MASIMO CORP
Form 10-K
February 15, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 29, 2012

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)
40 Parker 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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x 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 x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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. x

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

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

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 30, 2012, the last business day of the registrant s most recently completed second fiscal quarter, as reported on the NASDAQ Global Select Market, was approximately $938.1 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, 2013, the registrant had 57,376,086 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 2013 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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MASIMO CORPORATION

FISCAL YEAR 2012 FORM 10-K ANNUAL REPORT

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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 and 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 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 would, and similar 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 noninvasive patient monitoring products. Our mission is to improve patient outcomes and reduce 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. We invented Masimo Signal Extraction Technology®, or 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, or CCHD, in newborns, reduce retinopathy of prematurity in neonates, and decrease intensive care unit transfers and rapid response activations on the general floor.

Our products consist of a monitor or circuit board, and a recently introduced 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 original equipment manufacturer, or OEM, partners, for incorporation into their products. As of December 29, 2012, we estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET® was 1,088,000 units, based on an estimated 10 year field life assumption. Our installed base is the primary

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driver for the recurring sales of our sensors, most notably, single-patient adhesive sensors. Based on industry reports, we estimate that the worldwide pulse oximetry market was over $1 billion in 2012, the largest component of which was the sale of sensors.

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. In 2005, we launched our Masimo rainbow® SET platform, utilizing both Masimo SET® and licensed rainbow® technology, which we believe includes the first devices cleared by the U.S. Food and Drug Administration, or FDA, to noninvasively and continuously monitor multiple measurements that previously required invasive or complicated procedures. In 2005, we launched noninvasive carboxyhemoglobin, or SpCO®, allowing measurement of carbon monoxide levels in the blood. Carbon monoxide is the most common cause of poisoning in the world. When used with other clinical variables, SpCO® may help clinicians and emergency responders detect carbon monoxide poisoning and help determine treatment and additional test options. In 2006, we launched noninvasive methemoglobin, or SpMet®, allowing for the measurement of methemoglobin levels in the blood. 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. When used with other clinical variables, SpMet® may help clinicians detect methemoglobinemia and help determine treatment and additional test options. In 2007, we launched Masimo Pleth Variability Index, or PVI®. Fluid administration is critical to optimizing fluid status in surgery and critical care, but traditional invasive methods to guide fluid administration often fail to predict fluid responsiveness and newer methods are complicated and costly. When used with other clinical variables, PVI® may help clinicians assess fluid status and help determine treatment options. In March 2008, we debuted noninvasive hemoglobin, or SpHb®, and in March 2009, we began full market release of SpHb®. Hemoglobin is the oxygen-carrying component of red blood cells, and 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. When used with other clinical variables, SpHb® may help clinicians assess bleeding and anemia status and help determine treatment and additional test options. SpHb® has been shown to help clinicians reduce the number of red blood cell, or RBC, transfusions and in multiple cases demonstrate its lifesaving ability to detect bleeding earlier, without having to wait for traditional invasive blood tests results. In June 2010, we began a full commercial release of continuous and noninvasive monitoring of respiration rate, or RRa™, via rainbow Acoustic Monitoring™. Respiration rate is the number of breaths per minute. A low respiration rate is indicative of respiratory depression and 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. When used with other clinical variables, RRa™ may help clinicians assess respiratory status and help determine treatment options. In July 2010, we began selling the SEDLine® monitor, which measures the brain s electrical activity and provides information about a patient s response to anesthesia.

We also offer a remote monitoring and clinician notification solution called the Masimo Patient SafetyNet™, or Patient SafetyNet™, which includes our Masimo SET® or rainbow® SET monitors at the patient s bedside along with a central assignment station and wired or wireless server. Patient SafetyNet™ wirelessly notifies clinicians caring for multiple patients in different rooms when one of their patients has an alarm, allowing them to intervene sooner and provide potentially life-saving support. Masimo SET®, along with Patient SafetyNet™, is proven to help clinicians improve outcomes on the general floor. In October 2010, we debuted the Halo Index™, which allows continuous global trending and assessment of multiple physiological measurements of a patient with a single number displayed on the Patient SafetyNet™ screen. Halo Index™ is pending FDA 510(k) clearance.

In January 2012, we received FDA clearance for the Pronto-7®, a product designed specifically for spot-checking hemoglobin, along with oxygen saturation, pulse rate and perfusion index. In October 2012, we received both FDA clearance for $uSpO_2$™, a universal Board-in-Cable pulse oximetry solution, and CE mark for $SpfO_2$, a new parameter, which for the first time, allows the measurement of fractional arterial oxygen saturation noninvasively.

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In March 2012, we acquired Spire Semiconductor, LLC, a maker of advanced light emitting diode and other advanced component-level technologies. Masimo Semiconductor will operate the business going forward, and specialize in wafer epitaxy, foundry services, and device fabrication for biomedical, telecommunications, consumer products and other markets. The acquisition gives us an advanced ability to develop custom components, accelerate development cycles, and optimize future product costs.

In July 2012, we acquired PHASEIN AB, or 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.

In December 2012, we released $iSpO_2$, a pulse oximeter cable and sensor with Measure-Through Motion and Low Perfusion Masimo SET® technology for use with an iPhone, iPad or iPod touch. $iSpO_2$ uses Masimo SET® for Measure-Through Motion and Low Perfusion performance. The first version of $iSpO_2$ allows consumers to use their iPhone, iPad or iPod touch to check their own arterial blood oxygen saturation (SpO_2), pulse rate, and perfusion index measurements for short-term sports and aviation use, and is not intended for medical use. The $iSpO_2$ is available on-line through both iSpO2.com and amazon.com. The $iSpO_2$ Medical, the professional version for medical use, is pending CE mark and FDA 510(k) clearance. The $iSpO_2$ Medical will be made available through our existing distribution channels.

We offer Masimo SET® and rainbow® SET through our OEMs and our own end-user products, including the Radical-7®, Rad-87®, Rad-57™, Pronto®, Pronto-7®, Rad-8®, Rad-5® and Rad-5v™. Our strategy is to utilize the accuracy and clinical applications of our products to: 1) be the leading choice for pulse oximetry in traditionally monitored areas in and out of the hospital; 2) expand the use of pulse oximetry beyond the critical care settings, including to the general floor of the hospital; 3) enable the use of breakthrough rainbow® measurements by our hospital customers; and 4) bring rainbow® measurements to new markets such as the outpatient clinic.

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 December 29, 2012, we had 630 issued and pending patents worldwide. We have exclusively licensed from our development partner, Cercacor Laboratories, Inc., or Cercacor, the right to OEM selected rainbow® technology and to incorporate selected rainbow® technology into our products intended to be used by professional caregivers, including, but not limited to, hospital caregivers and alternate care facility caregivers.

Pulse Oximetry Background

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 in a matter of minutes. Our pulse oximeters are used primarily in critical care settings, including surgery, recovery rooms, intensive care units, or ICUs, emergency departments and alternative care settings, such as long-term care facilities and for home monitoring of patients with chronic conditions.

In addition, clinicians 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 under 96%, clinicians believe they can lower the

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incidence of hyperoxemia. Hyperoxemia can also cause problems for adults, such as increased risk of postoperative infection and tissue damage. In adults, to prevent hyperoxemia, clinicians use pulse oximetry monitoring to guide the administration of oxygen to maintain normal saturation levels.

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 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 immediately initiate treatment to prevent the serious clinical consequences of hypoxemia and hyperoxemia.

Limitations of Conventional Pulse Oximetry

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, which is partially depleted of oxygen, may cause falsely low oxygen saturation readings. Low perfusion can also cause conventional pulse oximeters to report inaccurate measurement, or in some cases, no measurement at all. Conventional pulse oximeters cannot distinguish oxygenated hemoglobin, or the component of red blood cells that carries 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, published research shows that conventional pulse oximeters are subject to operating limitations, including:

- inaccurate measurements, which can lead to the non-detection of a hypoxemic event or improper and unnecessary treatment;
- false alarms, which occur when the pulse oximeter falsely indicates a drop in the arterial blood oxygen saturation level, and which can lead to improper therapy, the inefficient use of clinical resources as clinicians respond to false alarms, or the non-detection of a true alarm if clinicians become desensitized to frequently occurring false alarms; and
- signal drop-outs, which is the loss of a real-time signal as the monitor attempts to find or distinguish the pulse, and which can lead to the non-detection of hypoxemic events.

Independent research shows 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 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 have averaged the signal over a longer period of time, known as long-averaging, in an attempt to reduce the effect of brief periods of motion. Still other competing devices extend the audible alarm notification delay, which reduces the awareness of inaccurate measurements. These competing solutions, commonly referred to as alarm management techniques, mask the limitations of conventional pulse oximetry. Several published studies have demonstrated that these alarm management techniques contribute to increased occurrences of undetected true alarms, or events where hypoxemia occurs, but is not detected by the pulse oximeter.

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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. In order for pulse oximetry to become a standard patient monitor in these settings, these limitations must be overcome.

In addition, 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.

We revolutionized pulse oximetry by inventing Signal Extraction Technology®, which allows pulse oximeters to measure through motion and low perfusion. In addition, with the invention of rainbow® technology, we can also measure noninvasive and continuous carboxyhemoglobin and methemoglobin, as well as hemoglobin. The invasive technology that measures carboxyhemoglobin and methemoglobin amongst other things, including arterial oxygen saturation and hemoglobin, is called a CO-Oximeter. We describe our noninvasive rainbow® technology as Pulse CO-Oximetry™.

Pulse Oximetry Market Opportunity

The pulse oximetry market consists of pulse oximeter devices, boards, and consumables, including single-patient use and reusable sensors, cables and other pulse oximetry accessories that are primarily sold to the hospital and alternative care markets. Based on available estimates for the U.S. and international market, we estimate that the worldwide pulse oximetry market was more than $1 billion in 2012.

According to a 2012 iData research report, the pulse oximetry market is expected to continue to grow, primarily due to an aging baby boomer population which will contribute to the increasing use of healthcare services. In addition, the market for peripheral pulse oximetry is expected to continue to grow with an industry-wide push for more low-acuity monitoring in both hospitals and alternate care facilities.

New Market Opportunities for Masimo SET® Pulse Oximetry

General Floor Monitoring Expansion

We believe there are opportunities to expand the market for pulse oximetry by applying Masimo SET® s proven benefits from critical care settings to non-critical care settings, as well as settings outside of the hospital. The 8th annual HealthGrades Patient Safety in American Hospitals Study looked at patient safety indicators for 40 million hospitalized patients and concluded that many deaths and permanent disabilities could be avoided if hospitals adopted safe practices and implemented systems that facilitate patient safety. The cost associated with post-operative respiratory failure is estimated to be over $2 billion.

A landmark study published in January 2010 by the Journal of Anesthesiology from Dartmouth-Hitchcock Medical Center demonstrated that clinicians using Masimo SET® and Patient SafetyNet™ identified patient distress earlier, which decreased rapid response team activations by 65% and ICU transfers by 48%, and reduced ICU days by 135 days annually. A follow up report in the Anesthesia Patient Safety Foundation journal by Dartmouth-Hitchcock in 2012 reported that since December 2007, no patients have died or had serious brain injuries as a result of respiratory depression from opioids. In addition, Dartmouth-Hitchcock reported that expanding the use of Masimo SET® and Patient SafetyNet™ to all general and thoraco-vascular post-surgical units produced similar results to those seen in the original orthopedic unit. They also reported savings of $58,459 per patient, or $1.5 million annually, for patients who were not transferred to the ICU from the original orthopedic unit.

In August 2012, the Joint Commission issued a sentinel event alert, urging all hospitals to introduce measures to improve safety for patient receiving opioids, including systematic protocols to assess pain and appropriate opioid

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dosing, as well as continuous monitoring of oxygenation and ventilation. We believe that this sentinel event alert will significantly increase the general floor monitoring rate of adoption of Masimo SET® and Patient SafetyNet™.

The American Hospital Association estimated that there were 947,000 staffed beds in all U.S.-registered hospitals in 2004. In 2000, according to a study published in the Journal of Critical Care Medicine, 87% of all hospital beds in the U.S. were located in a non-critical care setting, which suggests a non-critical care market potential of 820,000 beds in the U.S. alone. While some of these non-critical care beds have some form of monitoring capabilities today, we believe that 15% or more of the 820,000 beds in the U.S. alone could become continuous monitoring beds. We believe that Masimo SET® s ability to dramatically minimize false alarms due to patient motion while maximizing the sensitivity of pulse oximeters to report true alarms will allow hospitals to reliably and continuously monitor their patients in the general floors.

Alternate Care

According to a 2011 iData market research report, the fastest growing portion of the U.S. pulse oximetry equipment market is in the alternate care market. We believe that Masimo SET® technology offers significant advantages in some segments of this market, including home care, post-acute care hospitals, and sleep diagnostics. The proven ability of Masimo SET® to dramatically reduce false alarms and increase true event detection enables clinicians to make more reliable diagnoses of those who have pulmonary or cardiac abnormalities, need oxygen therapy, or need Continuous Positive Airway Pressure therapy. We plan to leverage this opportunity and expand our presence in this market.

New Market Opportunities for Pulse CO-Oximetry or Masimo rainbow® SET

Masimo rainbow® SET creates additional demand for our pulse oximetry circuit boards, monitors and sensors because customers desire the rainbow® SET noninvasive measurement capabilities that are not available with any other pulse oximeter technology. To date, over 20 OEM companies have released rainbow® SET-equipped products or announced rainbow® integration plans. Companies with released rainbow® SET products include Physio-Control, Welch Allyn, ZOLL, Dräger, GS Corpuls, BMEYE, Saadat and more. Companies that have announced rainbow® SET integration, but have not yet released products, include Atom Medical, CareFusion, GE Medical Systems and Philips. In addition, more than 20 additional companies are actively working on rainbow® integration but have not yet publicly announced their integration plans.

There are significant opportunities with rainbow® SET to create new hospital and alternate care markets by enabling the monitoring of additional noninvasive measurements beyond arterial blood oxygen saturation level and pulse rate.

Hemoglobin (SpHb®)

In May 2008, we received clearance from the FDA for our continuous hemoglobin monitoring technology and in September 2008, we began shipping, in a limited market release, these monitors and sensors. In March 2009, we fully launched our continuous noninvasive hemoglobin device. Hemoglobin is the part of a red blood cell that carries oxygen to the body and therefore a measurement of the hemoglobin parameter is an indicator of the oxygen carrying capacity of the blood. 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 RBC transfusion to sustain organ function and life. Because of its clinical importance, hemoglobin is one of the most commonly ordered lab diagnostic tests in the hospital and physician office. Each year in the U.S., over 400 million invasive hemoglobin tests are performed, which require multiple steps, including collecting the patient s blood sample, transferring the sample to the lab, analyzing the sample, documenting the results and reporting the results to the ordering clinician.

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A low or falling hemoglobin measurement provides the primary indication for whether a patient receives a RBC transfusion. A RBC transfusion is the most frequent procedure performed in U.S. hospitals, with one in ten inpatients receiving one or more units of blood. RBC transfusions are highly variable by institution, procedure and physician. Evidence from observational studies shows RBC transfusions can increase mortality by 69% and morbidity by 88%, while restrictive transfusion practices have been proven safe in multiple randomized controlled trials. Blood transfusions are costly between $522 and $1,183 per unit not accounting for morbidity costs. Many transfusions are unnecessary a systematic review of 494 studies showed that 59% are inappropriate . There is a growing recognition of the need to implement strategies to reduce transfusions by groups such as The Joint Commission and the American Medical Association, with RBC transfusions recently targeted as one of the top five procedures that are overused. In spite of the strong need to reduce RBC transfusions, existing tools for transfusion decision making are limited and may contribute to inappropriate transfusions. For example, estimated blood loss is commonly much higher than actual blood loss, and laboratory hemoglobin values are only available intermittently and are often delayed. It is estimated that with appropriate tools, processes and application of evidence-based medicine, RBC transfusions could be reduced and save the U.S. healthcare system up to $5 billion per year, while significantly improving quality and safety.

At the American Society of Anesthesiologists scientific meeting in October 2010, investigators from Massachusetts General Hospital presented the results of their study in which they evaluated the impact of SpHb® monitoring in a randomized controlled trial in orthopedic surgery patients. Patients in the standard care group had a 4.5% transfusion rate and patients in the SpHb® monitoring group had a 0.6% transfusion rate, an 87% reduction in transfusion frequency with SpHb®. Patients in the standard care group had an average of 0.10 units transfused and patients in the SpHb® monitoring group had an average of 0.01 units transfused, a 90% reduction in average units transfused. Based on the 0.09 unit lower blood utilization per patient shown in the study and an estimated blood cost of $522 to $1,183 per unit, SpHb® could reduce hospital costs by $47 to $106 per patient monitored. It is possible that SpHb® monitoring may have an even greater benefit in populations with greater transfusion frequency and a greater number of average units transfused.

A low or falling hemoglobin measurement also helps determine whether a patient has internal bleeding that requires further investigation and intervention. The later bleeding is discovered, the greater the patient risk and greater the potential for increased cost of treatment. Significant bleeding occurs in up to 35% of surgical and ICU patients. A low hemoglobin measurement is associated with almost 90% of patients with bleeding. However, traditional laboratory measurements are both delayed and infrequent, and as a result, are late in identifying bleeding.

According to a study published in January 2010 by Anesthesia and Analgesia, undetected bleeding also occurs in otherwise healthy patients, such as mothers who have just delivered babies. Postpartum hemorrhage, or PPH, is the leading cause of maternal mortality. The direct pregnancy-related maternal mortality rate in the U.S. is 7 to 10 women per 100,000 live births, and 19% of in hospital maternal deaths are caused by PPH. In the developing world, statistics suggest that 25% of maternal deaths are due to PPH, accounting for more than 140,000 maternal deaths per year, or 1 woman every 4 minutes.

When used with other clinical variables, Masimo SpHb® may help clinicians assess bleeding status and help determine treatment and additional test options. While clinical research studies on SpHb® are ongoing, clinicians inherently understand the value of continuous and noninvasive hemoglobin monitoring. A study by the consulting firm Capgemini concluded that the average 500 bed hospital would save $468,000 annually by implementing SpHb® and other rainbow® measurements. Because of the potential clinical and cost advantages of measuring hemoglobin noninvasively and continuously, we believe that a greater number of hospitals will adopt Masimo rainbow® SET technology.

A significant portion of invasive hemoglobin measurements are made outside of hospital settings, in the physician office to aid patient assessment and treatment, and in the blood donation market to qualify potential

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donors for eligibility to donate blood. We believe that a significant number of the estimated 200,000 U.S. physician offices and estimated 17 million annual U.S. blood donations could be aided by the noninvasive and immediate assessment of hemoglobin.

Beginning in January 2010, the American Medical Association approved a Current Procedural Terminology, or CPT, code and Medicare implemented pricing on the Medicare Clinical Lab Fee Schedule for noninvasive hemoglobin, enabling U.S. hospitals and physician offices that perform testing to recover their costs, in addition to the clinical benefits they receive from this measurement. In 2013, the Medicare reimbursement for SpHb® is $6.90 per test when testing eligible patients.

