply is interrupted or reduced or there is a significant increase in production costs, each of which could adversely affect our business, financial condition and results of operations.

If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934, as amended, and Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or if we fail to maintain adequate internal control over financial reporting, our business, results of operations and financial condition and investors' confidence in us could be materially and adversely affected.

As a public company, we are required to comply with the periodic reporting obligations of the Securities Exchange Act of 1934, as amended (the Exchange Act), including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner and meet our reporting obligations in their entirety could subject us to penalties under federal securities laws and regulations of The NASDAQ Stock Market LLC, expose us to lawsuits and restrict our ability to access financing on favorable terms, or at all.

In addition, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), we are required to evaluate and provide a management report on our systems of internal control over financial reporting, and our independent registered public accounting firm is required to attest to our internal control over financial reporting. During the course of the evaluation of our internal control over financial reporting, we may identify areas requiring improvement and may be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time from other activities. In addition, if we fail to maintain the adequacy of our internal controls over financial reporting, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. Any failure

to maintain compliance with the requirements of Section 404 could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business, negatively impact the trading price of our stock, and adversely affect investors' confidence in our company and our ability to access capital markets for financing.

Changing laws and increasingly complex corporate governance and public disclosure requirements could have an adverse effect on our business and operating results.

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Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the California Transparency in Supply Chains Act and new regulations issued by the SEC and The NASDAQ Stock Market LLC, have and will create additional compliance requirements for companies such as ours. To maintain high standards of corporate governance and public disclosure, we have invested in, and intend to continue to invest in, reasonably necessary resources to comply with evolving standards.

For example, the Dodd-Frank Act includes provisions regarding “conflict minerals” (generally tin, tantalum, tungsten and gold)that are mined in the Democratic Republic of Congo and adjoining countries (the DRC region), and similar rules are under consideration in the European Union. Since certain of these conflict minerals are used in the manufacture of our products, the Dodd Frank Act provisions require us to undertake comprehensive due diligence to determine whether conflict minerals used in our products, including any portion of our products manufactured by third parties, financed or benefited armed groups in the DRC region. The rules also require us to file conflict mineral reports with the SEC annually. We have incurred, and expect to continue to incur, additional costs to comply with these rules, including costs related to determining the source of origin of conflict minerals used in our products. Given the complexity of our supply chain, we may face difficulties if our suppliers are unwilling or unable to verify the origin of all conflict minerals used in our products. Furthermore, our ongoing compliance with these rules could affect the pricing, sourcing and availability of minerals used in the manufacture of our products. We may also encounter challenges with our customers and stockholders if we are unable to certify that our products are free of conflict minerals. To maintain high standards of corporate governance and public disclosure, we have invested in, and intend to continue to invest in, reasonably necessary resources to comply with such evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

If product liability claims are brought against us, we could face substantial liability and costs.

The manufacture and sale of products using Masimo SET® and licensed rainbow® technology expose us to product liability claims and product recalls, including, but not limited to, those that may arise from unauthorized off-label use, which is use of a device in a manner outside the measurement or measurements cleared by the FDA, malfunctions, design flaws or manufacturing defects related to our products or the use of our products with incompatible components or systems. For example, on April 21, 2014, an amended putative class action complaint was filed against us alleging product liability and negligence claims in connection with pulse oximeters that we modified and provided at the request of the study investigators for use in a randomized trial at the University of Alabama. The amended complaint seeks unspecified damages, costs, interest, attorney fees and injunctive and other relief. While we believe we have good and substantial defenses to the claims, there is no guarantee that we will prevail. In addition, we cannot be certain that our product liability insurance will be sufficient to cover any or all damages or claims asserted in this case or any other product liability claims that may be brought against us in the future. Furthermore, we may not be able to obtain or maintain insurance in the future at satisfactory rates or in adequate amounts to protect us against any product liability claims. Any losses that we may suffer from product liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our technology and products, together with the corresponding diversion of the attention of our key employees, may subject us to significant damages and could adversely affect our business, financial condition and results of operations.

We may incur environmental and personal injury liabilities related to certain hazardous materials used in our operations.

Our manufacturing processes involve the use, generation and disposal of certain hazardous materials and wastes, including silicone adhesives, solder and solder paste, sealants, epoxies and various solvents such as methyl ethyl ketone, acetone and isopropyl alcohol. As a result, we are subject to stringent federal, state and local laws relating to the protection of the environment, including those governing the use, handling and disposal of hazardous materials and wastes. We may incur significant costs to comply with environmental regulations.

Products that we sell in Europe are subject to regulation in the EU markets under the Restriction of the Use of Hazardous Substances Directive (RoHS). RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated

diphenyl ethers, in EU member states. In addition, the EU's Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products. Complying with this regulation may result in significant product transition costs, including potential risk to the carrying value of the related inventory, or delays in sales of our products in the EU.

From time to time, new regulations are enacted and it is difficult to anticipate how such regulations will be implemented and enforced. We continue to evaluate the necessary steps for compliance with environmental regulations as they are enacted. Future environmental laws may significantly affect our operations by, for example, requiring our manufacturing processes to be altered or requiring us to use different types of materials in manufacturing our products. Any changes to our operations may increase our manufacturing costs, detrimentally impact the performance of our products, add greater testing lead-times for

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product introductions or have other similar effects. In our research and manufacturing activities, we use, and our employees may be exposed to, materials that are hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury to our employees or contamination from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any resulting damages and any such liability could exceed our reserves. Although we maintain general liability insurance, we do not specifically insure against environmental liabilities. If an enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action on terms favorable to us.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Our ability to effectively manage and maintain our internal business information, and to ship products to customers and invoice them on a timely basis, depends significantly on our enterprise resource planning system and other information systems. Portions of our information technology systems may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The failure of these systems to operate effectively or to integrate with other systems, or a breach in security or other unauthorized access of these systems, may also result in delays in product fulfillment and reduced efficiency of our operations, and could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, financial condition and results of operations.

Our operating results may be adversely affected by unfavorable economic and market conditions.

Many of the countries in which we operate, including the United States and several of the members of the EU, have experienced and continue to experience uncertain economic conditions. Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions. In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition.

Our Credit Agreement contains certain covenants and restrictions that may limit our flexibility in operating our business.

Our Credit Agreement with JPMorgan Chase Bank, N.A., as Administrative Agent and Lender, and Bank of America, N.A., as a Lender, contains various affirmative covenants and restrictions that limit our ability to engage in specified types of transactions, including:

- incur specified types of additional indebtedness (including guarantees or other contingent obligations);
- pay dividends on, repurchase, or make distributions in respect to our common stock or make other restricted payments, subject to specified exceptions;
- make specified investments (including loans and advances);
- sell or transfer certain assets;
- create certain liens;
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets; and
- enter into certain transactions with any of our affiliates.

In addition, under our Credit Agreement, we are required to satisfy and maintain specified financial ratios and other affirmative covenants. Our ability to meet those financial ratios and affirmative covenants could be affected by events beyond our control, and therefore, we cannot be assured that we be able to continue to satisfy these requirements. A breach of any of these ratios or covenants could result in a default under the Credit Agreement. Upon the occurrence of an event of a default, our lenders could elect to declare all amounts outstanding under our Credit Agreement to be

immediately due and payable, terminate all commitments to extend further credit and pursue legal remedies for recovery, all of which could adversely affect our business and financial condition. As of January 3, 2015, we had $125.0 million outstanding under the Credit Agreement and were in compliance with all applicable covenants.

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Risks Related to Our Stock

Our stock price may be volatile, and your investment in our stock could suffer a decline in value.

There has been significant volatility in the market price and trading volume of equity securities, which is often unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our stock. From December 29, 2013 to January 3, 2015, our closing stock price ranged from $20.69 to $31.88 per share. You may not be able to resell your shares at or above the price you paid for them due to fluctuations in the market price of our stock caused by changes in our operating performance or prospects and other factors.