Carboxyhemoglobin (SpCO®)

Carbon monoxide 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. Carbon monoxide 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. Carbon monoxide poisoning, which involves carbon monoxide 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 carbon monoxide poisoning is critical in saving lives and preventing long-term damage, but the condition is often misdiagnosed because symptoms are similar to the flu. Historically, carbon monoxide levels in the blood have been 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. In one region of the country, it is estimated that only one-half of acute care hospitals has laboratory CO-Oximetry capabilities. Additional delays occur if a patient needs hyperbaric oxygen therapy, which often requires transfer to yet another medical center with hyperbaric capability.

When used with other clinical variables, Masimo SpCO® may help clinicians detect carbon monoxide poisoning and help determine treatment and additional test options. According to a 2008 study by Brown University, an emergency department using Masimo rainbow® SET carbon monoxide monitoring identified 60% more carbon monoxide poisoning cases than the conventional approach, and estimated that as many as 11,000 carbon monoxide poisoning cases per year in the U.S. were being missed with the conventional approach. In a 2012 study, based on three years of U.S. data from the Undersea and Hyperbaric Medicine Society s carbon monoxide poisoning surveillance system (supported by the Centers for Disease Control), researchers analyzed cases of carbon monoxide poisoning treated with hyperbaric oxygen with initial carboxyhemoglobin level measured by either laboratory CO-Oximetry or with SpCO® from a rainbow® Pulse CO-Oximeter®. Patients who were initially measured using rainbow® Pulse CO-Oximetry had a significantly shorter time to measurement of carbon monoxide (1.1 versus 1.7 hours) and a shorter period of time from the end of carbon monoxide exposure to treatment (4.4 versus 5.3 hours). Three hours after exposure, 45% of patients evaluated by Pulse CO-Oximetry had started treatment versus just 25% of patients evaluated by laboratory CO-oximetry that had started treatment.

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 assessment for carbon monoxide poisoning is appropriate when exposure is suspected or when an individual presents symptoms that could indicate such poisoning. In addition, the National Fire Protection Association, or NFPA, included carbon monoxide screening by Pulse CO-Oximetry as an available method as part of a new national healthcare standard for firefighters potentially exposed to carbon monoxide poisoning. NFPA s consensus codes and standards serve as the worldwide authoritative source on fire prevention and public safety.

In addition, the United Kingdom House of Commons All Party Parliamentary Gas Safety Group, in a report published in January 2009, aimed at increasing the awareness of carbon monoxide poisoning among medical professionals, recommended noninvasive carbon monoxide testing for Emergency Department and alternate care

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market providers as a way to improve the country s rate of detection and diagnosis of carbon monoxide poisoning. For the preparation of this report, the United Kingdom Group used Masimo rainbow® SET Rad-57™ devices for 12 months and reported successful cases with the Rad-57™ devices.

Beginning January 2009, the American Medical Association approved a CPT code and Medicare implemented pricing on the Medicare Clinical Lab Fee Schedule for noninvasive carboxyhemoglobin, enabling U.S. hospitals that perform testing to recover their costs, in addition to the clinical benefits they receive. In 2013, the Medicare reimbursement for SpCO® is $6.90 per day when testing eligible patients.

We believe that the first and greatest opportunity for noninvasive blood carbon monoxide monitoring is in the alternate care market and emergency department settings. In the U.S. alone, there are 30,000 fire departments / alternate care market locations and 5,000 hospitals that would benefit from noninvasive carbon monoxide testing.

Methemoglobin (SpMet®)

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.

According to a study published in September 2004 by researchers at Johns Hopkins University, over a 28 month period there were 414 cases, or 19% of all patients reviewed, of acquired methemoglobinemia. In these cases, the methemoglobinemia resulted in one fatality and three near-fatalities. 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.

When used with other clinical variables, Masimo SpMet® may help clinicians detect methemoglobinemia and help determine treatment and additional test options. We believe the initial opportunity for methemoglobin monitoring is in outpatient procedure labs in hospitals, such as esophageal echocardiography and gastrointestinal labs where use of topical caines , such as benzocaine, is prevalent, monitoring HIV patients who receive dapsone, as well as monitoring neonates who receive inspired nitric oxide in the neonatal ICUs.

Beginning January 2009, the American Medical Association approved a CPT code and Medicare implemented pricing on the Medicare Clinical Lab Fee Schedule for noninvasive methemoglobin, enabling U.S. hospitals that perform testing to recover their costs, in addition to the clinical benefits they receive. In 2013, the Medicare reimbursement for SpMet® is $6.90 per day when testing eligible patients.

PVI®

Fluid is administered through intravenous catheters to surgical and intensive care patients as part of a key objective to ensure that vital tissues are getting enough oxygen. However, too much fluid may cause harm to patients. Therefore, the decision of whether to administer fluid is of fundamental importance in critically-ill and surgical patients. Ideally, a clinician would know prior to giving fluid whether the patient would respond favorably to the fluid, which is known as fluid responsiveness. However, traditional methods such as central venous pressure monitoring often fail to predict fluid responsiveness, and newer methods are invasive, complicated and/or costly.

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Multiple studies have shown that, when used with other clinical variables, PVI® helps clinicians assess fluid responsiveness, defined as an increase in the amount of blood flow the heart pumps per minute, or cardiac output. Mechanical ventilation means that a machine called a respirator is controlling patient breathing. PVI®, which has been shown to help clinicians improve fluid management, has also been used by clinicians in Goal Directed Therapy to reduce patient risk. Fluid management was improved by PVI® by helping reduce the amount of fluid given to surgical patients, which lowered their patient risk as evidenced by a lowering of a key patient risk marker called lactate level.

We believe the primary opportunity for PVI® monitoring is in mechanically ventilated adult patients during surgery and in the intensive care department in hospitals, but it is also possible that future studies may reveal application in non-mechanically ventilated adult patients in the hospital and other out-of-hospital patient populations.

Respiration Rate (RRa™)

We received FDA clearance for RRa™ with rainbow Acoustic Monitoring™ technology in November 2009, announced initial market release of the parameter in December 2009, and announced full market release in June 2010.

Respiration rate is defined as the number of breaths per minute, and changes in respiration rate provide an early warning sign of deterioration in patient condition. Current methods to monitor respiration rate include end tidal CO_2 monitoring, which requires a special tube to be inserted in the patient s nose and therefore has low patient compliance, and impedance monitoring, which is considered unreliable. Multiple clinical studies have shown that RRa™ provides as good or better accuracy to monitoring 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. Our noninvasive respiration rate parameter is available in our Masimo rainbow® SET platforms with the launch of MX-3 circuit board, which was released in November 2009. These devices with the RRa™ software and our acoustic respiration sensor are placed on the patient s neck and connected to the bedside monitor with a separate cable. Should the respiration rate change or stop, an alarm will be displayed on the device and in addition, can be sent to the Patient SafetyNet™ system. Patient SafetyNet™ can then notify the attending clinician or nurse of the condition, directly on the monitor or remotely via a pager.

When used with other clinical variables, RRa™ may help clinicians assess respiratory status and help determine treatment options. We believe this noninvasive measurement will become a key and important measurement in the general floor environment, in the post-anesthesia care unit, during procedural sedation such as in the gastrointestinal lab, as well as in the monitoring of non-mechanically ventilated patients during surgery.

Fractional Arterial Oxygen Saturation ($SpfO_2$™)

In October 2012, we debuted $SpfO_2$™, a new parameter which, for the first time, allows the measurement of *fractional* arterial oxygen saturation noninvasively. This parameter has received CE mark for the European Union, but it is subject to FDA 510(k) clearance before commercialization in the U.S. Until now, pulse oximeters could only measure and display functional oxygen saturation, or SpO_2. Therefore, when patients had elevated carboxyhemoglobin (from carbon monoxide 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. Utilizing more than seven wavelengths of light and breakthrough signal processing, Masimo rainbow® Pulse CO-Oximeters® can measure and display *fractional* arterial oxygen saturation. $SpfO_2$ allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to *functional* oxygen saturation. $SpfO_2$ may allow earlier interventions and more timely therapeutic decisions.

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Halo Index™

In October 2010, we debuted Halo Index™, which has received CE mark for the European Union, but it is subject to FDA 510(k) clearance before commercialization in the U.S. Halo Index™ is a dynamic indicator that facilitates continuous global trending and assessment of multiple physiological measurements to quantify changes in patient status. Currently, clinicians monitor multiple clinical measurements on each patient and respond independently to each of the measurement. Halo Index™ is a single displayed value on the Patient SafetyNet™ remote monitoring and notification system, which facilitates simple and comprehensive assessment within a single index. In the future, subject to FDA 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 Vivo Adjustment™

In October 2011, In Vivo Adjustment™ received CE marking in the European Union but is subject to FDA 510(k) clearance in the U.S. In the 2011 and 2012 Radical-7®, In Vivo Adjustment™ enables clinicians, for the first time, to adjust the noninvasive measurement of SpHb® to the specific patient and laboratory reference device they use for invasive blood testing. In Vivo Adjustment™ is considered helpful to clinicians because the reference standard used in their hospital may differ from the reference standard used by Masimo for calibration, inducing differences in the noninvasive measurement and the invasive measurement. In addition, while calibration curves are developed over a large number of patients, variation can occur from the calibration curve for any single patient.

Disruptive New Technologies

In general, our recent noninvasive measurement technologies are breakthrough products that are considered disruptive. These disruptive technologies have performance levels that we believe are acceptable for many clinical environments, but in their present form may be insufficient in others. In addition, these noninvasive measurement technologies may perform better in some patients and settings than others. The performance of these technologies shows variability across a population that follows a standard gaussian distribution described in the accuracy specifications. Over time, we hope to reduce this variability and, if we do, we expect these recent noninvasive measurement technologies to become more useful in additional environments and to become more widely adopted. This is the adoption pattern experienced historically with our other new noninvasive measurements, such as oxygen saturation, and what we expect to experience in the future with our current and future technologies.

SEDLine® Brain Function Monitoring

In July 2010, we began selling the SEDLine® monitor, which measures the brain s electrical activity and provides information about a patient s response to anesthesia. SEDLine® enables monitoring of both sides of the brain simultaneously and provides Density Spectral Array for immediate detection of asymmetrical activity. SEDLine® monitors enable more individualized titration of anesthesia and sedation for faster emergence, while offering reliable monitoring during challenging conditions such as electrocautery.

Capnography and Gas Monitoring

In July 2012, we acquired 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.

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Future Measurements

We believe that our core signal processing and sensor technologies are widely applicable and may develop and launch future applications utilizing our proprietary technology platforms. However, we do not plan to communicate the priority, status or timing of future measurements in development until such time that they have reached feasibility and/or received regulatory clearance.

The Masimo Solution

Masimo SET® was designed to overcome the primary limitations of conventional pulse oximetry, which involve maintaining accuracy in the presence of motion artifact 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. In addition, our products benefits have been validated in over 100 independent clinical and laboratory studies. Masimo SET® utilizes five signal processing algorithms, four of which are proprietary, in parallel, to deliver high precision, sensitivity and specificity in the measurement of arterial blood oxygen saturation levels. Sensitivity is the ability to detect true events and specificity is the 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.

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. 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. Our neonatal adhesive sensors have been clinically proven to exhibit greater durability compared to competitive sensors.

In response to the hospital market s growing needs to implement environmentally friendly, or green , products and to decrease costs to remain competitive, we developed the Pulse Oximetry ReSposable sensor system and began a limited market release in December 2010. The 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. ReSposable sensors produce 90% less waste and 41% fewer carbon emissions than disposable sensors, while recycled sensors only decrease waste by 34% and actually increase carbon emissions by 43% compared to disposable sensors.

In 2005, we introduced our Masimo rainbow® SET platform, leveraging our Masimo SET® technology and incorporating licensed rainbow® technology to enable reliable, real-time monitoring of additional measurements beyond arterial blood oxygen saturation and pulse rate. The Masimo rainbow® SET platform has the unique ability to distinguish oxygenated hemoglobins from certain dyshemoglobins, hemoglobins incapable of transporting oxygen, and allows for the rapid, noninvasive monitoring of hemoglobin, carboxyhemoglobin, methemoglobin and PVI, which we refer to as Pulse CO-Oximetry. Along with the release of our rainbow® Pulse CO-Oximetry products, we have 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 believe the addition of RRa™ with 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.

Additionally, we market our Patient SafetyNet™ remote monitoring and clinician notification system for use with our Masimo SET® pulse oximeters and rainbow® Pulse CO-Oximeters®, which allow monitoring of the oxygen saturation and pulse rate of up to 80 patients simultaneously. Patient SafetyNet™ offers a rich user

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interface with trending, and 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 Masimo 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. Patient SafetyNet™ also allows the display of the new Halo Index™, discussed earlier. 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.

We believe that our technologies and products offer multiple clinical and financial benefits, including:

Masimo SET® Pulse Oximetry

Fewer false alarms and better true alarm detection. Over 100 independent and objective studies have now proven Masimo SET® accuracy during challenging conditions in adult, pediatric and neonatal patients.

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 increases the detection of this potentially fatal disease before the baby 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 has cleared specific labeling indicating the use of pulse oximeters, in conjunction with a physical exam, to screen newborns for CCHD.

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 similar results as the center already using Masimo SET®

Fewer arterial blood gas measurements, faster oxygen weaning time, and lower length of stay in the ICU. With more accurate and reliable measurements from Masimo SET®.

Lower sensor utilization. Due to sensor durability and the ease of obtaining measurements with Masimo SET®.

Expansion into Non-Critical Care Settings. We believe the ability of Masimo SET® products to provide reliable monitoring with fewer false alarms has expanded and will continue to expand the use of pulse oximetry into other settings where patient motion and false alarms have historically prevented its use. Since the introduction of Masimo SET®, we believe that pulse oximetry has become a standard of care in the alternate care market.

Earlier detection of patient distress on the general floor, enabling reduced ICU Transfers and Rapid Response Activations. Many patients in the general care areas are at risk of dying due to inadequate oxygenation. To mitigate this risk, patients in the general care areas need to be continuously monitored. Our Patient SafetyNet™ systems enable the Masimo SET® and rainbow® SET platforms to wirelessly

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and remotely monitor patients in the general care areas of the hospital that are not under the constant supervision of clinicians. A landmark study published in 2010 by Dartmouth-Hitchcock Medical Center demonstrated that 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 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.

Upgradeable rainbow® SET Platform for Earlier and Better Decisions About Patient Care. 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 will have the option of purchasing a software measurement, which will allow the customer to expand their patient monitoring systems to monitor additional measurements with a cost-effective solution. The rainbow® platform enables breakthrough noninvasive monitoring of measurements that previously required invasive testing, which may lead to earlier and better clinical decisions and decreased costs compared to standard care. Examples of the many benefits of breakthrough rainbow® measurements include:

Hemoglobin (SpHb®)

Helping clinicians reduce the risk and cost associated with RBC transfusions

Helping clinicians identify undetected bleeding earlier in surgical, intensive care, trauma, and obstetric patients

Helping clinicians identify anemia more rapidly and efficiently, and allowing them to assess patients for anemia in developing countries around the world

Carboxyhemoglobin (SpCO®)

Helping clinicians identify deadly carbon monoxide poisoning earlier and more often, reducing incorrect diagnoses

Methemoglobin (SpMet®)

Helping clinicians identify dangerous methemoglobinemia earlier and more often, reducing incorrect diagnoses

Pleth Variability Index (PVI®)

Helping clinicians assess fluid responsiveness and improve fluid management in surgical and intensive care patients who are mechanically ventilated

Respiration Rate (RRa™)

Helping clinicians identify respiratory depression and respiratory distress earlier and more often

Halo Index™

Potentially helping clinicians identify patient distress earlier, more effectively, more easily, and more efficiently

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SEDLine® Brain Function Monitoring

Enabling more individualized titration of anesthesia and sedation for faster emergence, while offering reliable monitoring during challenging conditions such as electrocautery

Fractional Arterial Oxygen Saturation ($SpfO_2$™)

Allowing more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to *functional* oxygen saturation (SpO_2)

Capnography and Gas Monitoring

Allowing continuous monitoring of ventilation in mechanically ventilated patients, monitoring ventilation during cardiopulmonary resuscitation, and monitoring gas concentrations to help titrate anesthesia

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 to improve our market position by pursuing the following strategies:

Continue to Expand Our Market Share in Pulse Oximetry. We grew our product revenue to $464.9 million in 2012 from $300.1 million in 2009, representing a three year CAGR of 15.7%. This growth can be attributed to the increased access to pulse oximetry customers through our agreements with group purchasing organizations, or GPOs, our increased relationships with OEM partners, the expansion of our direct sales force, and strong, independent clinical evidence that demonstrates the benefits of our technology. We supplement our direct sales with sales through our distributors. Direct and distributor sales increased to $396.2 million, or 85.2%, of product revenue in 2012, from $241.7 million, or 80.5%, of product revenue in 2009.

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 care areas 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 thus 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 the Hospital Setting. We believe the noninvasive measurement of rainbow® Pulse CO-Oximetry (hemoglobin, carboxyhemoglobin, methemoglobin, PVI), rainbow Acoustic Monitoring™ (respiration rate), 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 our revenues, directly and through a greater ability to convert non-Masimo hospitals to Masimo hospitals due to our expanded 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, emergency departments, and blood donation centers, and noninvasive carboxyhemoglobin in the fire/alternate care market. To date, we have introduced our first noninvasive spot-check hemoglobin device called Pronto® and, in January 2012, we began full market release of Pronto-7®, utilizing the new

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rainbow 4D™ technology, as a noninvasive spot-check hemoglobin device, along with oxygen saturation, pulse rate and perfusion index. The Pronto® and Pronto-7® allow users to simply and quickly perform a spot-check measurement of hemoglobin levels, one of the most common invasive laboratory measurements. We believe that the ability to noninvasively measure hemoglobin will increase efficiency and improve clinical decision making in physician offices, emergency departments and blood donation centers, by enabling quick determination of hemoglobin levels and reducing the time required to take an invasive blood draw, create the labeling, send the sample to the lab, wait for the lab results (often not until the next day), and communicate these results to the patient.

Utilize Our Customer Base and OEM Relationships to Market Our Masimo rainbow® SET Products Incorporating Licensed rainbow® Technology. We sold our first Masimo rainbow® Pulse CO-Oximetry products in September 2005. We are currently selling our rainbow® SET products through our direct sales force and distributors. In addition, we plan to sell our MX circuit boards in our own pulse oximeters and to our OEM partners, equipped with circuitry to support rainbow® Pulse CO-Oximetry measurements which can be activated at time of sale or through a subsequent software upgrade. We believe that 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, which all previously required invasive testing. With our introduction of RRa™ with rainbow Acoustic Monitoring™ technology, we believe we have launched the first platform to enable noninvasive and continuous monitoring through an easy to use single patient adhesive acoustic sensor. In October 2010, we debuted Halo Index™ (pending FDA 510(k) clearance in the U.S.). Halo Index™ is a dynamic indicator that facilitates continuous global trending and assessment of multiple physiological measurements to quantify changes in patient status. We plan to continue to innovate and develop new technologies and products, internally and through our collaboration with Cercacor, whom we currently license carboxyhemoglobin, methemoglobin and hemoglobin from, for the noninvasive monitoring of other measurements.

Our future growth strategy is also closely tied to our focus on international expansion opportunities. Since 2007, we have been aggressively expanding our sales and marketing presence in Europe, Asia, Canada and Latin America. We have accomplished this through both additional staffing and by adding or expanding sales offices in many of these territories. During the fourth quarter of 2008, we established a new international business structure designed to better serve and support our growing international business. By centralizing our international operations, including sales management, marketing, customer support, planning, logistics and administrative functions, we believe we have developed a more efficient and scalable international organization capable of being even more responsive to the business needs of our international customers all under one centralized management structure. As a result of these investments and focus on our international operations, we believe that our international product revenues, as a percent of total product revenues, will continue to increase.

Our Products

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

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

Product Components	Description	Markets and Methods of Distribution
Patient Monitoring Solutions:		
Circuit Boards (e.g., MX-1®, MX-3, MS-2011, MS-2040, uSpO$_2$™, ISA™, and IRMA™)	Signal processing apparatus for all Masimo technology platforms	Incorporated and sold to OEM partners who incorporate our circuit boards into their patient monitoring systems
	Mainstream and sidestream capnography and gas monitors	
Monitors / Devices (e.g., Radical-7®, Pronto-7®, Rad-57™ and EMMA™)	Bedside and handheld monitoring devices that incorporate Masimo SET® with and without licensed Masimo rainbow® SET technology	Sold directly to end-users and through distributors and in some cases to our OEM partners who sell to end-users
	Compact and self-contained capnometer which monitors CO_2 concentration	
Sensors (e.g., SET®, rainbow® Pulse CO-Oximetry, rainbow Acoustic Sensors™, and SEDLine)	Extensive line of both single- patient, reusable and ReSposable sensors	Sold directly to end-users and through distributors and to OEM partners who sell to end-users
	Patient cables, as well as adapter cables that enable the use of our sensors on certain competitive monitors	
Line filters, cannulas, and mainstream adapters (e.g., capnography and gas disposables)	Line of disposables to measure 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., Masimo Patient SafetyNet™)	Network-linked, wired or wireless, multiple patient floor monitoring solutions	Sold directly to end-users
	Standalone wireless alarm notification solutions	
Software (e.g., SpHb®, SpCO®, SpMet®, PVI®, RRa™, 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
Consumer product (e.g., iSpO$_2$™)	Pulse oximeter cable and sensor for use with an iPhone, iPad or iPod touch	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

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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 the new 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 measure arterial blood oxygen saturation levels and pulse rate, and have the circuitry to enable the measurement of hemoglobin, oxygen content, carboxyhemoglobin, methemoglobin, PVI, respiration rate and halo index™, along with other potential measurements in the future. 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. As additional measurements are developed, each new measurement may be available as a software upgrade to the existing system.

uSpO$_2$™ Cable/Board. Our new 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®. We believe that the Radical-7® offers features that do not exist in any other pulse oximeter. The Radical-7® incorporates the MX circuit board, which enables rainbow® SET measurements, and offers three-in-one capability to 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 multi-parameter patient monitors to Masimo SET® while displaying rainbow® measurements on the Radical-7® itself.

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.

SatShare® technology enables a conventional monitor to upgrade to 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.

Rad-87®. The Rad-87®, which also contains Masimo rainbow® SET technology, is a compact, lightweight and easy-to-use device designed specifically for use in less acute settings than the Radical-7®. The Rad-87® is available with a built-in bi-directional wireless radio for use as part of the Patient SafetyNet™ remote monitoring and clinician notification system.

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Pronto®. The Pronto® is a handheld noninvasive multi-parameter 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 multi-parameter device utilizing rainbow 4D™ that provides spot-check hemoglobin testing along with oxygen saturation, pulse rate and perfusion index results. With a touch screen for easy operation and wireless 802.11 and Bluetooth for printing and communication, the Pronto-7® is well-suited for hemoglobin spot-check testing in almost any environment.

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, allowing it to be offered at a lower price point than the Radical-7® or Rad-87®.

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® monitor. The SEDLine® monitor measures brain function on a continuous basis. The SEDLine® monitor, an EEG-based brain function monitor, provides information about a patient s response to anesthesia.

Capnography and Gas Monitoring. In July 2012, we acquired Phasein, a developer and manufacturer of ultra-compact mainstream and sidestream capnography, gas analyzers and handheld capnometry solutions. The gas analyzers, or IRMA™ and ISA™, and emergency capnometer, or EMMA™, enable our customers to benefit from CO_2, N_2O, O_2, and anesthetic agent monitoring in many hospital environments.

iSpO$_2$ pulse oximeter for use with an iPhone, iPad or iPod touch. The iSpO$_2$ uses Masimo SET® for Measure-Through Motion and Low Perfusion performance, for consumers to check their own arterial blood oxygen saturation (SpO_2), pulse rate, and perfusion index measurements for short-term sports and aviation use. This version is not intended for medical use. The iSpO$_2$ Medical, the professional version for medical use, is pending CE mark and FDA 510(k) clearance.

Sensors

Sensors and Cables. We have developed one of the broadest lines of single-patient use (disposable), reusable and 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 through our direct sales force and 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 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.

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Trauma and Newborn Sensors. We believe we were the first to develop 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®, 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. In 2005, we introduced what we believe to be the first FDA-cleared sensor to accurately monitor arterial blood oxygen saturation levels in cyanotic infants and children with abnormally low oxygen saturation levels.

E1™ Ear Sensor. In 2011, we introduced 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™ Sensor is ideal for field emergency medical services utilization.

Rainbow® Sensors. We believe we were the first to develop proprietary, multi-wavelength sensors for use with our rainbow® Pulse CO-Oximetry products. As opposed 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, ReSposable, and reusable spot-check sensor types.

Rainbow Acoustic Sensors™. We believe we were the first to develop 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 exclusively with the SEDLine® monitor, the SEDLine® sensor is a disposable sensor that collects a high volume of brain function data from key areas of the frontal lobe.

Rainbow® Universal ReSposable SuperSensor™. This sensor (pending FDA 510(k) clearance in the U.S.), is the first noninvasive sensor to provide simultaneous monitoring of SpHb®, SpCO®, SpMet®, $SpfO_2$™, SpOC™, Perfusion Index, PVI®, and Measure-Through Motion and Low Perfusion SpO_2 and pulse rate.

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, and Masimo ReSposable Sensors, offering unprecedented sustainability with a lower carbon footprint and greater waste reduction than reprocessing or new sensors. Masimo 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.

Software

All of our monitors, 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.

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In addition, in October 2010 we debuted Halo Index™ (pending FDA 510(k) clearance in the U.S.), which is a dynamic indicator that facilitates continuous global trending and assessment of multiple physiological measurements to quantify changes in patient status. Currently, clinicians monitor multiple clinical measurements on each patient and respond independently to each of the measurements. Halo Index™ is a single displayed value on the Patient SafetyNet™ remote monitoring and notification system, which facilitates simple and comprehensive assessment within a single index. 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.

X-Cal™

In 2011, we implemented a technology called X-Cal™ in our sensors, cables and instruments to enhance patient safety and improve clinician efficiency. 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 severely 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 warrantied 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

- Third-party reprocessed pulse oximetry sensors introduce challenges in the clinical environment because they are adulterated testing indicates that 91% of a leading third-party reprocessor s sensors tested fail 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, as available with Masimo SET® sensors. Also, no third-party company has attempted to reprocess rainbow® SET sensors.

Sales and Marketing

We have sales and marketing employees in the U.S. and abroad. We expect to continue to increase our worldwide sales and sales support organizations as we continue to expand our presence throughout both the U.S. and throughout the world including Europe, the Middle East, Asia, Latin America, Canada and Australia. We currently sell all of our products both directly to hospitals and the alternate care market via our sales force, and certain distributors.

The primary focus of our sales representatives is to facilitate the conversion of competitor accounts to our Masimo SET® pulse oximetry products, expand the use of Masimo SET® and Patient SafetyNet™ on the general floor, and create new 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,

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methemoglobin, PVI, acoustic respiration rate, and Halo Index™. Given the importance of continuous SpHb monitoring, we have also begun to build a new, incremental SpHb dedicated sales force whose primary focus will be working with hospitals to identify new opportunities to deploy this life-saving and cost reducing technology. While we have begun limited hiring in Q4 2012, we expect to increase the size of this new sales organization throughout the balance of 2013.Our direct and distributor revenue accounted for 85% of our total product revenue in 2012. For the year ended December 29, 2012, Owens & Minor and Cardinal Health, which are both just-in-time distributors, represented 14% and 11%, respectively, of our total revenue. These were the only customers that represented 10% or more of our revenue for the year ended December 29, 2012. Importantly, 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 will 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.

In order to facilitate our direct sales to hospitals, we have signed contracts with companies that we believe to be the five largest GPOs, 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 2012 and 2011, revenue from the sale of our pulse oximetry products to hospitals that are associated with GPOs amounted to $253.7 million and $223.8 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, sponsor accredited educational seminars for doctors, nurses, biomedical engineers, and respiratory therapists and conduct clinical evaluations. During 2013, we expect to modestly increase the size of our sales and marketing force worldwide, as we continue to establish and expand our sales channels on a global basis.

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. and its subsidiary Nellcor Puritan Bennett, Inc., currently hold 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 Nellcor sensors. We face substantial competition from larger medical device companies, including companies that develop products that compete with our proprietary Masimo SET®. 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. Some of the remaining companies, including GE Medical Systems and Mindray Medical International Ltd., are also currently OEM partners of ours.

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 respiration rate;

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competitive pricing;

sales and marketing capability;

access to hospitals which are members of GPOs;

access to OEM partners; and

patent protection.

Cercacor Laboratories, Inc.

Cercacor Laboratories, Inc., or 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 have a cross-licensing agreement, or the Cross-Licensing Agreement, with Cercacor for certain technologies. 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	
	Professional Caregiver and Alternate Care Market	**Patient and Pharmacist**
Measurements		
Vital Signs[1]	Masimo	Cercacor
	(owns)	(non-exclusive license)
Non-Vital Signs[2]	Masimo	Cercacor
	(exclusive license)	(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 all Masimo SET® owned by us 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. 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.

The Cercacor Market is defined as 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 care market professionals or otherwise, provided the product is intended to be recommended, or resold, for use by the patient or pharmacist.

Cercacor s License to us. We exclusively licensed 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. Additionally, we make and

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distribute products that monitor respiration rate via rainbow Acoustic Monitoring™, which is not required to be licensed from Cercacor. 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 in the Masimo Market that utilize rainbow® technology for the monitoring of other non-vital signs measurements, including blood glucose. These 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.

The Masimo Market is defined as those product markets where the product is intended to be used by a professional medical caregiver, including hospital caregivers, surgicenter caregivers, paramedic vehicle caregivers, doctor s offices caregivers, alternate care facility caregivers and vehicles where alternative care services are provided.

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 multi-parameter devices. Handheld products incorporating rainbow® technology will carry a 10% royalty rate. For other products, only the proportional amount attributable for that portion of our devices used to monitor non-vital signs measurements, rather than for monitoring vital signs measurements, and sensors and accessories for measuring only non-vital sign parameters will be included in the 10% rainbow® royalty base. For multi-parameter devices, the rainbow® royalty base will include 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 December 29, 2012 and going forward, we are subject to a certain specific annual minimum aggregate royalty payment obligation of $5.0 million per year.

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 the remaining non-vital signs measurements, including bilirubin, for an additional $500,000 each. As of December 29, 2012, feasibility on these measurements has not been attained. During the year ended December 29, 2012, Cercacor incurred a total of $6.1 million in operating expenses.

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;
- per product minimum royalties, to the extent less than the annual minimums, will be payable to Cercacor; and
- the minimum aggregate annual royalties for all licensed rainbow® measurements payable to Cercacor is $15.0 million per year until the exclusive period of the agreement ends, plus up to $2.0 million for each additional rainbow® measurement.

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;

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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 be subject to the 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. We have also entered into a services agreement, or the Services Agreement, with Cercacor. Under this Services Agreement, we provide Cercacor with accounting, human resources and legal services, which we collectively refer to as indirect expenses. 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, while we may terminate with a 180 day notice to Cercacor.

Cercacor s Expenses related to Pronto-7®. In February 2009, we and Cercacor agreed that in order to accelerate the development of the technology supporting this product, Cercacor would re-direct a substantial amount of its engineering development activities to focus on this project for our benefit. Accordingly, we and Cercacor agreed that from April 2009 through June 2010, the completion of this product development effort, 50% of Cercacor s engineering and engineering related expenses and all third-party engineering supplies expense related to Pronto-7® development would be charged to us. 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 December 29, 2012, the total funding for these additional Cercacor expenses was $3.6 million. Both companies have agreed to maintain this arrangement until we notify Cercacor that we no longer require this engineering support.

Research and Product Development

We believe that ongoing research and development efforts are essential to our success. We expect to increase the size of our research and development staff during 2013. Our research and development efforts focus primarily on continuing to enhance our technical expertise in pulse oximetry, enabling the 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 2012 were $47.0 million, which included $3.7 million related to expenses incurred by Cercacor pursuant to the Cross-Licensing Agreement. In 2011, our total research and development expenditures were $38.4 million, which included $3.4 million related to expenses incurred by Cercacor. In 2010, our total research and development expenditures were $36.0 million, which included

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$1.7 million related to expenses incurred by Cercacor. We expect our research and development expenses to increase in 2013 and beyond as we expand our research and development force, enhance our existing products and technologies and develop new product candidates.

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 December 29, 2012, we had 377 issued patents and 253 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. In addition, as of December 29, 2012, technology we licensed from our development partner, Cercacor, was supported by 152 issued patents and 138 pending applications in the U.S. and internationally. Some of our earliest patents began to expire in 2013. Some of Cercacor s earliest patents begin to expire in 2013. Additionally, as of December 29, 2012, we owned 52 U.S. registered trademarks and 149 foreign registered trademarks, as well as trade names that we use in conjunction with the sale of our products.

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 Item 1A Risk Factors.

Government Regulation

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive either 510(k) clearance, by filing a 510(k) pre-market notification, or PMA approval, by filing a Premarket Approval Application, or PMA, from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act. 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. It generally takes from one to three years or even longer. We cannot be sure that 510(k) clearance or PMA approval will ever be obtained for any product we propose to market.

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, or General Controls, for medical devices, which include compliance with the applicable portions of the FDA s Quality System Regulation, or QSR, facility registration and product listing, reporting of

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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, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure. All of our current devices are Class II devices.

Class III devices are those devices 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 premarket approval process described below. Premarket approval applications, and supplemental premarket approval applications, are subject to significantly higher user fees under the Medical Device User Fee and Modernization Act of 2002, or MDUFMA, than are 510(k) premarket notifications, and generally take much longer for the FDA to review.

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 in Class I, Class II, or is a 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. Pursuant to the MDUFMA and the MDUFMA II provisions of the Food and Drug Amendments Act of 2007, unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. 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. We have modified some of our 510(k) cleared devices, and in some cases, we have determined that new 510(k) clearances or PMA approvals are not required based on FDA guidance regarding when to submit a new 510(k) notification for changes to a cleared device. We cannot assure you that the FDA would agree with any of our decisions not to seek additional 510(k) clearances or even PMA approval for these or future device modifications. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval.

Class III devices are required to undergo the PMA approval process in which the manufacturer must establish the safety and effectiveness of the device to the FDA s satisfaction. A PMA application must provide extensive preclinical 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. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. A new PMA or a PMA Supplement is required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device s indications for use, manufacturing process, manufacturing facility, labeling and design. PMA Supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel. None of our products are currently approved under a PMA.

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A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an Investigational Device Exemption, or 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 at the clinical trial sites. 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 also recently launched the marketing of iSpO$_2$, a non-medical use pulse oximeter intended for short-term sports and aviation use. We are marketing these products 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 direct to consumers without first obtaining clearance of a 510(k). 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 these pulse oximeters. We also may be required to cease marketing and/or recall the products until we obtain a new 510(k) clearance.

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® or Masimo rainbow® SET circuit boards and 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.

In the future, we may be required to submit additional 510(k) submissions to the FDA to address new claims, uses or products. We cannot assure you that the FDA will not deem one or more of our future products, or those of our OEM partners, to be a Class III device subject to the more burdensome PMA approval process. The FDA also may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, 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;
- 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, or 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;

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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 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, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

fines and civil penalties;

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 approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; 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. Our failure, or the failure of our OEM partners, to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our business, financial condition and results of operations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that our promotional materials or training constitute promotion of an uncleared or unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a notice of violation, a warning letter, injunction, seizure, civil fine or criminal penalties. In that event, our reputation could be damaged and adoption of the products would be impaired.

Foreign Regulation

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

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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. Companies are now required to obtain the CE mark prior to sale of some medical devices within the European Union. During this process, the sponsor must demonstrate compliance with the International Organization for Standardization s manufacturing and quality requirements. We do have CE marking on all of our products that require such markings. We cannot assure you that we or our OEM partners will be able to obtain necessary foreign government approvals or successfully comply with foreign regulations. Our failure to do so could hurt our business, financial condition and results of operations.

Other U.S. 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, or Sunshine Act, which was enacted by Congress as part of the Patient Protection and Affordable Care Act, or PPACA, on March 23, 2010, requires medical device companies to track and publicly report, with limited exception, all payments and transfers of value to physicians and teaching hospitals in the U.S. Implementing regulations for these tracking and reporting obligations have not been finalized, but it is anticipated that companies will be required to begin tracking payments in early 2013 and will be required to report payments to the government by March 31, 2014, and annually thereafter. The government is required to post this data on a public, searchable, government maintained website. Failure to comply with the data collection and reporting obligations imposed by the Sunshine Act can result in civil monetary penalties.

In addition, the International Electrotechnical Commission, or IEC, 60601-1:2005 (3rd edition), was published in December 2005. 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, 2014 in Europe and will be required to be in place by June 1, 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. As a result, we could be found in breach of existing customer contracts and/or unable to obtain new contracts, both of which could adversely affect our business, financial condition and results of operations.

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. We currently estimate our medical device tax, which will be recorded within our selling, general and administrative expenses, to be in the range of $6.0 million to $7.0 million for 2013.

Environmental

Our manufacturing processes involve the use, generation and disposal of 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 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 European Union, or EU, markets under the Restriction of the Use of Hazardous Substances Directive, or RoHS. RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium,

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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.

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 Health Care Programs Anti-Kickback Law (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, or 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 will 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, or HIPAA, created new federal crimes, including: health care fraud and false statements related to health care matters. The health care fraud statute

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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 laws or regulations could adversely affect many of the arrangements we have with customers and physicians. 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. If our past or present operations are found to be in violation of any of these laws, we could be subject to civil and criminal penalties which could hurt our business, financial condition and results of operations.

Privacy and Security of Health Information

Numerous federal, state and international laws and regulations govern the collection, use, and disclosure of patient-identifiable health information, or PHI, including HIPAA. 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 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. We are not a covered entity but due to activities that we perform for or on behalf of covered entities, we are sometimes deemed to be a business associate of covered entities.