In addition to the other risk factors previously discussed above, there are many other factors that we may not be able to control that could have a significant effect on our stock price. These include, but are not limited to:

- actual or anticipated fluctuations in our operating results or future prospects;
- our announcements or our competitors' announcements of new products;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidance, interpretations or principles;
- changes in our growth rates or our competitors' growth rates;
- developments regarding our patents or proprietary rights or those of our competitors;
- ongoing legal proceedings;
- our inability to raise additional capital as needed;
- concerns or allegations as to the safety or efficacy of our products;
- changes in financial markets or general economic conditions, including the effects of recession or slow economic growth in the U.S. and abroad;
- sales of stock by us or members of our management team, our board of directors or certain institutional stockholders; and
- changes in stock market analyst recommendations or earnings estimates regarding our stock, other comparable companies or our industry generally.

Concentration of ownership among our existing directors, executive officers and principal stockholders may prevent new investors from influencing significant corporate decisions.

As of January 3, 2015, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 15.7% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, these stockholders may be able to exercise significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have some control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of us, or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our stock. In addition, these stockholders could use their voting influence to maintain our existing management and directors in office or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

You could experience substantial dilution of your investment as a result of subsequent exercises of our outstanding options or the grant of future equity awards by us.

As of January 3, 2015, an aggregate of approximately 15.7 million shares of our stock were reserved for future issuance under our three equity incentive plans, approximately 10.0 million of which were subject to options outstanding as of that date at a weighted-average exercise price of $23.59 per share. To the extent outstanding options are exercised, our existing stockholders may incur dilution. We rely on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

Future resales of our stock, including those by our insiders and a few investment funds, may cause our stock price to decline.

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A significant portion of our outstanding shares are held by directors, executive officers and a few investment funds. Resale by these stockholders of a substantial number of such shares, announcements of any proposed resale of substantial amounts of our stock or the perception that substantial resales may be made, could significantly reduce the market price of our stock. Some of our directors and executive officers have entered into Rule 10b5-1 trading plans pursuant to which they have arranged to sell shares of our stock from time to time in the future. Generally, these sales require public filings. Actual or potential sales by these insiders, including those under a pre-arranged Rule 10b5-1 trading plan, could be interpreted by the market as an indication that the insider has lost confidence in our stock and reduce the market price of our stock.

We have registered and expect to continue to register shares reserved under our equity plans pursuant to a Registration Statement on Form S-8. All shares issued pursuant to a Registration Statement on Form S-8 can be freely sold in the public market upon issuance, subject to restrictions on our affiliates under Rule 144. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our stock.

Our corporate documents and Delaware law contain provisions that could discourage, delay or prevent a change in control of our company, prevent attempts to replace or remove current management and reduce the market price of our stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our amended and restated certificate of incorporation authorizes our board of directors to issue up to 5.0 million shares of "blank check" preferred stock. As a result, without further stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third-party to acquire us. In addition, our amended and restated certificate of incorporation provides for a staggered board of directors, whereby directors serve for three year terms, with one third of the directors coming up for reelection each year. A staggered board will make it more difficult for a third-party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

We are also subject to anti-takeover provisions under the Delaware General Corporation Law. Under these provisions, if anyone becomes an "interested stockholder," we may not enter into a "business combination" with that person for three years without special approval, which could discourage a third-party from making a takeover offer and could delay or prevent a change in control of us. For purposes of these provisions, an "interested stockholder" generally means someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock during the past three years, subject to certain exceptions as described in the Delaware General Corporation Law.

In addition, we have adopted a stockholder rights plan. Under our stockholder rights plan, if any person becomes the beneficial owner of 15% or more of the outstanding shares of our stock, subject to a number of exceptions set forth in the plan, all of our stockholders other than the acquiring person will receive a right to purchase shares of our stock at a price of $136.00 per share. Our stockholder rights plan could discourage a takeover attempt and make an unsolicited takeover of our company more difficult. As a result, without the approval of our board of directors, you may not have the opportunity to sell your shares to a potential acquirer of us at a premium over prevailing market prices. This could reduce the market price of our stock.

We may elect not to declare cash dividends on our stock, may elect to only pay dividends on an infrequent or irregular basis, or may elect not to make any additional stock repurchases. As a result, any return on your investment may be limited to the value of our stock. In addition, the payment of any future dividends or the repurchase of our stock might limit our ability to pursue other growth opportunities.

Our board of directors (Board) may from time to time declare, and we may pay, dividends on our outstanding shares in the manner and upon the terms and conditions provided by law. However, we may elect to retain all future earnings for the operation and expansion of our business, rather than paying cash dividends on our stock. Any payment of cash dividends on our stock will be at the discretion of our Board and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our Board. In addition, under certain circumstances, our credit agreement may limit or restrict our ability to pay

cash dividends. In the event our Board declares any dividends, there is no assurance with respect to the amount, timing or frequency of any such dividends.

In February 2013, our Board authorized a stock repurchase program, whereby we may purchase up to 6.0 million shares of our common stock over a period of up to three years. In October 2014, our Board increased the number of shares authorized for repurchase under the program by 3.0 million shares, bringing the total number of shares authorized for repurchase under the program to 9.0 million shares. As of January 3, 2015, approximately 3.5 million shares remained authorized for repurchase under the program. Any repurchase of our common stock will be at the discretion of a committee comprised of our Chief Executive Officer and Chief Financial Officer, and will depend on several factors, including, but not limited to, results of operations, capital requirements, financial conditions, available capital from operations or other sources, and the market price of our common stock. Therefore, there is no assurance with respect to the amount, price or timing of any such repurchases. We

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may elect to retain all future earnings for the operation and expansion of our business, rather than repurchasing additional outstanding shares. In addition, under certain circumstances, our Amended Credit Agreement may limit or restrict our ability to repurchase our stock. In the event we pay dividends, or make any stock repurchases in the future, our ability to finance any material expansion of our business, including through acquisitions, investments or increased capital spending, or to fund our operations, may be limited. In addition, any repurchases we may make in the future may not prove to be at optimal prices. Our Board may modify or amend our stock repurchase program at any time at its discretion without stockholder approval.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

In May 2014, we completed the purchase of an approximately 213,000 square foot property located in Irvine, California. This property currently houses our corporate headquarters and will also soon house research and development. We continue to lease various buildings in Irvine, California approximating a total of 152,000 square feet for product manufacturing, warehousing, distribution and sales support operations. These leases expire from March 2015 through November 2019. We also operate an approximate 149,000 square feet of space in Mexicali, Mexico, for the manufacture of our products under a shelter labor agreement with Industrial Vallera de Mexicali, S.A. de C.V. (IVEMSA).IVEMSA leases this manufacturing space directly from the owner of the property under an agreement that expires in December 2020.

We lease an approximate 90,000 square foot facility in Hudson, New Hampshire, which is used to manufacture advanced light emitting diodes and other advanced component-level technologies, as well as warehousing and administrative operations. This lease expires in March 2017.

Our international headquarters are located in approximately 10,000 square feet of leased office space in Neuchatel, Switzerland. This office space is focused on operations including sales, marketing, customer service and other administrative functions. In addition, we currently lease approximately 18,000 square feet of space in Montreal, Canada, which we use primarily for research, development, sales and marketing activities. We also lease approximately 13,000 square feet in Danderyd, Sweden, primarily for manufacturing, research, development and administrative functions related to our capnography and gas monitoring products. Our operations in Tokyo, Japan, are located in approximately 12,000 square feet of leased space that we use for sales, marketing, customer service, administrative and warehousing operations. We also maintain a number of small sales offices throughout Europe, Asia and Australia. We believe that our existing facilities are adequate to meet our needs and that existing needs and future growth can be accommodated by leasing alternative or additional space.