In certain circumstances, the HIPAA rules require covered entities to contractually bind us, as a business associate, to protect the privacy and security of PHI we may encounter during activities like training customers on the use of our products or investigating product performance. The Health Information Technology for Economic and Clinical Health Act, or HITECH, enacted in February 2009, made significant amendments to the HIPAA Privacy and Security Rules. Most provisions of HITECH were effective February 17, 2010; however, the new federal health data breach notice provision which requires business associates to notify covered entities of any breach of unsecured PHI went into effect in September 2009. Prior to February 17, 2010, our business was not directly subject to the HIPAA Privacy and Security Rules. As a business associate, our privacy and security related obligations were solely contractual in nature and governed by the terms of each business associate agreement. HITECH fundamentally changed a business associate s obligations by imposing a number of HIPAA Privacy Rule requirements and all of HIPAA Security Rule provisions directly on business associates and making business associates directly subject to HIPAA civil and criminal enforcement and the associated penalties for violation of the Privacy and Security Rule requirements. HITECH increased civil penalty amounts for violations of HIPAA by either covered entities or business associates and requires the U.S. Department of Health and Human Services to conduct periodic audits to confirm compliance. In addition, HITECH authorizes state attorneys general to bring civil actions in response to violations of HIPAA Privacy and Security Rules that threaten the privacy of state residents. Final implementation regulations for many of these changes have not yet been released, and due to the very recent enactment of HITECH and expected final implementing regulations, we are unable to predict what the extent of the impact on our business will be. These new HITECH requirements may require us to incur additional costs and may restrict our business operations. If our past or present operations are found to be in violation of any of these laws, we could be subject to civil and criminal penalties, which could hurt our business, financial condition and results of operations.

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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.

New standards protecting health information, whether implemented pursuant to HIPAA, congressional action or otherwise, could have a significant effect on the manner in which we must handle health care related data, and the cost of complying with these standards could be significant. 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.

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, or 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 the 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.

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

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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, or 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, or 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. Since January 1, 2007, reimbursement for certain pulse oximetry monitoring services, including those using our products, has not been packaged, but rather may receive a separate payment when no other separately payable services are provided. Effective January 1, 2011, these services 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. We cannot be certain that a hospital will purchase our products, despite the clinical benefits and opportunity for cost savings that we believe can be derived from their use. If hospitals cannot obtain adequate coverage and reimbursement for our products, or the procedures in which they are used, our business, financial condition and results of operations could suffer.

Our success with rainbow® SET technologies in U.S. care areas with reimbursable test procedures, such as hospital emergency departments, hospital procedure labs, and the physician office will largely depend on the ability of providers to receive reimbursement for such testing procedures. Effective January 1, 2012, the maximum rates for noninvasive carboxyhemoglobin, methemoglobin and hemoglobin testing under the Medicare laboratory fee schedule were $7.10 per service. Effective January 1, 2013, the maximum fee schedule rates for these services is $6.90 per service. 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. Moreover, the sequestration order required by the Budget Control Act of 2011 could reduce Medicare payments for procedures using our products after January 2, 2013, unless Congress enacts legislation to avert the order.

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. There can be no assurance that reimbursement for our products, or the procedures in which our products are used, will be obtained or that such reimbursement will be adequate.

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Manufacturing

Our strategy is to manufacture products in-house when it is efficient and cost-effective for us to do so. We currently manufacture internally our bedside and handheld pulse oximeters, our full line of disposable and reusable sensors and most of our patient cables. We maintain a 15,000 square foot International Organization for Standardization 13485:2012 certified manufacturing area in our facility in Irvine, California, and a 95,600 square foot facility in Mexicali, Mexico. 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 term, termination and pricing. The initial terms of some of these agreements have expired, however, and in each case the parties have either continued to perform under the agreement or the agreement provides for automatic renewal. Most of these agreements allow for termination upon specified notice, ranging from 120 days 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 also guarantees us the most favorable pricing offered by the supplier to any of its other customers.

In March 2012, we acquired Spire Semiconductor, LLC and its manufacturing facility, in Hudson, New Hampshire. A portion of this 90,000 square foot facility is used to manufacture advanced light emitting diodes and other advanced component-level technologies. The acquisition gives us an advanced ability to develop custom components, accelerate development cycles and optimize future product costs.

In July 2012, we acquired Phasein and assumed the lease on their 10,000 square foot facility in Danderyd, Sweden. We use a portion of this facility to manufacture 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.

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 14 to our consolidated financial statements that are included in this Form 10-K.

Employees

As of December 29, 2012, we had 2,866 full-time employees and contract employees worldwide.

Address

Our principal executive offices are located at 40 Parker, Irvine, California 92618, and our telephone number at that address is (949) 297-7000. Our website address is www.masimo.com. Any information contained in, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way a part of, this Form 10-K.

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Executive Officers

Our executive officers, as of February 1, 2013, are set forth below:

Name	Age	Position(s)
Joe Kiani	48	Chief Executive Officer & Chairman of the Board of Directors
Jon Coleman	49	President, Worldwide Sales, Marketing and Clinical Research
Mark P. de Raad	53	Executive Vice President, Chief Financial Officer and Corporate Secretary
Rick Fishel	55	President, Worldwide OEM Business and Corporate Development
Yongsam Lee	48	Chief Information Officer and Executive Vice President, Operations and Regulatory Affairs
Anand Sampath	46	Executive Vice President, Engineering

Joe Kiani is the founder of Masimo and has served as Chief Executive Officer and Chairman of the Board of Directors since our inception in 1989. He is an inventor on more than 50 patents related to signal processing, sensors, and patient monitoring, including patents for the invention of Measure-Through Motion and Low Perfusion pulse oximetry. Mr. Kiani is currently on the Board of Directors of Saba Software, Inc., a publicly-traded software company focused on human capital development and management solutions. Mr. Kiani holds a B.S.E.E. and an M.S.E.E. from San Diego State University.

Jon Coleman has served as our President, Worldwide Sales, Marketing and Clinical Research since February 2011, and was our President, International from August 2008 to February 2011. From October 2007 to August 2008, Mr. Coleman was President and Chief Executive Officer of You Take Control, Inc., a healthcare information technology start-up company. He served as General Manager, Americas of Targus Group International, a supplier of mobile computing cases and accessories, from March 2006 to February 2007. From March 1994 to February 2006, he held progressive leadership positions with Pfizer, Inc., most recently Vice President and General Manager, Canada & Caribbean Region. Mr. Coleman holds a M.B.A. from Harvard Business School, and a B.A. in International Relations from Brigham Young University.

Mark P. de Raad has served as our Executive Vice President and Chief Financial Officer since June 2006 and as our Corporate Secretary since December 2009. From November 2002 through May 2006, Mr. de Raad served as Vice President, Chief Financial Officer and Secretary for Avamar Technologies, Inc., a start-up enterprise software development company. He served as Chief Financial Officer, Quantum Storage Solutions Group, a division of Quantum Corporation from June 2001 through November 2002. From September 1997 through June 2001, Mr. de Raad was Vice President, Finance and Chief Financial Officer for ATL Products, Inc., a manufacturer of automated tape libraries. Mr. de Raad is a Certified Public Accountant (inactive) and holds a B.S. in Accounting from the University of Santa Clara.

Rick Fishel has served as President, Worldwide OEM Business and Corporate Development since February 2011. From February 2009 to February 2011, he was our President, Americas and Worldwide OEM Business, and was President of Masimo Americas from June 2004 to February 2009. From January 2003 to June 2004, Mr. Fishel was Regional Vice President of Sales for the Information Solutions segment of the McKesson Corporation, a provider of supply, information and care management products and services. From January 2001 to January 2003, he served as National Vice President of Sales for the Consulting Services division of GE Medical Systems, Inc., a provider of medical technology and productivity solutions. Mr. Fishel holds a B.S. in Marketing from Arizona State University.

Yongsam Lee has served as our Chief Information Officer and Executive Vice President, Regulatory Affairs since November 2010. Mr. Lee has also reassumed the role of Executive Vice President of Operations since February 2013. From March 1996 to October 2001 and from April 2002 to November 2010, Mr. Lee held various positions with us, including Chief Information Officer, Vice President, IT and Executive Vice President, Operations. From October 2001 to April 2002, he served as Director of IT at SMC Networks, Inc., a provider of networking solutions. Mr. Lee holds a B.S. in Applied Physics from the University of California, Irvine.

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Anand Sampath has served as our Executive Vice President, Engineering since March 2007. He is an inventor on more than four patents relating to patient monitoring, wireless networks and communications. From April 2006 to March 2007, Mr. Sampath was our Director of Systems Engineering. From October 1995 to March 2006, he held various positions, including Program Manager, Engineering Manager and Distinguished Member of Technical Staff, at Motorola, Inc. Mr. Sampath holds a B.S. in Engineering from Bangalore University.

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Consequently, we are required to file reports and information with the SEC, including reports on the following forms: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. These reports and other information concerning us may be accessed through the SEC s website at www.sec.gov and on our website at www.masimo.com. Such filings are placed on our website as soon as reasonably practical after they are filed with the SEC. Information contained in, or that can be accessed through, our website is not part of this Form 10-K.

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ITEM 1A. RISK FACTORS

The following risk factors and other information included in this 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®. 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 be profitable. 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.

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.

Our products that have been recently introduced into the market, including, but not limited to, those based on rainbow® technology, a technology that we license, may not be accepted in the market. In September 2008, we began our limited market release of hemoglobin, and focused on obtaining data and clinical feedback on the performance of the product in the hospital. In October 2008, we received FDA clearance for Pronto®, a handheld noninvasive multi-parameter testing device that uses our rainbow® SET technology, to provide oxygen saturation, pulse rate, perfusion index and spot-checking of hemoglobin levels. In the first quarter of 2009, we fully launched our hemoglobin product for continuous and noninvasive monitoring in the hospital. In January 2012, we received FDA clearance for Pronto-7® and began full market release. In June 2010, we initiated a full commercial release of rainbow Acoustic Monitoring™ after a limited market release that allowed us to evaluate the product s performance in the field.

Given that certain rainbow® technology products are 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 will need 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 advantages of our products and their sales prices;

perceived safety and effectiveness of our products;

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reimbursement available through Centers for Medicare and Medicaid Services, or CMS, programs for using our products; and

introduction and acceptance of competing products or technologies.

In general, our recent noninvasive measurement technologies are novel products that may be 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. The performance of these technologies shows variability across a population that follows a standard gaussian distribution described in the accuracy specifications. Over time, we hope to reduce this variability and, if we do, we expect these recent technologies to become more useful in additional environments and to become more widely adopted. This is the adoption pattern we have experienced historically with our previously released measurements, such as oxygen saturation, and what we expect to experience in the future with our current and future technologies. Although we will seek to reduce this variability over time, we may not be successful. If our products do not gain market acceptance or if our customers prefer our competitors products, our potential growth would be limited, which would adversely affect our business, financial condition and results of operations.

Our ability to commercialize new products, new or improved technologies and additional applications for Masimo SET® and our right to use rainbow® technology are each limited to certain markets by our Cross-Licensing Agreement with Cercacor, which may impair our growth and adversely affect our 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, or 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 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 the measurement of only carbon monoxide, methemoglobin, fractional arterial oxygen saturation and hemoglobin, which includes hematocrit. As a result, the opportunity to expand the market for our products incorporating rainbow® technology is limited, which could limit our ability to maintain or increase our revenue and impair our growth.

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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 new products or alternative technologies developed by others, we could lose revenue opportunities and customers, and our ability to grow our business would be impaired.

A number of our competitors have substantially greater capital resources, larger customer bases, larger sales forces than ours, and have established stronger reputations with target customers and built relationships with GPOs that are more effective than ours. We face substantial competition from companies developing products that compete with our Masimo SET® platform for use with third-party monitoring systems. We also face competition from companies currently marketing 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 FDA-cleared products, or those of our original equipment manufacturer, or OEM, partners, whereby they may be able to 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, fewer orders for our products, a reduction of our gross margins and a loss of our market share.

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.

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 they 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 rather than 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 might acquire any of our OEM partners, will vigorously promote products incorporating Masimo SET® and licensed rainbow® technology, or at all. 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.

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

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bundling contract for another manufacturer s products, we may be prohibited from making sales to members of the GPO for the duration of the contractual arrangement. For the years ended December 29, 2012, December 31, 2011 and January 1, 2011, shipments of our pulse oximetry products to customers that are members of GPOs represented $253.7 million, $223.8 million and $183.8 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 sales, 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 business would be harmed.

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 for the procedures in which our products are used, may impact our customers purchasing decisions. Therefore, our customers inability to obtain adequate coverage and reimbursement for our products 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. 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. We are working with these payers to obtain reimbursement, but may not be successful. These trends could lead to pressure to reduce prices for our current products and product candidates and could cause a decrease in the size of the market or a potential increase in competition that could adversely affect 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, which could adversely affect our business, financial condition and results of operations.

Our customers are facing a growing level of uncertainties, such as lower overall hospital census for paying patients and the impact of that lower census on hospital budgets.

In addition, there are specific portions of our business, such as our OEM customers, that, due to their capital equipment sales model, could be impacted by the ongoing economic uncertainties and the resulting constraints on hospital budgets. These hospital budget constraints could cause our OEMs more difficulty in selling their large, relatively high priced multi-parameter devices which, 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, are sold with upfront license fees and more complex, and therefore, more expensive sensors could be impacted by hospital budget reductions.

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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, our SpCO® monitoring devices may be subject to authorization by individual states as part of Emergency Medical Services, or EMS, scope of practice procedures. The State of California recently categorized SpCO® as a laboratory test and therefore outside the scope of practice for EMS providers. Although a lack of inclusion into scope of practice procedures does not prohibit usage, it may limit adoption.

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 also 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 or groups of customers, or distributors, or that we will be able to attract and retain additional customers in the future. For the years ended December 29, 2012, December 31, 2011 and January 1, 2011, we had sales through two just-in-time distributors, which in total represented 25.4%, 24.7% and 23.0% of our total revenue, respectively. The loss of any large customer or distributor could have a material adverse effect on our financial condition and results of operations.

Organizations that manufacture imitation Masimo sensors and third-party medical device reprocessors that reprocess our single-patient-use sensors and then resell them to hospitals at a cost lower than our new sensors may harm our reputation and cause our revenue to decline. Our development of a new technology designed to provide hospitals, clinicians and their patients with sensors that reflect true Masimo quality and performance may not be accepted by all of our customers, which may adversely affect our business, financial condition and results of operations.

We are aware that other organizations are manufacturing 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 for other patients. Our experience with both these imitation sensors and 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 performance and risk of contamination, over the past two years there has been an increase in our customers awareness of these imitation sensors and reprocessing programs and some 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 to 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, and enforcing our proprietary rights against the imitation manufacturers and reprocessors and under our customer contracts.

We have developed a new technology that is designed to ensure our customers get the performance they expect by using genuine Masimo sensors. This new technology has been included in sensors shipped since the fourth quarter of 2011. While most customers will not observe any difference when compared to our prior 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. As a result, although we believe that this technology will be viewed favorably by the overwhelming majority of hospitals and

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clinicians, there are no assurances that all of our customers will view it positively, which may reduce certain customer demand for our new sensors and, as a result, have a material adverse effect on 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, we plan to substantially expand our sales force for noninvasive hemoglobin, or SpHb®, in the near term. Although we believe implementing new technologies and taking these actions are, and will continue to be, in the best interest of patient care, the company 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 operating results.

Covidien may seek to avoid paying any royalties to us after March 15, 2014, which would significantly reduce our royalty revenue, total revenues and adversely affect our business, financial condition and results of operations.

We are party to a settlement agreement with Covidien. Under the current settlement agreement, we earn royalties on Covidien s total U.S. based pulse oximetry sales. For the years ended December 29, 2012, December 31, 2011 and January 1, 2011, our royalties from the Covidien settlement agreement totaled $28.3 million, $32.5 million and $49.0 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 will 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 this 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, from March 15, 2011 through at least March 15, 2014. In exchange for this royalty payment, we have provided Covidien with a covenant not to sue for its current pulse oximetry products, but not for any other technologies that Covidien may add, pursuant to the second amendment. After March 15, 2014, Covidien may stop paying us any royalties, which would have a material adverse impact on our total revenue, gross margins, operating income and earnings per share.

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, as well as a combination of copyright and trademark laws and 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, or PTO, may deny or require 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. Our issued and licensed patents and those that may be issued or

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licensed in the future, may expire or may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related technologies. 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. We also must rely on contractual rights with the third parties that license technology to us to protect our rights in the technology licensed to us. There is no assurance that competitors will not be able to design around our patents. We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all 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, our 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;
- 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;

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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. In 2009, Philips Electronics North America Corporation filed antitrust and patent infringement counterclaims against us, as further explained in Part 1, 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 our 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 related to Philips FAST pulse oximetry technology and certain of Philips patient monitors. In December 2012, we filed a patent infringement and breach of contract suit against Mindray DS USA, Inc. and Shenzhen Mindray Bio-Medical Electronics Co, Ltd., which is an OEM partner of ours. Both of these suits are described in Part 1, Item 3 of this Annual Report on Form 10-K, and Note 13 to the accompanying consolidated financial statements. Both Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH are associated with Philips Medical Systems, another OEM partner of ours. There is no guarantee that we will prevail in either suit 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 either 510(k) clearance from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act by filing a 510(k) pre-market notification, or PMA, through submitting a PMA application. Even if regulatory clearance or approval of a product is granted,

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the clearance or approval may be subject to limitations on the indicated uses for which the product may be marketed. We cannot assure you 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 has historically taken approximately four to six months. However, over the past year we have experienced a significantly longer 510(k) clearance review process. Our more recent experience in seeking FDA 510(k) clearance, along with information we have received from other medical device manufacturers, suggests that the FDA may have modified its 510(k) review protocol and process. Specifically, it appears that the FDA s medical device product reviews currently require applicants to provide much more information and data than in prior periods, the FDA is not consistently relying upon prior precedents thereby leading to more review cycles or, in some cases, to non-substantially equivalent decisions, and that the FDA has broadened the scope of its reviews. As a result, we have experienced lengthier FDA 510(k) review periods over the past 12 months, which has delayed the 510(k) clearance process for our products and uses over this period compared to prior periods.

In addition, in September 2009, the FDA commissioned the Institute of Medicine to study the premarket notification program used to review and clear certain medical devices marketed in the U.S. In August 2010, the FDA issued its preliminary recommendations on reform of the 510(k) premarket notification process for medical devices. On January 19, 2011, the FDA announced its Plan of Action for implementing these recommendations. The Plan of Action included 25 action items, including revising existing guidance or developing guidance to clarify various aspects of the 510(k) process and to streamline the review process for innovative, lower risk products (the de novo classification process); improving training for the Center for Devices and Radiological Health staff and industry; increasing reliance on external experts; and addressing and improving internal processes. The FDA has already begun implementing many of these reforms, and may implement other reforms in the future, which could have the effect of making it more difficult and expensive for us to obtain 510(k) clearance in the future.