ITEM 3. LEGAL PROCEEDINGS

On February 3, 2009, we filed a patent infringement suit in the U.S. District Court for the District of Delaware against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH (collectively, Philips) related to Philips' FAST pulse oximetry technology and certain of Philips' patient monitors. On June 15, 2009, Philips answered our complaint and Philips Electronics North America Corporation filed antitrust and patent infringement counterclaims against us as well as counterclaims seeking declaratory judgments of invalidity of the patents asserted by us against Philips. On July 9, 2009, we filed our answer denying Philips' counterclaims and asserting various defenses. We also asserted counterclaims against Philips for fraud, intentional interference with prospective economic advantage and for declaratory judgments of noninfringement and invalidity with respect to the patents asserted by Philips against us. Philips later added a claim for infringement of one additional patent. Subsequently, the Court bifurcated Philips' antitrust claims and its patent misuse defense, as well as stayed the discovery phase on those claims pending trial in the patent case. In addition, we asserted additional patents in 2012, and the Court ordered that these patents and some of the originally asserted patents be tried in a second phase. On May 23, 2014, Philips filed a motion for leave to amend its answer and counterclaims to allege inequitable conduct. The Court granted Philips' motion for leave to amend. A jury trial commenced in September 2014, with respect to two of our patents and one of Philips' patents. On October 1, 2014, the jury determined that both of our patents were valid and that the damages amount for Philips' infringement was $466.8 million. The jury also determined that we did not infringe the Philips patent. Philips filed post-trial motions asking the Court to overturn the jury verdict on Masimo's patent, asking the court to adjust the

damages, and seeking a new trial. Philips has also said that it intends to appeal the verdict. The Court held a bench trial on the remaining equitable defenses raised by Philips and is scheduled to hear oral arguments on the post-trial motions in February 2015. The trial schedule for the patents in the second phase has not yet been set. We believe that we have good and substantial defenses to the antitrust and patent infringement claims asserted by Philips. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

On December 21, 2012, we filed suit against Mindray DS USA, Inc. and Shenzhen Mindray Bio-Medical Electronics Co, Ltd. (Shenzhen Mindray) in the U.S. District Court for the Central District of California. The complaint alleges patent infringement,

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breach of contract and other claims. Mindray DS USA, Inc. was dismissed from the case based on venue. On June 3, 2013, Shenzhen Mindray answered our complaint and filed antitrust and related counterclaims against us, as well as counterclaims seeking declaratory judgments of invalidity and non-infringement of the patents asserted by us against Shenzhen Mindray. On June 24, 2013, we filed our answer denying Shenzhen Mindray's counterclaims and asserting various defenses. On July 17, 2013, the Court granted Shenzhen Mindray's motion to dismiss the patent claims without prejudice to allow us to amend the complaint to provide additional detail supporting Shenzhen Mindray's direct and indirect infringement of our patents. On the same day, the Court denied Shenzhen Mindray's motion to dismiss our non-patent claims. On August 5, 2013, we filed our first amended complaint. On August 21, 2013, Shenzhen Mindray answered our complaint and reasserted the counterclaims it asserted on June 3, 2013, as well as two additional counterclaims alleging patent infringement. On September 16, 2013, we filed our answer denying Shenzhen Mindray's counterclaims and asserting various defenses. On October 31, 2013, the Court issued a scheduling order setting a trial date of November 4, 2014. On December 10, 2013, Shenzhen Mindray filed a second amended answer and counterclaims, including a new counterclaim for tortious interference. On January 2, 2014, we filed a motion for judgment on the pleadings as to Shenzhen Mindray's antitrust counterclaims and inequitable conduct counterclaims and defenses. The Court granted judgment on the pleadings with leave to amend. On March 27, 2014, Shenzhen Mindray filed a third amended answer and counterclaims. On April 10, 2014, Shenzhen Mindray filed a fourth amended answer and counterclaims. On May 5, 2014, Shenzhen Mindray filed a partial motion for summary judgment of no patent infringement, which the Court denied on June 19, 2014. On May 19, 2014, Shenzhen Mindray filed a motion for judgment on the pleadings contending that Masimo International SARL (our subsidiary), not Masimo Corporation, has standing to assert its claims relating to breach of contract. We opposed this motion and filed a motion to add Masimo International SARL as a plaintiff. On June 26, 2014, the Court granted our motion and denied Shenzhen Mindray's motion. The Court also vacated the case schedule. On July 7, 2014, we filed a second amended complaint adding Masimo International SARL as a plaintiff. On August 18, 2014, the Court adopted our proposed case schedule, setting a new trial date of December 1, 2015. We believe that we have good and substantial defenses to the antitrust, patent infringement and other counterclaims asserted by Shenzhen Mindray. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

On December 10, 2013, we filed a lawsuit against Mindray DS USA, Inc., (Mindray USA), Shenzhen Mindray and Mindray Medical International Ltd. in the Superior Court of New Jersey. The complaint alleges breach of contract and related claims. In January 2014, Mindray USA removed the case to the U.S. District Court for the District of New Jersey. In February 2014, we filed a motion to remand the action to the Superior Court of New Jersey. In May 2014, Mindray USA,Inc. filed an answer and counterclaims in the U.S. District Court asserting patent infringement and federal antitrust counterclaims. On January 7, 2015, the U.S. District Court remanded the action to the Superior Court of New Jersey. On January 22, 2015, Mindray USA filed an answer and counterclaims in the Superior Court of New Jersey asserting patent infringement and federal antitrust counterclaims, and again removed the case to the U.S. District Court of the District of New Jersey. On January 29, 2015, Mindray USA, Shenzhen Mindray and Mindray Medical International, Ltd. filed separate motions to dismiss the action, each of which is currently pending before the U.S. District Court. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

In September 2012, a shareholder derivative lawsuit was filed in the U.S. District Court for the District of Delaware by Joseph Ausikaitis naming certain of our directors and certain executive officers as defendants and us as the nominal defendant. The lawsuit alleges claims of breach of fiduciary duty and unjust enrichment in connection with the grant or receipt of stock options under our 2007 Stock Incentive Plan and related policies. The lawsuit seeks unspecified money damages on our behalf from the officer and director defendants, various forms of equitable and/or injunctive relief, attorneys' and other professional fees and costs and various other forms of relief. In November 2012, the defendants filed a motion to dismiss the action, which was denied by the Court in July 2013. On October 14, 2014, we filed motions for summary judgment, which are currently pending before the Court. The plaintiff filed a motion for summary judgment on October 15, 2014, which is also currently pending before the Court. Trial is currently scheduled to begin in April 2015. Although the outcome of this case cannot be determined, we do not expect it to have a material financial impact on our results of operations.

In April 2011, we were informed by the United States Attorney's Office for the Central District of California, Civil Division, that a qui tam complaint had been filed against us in the U.S. District Court for the Central District of California by three of our former physician office sales representatives. The qui tam complaint alleged, among other things, that our noninvasive hemoglobin products failed to meet their accuracy specifications, and that we misled the FDA and customers regarding the accuracy of the products. In November 2011, the United States declined to intervene in the case, and in October 2013, the District Court granted summary judgment in our favor. The former sales representatives have appealed the District Court's decision.

In September 2011, two of the same former sales representatives filed employment-related claims against us in arbitration also stemming from their allegations regarding our noninvasive hemoglobin products. On January 16, 2014, we were notified that the arbitrator awarded the plaintiffs approximately $5.4 million in damages. We challenged the arbitration award in the U.S. District Court for the Central District of California, and on April 3, 2014, the District Court vacated the award. The former sales representatives have appealed the District Court's decision. We are unable to predict the final outcome of the qui tam and

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employment matters, both of which are currently on appeal before the U.S. Court of Appeals for the Ninth Circuit. A reversal of the District Court's decision in either matter could have a material adverse effect on our results of operations.

In the third quarter of 2013, we were notified that the FDA and the United States Attorney's Office for the Central District of California, Criminal Division, are investigating the allegations regarding our noninvasive hemoglobin products. In the second quarter of 2014, we received grand jury subpoenas requesting documents pertaining to, among other things, the testing, marketing and sales of our Pronto® and Pronto-7® products. We and several of our executives, including our Chief Executive Officer, have signed agreements tolling the statute of limitations as to any charges that may be brought for a period of time ending July 3, 2015. We are fully cooperating with the investigation but cannot predict its outcome.

On January 2, 2014, a putative class action complaint was filed against us in the U.S. District Court for the Central District of California by Physicians Healthsource, Inc. The complaint alleges that we sent unsolicited facsimile advertisements in violation of the Junk Fax Protection Act of 2005 and related regulations. The complaint seeks $500 for each alleged violation, treble damages if the court finds the alleged violations to be knowing, plus interest, costs and injunctive relief. On April 14, 2014, we filed a motion to stay the case pending a decision on a related petition filed by us with the Federal Communications Commission (FCC). On May 22, 2014, the District Court granted the motion and stayed the case pending a ruling by the FCC on the petition. On October 30, 2014, the FCC granted some of the relief and denied some of the relief requested in the petition. Both parties appealed the FCC's decision on the petition. On November 25, 2014, the District Court granted the parties' joint request that the stay remain in place pending a decision on the appeal. We believe we have good and substantial defenses to the claims, but there is no guarantee that we will prevail.

On January 31, 2014, an amended putative class action complaint was filed against us in the U.S. District Court for the Northern District of Alabama by and on behalf of two participants in the Surfactant, Positive Pressure, and Oxygenation Randomized Trial at the University of Alabama. On April 21, 2014, a further amended complaint was filed adding a third participant. The complaint alleges product liability and negligence claims in connection with pulse oximeters that we modified and provided at the request of study investigators for use in the trial. A previous version of the complaint also alleged a wrongful death claim, which the court dismissed on January 22, 2014. The amended complaint seeks unspecified damages, costs, interest, attorney fees and injunctive and other relief. We believe we have good and substantial defenses to the remaining claims, but there is no guarantee that we will prevail.

From time to time, we are involved in legal proceedings and investigations in the normal course of business. Other than the proceedings described above, we believe that currently we are not a party to any legal proceedings which, individually or in the aggregate, would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our stock is traded on the NASDAQ Global Select Market under the symbol "MASI". The following table sets forth the high and low closing sales price of our stock for the periods indicated.

	Fiscal 2014		Fiscal 2013	
	High	Low	High	Low
Fiscal:				
First Quarter	$31.88	$25.37	$21.33	$19.51
Second Quarter	$27.90	$22.03	$22.50	$19.04
Third Quarter	$24.64	$20.69	$27.04	$21.55
Fourth Quarter	$27.00	$21.07	$29.61	$25.62

The above quotations reflect inter-dealer prices, without retail markup, markdown or commission and may not necessarily represent actual transactions.

As of January 31, 2015, the closing price of our stock on the NASDAQ Global Select Market was $25.52 per share, and the number of stockholders of record was 40. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our stock is held of record through brokerage firms in "street name."

Stock Performance Graph

The following stock performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following stock performance graph compares total stockholder returns for Masimo Corporation from January 2, 2010 through January 3, 2015 against the NASDAQ Market Composite Index and NASDAQ Medical Equipment Index, assuming a $100 investment made on January 2, 2010. Each of the two comparative measures of cumulative total return assumes reinvestment of dividends. The stock performance shown on the graph below is not necessarily indicative of future price performance.

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COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Masimo Corporation, the NASDAQ Market Composite Index, and
the NASDAQ Medical Equipment Index
*$100 invested on 01/02/10 in stock or 01/03/09 in index, including reinvestment of dividends. Indexes calculated on month-end basis.

Dividend Policy

Future determination as to the payment of cash (or stock) dividends will be at the discretion of our board of directors (Board) and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our Board. In October 2012, our Board declared a special dividend of $1.00 per share, or $57.3 million, which was paid in December 2012. This dividend was deemed to be a special dividend and there is no assurance, with respect to amount or frequency, that dividends will be declared again in the future.

Stock Repurchase Program

In February 2013, our Board authorized the repurchase of up to 6.0 million shares of common stock under a new repurchase program. In October 2014, our Board increased the number of shares of the Company’s common stock authorized for repurchase by 3.0 million shares, bringing the total number of shares of the Company’s common stock authorized for repurchase under such program to 9.0 million. The stock repurchase program may be carried out at the discretion of a committee comprised of the Company’s Chief Executive Officer and Chief Financial Officer through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. Any repurchases will be subject to the availability of stock, general market conditions, the trading price of the stock, available capital, alternative uses for capital and our financial performance. We paid for prior repurchases of stock with available cash and cash equivalents as well as borrowings under our revolving credit agreement.

During the year ended December 28, 2013, approximately1.0 million shares were repurchased at an average cost of $19.79 per share, totaling approximately $19.8 million. During the year ended January 3, 2015, approximately 4.5 million shares were repurchased at an average cost price of $23.00 per share, totaling approximately $102.5 million. The total remaining shares authorized for repurchase under the stock repurchase program approximated 3.5 million shares as of January 3, 2015.

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Period	Total Number of Shares Purchased	Average Cost Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs[1]
September 28, 2014 to October 25, 2014	27,659	$21.01	—	3,545,151
October 26, 2014 to November 29, 2014	—	—	—	3,545,151
November 30, 2014 to January 3, 2015	—	—	—	3,545,151
Total	27,659	$21.01	—	3,545,151

(1) In October 2014, our Board increased the number of shares of the Company's common stock authorized for repurchase by 3.0 million shares, bringing the total number of shares of the Company's common stock authorized under such repurchase program to 9.0 million.

ITEM 6. SELECTED FINANCIAL DATA

The following tables reflect selected financial data derived from our consolidated financial statements for each of the last five years. The consolidated statement of comprehensive income data for the years ended January 3, 2015, December 28, 2013 and December 29, 2012 and the consolidated balance sheet data as of January 3, 2015 and December 28, 2013 were derived from our audited consolidated financial statements included in this Annual Report on Form 10-K. The consolidated statement of comprehensive income data for the years ended December 31, 2011 and January 1, 2011, and the consolidated balance sheet data as of December 29, 2012, December 31, 2011 and January 1, 2011 were derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results. The selected financial data set forth below should be read in conjunction with our consolidated financial statements, the related notes and Item 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

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	Year ended January 3, 2015	Year ended December 28, 2013	Year ended December 29, 2012	Year ended December 31, 2011	Year ended January 1, 2011
	(dollars in thousands)				
Statement of Comprehensive Income Data[1]:					
Revenue:					
Product	$556,764	$517,429	$464,928	$406,487	$356,422
Royalty	29,879	29,816	28,305	32,501	48,985
Total revenue	586,643	547,245	493,233	438,988	405,407
Cost of goods sold	195,864	188,418	166,982	144,854	119,825
Gross profit	390,779	358,827	326,251	294,134	285,582
Operating expenses:					
Selling, general and administrative	241,016	215,469	193,948	169,205	174,089
Research and development	56,581	55,631	47,077	38,412	36,000
Litigation award and defense costs	(10,331)	8,010	—	—	—
Antitrust litigation expense[2]	—	—	—	—	(30,728)
Total operating expenses	287,266	279,110	241,025	207,617	179,361
Operating income	103,513	79,717	85,226	86,517	106,221
Non-operating (income) expense	1,472	3,991	1,405	(14)	(1,348)
Income before provision for income taxes	102,041	75,726	83,821	86,531	107,569
Provision for income taxes	27,678	20,005	21,883	22,478	34,164
Net income including noncontrolling interests	74,363	55,721	61,938	64,053	73,405
Net income (loss) attributable to noncontrolling interests	1,845	(2,660)	(334)	353	(125)
Net income attributable to Masimo Corporation stockholders	72,518	58,381	62,272	63,700	73,530
Other comprehensive income (loss), net of tax:					
Foreign currency translation adjustments	(6,088)	453	2,268	349	862
Comprehensive income attributable to Masimo Corporation stockholders	$66,430	$58,834	$64,540	$64,049	$74,392
Net income per common share attributable to Masimo Corporation stockholders[3]:					
Basic	$1.33	$1.03	$1.08	$1.07	$1.25
Diluted	$1.30	$1.02	$1.07	$1.05	$1.21
Weighted-average number of common shares:					
Basic	54,708	56,690	57,445	59,659	58,769
Diluted	55,571	57,480	58,374	60,845	60,609

(1) Pursuant to authoritative accounting guidance, our variable interest entity, Cercacor, is consolidated within our financial statements. Accordingly, all intercompany royalties, option and licensing fees, and other charges between us and Cercacor have been eliminated in the consolidation. For additional discussion of accounting for Cercacor, see Note 3 to our accompanying consolidated financial statements.