We have received FDA 510(k) clearance for the Pronto® and Pronto-7® for noninvasive spot-checking of hemoglobin and other measurements in clinical and non-clinical settings, including blood donation facilities. Before commercializing either device in U.S. blood donation centers, we are also pursuing specific regulatory clearance from the FDA Center for Biologics Evaluation and Research, which regulates the collection of blood and blood components used for transfusion or for the manufacture of pharmaceuticals derived from blood and blood components.

To date, the FDA has regulated pulse oximeters incorporating Masimo SET® and licensed rainbow® technology, and our sensors, cables and other products incorporating Masimo SET® and licensed rainbow® technology for pulse oximetry under the 510(k) process. Although 510(k) clearances have been obtained for all of our current products, these clearances may be withdrawn by the FDA at any time if substantial safety or effectiveness problems develop with 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.

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 will be 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 assure you 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.

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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 and promotional activities for such products, are subject to continual review and periodic inspections by the FDA and other regulatory bodies. In particular, we and our suppliers are required to comply with the FDA s Quality System Regulation, or QSR, which covers the methods and documentation of the design, control testing, production, component suppliers control, quality assurance, labeling control, packaging, storage and shipping of our products. The FDA enforces the QSR through announced and unannounced inspections. We are also subject to similar state requirements and licenses. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, discovery of previously unknown problems with our products (including unanticipated adverse events or adverse events of unanticipated severity or frequency), manufacturing problems, or failure to comply with regulatory requirements, or failure to adequately respond to any FDA observations concerning these issues, could result in, among other things, any of the following actions:

- warning letters or untitled letters issued by the FDA;
- fines, civil penalties, injunctions and criminal prosecution;
- 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; and
- operating restrictions.

Furthermore, our key component suppliers may not currently be, or may not continue to be, in compliance with applicable regulatory requirements. If any of these actions 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. Approval by one foreign regulatory authority does not ensure approval 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.

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 a PMA

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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. We have made modifications to our devices in the past and we may make additional modifications in the future. 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 conditions and results of operations.

Federal regulatory reforms may reduce the profit we are able to earn on the sale of our products.

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 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.

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 markets are legally required to report to the relevant authority in whose jurisdiction any serious or potentially serious incidents occurred involving devices produced or sold by the manufacturer.

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 we 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.

From our inception through December 29, 2012, we initiated five voluntary recalls of our products, none of which was material to our operating results. Each of these recalls was reported to the FDA 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.

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

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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. We must have adequate substantiation for our product performance claims. 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, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, we would be subject to extensive fines and penalties and 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:

- the Federal Health Care Programs Anti-Kickback Law, 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;

- the federal provisions of the HIPAA 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 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 or 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

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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. As previously disclosed, in November 2010 we voluntarily notified the FDA that we received allegations regarding the safety and efficacy of our Pronto® and Pronto-7® products from certain former sales representatives of ours. In April 2011, we were informed by representatives of the U.S. Department of Justice, or DOJ, that a qui tam complaint had been filed under seal against us by certain individuals. We cooperated fully with the government s investigation and in November 2011, we were informed that the DOJ declined to intervene in the case. Although we believe that our business practices comply in all material respects with applicable laws and regulations, complaints filed against us and any related government investigations may involve some distraction to management and cause us to incur additional expenses.

We have certain arrangements with hospitals that may be affected by these 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 Law 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 required to make costly system modifications to comply with the HIPAA privacy and security requirements. Our failure to comply may result in criminal and civil liability because the potential for enforcement action against business associates is greater as a result of the Health Information Technology for 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.

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.

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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 recently enacted 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. Significantly, President Obama signed health care reform legislation into law that will require most individuals to have health insurance, establish new regulations on health plans create insurance pooling mechanisms and reduce Medicare spending on services provided by hospitals and other providers. Additionally, this legislation imposes significant new taxes on medical device makers in the form of a 2.3% excise tax on U.S. medical device sales, beginning on January 1, 2013. We currently estimate our medical device tax to be in the range of $6.0 million to $7.0 million for 2013. It is expected that this medical device tax will also impose additional compliance and reporting obligations on us, and therefore increase our general and administrative expenses going forward. We are currently evaluating the impact of this tax on our business operations and may take none, one or several actions, in response. If we cannot offset some or all of this additional tax, it will have a material adverse effect on our financial condition and results of operations.

Moreover, the Physician Payment Sunshine Act, or 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 exception, all payments and transfers of value to physicians and teaching hospitals in the U.S. Implementing regulations for these tracking and reporting obligations have not been finalized, but it is anticipated that companies will be required to begin tracking payments in early 2013 and will be required to report payments to the government by March 31, 2014, and annually thereafter. 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 addition, many details of the recently enacted health care reform legislation will be addressed in the implementing regulations. 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.

In general, an expansion in 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 materially. In addition, as a result of the focus on health care reform in connection with the 2012 presidential election, 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.

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, the 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 regulation would have on

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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.

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.

Further, our success in international markets also depends 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.

Risks Related to Our Business and Operations

Cercacor has conducted most of the research and development of rainbow® technology and we are largely dependent upon Cercacor to develop improvements to certain rainbow® technologies.

Cercacor has conducted the substantial majority of research and development of certain rainbow® technologies. Although we expect Cercacor to continue its research and development activities related to certain rainbow® technology and specific noninvasive monitoring measurements, including blood glucose and hemoglobin, we have no assurance that it will do so. In the event Cercacor does not continue to develop and improve selected rainbow® technologies, our business, financial condition and results of operations could be adversely affected.

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 December 29, 2012, a number of stockholders of Cercacor continued to own shares of our stock. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Cercacor.

Jack Lasersohn, another 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 assure you 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.

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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 rainbow® technology, 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 their proprietary rainbow® technology. This includes handheld, table-top and multi-parameter 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.

Currently, we are required to consolidate Cercacor within our financial statements. Accordingly, the royalties that we owe to Cercacor are eliminated in our 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. To date, the amount of royalty expense has approximated the amount of engineering and administrative expense. 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 were not required to consolidate Cercacor s financial results within our financial statements, then our unconsolidated cost of sales 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 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,

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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.

It is generally more expensive for us to make products that incorporate rainbow® technology that we license than products that do not include licensed rainbow® technology, due to increased royalties that we must pay to Cercacor for the licenses. 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.

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. Under the Cross-Licensing Agreement, a change in control includes, but is not limited to, the resignation or termination of Joe Kiani from his position of Chief Executive Officer of either Masimo or Cercacor. Additionally, our per product royalties payable to Cercacor will become subject to specified minimums, and the minimum aggregate annual royalties for all licensed rainbow® measurements payable to Cercacor is $15.0 million for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, hemoglobin and blood glucose, plus up to $2.0 million per 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 and we may not maintain our recent profitability and changes to existing accounting pronouncements or taxation rules may affect how we conduct our business and affect our reported 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:

- delays or interruptions in manufacturing and shipping of our products;
- varying demand for and market acceptance of our technologies and products;
- 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;

inability to efficiently scale operations and establish processes to accommodate business growth;

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- 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.

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.

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 or the adoption of new rules may adversely affect our reported financial results or the way we conduct our business.

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 to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management, engineers and field sales personnel is intense and 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 could prevent the implementation and completion of our objectives, including the development and introduction of our products. In general, our officers may terminate their employment at any time without notice for any reason. We carry key person life insurance on only Mr. Kiani, who is also the Chief Executive Officer of Cercacor. Mr. Kiani devotes most of his time to us.

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;

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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.

Our international business structure may not result in expected operational benefits.

In 2008, we implemented a new international business structure designed to better serve and support our growing international business. By centralizing our international operations, including sales management, marketing, customer support, planning, logistics and administrative functions, we believe we will be able to develop a more efficient and scalable international organization capable of being even more responsive to the business needs of our international customers all under one centralized management structure. We commenced the implementation of an international business structure to align our operations with the business needs of our non-U.S. customers and we believe that we may, in the long run, also benefit from certain operational benefits and achieve a lower overall tax rate. However, there can be no assurance that our efforts will produce any anticipated operational benefits or provide an overall lower tax rate. Realization of the expected benefits will depend on a number of factors, including our future business results and profitability, changes in U.S. or international tax law and the geographic composition of our pre-tax income. Legislative action may be taken by the U.S. Congress which, if ultimately enacted, could adversely affect our effective tax rate and/or require us to take further action, at potentially significant expense, to seek to preserve our effective tax rate. We cannot predict the outcome of any specific legislative proposals. However, if proposals were enacted that had a negative effect on our international business structure, we could be subjected to increased taxation and/or potentially significant expense.

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 each of the years ended December 29, 2012, December 31, 2011 and January 1, 2011, 29.5%, 29.4% and 27.9%, 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.

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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;
- 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;
- 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.

In addition, 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 making improper payments to non-U.S. officials for the purpose of obtaining or retaining 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. A majority of our sales and expenditures are transacted in U.S. dollars. We transact with foreign customers 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. In addition, we are exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables. When converted to U.S. dollars, these receivables can vary depending on the monthly exchange rates at the end of the period. Certain of our foreign sales support subsidiaries transact 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. Certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses. 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

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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.

If we decide in the future to hedge our foreign currency 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 in 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 would be forced to rely on third-party manufacturers if we could not shift production to our other manufacturing facility. 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 are also vulnerable to disruptions which may 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 and any expansion of our operations to additional locations 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. In addition, any disruption, delay, transition or expansion of our manufacturing operations could impair our ability to meet the demand of our customers and our customers may cancel orders or purchase products from our competitors, which could adversely affect our business, financial condition and results of operations.

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.

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If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934 and Section 404 of the Sarbanes-Oxley Act of 2002, 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, or 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, or the Sarbanes-Oxley Act, we are required to evaluate and provide a management report of 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 the requirements of Section 404 on a timely basis 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.

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, new regulations of 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, and intend to continue to invest, in reasonably necessary resources to comply with 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, or malfunction of, or design flaws or manufacturing defects in, our products or the use of our products with incompatible components or systems. 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 cannot be certain that our product liability insurance will be sufficient to cover any or all damages or claims. 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.

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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.

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 because, for instance, our manufacturing processes may be required to be altered or we may be required to use different types of materials in manufacturing our products, which may increase our manufacturing costs, detrimentally impact the performance of our products, add greater testing lead-times for 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, including 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 manage and maintain our internal reports effectively, 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.

The current uncertainty in the global economy, including the continuing effects of recession or slow economic growth and the on-going financial crisis in Europe, have been unprecedented and challenging with tighter credit conditions and recession in most major economies. Continued concerns about the systemic impact of the recent recession, energy costs, geopolitical issues, the availability and cost of credit, and the global housing and mortgage markets have contributed to increased market volatility and diminished expectations for western and emerging economies. As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. These factors have led to a decrease in spending by businesses and consumers alike. Turbulence in the U.S. and international markets and economies and prolonged declines in spending may adversely affect our liquidity and financial condition, and the liquidity and financial condition of our distributors, customers and suppliers, including our ability to refinance maturing liabilities and access the capital markets to meet liquidity needs. The liquidity of our customers and

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suppliers may also be affected by adverse global economic conditions. If our suppliers experience credit or liquidity problems, important sources of raw materials or manufactured goods may be affected. If our customers liquidity and creditworthiness is negatively impacted by the condition of the economy, our ability to collect on our outstanding invoices and our collection cycles may be adversely affected. In addition, our operating results in one or more geographic regions may also be affected by uncertain or changing economic conditions within that region. If economic and market conditions in the global economy weaken further, we may experience material adverse impacts on our business, financial condition and results of operations.

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 January 1, 2012 to December 29, 2012, our closing stock price ranged from $18.42 to $24.87 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.

Some specific factors, in addition to the other risk factors identified above, may have a significant effect on our stock market price, many of which we cannot control. 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 December 29, 2012, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned 13.8% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, the stockholders may be able to exercise a significant influence over matters

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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, delay or prevent changes in control of us, 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 December 29, 2012, an aggregate of 13.3 million shares of our stock were reserved for future issuance under our three equity incentive plans, 8.4 million of which were subject to options outstanding as of that date at a weighted average exercise price of $22.78 per share. To the extent outstanding options are exercised, our existing stockholders may incur dilution. We rely heavily 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.

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 shares, announcements of the 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 under 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 five 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.

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We are also subject to the anti-takeover provisions of 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. An interested stockholder means, generally, 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 the stockholder rights plan if any person becomes the beneficial owner of 15% or more of the outstanding shares of 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 to not declare cash dividends on our stock, may elect to only pay dividends on an infrequent or irregular basis, or we may elect to not make any additional stock repurchases, and any return on your investment may be limited to the value of our stock. However, 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 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 of directors 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 of directors. In the event our board of directors declares any dividends, there is no assurance with respect to the amount, timing or frequency of any such dividends.

In February 2013, our board of directors authorized a stock repurchase program, whereby we may purchase up to 6 million shares of our common stock over a period of up to three years. 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 may elect to retain all future earnings for the operation and expansion of our business, rather than repurchasing additional outstanding shares. 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 of directors 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

We lease 230,000 square feet of space in Irvine, California, for our corporate headquarters, product manufacturing, research and development, warehousing and distribution operations. The leases covering most of this space expire in September 2014.

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We also lease 95,600 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., or IVEMSA. IVEMSA is a Mexican maquiladora, which is a shelter services provider incorporated in Mexico that is licensed to operate factories and plants in Mexico. The shelter program allows foreign companies to manufacture products in Mexico without being required to organize and operate their own subsidiary, for example, as a Mexican corporation. As a result, the risks of labor liability, ownership of facilities and legal presence of foreign corporations in Mexico are avoided. We entered into the agreement with IVEMSA to establish and run a facility to manufacture our products. IVEMSA leases the space directly from the owner of the property under an agreement that expires in August 2014. In March 2012, we acquired Spire Semiconductor, LLC and its manufacturing facility, in Hudson, New Hampshire. This 90,000 square foot facility is used to manufacture advanced light emitting diodes and other advanced component-level technologies, as well as warehousing and administrative operations.

For our international headquarters in Neuchatel, Switzerland, we lease 7,000 square feet of office space. This office space is focused on operations including sales, marketing, customer service and other administrative functions. In addition, we currently lease 10,000 square feet of space in Montreal, Canada, which we use primarily for research, development, sales and marketing activities. We also lease 10,000 square feet in Danderyd, Sweden, primarily for manufacturing, research, development and administrative functions related to our capnography and gas monitoring products. We also lease 9,200 square feet of space in Tokyo, Japan, which we use for sales, marketing, customer service and administrative functions, as well as maintaining product inventory. We also maintain small sales offices in Europe, Asia, Australia and the United Kingdom. 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 against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH related to Philips FAST pulse oximetry technology and certain of Philips patient monitors. The suit was brought in the U.S. District Court for the District of Delaware. Two patents originally asserted in this suit, related to our Measure-Through Motion technology, were successfully enforced in our previous suit against Nellcor. On June 15, 2009, Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH 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 on 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. On October 4, 2010, the Court limited the number of patents to be construed to four for us and three for Philips. In addition, on October 6, 2010, the Court denied Philips motion to bifurcate and stay damages in the patent case. In December 2010, the Court held a hearing regarding the construction of the patent claims and the Magistrate Judge issued a Report and Recommendation on claim construction on February 18, 2011. On January 17, 2012, the District Court Judge issued a claim construction order, adopting the Report and Recommendation of the Magistrate Judge, except with respect to one construction on one of our patents to which we had objected. With respect to this one claim construction, the District Court Judge did not adopt the recommendation from the Magistrate Judge and adopted the construction proposed by us. In 2012, the parties completed expert reports, discovery on some of the patents, and summary judgment motions are currently pending before the Court and no decision has been issued. In addition, in 2012, we asserted additional patents, and the Court ordered that these patents and some of the originally asserted patents would be tried in a different phase. Discovery is currently proceeding on our patents and one Philips patent which are not part of the first phase trial. 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.

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On December 21, 2012, we filed suit against Mindray DS USA, Inc. and Shenzhen Mindray Bio-Medical Electronics Co, Ltd. in the U.S. District Court for the Central District of California. The complaint alleges patent infringement, breach of contract and other claims. Mindray has not yet filed its response to the complaint.

From time to time, we are involved in legal proceedings 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.

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.

	Price Range	
	High	**Low**
Fiscal 2012:		
First Quarter	$ 23.52	$ 18.46
Second Quarter	$ 23.89	$ 18.42
Third Quarter	$ 24.87	$ 21.00
Fourth Quarter	$ 24.11	$ 20.22
Fiscal 2011:		
First Quarter	$ 33.27	$ 27.58
Second Quarter	$ 34.83	$ 28.18
Third Quarter	$ 30.91	$ 20.96
Fourth Quarter	$ 22.87	$ 17.84

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

As of January 31, 2013, the closing price of our stock on the NASDAQ Global Select Market was $20.30 per share, and the number of stockholders of record was 54. 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.

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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 December 29, 2007 through December 29, 2012 against the NASDAQ Market Composite Index and NASDAQ Medical Equipment Index, assuming a $100 investment made on December 29, 2007. 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.

Dividend Policy

Future determination as to the payment of cash (or stock) dividends will depend upon many factors, including our financial condition and results of operations, the capital requirements of our businesses and any other relevant factors deemed relevant by our board of directors. The dividends declared in both 2010 and 2012 were deemed to be special dividends and there is no assurance, with respect to amount or frequency, that dividends will be declared again in the future.

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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 December 29, 2012, December 31, 2011 and January 1, 2011 and the consolidated balance sheet data as of December 29, 2012 and December 31, 2011 are derived from our audited consolidated financial statements included in this Form 10-K. The consolidated statement of comprehensive income data for the years ended January 2, 2010 and January 3, 2009, and the consolidated balance sheet data as of January 1, 2011, January 2, 2010 and January 3, 2009 are derived from our audited consolidated financial statements not included in this 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 Form 10-K.

	Year ended December 29, 2012	Year ended December 31, 2011	Year ended January 1, 2011	Year ended January 2, 2010	Year ended January 3, 2009
	(in thousands, except per share information)				
Statement of Comprehensive Income Data[1]:					
Revenue:					
Product	$ 464,928	$ 406,487	$ 356,422	$ 300,143	$ 259,592
Royalty	28,305	32,501	48,985	48,972	47,482
Total revenue	493,233	438,988	405,407	349,115	307,074
Cost of goods sold	166,982	144,854	119,825	100,313	89,454
Gross profit	326,251	294,134	285,582	248,802	217,620
Operating expenses:					
Selling, general and administrative	193,948	169,205	174,089	134,577	120,069
Research and development	47,077	38,412	36,000	31,701	25,495
Antitrust litigation expense (proceeds)[2]			(30,728)	298	706
Total operating expenses	241,025	207,617	179,361	166,576	146,270
Operating income	85,226	86,517	106,221	82,226	71,350
Non-operating income (expense)	(1,405)	14	1,348	(46)	1,041
Income before provision for income taxes	83,821	86,531	107,569	82,180	72,391
Provision for income taxes	21,883	22,478	34,164	28,158	40,464
Net income including noncontrolling interests	61,938	64,053	73,405	54,022	31,927
Net (income) loss attributable to noncontrolling interests	334	(353)	125	(794)	
Net income attributable to Masimo Corporation stockholders	62,272	63,700	73,530	53,228	31,927
Other comprehensive income, net of tax:					
Foreign currency translation adjustments	2,268	349	862	70	1,027
Comprehensive income attributable to Masimo Corporation stockholders	$ 64,540	$ 64,049	$ 74,392	$ 53,298	$ 32,954
Net income per common share attributable to Masimo Corporation stockholders[3]:					
Basic	$ 1.08	$ 1.07	$ 1.25	$ 0.92	$ 0.57
Diluted	$ 1.07	$ 1.05	$ 1.21	$ 0.88	$ 0.53

Weighted-average number of common shares:					
Basic	57,445	59,659	58,769	57,603	56,321
Diluted	58,374	60,845	60,609	60,171	60,190

(1) Pursuant to authoritative accounting guidance, 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. Also, all direct engineering expenses that have been incurred by us and charged to Cercacor have not been eliminated and are included as research and development expense in our consolidated statements of comprehensive income. For additional discussion of accounting for Cercacor, see Note 3 to the consolidated financial statements.