(2) During the year ended January 1, 2011, we completed negotiations to resolve the merits of our antitrust litigation with Covidien. As a result, we recovered a total of $30.8 million in litigation expenses from Covidien.

(3) See Note 2 to our accompanying consolidated financial statements for a description of the method used to compute basic and diluted net income per common share.

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	January 3, 2015	December 28, 2013	December 29, 2012	December 31, 2011	January 1, 2011
	(in thousands, except dividends declared per common share)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$134,453	$95,466	$71,554	$129,882	$88,305
Working capital	191,247	168,008	129,808	186,982	147,408
Total assets	565,006	438,662	374,661	366,104	310,235
Total debt	125,224	336	115	122	172
Total equity	307,741	326,401	275,668	279,666	230,039
Dividends declared per common share[4]	$—	$—	$1.00	$—	$2.75

(4) During the years ended December 29, 2012 and January 1, 2011, our Board evaluated a variety of options to return value to stockholders, including acquisition opportunities, stock buy-back programs and dividends. After considering all available options during those periods, our Board concluded that the best and most direct way to reward stockholders for their continued investment and confidence in Masimo was through the declaration of three special cash dividends. In February 2010, our Board declared a special dividend of $2.00 per share, or $117.5 million, which was paid in March 2010. In November 2010, our Board declared a second special dividend of $0.75 per share, or $44.5 million, which was paid in December 2010. In October 2012, our Board declared a third special dividend of $1.00 per share, or $57.3 million, which was paid in December 2012.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read this discussion together with the financial statements, related notes and other financial information included in this Annual Report on Form 10-K. The following discussion may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under Item 1A—"Risk Factors" and elsewhere in this Annual Report on Form 10-K. These risks could cause our actual results to differ materially from any future performance suggested below.

Executive Overview

We are a global medical technology company that develops, manufactures and markets a variety of noninvasive monitoring technologies. Our mission is to improve patient outcomes and reduce cost of care by taking noninvasive monitoring to new sites and applications. We invented Masimo SET®, which provides the capabilities of Measure-Through-Motion and Low-Perfusion pulse oximetry to address the primary limitations of conventional pulse oximetry. Pulse oximetry is the noninvasive measurement of the oxygen saturation level of arterial blood, or the blood that delivers oxygen to the body's tissues, and pulse rate. Pulse oximetry is one of the most common measurements made in and out of hospitals around the world. Masimo SET® has been validated in over 100 independent clinical studies and is the only pulse oximetry technology we are aware of that has been proven to help clinicians detect critical congenital heart disease in newborns, reduce retinopathy of prematurity in neonates, and decrease intensive care unit transfers and rapid response activations on the general floor.

After introducing Masimo SET®, we have continued to innovate by introducing breakthrough noninvasive measurements beyond arterial blood oxygen saturation level and pulse rate, which create new market opportunities in both the hospital and non-hospital care settings. We believe our Masimo rainbow® SET® platform, which utilizes both Masimo SET® and licensed rainbow® technology, includes the first devices cleared by the U.S. Food and Drug Administration (the FDA) to noninvasively and continuously monitor multiple measurements that previously required invasive or complicated procedures. SpCO®, our noninvasive carboxyhemoglobin parameter, allows measurement of carbon monoxide levels in the blood. Carbon monoxide is the most common cause of poisoning in the world. SpMet®, our noninvasive methemoglobin sensor, allows for the measurement of methemoglobin levels in the blood. Methemoglobin in the blood leads to a dangerous condition known as methemo-globinemia, which occurs as a reaction to some common drugs used in hospitals and outpatient procedures. Our PVI® parameter measures dynamic changes in PI during the respiratory cycle and can assist clinicians with fluid administration.Our noninvasive hemoglobin sensor, SpHb®, monitors hemoglobin, the oxygen-carrying component of red blood cells. Hemoglobin measurement is one of the most frequent invasive laboratory measurements in the world, often measured as part of a complete blood count. A low hemoglobin status is called anemia, which is generally caused by bleeding or the inability of the body to produce red blood cells. RRa® allows for the continuous and noninvasive monitoring of respiration rate, via rainbow Acoustic Monitoring.™ Respiration rate is the number of breaths per minute. A low respiration rate is indicative of respiratory depression and a high respiration rate is indicative of patient distress. Traditional methods used to measure respiration rate are often considered inaccurate or are not tolerated well by patients.

Our products consist of a monitor or circuit board, and a "Board-in-Cable" solution, for use with our proprietary single-patient use and reusable sensors and cables. We sell our products to end-users through our direct sales force and certain distributors, and also sell some of our products to our OEM partners, for incorporation into their equipment. As of January 3, 2015 we estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET® and rainbow® SET® was more than 1.3 million units. Our installed base is the primary driver for the recurring sales of our sensors, most notably single-patient adhesive sensors.

We offer Masimo SET® and rainbow® SET® through our OEMs and our own end-user products, including the Radical-7®, Rad-57®, Pronto®, Pronto-7®, Rad-8®, Rad-5® and Rad-5v.™ Our solutions and related products are based upon our proprietary Masimo SET® and rainbow® algorithms. This software-based technology is incorporated into a variety of product platforms depending on our customers' specifications. Our technology is supported by a substantial intellectual property portfolio that we have built through internal development and, to a lesser extent, acquisitions and license agreements. As of January 3, 2015, we had 702 issued and pending patents worldwide. We have exclusively

licensed from our development partner, Cercacor, the right to OEM rainbow® technology and incorporate rainbow® technology into our products intended to be used by professional caregivers, including, but not limited to, hospital caregivers and alternate care facility caregivers.

Dividend Payments

Our board of directors (Board) continuously evaluates a variety of options to return value to stockholders, including acquisition opportunities, stock buy-back programs and dividends. In 2012, after considering all available options at those times, our Board concluded that the best and most direct way to reward stockholders for their continued investment and confidence in Masimo was through the declaration of cash dividends. As a result, our Board declared a special dividend of $1.00 per share, or $57.3

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million, in October 2012, which was paid out on December 11, 2012 to stockholders of record as of the close of business on November 27, 2012. The 2012 special dividend represented only a portion of our cash reserves, which our Board believed was sufficient to cover our current operational needs and to fund continued research and development investments and current strategic initiatives. Our Board did not declare any dividends during fiscal years 2013 or 2014, and there is no assurance with respect to the payment of any dividends in the future.

Stock Repurchase Program

In August 2011, our board of directors (Board) authorized the repurchase of up to 3.0 million shares of common stock under a repurchase program, which terminated pursuant to its terms in April 2012 when all 3.0 million shares had been repurchased. In February 2013, our Board authorized the repurchase of up to 6.0 million shares of common stock under a new repurchase program (2013 Plan) which is expected to continue for a period of up to 36 months from the effective date of the program unless it is terminated earlier by our Board. In October 2014, our Board increased the number of shares of our common stock authorized for repurchase under the 2013 Plan by 3.0 million shares, bringing the total number of shares of our common stock authorized for repurchase under the 2013 Plan to 9.0 million. For further details regarding our stock repurchase program see Note 13 to our accompanying consolidated financial statements.

Cercacor

Cercacor is an independent entity spun off from the Company to our stockholders in 1998. Joe Kiani and Jack Lasersohn, members of our Board, are also members of the board of directors of Cercacor. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Cercacor. We are a party to a cross-licensing agreement with Cercacor, which was amended and restated effective January 1, 2007 (Cross-Licensing Agreement), that governs each party's rights to certain intellectual property held by the two companies.