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(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 retained a total of $30.8 million from Covidien.

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

	December 29, 2012	December 31, 2011	January 1, 2011	January 2, 2010	January 3, 2009
	(in thousands, except dividends declared per common share)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 71,554	$ 129,882	$ 88,305	$ 189,043	$ 146,910
Working capital	129,808	186,982	147,408	229,947	166,595
Total assets	375,946	366,104	310,235	356,345	293,348
Long term debt, including current portion	115	122	172	231	622
Total equity	275,668	279,666	230,039	289,688	219,498
Dividends declared per common share[4]	$ 1.00	$	$ 2.75	$	$

(4) During the years ended December 29, 2012 and January 1, 2011, our board of directors, or Board, evaluated a variety of options to return value to shareholders, including acquisition opportunities, stock buy-back programs and dividends. After considering all available options during those periods, the Board concluded that the best and most direct way to reward shareholders for their continued investment and confidence in Masimo was through the declaration of three special cash dividends. In February 2010, the Board declared a special dividend of $2.00 per share, or $117.5 million, which was paid in March 2010. In November 2010, the Board declared a second special dividend of $0.75 per share, or $44.5 million, which was paid in December 2010. In October 2012, the 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 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 Form 10-K. These risks could cause our actual results to differ materially from any future performance suggested below.

Overview

We are a global medical technology company that develops, manufactures, and markets noninvasive patient monitoring products. 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.

Our products consist of a monitor or circuit board, and a recently introduced 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 products. As of December 29, 2012, we estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET® was 1,088,000 units, based on an estimated 10 year field life assumption. Our installed base is the primary driver for the recurring sales of our sensors, most notably, single-patient adhesive sensors. Based on industry reports, we estimate that the worldwide pulse oximetry market was over $1 billion in 2012, the largest component of which was the sale of sensors.

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. In 2005, we launched our Masimo rainbow® SET platform utilizing both Masimo SET® and licensed rainbow® technology, which we believe includes the first devices cleared by the FDA to noninvasively and continuously monitor multiple measurements that previously required invasive or complicated procedures. Also, in 2005, we launched noninvasive carboxyhemoglobin, or SpCO®, allowing measurement of carbon monoxide levels in the blood. Carbon monoxide is the most common cause of poisoning in the world. In 2006, we launched noninvasive methemoglobin, or SpMet®, allowing for the measurement of methemoglobin levels in the blood. 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. In 2007, we launched Masimo PVI®. Fluid administration is critical to optimizing fluid status in surgery and critical care, but traditional invasive methods to guide fluid administration often fail to predict fluid responsiveness and newer methods are complicated and costly. In March 2008, we debuted noninvasive hemoglobin, or SpHb®, and in March 2009, we began full market release of SpHb®. Hemoglobin is the oxygen-carrying component of red blood cells, and 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. In June 2010, we began a full commercial release of continuous and noninvasive monitoring of respiration rate, or RRa™, via rainbow Acoustic Monitoring™. Respiration rate is the number of breaths per minute. A low respiration rate is indicative of respiratory depression and 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. In October 2010, we debuted the Halo Index™, which

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allows continuous global trending and assessment of multiple physiological measurements of a patient with a single number displayed on the Patient SafetyNet™ screen. Halo Index™ is pending FDA 510(k) clearance.

In July 2010, we began selling the SEDLine® monitor, which measures the brain s electrical activity and provides information about a patient s response to anesthesia. In January 2012, we received FDA clearance for the Pronto-7®, a product designed specifically for spot-checking hemoglobin, along with oxygen saturation and pulse rate. In December 2012, we released $iSpO_2$, a pulse oximeter cable and sensor with Measure-Through Motion and Low Perfusion Masimo SET® technology for use with an iPhone, iPad or iPod touch. We also offer a remote monitoring and clinician notification solution called Patient SafetyNet™, which includes our which includes our Masimo SET® or rainbow® SET monitors at the patient s bedside along with a central assignment station and wired or wireless server. Patient SafetyNet™ wirelessly notifies clinicians who are taking care of multiple patients in different rooms when one of their patients has an alarm, allowing them to intervene sooner and provide potentially life-saving support.

We offer Masimo SET® and rainbow® SET through our OEMs and our own end-user products, including the Radical-7®, Rad-87®, 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 December 29, 2012, we had 630 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.

Antitrust Litigation Proceeds

During the year ended January 1, 2011, we completed negotiations to resolve the merits of our antitrust litigation with Covidien. As a result, we retained a total of $30.8 million from two payments from Covidien following the Ninth Circuit Court of Appeals October 2009 affirmance of a Federal District Court decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products. The gross payment amount from Covidien was $59.0 million, but excluding reimbursement of legal fees, costs and interest, the net amount was $43.5 million. Of this amount, we retained $30.1 million and the remainder was paid to the law firm that handled the trial for us. Subsequently, we received a second payment of $1.3 million from Covidien that related to our appeal attorneys fees and related expenses. Of this second amount, we retained $0.8 million, with the remainder paid to our attorneys.

Dividend Payments

Our board of directors continuously evaluates a variety of options to return value to shareholders, including acquisition opportunities, stock buy-back programs and dividends. In 2012 and 2010, after considering all available options at those times, the Board concluded that the best and most direct way to reward shareholders for their continued investment and confidence in Masimo was through the declaration of cash dividends. In February 2010, the Board declared a special dividend of $2.00 per share, or $117.5 million, which was paid in March 2010. In November 2010, the Board declared a second special dividend of $0.75 per share, or $44.5 million, which was paid in December 2010. In October 2012, the Board declared another special dividend of $1.00 per share, or $57.3 million, which was paid out on December 11, 2012 to stockholders of record as of the close of business on November 27, 2012. Both the 2012 and 2010 special dividends represented only a portion of our cash reserves, which the Board believed was sufficient to cover our current operational needs, and to fund continued research and development investments and current strategic initiatives.

Stock Repurchase Program

In August 2011, our board of directors 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. The stock repurchase program

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was carried out at the discretion of a committee comprised of our Chief Executive Officer and Chief Financial Officer through open market purchases under a Rule 10b5-1 trading plan. We paid for these repurchases with available cash and cash equivalents. During the year ended December 31, 2011, 1.8 million shares were repurchased, at an average price of $19.61 per share, totaling $36.2 million. During the year ended December 29, 2012, 1.2 million shares were repurchased, at an average price of $22.74 per share, totaling $26.3 million, which completed the stock repurchase program.

Cercacor

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, or the Cross-Licensing Agreement, which was amended and restated effective January 1, 2007, 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, which includes hematocrit. 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 non-vital signs 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, Pronto-7®, we agreed to fund additional Cercacor s engineering expenses. Specifically, these expenses included third-party engineering materials and supplies expense, as well as 50% of total Cercacor s engineering and engineering related payroll expenses from April 2009 through June 2010, the original anticipated completion date of this product development effort. Since July 2010, Cercacor has continued to assist us with 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%. During the year ended December 29, 2012, and until both parties agree to end these services, Cercacor has and will continue to assist us with continuing productization efforts of the new handheld noninvasive multi-parameter testing device, that provides spot-check hemoglobin testing. During the year ended December 29, 2012, the total expenses for these additional services, material and supplies totaled $3.6 million.

Pursuant to authoritative accounting guidance, Cercacor is consolidated within our financial statements for all periods presented. This determination is based on our ability to direct the activities that most significantly impact Cercacor s economic performance, and our obligation to absorb Cercacor s expected losses. 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, or VIE, or in the event that we are no longer the primary beneficiary of Cercacor, we may discontinue consolidating the entity. For additional discussion of Cercacor, see Note 3 to the consolidated financial statements.

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SEDLine, Inc.

SEDLine, Inc., or SEDLine, a privately held entity that was formed in the fourth quarter of 2009, is a company that designs, manufactures, markets and sells brain function monitoring technology into the hospital marketplace. During 2009, we made loans to SEDLine totaling $3.0 million. These loans carried an interest rate of 7% and could be converted into equity upon certain predetermined conditions. Concurrently with the loans, we entered into a merger agreement with SEDLine, whereby we could acquire SEDLine at certain predetermined valuations.

Pursuant to authoritative accounting guidance, it was determined that SEDLine was a VIE and that we were the primary beneficiary during 2009 and the first six months of 2010. As a result, beginning in December 2009, we were required to consolidate SEDLine s assets, liabilities and equity as a VIE. On July 2, 2010, upon conversion of our $3.0 million note receivable and the related accrued interest due from SEDLine into 100% of the authorized common stock of SEDLine, SEDLine became a wholly-owned subsidiary of ours. For additional discussion of SEDLine, see Note 3 to the consolidated financial statements.

Spire Semiconductor Acquisition

On March 9, 2012, we acquired substantially all of the assets of Spire Semiconductor, LLC, or Spire, a maker of advanced light emitting diode and other advanced component-level technologies. Masimo Semiconductor, Inc., or Masimo Semiconductor, a recently formed, wholly-owned subsidiary of ours, will operate the business going forward. Under the acquisition agreement, we paid $7.2 million and assumed $1.2 million of Spire s liabilities. Simultaneous with this asset acquisition, we entered into a lease agreement with a related party to Spire Corporation, to lease manufacturing and office space through March 2017.

The acquisition gives us an advanced ability to develop custom components, accelerate development cycles, and optimize future product costs. Masimo Semiconductor will specialize in wafer epitaxy, foundry services, and device fabrication for biomedical, telecommunications, consumer products and other markets. For additional information, see Note 4 to the consolidated financial statements.

Phasein Acquisition

On July 27, 2012, we acquired PHASEIN AB, or 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.

We paid $30.5 million for all outstanding shares of Phasein. The final purchase price allocation resulted in $16.1 million assigned to goodwill, $12.6 million assigned to intangible assets, $1.4 million assigned to inventory, $2.4 million assigned to various other assets and $2.0 million assigned to various liabilities. Phasein s assets acquired and liabilities assumed, as well as its results of operations since the acquisition date, are included in our consolidated financial statements as of December 29, 2012. We funded the acquisition entirely with existing cash and cash equivalents.

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Results of Operations

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

	Year ended December 29, 2012		Year ended December 31, 2011		Year ended January 1, 2011	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(in thousands, except percentages)					
Revenue:						
Product	$ 464,928	94.3%	$ 406,487	92.6%	$ 356,422	87.9%
Royalty	28,305	5.7	32,501	7.4	48,985	12.1
Total revenue	493,233	100.0	438,988	100.0	405,407	100.0
Cost of goods sold	166,982	33.9	144,854	33.0	119,825	29.6
Gross profit	326,251	66.1	294,134	67.0	285,582	70.4
Operating expenses:						
Selling, general and administrative	193,948	39.3	169,205	38.5	174,089	42.9
Research and development	47,077	9.5	38,412	8.8	36,000	8.9
Antitrust litigation proceeds					(30,728)	(7.6)
Total operating expenses	241,025	48.9	207,617	47.3	179,361	44.2
Operating income	85,226	17.3	86,517	19.7	106,221	26.2
Non-operating income (expense)	(1,405)	(0.3)	14		1,348	0.3
Income before provision for income taxes	83,821	17.0	86,531	19.7	107,569	26.5
Provision for income taxes	21,883	4.4	22,478	5.1	34,164	8.4
Net income including noncontrolling interests	61,938	12.6	64,053	14.6	73,405	18.1
Net (income) loss attributable to noncontrolling interests	334	0.1	(353)	(0.1)	125	
Net income attributable to Masimo Corporation stockholders	$ 62,272	12.6%	$ 63,700	14.5%	$ 73,530	18.1%

Comparison of the Year ended December 29, 2012 to the Year ended December 31, 2011

Revenue. Total revenue increased $54.2 million, or 12.4%, to $493.2 million for the year ended December 29, 2012 from $439.0 million for the year ended December 31, 2011. Product revenues increased $58.4 million, or 14.4%, to $464.9 million in the year ended December 29, 2012 from $406.5 million in the year ended December 31, 2011. 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 1,088,000 units at December 29, 2012, up from 979,000 units at December 31, 2011. Contributing to the increase in our product revenue was our rainbow® technology product revenues, which increased $6.2 million, or 18.2%, to $40.3 million in the year ended December 29, 2012 from $34.1 million in the year ended December 31, 2011. Product revenue of $464.9 million during the year ended December 29, 2012 included $4.4 million and $3.1 million from the recently acquired Phasein and Masimo Semiconductor businesses, respectively. Revenue generated through our direct and distribution sales channels increased $53.3 million, or 15.6%, to $396.2 million for the year ended December 29, 2012, compared to $342.9 million for the year ended December 31, 2011. During the year ended December 29, 2012, revenues from our OEM channel increased $5.1 million, or 8.0%, to $68.7 million from $63.6 million in the year ended December 31, 2011. Included in this increase was $3.6 million from the recently acquired Phasein business.

Our royalty revenue decreased $4.2 million to $28.3 million in the year ended December 29, 2012 from $32.5 million in the year ended December 31, 2011. This reduction in revenue was primarily due to a reduction in the royalty rate from 13.0% to 7.75% of Covidien s U.S. pulse

oximetry sales, which became effective on

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March 15, 2011. This rate reduction was the result of a second amendment to the original settlement agreement with Covidien, which we entered into on January 28, 2011.

Cost of Goods Sold. Cost of goods sold increased $22.1 million to $167.0 million in the year ended December 29, 2012 from $144.9 million in the year ended December 31, 2011. Our total gross margin decreased to 66.1% for the year ended December 29, 2012 from 67.0% for the year ended December 31, 2011. Excluding royalties, product gross margin declined to 64.1% for the year ended December 29, 2012 from 64.4% for the year ended December 31, 2011. This decline in product margin was primarily due to the incremental costs associated with the roll out of a new sensor technology, called X-Cal™, and the impact of lower product margins associated with the recently acquired Masimo Semiconductor and Phasein businesses. These declines were partially offset by decreased amortization costs associated with equipment placed at hospitals, selected inventory charge-offs related to product redesign and transition activities in 2011 that did not reoccur in 2012, and manufacturing efficiency improvements in 2012. Excluding Masimo Semiconductor and Phasein, our product gross margin would have been 65.2% for the year ended December 29, 2012. We incurred $5.0 million in Cercacor royalty expenses for both the year ended December 29, 2012 and December 31, 2011, 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 63.0% and 63.1% for the year ended December 29, 2012 and December 31, 2011, respectively.

Selling, General and Administrative. Selling, general and administrative expenses increased $24.7 million, or 14.6%, to $193.9 million for the year ended December 29, 2012 from $169.2 million for the year ended December 31, 2011. Excluding Masimo Semiconductor and Phasein, selling, general and administrative expenses would have increased $21.6 million to $190.8 million for the year ended December 29, 2012. This increase was primarily due to a $9.8 million increase in payroll and related costs associated with increased staffing levels. In addition, total trade show, advertising and training expenses increased by $7.4 million, primarily due to additional trade shows attended, including a worldwide trade show in Q1 2012, which is only held once every four years. Also, legal fees increased $2.0 million due to increased litigation activity. Included in total selling, general and administrative expenses are $2.5 million and $1.9 million of direct expenses incurred by Cercacor for the year ended December 29, 2012 and December 31, 2011, respectively.

Research and Development. Research and development expenses increased $8.7 million, or 22.6%, to $47.1 million for the year ended December 29, 2012 from $38.4 million for the year ended December 31, 2011. Excluding Masimo Semiconductor and Phasein, research and development expenses would have increased $8.0 million, or 20.7%, to $46.4 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 $2.2 million related to new product development projects and additional clinical trial costs. Included in total research and development expenses are $3.7 million and $3.4 million of engineering expenses incurred by Cercacor for the year ended December 29, 2012 and December 31, 2011, respectively.

Non-operating income (expense). Non-operating expense was $1.4 million for the year ended December 29, 2012, as compared to non-operating income of $14,000 for the year ended December 31, 2011. This net change of $1.4 million was primarily due to the recognition of net realized and unrealized losses on foreign currency denominated transactions during the year ended December 29, 2012 of $1.6 million, as compared to the recognition of net realized and unrealized losses on foreign currency denominated transactions of $0.1 million during the year ended December 31, 2011. The net realized and unrealized losses recognized during the year ended December 29, 2012 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. The realized and unrealized net losses on foreign currency denominated transactions recognized during the year ended December 31, 2011 resulted primarily from losses due to the strengthening of the U.S. dollar against the Euro, the British pound, the Canadian dollar and the Australian dollar, offset by gains due to the weakening of the U.S. dollar against the Japanese Yen.

Provision for Income Taxes. Our provision for income taxes was $21.9 million for the year ended December 29, 2012 compared to $22.5 million for the year ended December 31, 2011. Our effective tax rate increased to 26.1%

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for the year ended December 29, 2012, compared to 26.0% for the year ended December 31, 2011. This increase in the effective tax rate was due primarily to the suspension of the federal research tax credit and increase in non-deductible items, which was offset by an effective tax rate decrease due to the income tax benefit resulting from the conclusion of a prior year tax audit, and the derecognition of uncertain tax positions due to the expiration of the statute of limitations. The American Taxpayer Relief Act of 2012, or the Tax Act, extended the research tax credit retroactively to 2012 and prospectively through the end of 2013. The effects of the change in the tax law will be recognized in the first quarter of fiscal 2013, which is the quarter when the law was enacted. If the Tax Act had been enacted as of December 29, 2012, the research tax credit would have reduced our 2012 effective tax rate by 1.2%. Our future effective income tax rate will depend on various factors, including profits (losses) before taxes, changes to tax law, the recognition and derecognition of tax benefits associated with uncertain tax positions and the geographic composition of pre-tax income.

Comparison of the Year ended December 31, 2011 to the Year ended January 1, 2011

Revenue. Total revenue increased $33.6 million, or 8.3%, to $439.0 million for the year ended December 31, 2011 from $405.4 million for the year ended January 1, 2011.