Under the Cross-Licensing Agreement, we granted Cercacor an exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET® owned by us, including all improvements on this technology, for the monitoring of non-vital signs measurements and to develop and sell devices incorporating Masimo SET® for monitoring non-vital signs measurements in any product market in which a product is intended to be used by a patient or pharmacist, which we refer to as the Cercacor Market, rather than a professional medical caregiver. We also granted Cercacor a non-exclusive, perpetual and worldwide license, with sublicense rights to use all Masimo SET® for the measurement of vital signs in the Cercacor Market.

We exclusively license from Cercacor the right to make and distribute products in the professional medical caregiver markets, referred to as the Masimo Market, that utilize rainbow® technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation and hemoglobin. In December 2013, we exercised our option to license five additional parameters at the pre-established price of $0.5 million per parameter. The license is currently subject to certain specific annual minimum aggregate royalty payment obligations in the amount of $5.0 million per year. To date, we have developed and commercially released devices that measure carbon monoxide, methemoglobin and hemoglobin using licensed rainbow® technology. We also have the option to obtain exclusive licenses to make and distribute products that utilize rainbow® technology for the monitoring of other measurements, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver. In February 2009, in order to accelerate the product development of an improved hemoglobin spot-check measurement device, we agreed to fund additional engineering expenses of Cercacor. Specifically, these expenses included third-party engineering materials and supplies expense, as well as 60% of Cercacor's total engineering and engineering-related payroll expenses. During the years ended January 3, 2015 and December 28, 2013, the total expenses for these additional services, materials and supplies totaled $3.1 million, and $4.1 million respectively. This funding arrangement has been discontinued by mutual agreement effective as of January 4, 2015.

Pursuant to authoritative accounting guidance, Cercacor is consolidated within our financial statements for all periods presented. For the foreseeable future, we anticipate that we will continue to consolidate Cercacor pursuant to the current authoritative accounting guidance; however, in the event that Cercacor is no longer considered a variable interest entity (VIE) under such accounting guidance, we may discontinue consolidating the entity. For additional discussion of Cercacor, see Note 3 to our accompanying consolidated financial statements.

Business Combinations

On March 9, 2012, we acquired substantially all of the assets of Spire Semiconductor, LLC, a maker of advanced light emitting diode and other advanced component-level technologies. Masimo Semiconductor, Inc. (Masimo Semiconductor), our wholly-owned subsidiary, operates the business. This acquisition provided us an advanced ability to develop custom components, accelerate development cycles and optimize future product costs. Masimo Semiconductor specializes in wafer epitaxy, foundry services and device fabrication for biomedical, telecommunications, consumer products and other markets. For additional information, see Note 4 to our accompanying consolidated financial statements.

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On July 27, 2012, we acquired PHASEIN AB (Phasein), a developer and manufacturer of ultra-compact mainstream and sidestream capnography and gas monitoring technologies. The acquisition of Phasein's technologies complements our breakthrough innovations for patient monitoring with a portfolio of products ranging from OEM solutions for external "plug-in-and-measure" capnography and gas analyzers and integrated modules to handheld capnometer devices. With multiple measurements delivered through either mainstream or sidestream options, our customers can benefit from CO_2, N_2O, O_2 and anesthetic agent monitoring in many hospital environments, such as operating rooms, procedural sedation and intensive care units. For additional information, see Note 4 to our accompanying consolidated financial statements.

Results of Operations

The following table sets forth, for the periods indicated, our results of operations expressed as U.S. Dollar amounts and as a percentage of revenue.

	Year ended January 3, 2015		Year ended December 28, 2013		Year ended December 29, 2012	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)					
Revenue:						
Product	$556,764	94.9 %	$517,429	94.6 %	$464,928	94.3 %
Royalty	29,879	5.1	29,816	5.4	28,305	5.7
Total revenue	586,643	100.0	547,245	100.0	493,233	100.0
Cost of goods sold	195,864	33.4	188,418	34.4	166,982	33.9
Gross profit	390,779	66.6	358,827	65.6	326,251	66.1
Operating expenses:						
Selling, general and administrative	241,016	41.1	215,469	39.4	193,948	39.3
Research and development	56,581	9.6	55,631	10.2	47,077	9.5
Litigation award and defense costs	(10,331)	(1.8)	8,010	1.5	—	—
Total operating expenses	287,266	49.0	279,110	51.0	241,025	48.9
Operating income	103,513	17.6	79,717	14.6	85,226	17.3
Non-operating expense	1,472	0.3	3,991	0.7	1,405	0.3
Income before provision for income taxes	102,041	17.4	75,726	13.8	83,821	17.0
Provision for income taxes	27,678	4.7	20,005	3.7	21,883	4.4
Net income including noncontrolling interests	74,363	12.7	55,721	10.2	61,938	12.6
Net income (loss) attributable to noncontrolling interests	1,845	0.3	(2,660)	(0.5)	(334)	(0.1)
Net income attributable to Masimo Corporation stockholders	$72,518	12.4 %	$58,381	10.7 %	$62,272	12.6 %

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Comparison of the Year ended January 3, 2015 to the Year ended December 28, 2013

Revenue. Total revenue increased $39.4 million, or 7.2%, to $586.6 million for the year ended January 3, 2015, from $547.2 million for the year ended December 28, 2013.The following chart details the Company's total product revenues by the geographic area to which the products were shipped for fiscal years 2014 and 2013 (dollars in thousands):

	Year ended January 3, 2015			Year ended December 28, 2013			Increase/ (Decrease)	Percentage Change	
North and South America	$398,066	71.5	%	$378,894	73.2	%	$19,172	5.1	%
Europe, Middle East and Africa	100,747	18.1		83,338	16.1		17,409	20.9	
Asia and Australia	57,951	10.4		55,197	10.7		2,754	5.0	
Total Product Revenue	$556,764	100.0	%	$517,429	100.0	%	$39,335	7.6	%
Royalty	29,879			29,816			63.0		
Total Revenue	$586,643			$547,245			$39,398		

Product revenues increased $39.3 million, or 7.6%, to $556.8 million in the year ended January 3, 2015 from $517.4 million in the year ended December 28, 2013. Approximately $5.0 million of this increase was due to the extra week in the current fiscal year (which consisted of 53 weeks versus 52 weeks in the prior fiscal year) and higher consumable product sales resulting from an increase in our installed base of circuit boards and pulse oximeters, which we estimate totaled 1,313,000 units at January 3, 2015, up from 1,205,000 units at December 28, 2013. Offsetting this increase was approximately $4.3 million related to unfavorable movements in foreign exchange rates during the year that reduced the U.S. Dollar value of foreign sales denominated in various foreign currencies relative to fiscal 2013. Total rainbow® product revenue increased $2.9 million, or 6.0%, to $51.8 million in the year ended January 3, 2015 from $48.8 million in the year ended December 28, 2013. Our royalty revenue increased $0.1 million to $29.9 million in the year ended January 3, 2015, from $29.8 million in the year ended December 28, 2013.

Total product revenues by sales channel were as follows (dollars in thousands):

	Year ended January 3, 2015			Year ended December 28, 2013			Increase/ (Decrease)	Percentage Change	
Direct/Distribution	$472,711	84.9	%	$438,819	84.8	%	$33,892	7.7	%
OEM	84,053	15.1		78,610	15.2		5,443	6.9	
Total Product Revenue	$556,764	100.0	%	$517,429	100.0	%	$39,335	7.6	%

Revenue generated through our direct/distribution sales channels increased $33.9 million, or 7.7%, to $472.7 million for the year ended January 3, 2015, compared to $438.8 million for the year ended December 28, 2013. During the year ended January 3, 2015, revenues from our OEM channel increased $5.4 million, or 6.9%, to $84.1 million from $78.6 million in the year ended December 28, 2013. The increase in revenue for both our direct/distribution and OEM channels was consistent with our overall product revenue growth of 7.6% for the year ended January 3, 2015.

Gross Profit. Gross profit consists of total revenue less cost of goods sold. Our gross profit for fiscal years 2014 and 2013 was as follows (dollars in thousands):

Gross Profit

	Year ended January 3, 2015	Percentage of Net Revenues		Year ended December 28, 2013	Percentage of Net Revenues		Increase/ (Decrease)	Percentage Change	
Product Gross Profit	$360,900	64.8	%	$329,011	63.6	%	$31,889	9.7	%
Royalty Gross Profit	29,879	100.0		29,816	100.0		63	0.2	
Total Gross Profit	$390,779	66.6	%	$358,827	65.6	%	$31,952	8.9	%

Cost of goods sold includes labor, material, overhead and other similar costs related to the production, supply, distribution and support of our products. Cost of goods sold increased $7.4 million to $195.9 million in the year ended January 3, 2015 from $188.4 million in the year ended December 28, 2013. Our total gross margin increased to 66.6% for the year ended January 3, 2015 from 65.6% for the year ended December 28, 2013. Excluding royalties, product gross margin increased to 64.8% for the year ended January 3, 2015 from 63.6% for the year ended December 28, 2013. This increase in product gross margin was primarily due to the benefits of our continued cost reduction efforts, and the non-recurrence of an inventory valuation adjustment from the prior year. These items were partially offset by the unfavorable movements in foreign exchange rates that reduced the U.S. Dollar translation of foreign sales denominated in various foreign currencies, primarily during the fourth quarter of fiscal

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year 2014. We incurred $5.5 million and $5.4 million in Cercacor royalty expenses for the years ended January 3, 2015 and December 28, 2013, respectively, which have been eliminated in our consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 63.8% and 62.6% for the years ended January 3, 2015 and December 28, 2013, respectively.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of salaries and related expenses for sales, marketing and administrative personnel, sales commissions, advertising and promotion costs, professional fees related to legal, accounting and other outside services, public company costs and other corporate expenses. Selling, general and administrative expenses for fiscal years 2014 and 2013 were as follows (dollars in thousands):

Selling, General and Administrative

Year ended January 3, 2015	Percentage of Net Revenues	Year ended December 28, 2013	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$241,016	41.1%	$215,469	39.4%	$25,547	11.9%

Selling, general and administrative expenses increased $25.5 million, or 11.9%, to $241.0 million for the year ended January 3, 2015 from $215.5 million for the year ended December 28, 2013. This increase was primarily attributable to higher legal expenses of approximately $10.0 million, increased headcount costs of approximately $7.1 million, of which approximately $2.1 million resulted from the extra week in the current fiscal year (which consisted of 53 weeks versus 52 weeks in the prior fiscal year), higher marketing-related expense of approximately $2.5 million and increased charitable donations to the Masimo Foundation for Ethics, Innovation and Competition in Healthcare of approximately $2.7 million. Approximately $8.8 million and $9.4 million of share-based compensation expense was included in selling, general and administrative expenses for the years ended January 3, 2015 and December 28, 2013, respectively. Also included in total selling, general and administrative expenses are $2.8 million and $2.5 million of direct expenses incurred by Cercacor for the years ended January 3, 2015 and December 28, 2013, respectively.

Research and Development. Research and development expenses consist primarily of salaries and related expenses for engineers and other personnel engaged in the design and development of our products. These expenses also include third-party fees paid to consultants, prototype and engineering supply expenses and the costs of clinical trials. Research and development expenses for fiscal years 2014 and 2013 were as follows (dollars in thousands):

Research and Development

Year ended January 3, 2015	Percentage of Net Revenues	Year ended December 28, 2013	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$56,581	9.6%	$55,631	10.2%	$950	1.7%

Research and development expenses increased $1.0 million, or 1.7%, to $56.6 million for the year ended January 3, 2015 from $55.6 million for the year ended December 28, 2013. This increase was primarily due to higher headcount related costs of approximately $1.8 million, of which approximately $0.6 million resulted from the extra week in the current fiscal year (which consisted of 53 weeks versus 52 weeks in the prior fiscal year), which was partially offset by lower engineering project-related expenses. Included in research and development expenses was approximately $1.8 million and $1.9 million of share-based compensation expense for the years ended January 3, 2015 and December 28, 2013, respectively. Also included in total research and development expenses were $3.1 million and $3.9 million of engineering expenses incurred by Cercacor for the year ended January 3, 2015 and December 28, 2013, respectively.

Litigation Award and Defense Costs. Litigation award and defense costs for fiscal years 2014 and 2013 were as follows (dollars in thousands):

Litigation Award and Defense Costs

Year ended January 3, 2015	Percentage of Net Revenues	Year ended December 28, 2013	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$(10,331)	(1.8)%	$8,010	1.5%	$(18,341)	(229.0)%

Two of our former physician office sales representatives filed employment-related claims against us in 2011 regarding our noninvasive hemoglobin monitoring products. In January 2014, an arbitrator awarded the plaintiffs approximately $5.4 million in damages. As a result of this award, we recorded a charge of $8.0 million in the fiscal quarter ended December 28, 2013, which included $5.4 million in damages and $2.6 million in defense-related costs. We challenged the award in the U.S. District Court

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for the Central District of California, and in April 2014, the District Court vacated the award. Accordingly, we reversed the previous $8.0 million charge in the fiscal quarter ended March 29, 2014.

In July 2014, an arbitration panel issued a final award of $4.0 million to Cercacor, our VIE, in connection with the breach by a third party of a supply agreement, payment for which was received by Cercacor in August 2014. Cercacor recorded this award in the quarter ended September 27, 2014 as a reduction to operating expenses, net of approximately $1.6 million in related legal costs. The net recovery of $2.4 million was entirely attributable to noncontrolling interests, and therefore, is not included in “net income attributable to Masimo Corporation stockholders” within our results of operations.

Non-operating Expense. Non-operating expense consists primarily of interest income, interest expense and foreign exchange losses. Non-operating expense for fiscal years 2014 and 2013 were as follows (dollars in thousands):

Non-operating expense

Year ended January 3, 2015	Percentage of Net Revenues	Year ended December 28, 2013	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$1,472	0.3%	$3,991	0.7%	$(2,519)	(63.1)%

Non-operating expense was $1.5 million for the year ended January 3, 2015, as compared to $4.0 million for the year ended December 28, 2013. This net change of $2.5 million was primarily due to the recognition of $1.0 million of net realized and unrealized losses on foreign currency denominated transactions during the year ended January 3, 2015, as compared to $4.0 million during the year ended December 28, 2013. The net realized and unrealized losses recognized during the year ended January 3, 2015 resulted primarily from the strengthening of the U.S. Dollar against the Japanese Yen and the Euro, partially offset by the strengthening of the U.S. Dollar against the Swedish Krona. The net realized and unrealized losses recognized during the year ended December 28, 2013 resulted primarily from the strengthening of the U.S. Dollar against the Japanese Yen, partially offset by the weakening of the U.S. Dollar against the Euro. We also incurred higher interest expense of approximately $0.6 million during the year ended January 3, 2015 related to borrowings under our revolving credit agreement.

Provision for Income Taxes. Our provision for income taxes for fiscal years 2014 and 2013 were as follows (dollars in thousands):

Provision for Income Taxes

Year ended January 3, 2015	Percentage of Net Revenues	Year ended December 28, 2013	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$27,678	4.7%	$20,005	3.7%	$7,673	38.4%

Our provision for income taxes was $27.7 million for the year ended January 3, 2015 compared to $20.0 million for the year ended December 28, 2013. Our effective tax rate was 27.1% for the year ended January 3, 2015 compared to 26.4% for the year ended December 28, 2013. This increase in our effective tax rate during the year ended January 3, 2015 was primarily due to the realization of a one-time tax rate benefit of 1.4% during the year ended December 28, 2013 related to the American Taxpayer Relief Act of 2012 (Tax Act), which retroactively reinstated the federal research tax credit back to fiscal year 2012. Also contributing to the increased tax rate during the year ended January 3, 2015 was an unfavorable shift in the geographic composition of our pre-tax earnings between higher tax and lower tax jurisdictions during the year ended January 3, 2015. Partially offsetting these increases was the non-recurrence of a $2.0 million tax charge recorded during the year ended December 28, 2013 related to the establishment of a valuation allowance against the net deferred tax assets of Cercacor. This $2.0 million charge was entirely attributable to noncontrolling interests, and therefore, is not included in “Net income attributable to Masimo Corporation stockholders” within our results of operations.