Product revenue increased $50.1 million, or 14.0%, to $406.5 million for the year ended December 31, 2011 from $356.4 million in the year ended January 1, 2011. This increase was primarily due to an increase in our installed base of pulse oximeter circuit boards and pulse oximeters to 979,000 units at December 31, 2011, from 855,000 units at January 1, 2011, based on an estimated 10 year field life assumption. Product revenue generated by our direct and distribution sales channels increased $59.3 million, or 20.9%, to $342.9 million for the year ended December 31, 2011 from $283.6 million in the year ended January 1, 2011, while revenues from our OEM channel decreased $9.2 million, or 12.7%, to $63.6 million for the year ended December 31, 2011 from $72.8 million in the year ended January 1, 2011. Our U.S. product revenue increased $30.1 million, or 11.7%, to $287.1 million for the year ended December 31, 2011 from $257.0 million in the year ended January 1, 2011. Additionally, our non-U.S. product revenue increased $19.9 million, or 20.0%, to $119.4 million for the year ended December 31, 2011 from $99.5 million in the year ended January 1, 2011. Rainbow® technology product revenues were $34.1 million and $32.9 million for the years ending December 31, 2011 and January 1, 2011, respectively.

Our royalty revenue was $32.5 million for the year ended December 31, 2011 and $49.0 million for the year ended January 1, 2011. This reduction in revenue was primarily due to a reduction in the royalty rate from 13.0% to 7.75% of Covidien s U.S. pulse oximetry sales, which became effective on March 15, 2011. This rate reduction was the result of a second amendment to the original settlement agreement with Covidien, which we entered into on January 28, 2011. These amounts were based upon actual royalties received for the first nine months of each year, and an estimate of Covidien s U.S. pulse oximeter sales for the last three months of each year, at the contractual royalty rate as prescribed by the 2006 settlement agreement and second amendment to the settlement agreement.

Cost of Goods Sold. Cost of goods sold increased $25.1 million, or 20.9%, to $144.9 million for the year ended December 31, 2011 from $119.8 million for the year ended January 1, 2011. Our gross margin decreased to 67.0% for the year ended December 31, 2011 from 70.4% for the year ended January 1, 2011. Excluding royalties, product gross profit margins decreased by 2.0% to 64.4% for the year ended December 31, 2011 from 66.4% for the year ended January 1, 2011. This decrease was primarily due to increased amortization costs associated with increased equipment placed at hospitals and selected inventory charge-offs related to product redesign and transition activities. We incurred $5.0 million in Cercacor s royalty expenses for each of the years ended December 31, 2011 and January 1, 2011, 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 63.1% and 65.0% for the years ended December 31, 2011 and January 1, 2011, respectively.

Selling, General and Administrative. Selling, general and administrative expenses decreased $4.9 million, or 2.8%, to $169.2 million for the year ended December 31, 2011 from $174.1 million for the year ended January 1,

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2011, which included $14.7 million of one-time marketing related expenses related to the establishment of the Masimo Foundation and various one-time grants and marketing initiatives. Excluding the impact of these one-time expenses, total selling, general and administrative expenses increased $9.8 million, or 6.1%, to $169.2 million for the year ended December 31, 2011 compared to $159.4 million for the year ended January 1, 2011. This increase was primarily due to an increase in commission and payroll costs of $8.0 million, associated with higher product sales and increased staffing levels. Also, expenses related to legal fees increased by $2.2 million due to additional legal activity and travel related expenses increased by $1.3 million. These increases in expense were offset by a decrease of $1.3 million in sample related expenses. Included in these total selling, general and administrative expenses are $1.9 million and $2.7 million of direct expenses incurred by our VIEs for the years ended December 31, 2011 and January 1, 2011, respectively.

Research and Development. Research and development expenses increased $2.4 million, or 6.7%, to $38.4 million for the year ended December 31, 2011 from $36.0 million for the year ended January 1, 2011. The increase was primarily due to increased payroll and payroll related costs of $0.9 million associated with increased staffing levels, as well as $0.6 million in increased engineering supplies related to new product development. Also, contributing to the increase was an increase in depreciation expense of $0.3 million due to additional capital equipment purchased to support the growth of our business. Included in these total research and development expenses are $3.4 million and $2.0 million of engineering expenses incurred by our VIEs for the years ended December 31, 2011 and January 1, 2011, respectively.

Antitrust litigation proceeds. Antitrust litigation proceeds were $0 for the year ended December 31, 2011 as compared to net proceeds of $30.7 million for the year ended January 1, 2011. The $30.7 million received in the year ended January 1, 2011, was the result of payments from Covidien relating to the antitrust litigation following the Ninth Circuit Court of Appeals October 2009 affirmance of a Federal District Court decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products.

Non-operating income (expense). Non-operating income was $14,000 for the year ended December 31, 2011, as compared to $1.3 million for the year ended January 1, 2011. This decrease of $1.3 million was primarily due to realized and unrealized net losses on foreign currency denominated transactions of $0.1 million recognized during the year ended December 31, 2011 compared to net gains of $1.0 million recognized during the year ended January 1, 2011. The realized and unrealized net losses on foreign currency denominated transactions recognized during the year ended December 31, 2011 resulted primarily from losses due to the strengthening of the U.S. dollar against the Euro, the British pound, the Canadian dollar and the Australian dollar, offset by gains due to the weakening of the U.S. dollar against the Japanese yen. The realized and unrealized net gains on foreign currency denominated transactions recognized during the year ended January 1, 2011 resulted primarily from gains due to the weakening of the U.S. dollar against the Japanese yen, partially offset by the losses due to the strengthening of the U.S. dollar against the Euro.

Provision for Income Taxes. Our provision for income taxes was $22.5 million for the year ended December 31, 2011, compared to $34.2 million for the year ended January 1, 2011. Our effective tax rate decreased to 26.0% for the year ended December 31, 2011 from 31.8% for the year ended January 1, 2011. This decrease in tax provision and effective tax rate was due primarily to the effect of electing the California single sales factor method for state apportionment, the change in geographic composition of pre-tax income in jurisdictions in which we do business and the decrease in uncertain tax liabilities as a result of an expiring statute of limitations. Our future effective income tax rate will depend on various factors, including profits (losses) before taxes, changes to tax law, and the geographic composition of pre-tax income.

Liquidity and Capital Resources

As of December 29, 2012, we had cash and cash equivalents of $71.6 million, of which $32.0 million was invested in U.S. Treasury bills, $1.6 million was in money market accounts with major financial institutions and $38.0 million was in checking accounts. These U.S. Treasury bills are classified as cash equivalents since they

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are highly liquid investments, with a maturity of three months or less at the date of purchase. We carry cash equivalents at cost which approximates fair value.

As of December 29, 2012, we have cash totaling $28.0 million held outside of the U.S. A substantial portion of this cash held offshore is accessible without a significant tax cost. In managing our day-to-day liquidity and our capital structure, we do not rely on foreign earnings as a source of funds. We currently have sufficient funds for domestic operations and do not anticipate the need to repatriate funds associated with our permanently reinvested foreign earnings. In the event funds that are treated as permanently reinvested are repatriated, we may be required to accrue and pay additional U.S. taxes to repatriate these funds.

In 2012, 2011 and 2010, we received $28.3 million, $37.4 million and $48.5 million, respectively, in cash receipts from Covidien for royalties pursuant to our settlement agreement. Through March 14, 2011, we received a royalty payment based on a rate of 13% of Covidien s U.S. pulse oximetry sales. On January 28, 2011, we entered into a second amendment to the settlement agreement with Covidien. As part of this amendment, which became effective as of March 14, 2011, Covidien agreed to pay us a royalty of 7.75% for its U.S. pulse oximetry revenue, as specifically defined in that second amendment, generated at least through March 15, 2014.

In August 2011, our board of directors authorized the repurchase of up to 3.0 million shares of common stock under a repurchase program. During the year ended December 31, 2011, 1.8 million shares were repurchased, at an average price of $19.61 per share, totaling $36.2 million. During the year ended December 29, 2012, 1.2 million shares were repurchased, at an average price of $22.74 per share, totaling $26.3 million, which completed the stock repurchase program. We paid for these repurchases with available cash and cash equivalents. In October 2012, our Board declared a special $1.00 per share cash dividend, payable in December 2012, which totaled $57.3 million.

Cash Flows from Operating Activities. Cash provided by operating activities was $75.4 million in 2012. The source of cash consists primarily of net income including noncontrolling interests of $61.9 million, and non-cash expense for share-based compensation and depreciation and amortization of $14.1 million and $9.4 million, respectively. In addition, accrued compensation increased $4.8 million primarily due to higher staffing levels. These sources of cash were partially offset by an increase in accounts receivable of $10.1 million due to growth of our business, and an increase in benefit from deferred income taxes of $6.8 million due to timing differences of taxable income.

Cash provided by operating activities was $79.0 million in 2011. The source of cash consists primarily of net income including noncontrolling interests of $64.1 million, resulting from continued growth of our business. Also, non-cash expense for share-based compensation and depreciation and amortization were $13.7 million and $7.3 million, respectively, in 2011. In addition, accounts payable increased $5.2 million due to continued growth of our business and inventory purchases in anticipation of future demand for our products, and royalties receivable decreased by $4.9 million due to the decline in the royalty rate from Covidien. These sources of cash were partially offset by an increase in accounts receivable of $7.5 million due to the growth of our business, and an increase in deferred cost of goods sold of $4.5 million due to shipments of equipment to customers pursuant to long-term sensor contracts.

Cash Flows from Investing Activities. Cash used in investing activities for 2012 was $51.9 million primarily due to payments totaling $37.4 million for the acquisitions of Phasein and the Spire Semiconductor assets, net of cash acquired and excess liabilities assumed. Additionally, $10.8 million was used for purchases of property and equipment to primarily support our manufacturing operations. Cash used in investing activities for 2011 was $7.5 million primarily consisting of $5.1 million of cash to purchase property and equipment to support our manufacturing operations.

Cash Flows from Financing Activities. Cash used in financing activities for 2012 was $82.1 million primarily due to $57.3 million of dividend payments and $26.3 million in common stock repurchases. Cash used in financing activities for 2011 was $30.2 million resulting from $36.2 million in common stock repurchases and partially offset by $5.9 million of proceeds from the issuance of common stock associated with the exercise of stock options.

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Future Liquidity Needs. In the future, in addition to funding our working capital requirements, we anticipate our primary use of cash to be the equipment that we provide to hospitals under our long-term sensor purchase agreements. We anticipate additional capital purchases related to expanding our worldwide international operations including manufacturing, sales, marketing and other areas of necessary infrastructure growth. Our focus on international expansion will also require both continuing and incremental investments in facilities and infrastructure in the Americas, Europe and Asia. We also anticipate possible uses of cash for the acquisition of technologies or the acquisition of technology companies. The amount and timing of our actual investing activities will vary significantly depending on numerous factors, such as the progress of our product development efforts, our timetable for international sales operations and manufacturing expansion, both domestic and international regulatory requirements and opportunities to acquire technologies and technology companies at prices we believe are favorable.

In February 2013, our Board of Directors authorized the repurchase of up to 6 million shares of our common stock. This stock repurchase program may be carried out through open market purchases, block trades, one or more trading plans adopted in accordance with Rule 10b5-1 of the SEC, and in privately negotiated transactions. The repurchase program will become effective in February 2013 and is expected to continue for a period of up to 36 months unless it is terminated earlier by our Board of Directors. In the event that we repurchase shares of stock, these 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. Additionally, we expect to fund any potential stock repurchases through our available cash, future cash from operations, or other potential sources of capital.

Despite these possible capital investment requirements and any potential stock repurchases or dividend payments, we anticipate that our existing cash and cash equivalents will be sufficient to meet our working capital requirements, capital expenditures and operations for at least the next 12 months.

Current Financing Arrangements. As of December 29, 2012, other than capital leases, we did not have any other long term borrowings. The capital lease amounts represent principal and interest due on leased office equipment.

Contractual Obligations. The following table summarizes our outstanding contractual obligations as of December 29, 2012 and the effect those obligations are expected to have on our cash liquidity and cash flow in future periods (in thousands):

	Payments Due By Period				
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Operating Leases[1]	$ 5,491	$ 6,498	$ 2,758	$ 20	$ 14,767
Capital Leases (including interest)[2]	59	49	15		123
Purchase Commitments[3]	48,885				48,885
Total Contractual Obligations	$ 54,435	$ 6,547	$ 2,773	$ 20	$ 63,775

(1) Facility, equipment and automobile leases.
(2) Leased office equipment.
(3) Certain inventory items under non-cancellable purchase orders.

Other obligation: As of December 29, 2012, the liability for uncertain tax positions, including interest, was $7.4 million. Due to the high degree of uncertainty regarding the timing of potential cash flows associated with these liabilities, we are unable to make a reasonably reliable estimate of the amounts and periods in which these liabilities might be made.

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In addition to these contractual obligations, we had the following annual minimum royalty commitments to Cercacor, as of December 29, 2012 (in thousands):

	Payments Due By Period			
	Less than 1 year	1-3 years	3-5 years	More than 5 years
Minimum royalty commitment to Cercacor	$ 5,000	$ 10,000	$ 10,000	[1]

(1) Subsequent to 2017, the royalty arrangement requires a $5.0 million minimum annual royalty payment unless the agreement is amended, restated or terminated.

Cercacor is consolidated within our financial statements for all periods presented. Accordingly, all intercompany royalties, option and license fees and other charges between us and Cercacor have been eliminated in the consolidation. For additional discussion of Cercacor, see Note 3 to the consolidated financial statements.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenue and expenses for each reporting period. Management regularly evaluates its estimates and assumptions. These estimates and assumptions are based on historical experience and on various other factors that are believed to be reasonable under the circumstances, and form the basis for making management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

Inventory/Reserves for Excess or Obsolete Inventory

Inventories are stated at the lower of cost or market. Cost is determined using a standard cost method, which approximates FIFO (first-in, first-out). Inventory valuation reserves are recorded for materials that have become obsolete or are no longer used in current production and for inventory that has a market value less than the carrying value in inventory. We generally purchase raw materials in quantities that we anticipate will be fully used within one year. However, changes in operating strategy and customer demand, and frequent unpredictable fluctuations in market values for such materials can limit our ability to effectively utilize all of the raw materials purchased and sold through resulting finished goods to customers for a profit. We regularly monitor potential inventory excess, obsolescence and lower market values compared to standard costs and, when necessary, reduce the carrying amount of our inventory to its market value.

We develop our inventory reserve based on an evaluation of the expected future use of our inventory on an item by item basis. We apply historical obsolescence rates to estimate the loss on inventory expected to have a recovery value below cost. Our historical obsolescence rates are developed from our company specific experience for major categories of inventory, which are then applied to excess inventory on an item by item basis. We also develop other specific inventory reserves when we become aware of other unique events that result in a known recovery value below cost. For inventory items that have been written down, either due to the inventory reserve analysis or due to a specific event, the reduced value becomes the new cost basis. The new cost

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basis of an inventory item is not marked up in subsequent periods. Our inventory reserve was $6.0 million and $5.4 million at December 29, 2012 and December 31, 2011, respectively. If our estimates for potential inventory losses prove to be too low, then our future earnings will be affected when the related additional inventory losses are recorded.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is used to state trade receivables at a net estimated realizable value. We rely on prior experience to estimate the amount that we expect to collect on the gross receivables outstanding, which cannot be known with exact certainty as of the time of issuance of this report. We maintain a specific allowance for customer accounts that we know may not be collectible due to customer liquidity issues. We also maintain a general allowance for future collection losses that arise from customer accounts that do not indicate an inability, but may be unable, to pay. Although such losses have historically been within our expectations and the allowances we have established, we cannot guarantee that we will continue to experience the same loss rates that we have in the past, especially given the recent deterioration of the credit markets of the worldwide economy. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in our receivable collections and additional allowances may be required. Our accounts receivable balance was $67.9 million and $57.0 million, net of allowances for doubtful accounts of $2.0 million and $1.8 million at December 29, 2012 and December 31, 2011, respectively.

Share-Based Compensation

Effective January 1, 2006, we adopted an accounting standard for share-based compensation using the prospective method, which requires us to expense the estimated fair value of employee stock options and similar awards based on the fair value of the award on the date of grant. To calculate the fair value of stock options, we use the Black-Scholes option pricing model which requires the input of subjective assumptions. These assumptions include estimating the length of time employees will retain their stock options before exercising them, the estimated volatility of our stock price over the expected term and the number of options that will ultimately be forfeited prior to meeting their vesting requirements. Pursuant to the prospective transition method, stock options granted prior to January 1, 2006 continue to be accounted for under the prior existing guidance for stock issued to employees.

We estimate the length of time in which stock options are expected to be outstanding based on both our specific historical option exercise experience, as well as expected term information available from a peer group of companies with a similar vesting schedule. The estimated volatility is based on historical and implied volatilities of our share price and historical and implied volatilities of a peer group of companies over the expected term of the option. As we obtain more historical data as a publicly traded company, we expect to rely increasingly on our specific information for our estimate of volatility.

We are required to develop an estimate of the number of stock options that will be forfeited due to employee turnover. Adjustments in the estimated forfeiture rates can have a significant effect on our reported share-based compensation, as we recognize the cumulative effect of the rate adjustments for all expense amortization in the period the estimated forfeiture rates were adjusted. We estimate and adjust forfeiture rates based on a periodic review of recent forfeiture activity and expected future employee turnover. Adjustments in the estimated forfeiture rates could also cause changes in the amount of expense that we recognize in future periods.

Share-based compensation expense was $14.1 million, $13.7 million and $12.3 million for the years ended December 29, 2012, December 31, 2011 and January 1, 2011. The fair market value of our stock may also increase the cost of future stock option grants. To the extent that the fair market value of our stock increases, the overall cost of granting these options will also increase. For further details regarding our share-based compensation see Note 12 of our consolidated financial statements.

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Revenue Recognition and Deferred Revenue

We follow the current authoritative guidance for revenue recognition. Based on these requirements, we recognize revenue when: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. We enter into agreements to sell pulse oximetry and related products and services as well as multiple deliverable arrangements that include various combinations of products and services. While the majority of our sales transactions contain standard business terms and conditions, there are some transactions that contain non-standard business terms and conditions. As a result, contract interpretation is sometimes required to determine the appropriate accounting, including: (a) whether an arrangement exists, (b) how the arrangement consideration should be allocated among the deliverables if there are multiple deliverables, (c) when to recognize revenue on the deliverables, and (d) whether undelivered elements are essential to the functionality of the delivered elements. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

In September 2009, the Financial Accounting Standards Board, or FASB, amended the accounting standards related to revenue recognition for arrangements with multiple deliverables. The new standard changes the requirements for establishing separate units of accounting in a multiple element arrangement and requires the allocation of arrangement consideration to each deliverable to be based on relative selling prices. The FASB also amended the accounting standards for revenue recognition to exclude software that is contained in a tangible product from the scope of software revenue guidance if the software is essential to the tangible product s functionality. We adopted these new standards on a prospective basis. Therefore, the new standards apply only to revenue arrangements entered into or materially modified beginning January 2, 2011. For revenue arrangements that were entered into or materially modified after the adoption of these standards, implementation of this new authoritative guidance had no significant impact on our reported revenue during either the year ended December 31, 2011, as compared to revenue if the related arrangements entered into or materially modified after January 2, 2011 were subject to the accounting requirements in effect in the prior year.