We have made no provision for U.S. income taxes or foreign withholding taxes on the earnings of our foreign subsidiaries as these amounts are intended to be indefinitely reinvested in operations outside the U.S. Our effective tax rate was lower than the U.S. federal statutory rate primarily due to research and development tax credits and a portion of our earnings being generated from countries other than the U.S., where such earnings are generally subject to lower tax rates than the U.S. While we expect our effective tax rate will continue to be lower than the U.S. federal statutory

rate, our actual future effective income tax rate will depend on various factors, including changes in tax laws, changes in deferred tax asset valuation allowances, the recognition and derecognition of tax benefits associated with uncertain tax positions and the geographic composition of our pre-tax income. In addition, we believe that the expiration of the federal research and development tax credit as of December 31, 2014 will have a negative impact on our effective tax rate in the future.

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Comparison of the Year ended December 28, 2013 to the Year ended December 29, 2012

Revenue. Total revenue increased $54.0 million, or 11.0% to $547.2 million for the year ended December 28, 2013, from $493.2 million for the year ended December 29, 2012. The following chart details the our total product revenues by the geographic area to which the products were shipped for fiscal years 2013 and 2012 (dollars in thousands):

	Year ended December 28, 2013			Year ended December 29, 2012			Increase/ (Decrease)	Percentage Change	
North and South America	$378,894	73.2	%	$341,672	73.5	%	$37,222	10.9	%
Europe, Middle East and Africa	83,338	16.1		68,010	14.6		15,328	22.5	
Asia and Australia	55,197	10.7		55,246	11.9		(49)	(0.1)	
Total Product Revenue	$517,429	100.0	%	$464,928	100.0	%	$52,501	11.3	%
Royalty	29,816			28,305			1,511		
Total Revenue	$547,245			$493,233			$54,012		

Product revenues increased $52.5 million, or 11.3%, to $517.4 million in the year ended December 28, 2013 from $464.9 million in the year ended December 29, 2012. This increase was primarily due to higher consumable sales resulting from an increase in our installed base of circuit boards and pulse oximeters which we estimate totaled 1,205,000 units at December 28, 2013, up from 1,088,000 units at December 29, 2012. Contributing to the increase in our product revenue was our rainbow® technology product revenues, which increased $8.5 million, or 21.3%, to $48.8 million in the year ended December 28, 2013 from $40.3 million in the year ended December 29, 2012. Product revenue related to our acquisition of the Phasein and Masimo Semiconductor businesses approximated $12.8 million and $3.8 million, respectively for the year ended December 28, 2013, compared to $4.4 million and $3.1 million, respectively, for the year ended December 29, 2012. Our royalty revenue increased $1.5 million to $29.8 million in the year ended December 28, 2013, from $28.3 million in the year ended December 29, 2012.

Total product revenues by sales channel for the fiscal year 2013 and 2012 were as follows (dollars in thousands):

	Year ended December 28, 2013			Year ended December 29, 2012			Increase/ (Decrease)	Percentage Change	
Direct/Distribution	$438,819	84.8	%	$396,218	85.2	%	$42,601	10.8	%
OEM	78,610	15.2		68,710	14.8		9,900	14.4	
Total Product Revenue	$517,429	100.0	%	$464,928	100.0	%	$52,501	11.3	%

Revenue generated through our direct and distribution sales channels increased $42.6 million, or 10.8%, to $438.8 million for the year ended December 28, 2013, compared to $396.2 million for the year ended December 29, 2012. During the year ended December 28, 2013, revenues from our OEM channel increased $9.9 million, or 14.4%, to $78.6 million from $68.7 million in the year ended December 29, 2012.

Gross Profit. Our gross profit for fiscal years 2013 and 2012 was as follows (dollars in thousands):

	Gross Profit								
	Year ended December 28, 2013	Percentage of Net Revenues		Year ended December 29, 2012	Percentage of Net Revenues		Increase/ (Decrease)	Percentage Change	
Product Gross Profit	$329,011	63.6	%	$297,946	64.1	%	$31,065	10.4	%
Royalty Gross Profit	29,816	100.0		28,305	100.0		1,511	5.3	
Total Gross Profit	$358,827	65.6	%	$326,251	66.1	%	$32,576	10.0	%

Our cost of goods sold increased $21.4 million to $188.4 million in the year ended December 28, 2013 from $167.0 million in the year ended December 29, 2012. Our total gross margin decreased to 65.6% for the year ended December 28, 2013 from 66.1% for the year ended December 29, 2012. Excluding royalties, product gross margin declined to 63.6% for the year ended December 28, 2013 from 64.1% for the year ended December 29, 2012. This slight decline in product gross margin was primarily due to incremental inventory and asset valuation provisions

associated with product and sourcing transitions as well as the negative impact of foreign exchange rates, which were partially offset by other manufacturing cost reductions. We incurred $5.4 million and $5.0 million in Cercacor royalty expenses for the years ended December 28, 2013 and December 29, 2012, respectively, which have been eliminated in our consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 62.6% and 63.0% for the year ended December 28, 2013 and December 29, 2012, respectively.

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Selling, General and Administrative. Selling, general and administrative expenses for fiscal years 2013 and 2012 were as follows (dollars in thousands):

Selling, General and Administrative

Year ended December 28, 2013	Percentage of Net Revenues	Year ended December 29, 2012	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$215,469	39.4%	$193,948	39.3%	$21,521	11.1%

Selling, general and administrative expenses increased $21.5 million, or 11.1%, to $215.5 million for the year ended December 28, 2013 from $193.9 million for the year ended December 29, 2012. Excluding the new medical device excise tax of $6.3 million, selling, general and administrative expenses increased $15.2 million, or 7.9%, to $209.1 million for the year ended December 28, 2013 from $193.9 million for the year ended December 29, 2012. This increase was primarily due to $8.4 million of additional payroll and related costs associated with higher staffing, a significant portion of which related to the establishment of our new worldwide blood management sales team and approximately $6.0 million in higher legal expenses. Included in total selling, general and administrative expenses is $2.5 million of direct expenses incurred by Cercacor for each of the years ended December 28, 2013 and December 29, 2012.

Research and Development. Research and development expenses for fiscal years 2013 and 2012 were as follows (dollars in thousands):

Research and Development

Year ended December 28, 2013	Percentage of Net Revenues	Year ended December 29, 2012	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$55,631	10.2%	$47,077	9.5%	$8,554	18.2%

Research and development expenses increased $8.5 million, or 18.2%, to $55.6 million for the year ended December 28, 2013 from $47.1 million for the year ended December 29, 2012. This increase was primarily due to increased payroll and payroll related costs of $4.1 million associated with increased research and development staffing levels due to investment in research and development efforts. In addition, new project costs and engineering supplies increased $1.2 million as a result of new product development projects and additional clinical trial costs. Included in total research and development expenses are $3.9 million and $3.7 million of engineering expenses incurred by Cercacor for the year ended December 28, 2013 and December 29, 2012, respectively.

Litigation Award and Defense Costs. Litigation award and defense costs for fiscal years 2013 and 2012 were as follows (dollars in thousands):

Litigation Award and Defense Costs

Year ended December 28, 2013	Percentage of Net Revenues	Year ended December 29, 2012	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$8,010	1.5%	$—	—%	$8,010	100%

For the year ended December 28, 2013, we recorded a charge of $5.4 million due to damages awarded by an arbitrator on an employment claim filed by certain of our former physician office sales representatives. In addition, we recorded a charge of $2.6 million for defense costs that, as a result of the arbitrator decision, were no longer deemed to be reimbursable by our insurance carrier. We challenged the award in the U.S. District Court for the Central District of California, and in April 2014, the District Court vacated the award. Accordingly, we reversed the previous $8.0 million charge in our fiscal quarter ended March 29, 2014. We did not record any similar charges in the year ended December 29, 2012.