The new standards establish a hierarchy to determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor-specific objective evidence of fair value, or VSOE, (ii) third-party evidence of selling price, or TPE, and (iii) best estimate of the selling price, or ESP. VSOE of fair value is defined as the price charged when the same element is sold separately. VSOE generally exists only when the deliverable is sold separately and is the price actually charged for that deliverable. TPE generally does not exist for the majority of our products because of their uniqueness. The objective of ESP is to determine the price at which we would transact a sale if the product was sold on a stand-alone basis. In the absence of VSOE and TPE, we determine ESP for our products by considering multiple factors including, but not limited to, features and functionality of the product, geographies, type of customer, contractual prices pursuant to GPO contracts, our pricing and discount practices and market conditions.

A deliverable in an arrangement qualifies as a separate unit of accounting if the delivered item has value to the customer on a stand-alone basis. Most of our products in a multiple deliverable arrangement qualify as separate units of accounting. In the case of our monitoring equipment products containing embedded Masimo SET® software, we have determined that the hardware and software components function together to deliver the products essential functionality, and therefore, represent a single deliverable. In accordance with the new guidance, the revenue from the sale of these products no longer falls within the scope of the software revenue recognition guidance. Software deliverables, such as rainbow® parameter software, which do not function together with hardware components to provide the products essential functionality, continue to be accounted for under software revenue recognition guidance. Our multiple deliverable arrangements may therefore have software deliverables that are subject to the existing software revenue recognition guidance. The revenue for these multiple-element arrangements is allocated to the software deliverables and the non-software deliverables based on the relative selling prices of all of the deliverables in the arrangement using the hierarchy in the new revenue recognition accounting guidance for arrangements with multiple deliverables.

Our sales under long-term sensor purchase contracts are generally structured such that we agree to provide up-front and at no initial charge certain monitoring equipment, software, installation, training and ongoing warranty support in exchange for the hospital s agreement to purchase sensors over the term of the agreement, which

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ranges from three to six years. The sensors are essential to the functionality of the monitoring equipment and, therefore, represent a substantive performance obligation. We do not recognize any revenue when the monitoring and related equipment and software is delivered to the hospitals and installation and training is complete. We recognize revenue for these delivered elements, on a pro-rata basis, as the sensors are delivered under the long-term purchase commitment. The adoption of the new guidance for revenue recognition did not change this pattern of revenue recognition for long-term sensor purchase contracts. The cost of the monitoring equipment initially placed at the hospitals is deferred and amortized to cost of goods sold over the life of the underlying long-term sensor purchase contract.

To the extent that the allocation of revenue to multiple deliverables under long-term sensor agreements depends on our estimated selling prices, there is uncertainty over the percentage allocation to equipment, sensors and software. A change in the factors we use to estimate selling price, the weighting we assign to different factors, or a change in our pricing and discounting strategy could result in a different allocation to the deliverables in an arrangement. However, because we recognize revenue as sensors are delivered over the term of the agreement, the total revenue recognized under long-term sensor agreements in any period is not dependent on the allocation to the deliverables. The total amount of revenue recognized under long-term sensor agreements in a period is dependent on the amount of sensors shipped in the period. Our long-term sensor agreements provide for a minimum annual purchase commitment by our customers, but the timing and amount of customer purchases may vary from period to period.

Accounting for Income Taxes

As part of the process of preparing our consolidated financial statements, we are required to determine our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax expenses and assessing temporary differences resulting from recognition of items for income tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must reflect this increase as an expense within the tax provision in the statement of operations.

Management s judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We continue to monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly.

At December 29, 2012, we have $20.0 million of net operating loss carryforwards from our subsidiary in Sweden, which will carryforward indefinitely. We believe that it is more likely than not, that $9.3 million of such losses will not be realized. A valuation allowance has been provided on such loss carryforwards. We also have $0.4 million of net operating losses from various states, which will begin to expire in 2014, all of which will be recorded in equity when realized. We have state research and development credits of $2.1 million which will carryforward indefinitely. Additionally, we have $0.5 million of investment tax credit on research and development expenditures from its operations in Canada which will begin to expire in 2019. We believe it is more likely than not that these deferred tax assets will be realized. In making this determination, we consider all available positive and negative evidence, including scheduled reversals of liabilities, projected future taxable income, tax planning strategies and recent financial performances. Our consolidated income tax provision or benefit and the net deferred tax assets include Cercacor s income taxes provision or benefit and deferred tax assets. For income tax purposes, Cercacor is not a member of our consolidated group and files its separate federal and California income tax returns.

On January 1, 2007, we adopted an accounting standard which prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As of December 29, 2012 and December 31, 2011, the balance

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of gross unrecognized tax benefits was $6.7 million and $8.4 million, respectively. The amount of unrecognized benefits which, if ultimately recognized, could favorably affect the tax rate in a future period was $5.7 million and $7.4 million as of December 29, 2012 and December 31, 2011, respectively. Both amounts are net of any federal and/or state benefits. It is reasonably possible that the amount of unrecognized tax benefits in various jurisdictions may change in the next 12 months due to the expiration of statutes of limitation or audit settlements. However, due to the uncertainty surrounding the timing of such events, an estimate of the change within the next 12 months cannot be made. Interest and penalties related to unrecognized tax benefits are recognized in income tax expense. At December 29, 2012, we had accrued $0.8 million for the payment of interest.

We conduct business in multiple jurisdictions, and as a result, one or more of our subsidiaries files income tax returns in the U.S. federal, various state, local and foreign jurisdictions. We have concluded on all U.S. federal income tax matters for years through 2008. All material state, local and foreign income tax matters have been concluded for years through 2005.

Recent Accounting Pronouncements

In July 2012, the FASB issued Accounting Standards Update No. 2012-02, or ASU 12-02, *Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, to allow entities to use a qualitative approach to test indefinite-lived intangible assets for impairment. ASU 12-02 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, then a quantitative impairment test that exists under current authoritative accounting guidance must be completed. Otherwise, the quantitative impairment test is not required. ASU 12-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption of this update is permitted. We do not expect the adoption of this update to have a material impact on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks that may arise from adverse changes in market rates and prices, such as interest rates, foreign exchange fluctuations and inflation. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense we must pay with respect to our various outstanding debt instruments. Our risk associated with fluctuation in interest expense is limited to our outstanding capital lease arrangements, which have fixed interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities. Our investment portfolio consists of highly liquid investments with an original maturity from the date of purchase of three months or less, that have historically been held to maturity. Therefore, a hypothetical 100 basis point change in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest-sensitive financial instruments at December 29, 2012. Declines in interest rates over time will, however, reduce our interest income and expense while increases in interest rates will increase our interest income and expense.

Foreign Currency Exchange Rate Risk

A majority of our assets and liabilities are maintained in the United States in U.S. dollars and a majority of our sales and expenditures are transacted in U.S. dollars. However, we transact with foreign customers 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. In addition, we are exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables and payables. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of comprehensive income as

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incurred. Certain of our foreign sales support subsidiaries transact 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. Certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses. These foreign currency gains or losses are included in our statements of comprehensive income as incurred. In addition, any other transactions between us or our subsidiaries and a third-party, denominated in a currency different from the functional currency, are a foreign currency transaction. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of comprehensive income as incurred and are converted to U.S. dollars at average exchange rates for a respective period.

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.

Our primary foreign currency exchange rate exposures are with the Euro, the Japanese yen, the Canadian dollar, the British pound and the Australian dollar against the U.S. dollar. Foreign currency exchange rates have experienced significant movements recently and may continue in the future. We currently do not enter into forward exchange contracts to hedge exposures denominated in foreign currencies and do not use derivative financial instruments for trading or speculative purposes. The effect of a 10% change in foreign currency exchange rates could have a material effect on our future operating results or cash flows, depending on which foreign currency exchange rates change and depending on the directional change (either a strengthening or weakening against the U.S. dollar). As our foreign operations continue to grow, our exposure to foreign currency exchange rate risk may become more significant.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the periods presented. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could have a material adverse effect on our business, financial condition and results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15(a)(1) and 15(a)(2), respectively.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. We recognize that any controls and procedures, no matter how well designed

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and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated by the SEC under the Exchange Act. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 29, 2012.

Grant Thornton LLP, the independent registered public accounting firm that audited the financial statements included in this Form 10-K, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 29, 2012. This report, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 29, 2012, is included herein.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 29, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item concerning our directors, compliance with Section 16 of the Exchange Act and our code of ethics that applies to our principal executive officer, principal financial officer and principal accounting officer is incorporated by reference from the information set forth in the sections under the headings Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Election of Directors Information Regarding the Board of Directors and Corporate Governance in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders to be held in 2013, or the 2013 Proxy Statement.

Information regarding our executive officers is set forth in Item 1 Business of this Form 10-K under the caption Executive Officers of the Registrant.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information in the 2013 Proxy Statement under the heading Compensation of Executive Officers.

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ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information in the 2013 Proxy Statement under the headings Equity Compensation Plan Information and Security Ownership of Certain Beneficial Owners and Management.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information in the 2013 Proxy Statement under the headings Transactions with Related Persons and Election of Directors Information Regarding the Board of Directors and Corporate Governance.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the information in the 2013 Proxy Statement under the heading Ratification of Selection of Independent Auditors Principal Accountant Fees and Services.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The Consolidated Financial Statements of Masimo Corporation and Report of Grant Thornton LLP, Independent Registered Public Accounting Firm, are included in a separate section of this Form 10-K beginning on page F-1.

(a)(2) Financial Statement Schedules

Schedules not listed above have been omitted because they are not applicable or are not required or the information required to be set forth therein is included in the Consolidated Financial Statements or the Notes thereto.

(a)(3) Exhibits

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation (Exhibit 3.2)
3.2(2)	Certificate of Designation of Series A Junior Participating Preferred Stock (Exhibit 3.1)
3.3(11)	Amended and Restated Bylaws (Exhibit 3.2)
4.1(1)	Form of Common Stock Certificate (Exhibit 4.1)
4.2(1)	Fifth Amended and Restated Registration Rights Agreement made and entered into as of September 14, 1999 between the Registrant and certain of its stockholders (Exhibit 4.2)
4.3(2)	Rights Agreement, dated November 9, 2007, between the Registrant and Computershare Trust Company, N.A., as Rights Agent (Exhibit 4.1)
4.4(4)#	Masimo Retirement Savings Plan (Exhibit 4.7)

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Exhibit Number	Description of Document
10.1(1)#	Form of Indemnity Agreement between the Registrant and its officers and directors (Exhibit 10.1)
10.2#	Amended and Restated Employment Agreement, dated February 7, 2012, between Joe Kiani and the Registrant
10.3(1)#	Offer Letter, dated February 15, 1996, between Yongsam Lee and the Registrant (Exhibit 10.7)
10.4(6)#	Offer Letter, dated May 21, 2004, between Rick Fishel and the Registrant (Exhibit 10.13)
10.5(1)#	Offer Letter, dated June 9, 2006, between Mark P. de Raad and the Registrant (Exhibit 10.9)
10.6(1)#	Offer Letter, dated March 30, 2007, between Anand Sampath and the Registrant (Exhibit 10.8)
10.7(6)#	Offer Letter, dated July 23, 2008, between Jon Coleman and the Registrant (Exhibit 10.9)
10.8(10)#	Executive Annual Cash Bonus Award Plan, effective January 1, 2007 (Exhibit 10.2)
10.9(1)#	Executive Multi-Year Cash Bonus Award Plan, effective January 1, 2008 (Exhibit 10.41)
10.10(6)#	CEO and Executive Officer Equity Award Compensation Policy, effective January 4, 2008 (Exhibit 10.53)
10.11#*	Amended and Restated 2007 Severance Protection Plan and Summary Plan Description, effective December 31, 2008
10.12(3)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Mark P. de Raad (Exhibit 10.2)
10.13(3)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Yongsam Lee (Exhibit 10.3)
10.14(6)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Rick Fishel (Exhibit 10.57)
10.15#*	2007 Severance Protection Plan Limited Participation Agreement, dated February 18, 2009, by and between the Registrant and Jon Coleman
10.16#*	Amended and Restated 2007 Severance Protection Plan Limited Participation Agreement, dated May 12, 2009, by and between the Registrant and Anand Sampath
10.17(1)#	Third Amended and Restated 1996 Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan of the Registrant, as amended, and forms of agreements related thereto (Exhibit 10.31)
10.18(1)#	2004 Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan of the Registrant, as amended, and forms of agreements related thereto (Exhibit 10.32)
10.19(1)#	2007 Stock Incentive Plan of the Registrant, and forms of agreements related thereto (Exhibit 10.33)
10.20(1)+	Purchase Agreement, dated July 26, 2001, between Jabil Circuit, Inc. and the Registrant (Exhibit 10.15)
10.21(1)+	Shelter Labor Services Agreement, dated December 27, 2000, between Industrial Vallera de Mexicali, S.A. de C.V. and the Registrant (Exhibit 10.11)
10.22(5)+	Lease Agreement effective as of September 1, 2007, by and among Industrias Asociadas Maquiladoras, S.A. de C.V., Industrial Vallera de Mexicali, S.A. de C.V. and the Registrant, as guarantor (Exhibit 10.1)

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Exhibit Number	Description of Document
10.23(7)+	Lease Agreement, relating to the premises at 40 Parker, effective as of November 1, 2009, between the Registrant and Northwestern Mutual Life Insurance Company (Exhibit 10.1)
10.24(7)+	Amendment No. 1 to Lease Agreement, relating to the premises at 50 Parker, dated April 30, 2009, between the Registrant and Northwestern Mutual Life Insurance Company (Exhibit 10.3)
10.25(7)+	Lease Agreement, relating to the premises at 60 Parker, effective as of August 1, 2009, between the Registrant and Northwestern Mutual Life Insurance Company (Exhibit 10.2)
10.26(1)	Settlement Agreement and Release of Claims, dated January 17, 2006, between Cercacor Laboratories, Inc., Nellcor Puritan Bennett, Inc., Mallinckrodt, Inc., Tyco Healthcare Group LP, Tyco International Ltd., Tyco International (US) Inc. and the Registrant (Exhibit 10.30)
10.27(9)	Second Amendment to the January 17, 2006 Settlement Agreement and Release of Claims, as amended pursuant to the January 24, 2006 Amendment to Settlement Agreement and Release of Claims, dated January 28, 2011, by and among Masimo Corporation, Masimo Laboratories, Inc., Nellcor Puritan Bennett LLC, Mallinckrodt Inc., Tyco Healthcare Group LP and Covidien Inc. (Exhibit 10.1)
10.28(1)+	Amended and Restated Cross-Licensing Agreement, effective January 1, 2007, between Cercacor Laboratories, Inc. and the Registrant (Exhibit 10.34)
10.29(1)	Services Agreement, effective January 1, 2007, between Cercacor Laboratories, Inc. and the Registrant (Exhibit 10.35)
12.1*	Statement Regarding the Computation of Ratio of Earnings to Fixed Charges
21.1*	List of Registrant s subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Joe Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Mark P. de Raad, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Joe Kiani, Chief Executive Officer, and Mark P. de Raad, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 29, 2012 and December 31, 2011, (ii) Consolidated Statements of Comprehensive Income for the years ended December 29, 2012, December 31, 2011 and January 1, 2011, (iii) Consolidated Statements of Equity for the years ended December 29, 2012, December 31, 2011 and January 1, 2011, (iv) Consolidated Statements of Cash Flows for the years ended December 29, 2012, December 31, 2011 and January 1, 2011, and (v) Notes to Consolidated Financial Statements.

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(1) Incorporated by reference to the exhibits to the Registrant s Registration Statement on Form S-1 (No. 333-142171), originally filed on April 17, 2007. The number given in parenthesis indicates the corresponding exhibit number in such Form S-1, as amended.
(2) Incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on November 9, 2007. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
(3) Incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K, filed on January 17, 2008. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
(4) Incorporated by reference to the exhibit to the Registrant s Registration Statement on Form S-8, filed on February 11, 2008. The number given in parenthesis indicates the corresponding exhibit number in such Form S-8.
(5) Incorporated by reference to the exhibit to the Registrant s Current Report on Form 8-K, filed on June 5, 2008. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
(6) Incorporated by reference to the exhibit to the Registrant s Annual Report on Form 10-K, filed on March 4, 2009. The number given in parenthesis indicates the corresponding exhibit number in such Form 10-K.
(7) Incorporated by reference to the exhibit to the Registrant s Quarterly Report on Form 10-Q, filed on November 4, 2009. The number given in parenthesis indicates the corresponding exhibit number in such Form 10-Q.
(8) Incorporated by reference to the exhibits to the Registrant s Current Report on Form 8-K filed on May 18, 2010. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
(9) Incorporated by reference to the exhibit to the Registrant s Current Report on Form 8-K filed on January 31, 2011. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
(10) Incorporated by reference to the exhibit to the Registrant s Quarterly Report on Form 10-Q, filed on May 4, 2011. The number given in parenthesis indicates the corresponding exhibit number in such Form 10-Q.
(11) Incorporated by reference to the exhibit to the Registrant s Current Report on Form 8-K, filed on October 26, 2011. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
* Filed herewith.
# Indicates management contract or compensatory plan.
+ The SEC has granted confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

(b) Exhibits

See Item 15(a)(3) above.

(c) Financial Statement Schedules

See Item 15(a)(2) above.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 14, 2013 By: /s/ Joe Kiani
Joe Kiani

Chairman of the Board & Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE(S)	DATE
/s/ Joe Kiani Joe Kiani	Chairman of the Board & Chief Executive Officer (Principal Executive Officer)	February 14, 2013
/s/ Mark P. de Raad Mark P. de Raad	Executive Vice President & Chief Financial Officer (Principal Financial and Accounting Officer)	February 14, 2013
/s/ Steven Barker, M.D., Ph.D. Steven Barker, M.D., Ph.D.	Director	February 14, 2013
/s/ Edward L. Cahill Edward L. Cahill	Director	February 14, 2013
/s/ Robert Coleman, Ph.D. Robert Coleman, Ph.D.	Director	February 14, 2013
/s/ Sanford Fitch Sanford Fitch	Director	February 14, 2013
/s/ Jack Lasersohn Jack Lasersohn	Director	February 14, 2013

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MASIMO CORPORATION

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Masimo Corporation

We have audited the accompanying consolidated balance sheets of Masimo Corporation (the Company) as of December 29, 2012 and December 31, 2011, and the related consolidated statements of comprehensive income, equity and cash flows for each of the three years in the period ended December 29, 2012. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Masimo Corporation as of December 29, 2012 and December 31, 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 29, 2012 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Masimo Corporation s internal control over financial reporting as of December 29, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 14, 2013 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

Irvine, California

February 14, 2013

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Masimo Corporation

We have audited Masimo Corporation s (the Company) internal control over financial reporting as of December 29, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Masimo Corporation maintained, in all material respects, effective internal control over financial reporting as of December 29, 2012, based on criteria established in *Internal Control Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Masimo Corporation as of December 29, 2012 and December 31, 2011, and the related consolidated statements of comprehensive income, equity and cash flows for each of the three years in the period ended December 29, 2012 and our report dated February 14, 2013 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

Irvine, California

February 14, 2013

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MASIMO CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 29, 2012	December 31, 2011
ASSETS		