MASIMO CORP
Form 10-K
February 17, 2012
Table of Contents

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 31, 2011

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 Stock Market, LLC

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 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 July 2, 2011, the last business day of the registrant s most recently completed second fiscal quarter, as reported on the NASDAQ Global Select Market, was approximately $1.22 billion. 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 27, 2012 the registrant had 58,255,816 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 2011 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.

Table of Contents

MASIMO CORPORATION

FISCAL YEAR 2011 FORM 10-K ANNUAL REPORT

TABLE OF CONTENTS

Table of Contents

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; 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 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 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 some of our products to our original equipment manufacturer, or OEM, partners, for incorporation into their products. As of December 31, 2011, we estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET® was 979,000 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 2011, 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

1

Table of Contents

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®. In May 2008, we received FDA clearance for SpHb®, and in March 2009, we began full market release of SpHb®. Hemoglobin is defined as 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 blood transfusions and in multiple cases demonstrate its lifesaving ability to detect bleeding earlier, without having to wait for traditional invasive blood tests results. In November 2009, we received FDA clearance for continuous and noninvasive monitoring of respiration rate, or RRa™, via rainbow Acoustic Monitoring™. Respiration rate is the number of breaths per minute, and often the leading indicator 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 June 2010, we began a full commercial release of RRa™. In July 2010, we began selling the SEDLine® monitor, which measures brain function on a continuous basis 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.

We also offer a remote monitoring and clinician notification solution called the Masimo SafetyNet™, or 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. 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 avoid negative outcomes. Masimo SET®, along with 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 SafetyNet™ screen. Halo Index™ is pending FDA 510(k) clearance.

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 Masimo 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 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 31, 2011, we had 603 issued and pending patents worldwide. We have exclusively licensed from our development partner, Cercacor Laboratories, Inc., or 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 market, facility caregivers.

Pulse Oximetry Background

Pulse oximetry, considered the 5th vital sign, 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 brain damage or death in a matter of minutes. Masimo pulse oximeters are used primarily in critical care settings, including emergency departments, surgery, recovery rooms, intensive care units, or ICUs, and alternative care settings, such as long-term care facilities and for home monitoring in 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 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 oximeters to administer the minimum level of oxygen necessary to maintain normal saturation levels.

Table of Contents

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 designated range. As a result, clinicians are able 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, arterial blood signal recognition can be distorted by motion artifact, or patient movement, and low perfusion, or low arterial blood flow. 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 oximeter to report inaccurate measurement, or some cases, no measurement at all. Conventional pulse oximeters cannot distinguish oxygenated hemoglobin, or the component of red blood cells that carries oxygen, from dyshemoglobin, which is hemoglobin that is 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, 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, which can lead to the non-detection of hypoxemic events.

Published 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 failed to give measurements at all 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 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 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. These solutions, commonly referred to as alarm management techniques, mask the limitations of conventional pulse oximetry. Several published studies have demonstrated that some of these alarm management techniques have actually contributed to increased occurrences of undetected true alarms, or events where hypoxemia occurs, but is not detected by the pulse oximeter.

Conventional pulse oximetry technology also has several practical limitations. Because the technology cannot consistently measure oxygen saturation levels of arterial blood in the presence of motion artifact or low perfusion, the technology 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 inventions of rainbow®, we can also measure noninvasively and continuously carboxyhemoglobin and methemoglobin, as well as hemoglobin. We call this new product a Pulse CO-Oximeter.

Pulse Oximetry Market Opportunity

The pulse oximetry market consists of pulse oximeters 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 2011.

Table of Contents

In a December 2008 report, Frost & Sullivan stated that it expects the growth in the U.S. pulse oximetry market to be driven by:

- ongoing adoption of low perfusion, motion-tolerant technology;
- rising patient acuity, or severity of illnesses, which increases the need for monitoring in the intermediate and sub-acute settings;
- expansion of the market for pulse oximetry monitoring to the general surgical floor;
- greater efficiencies for the health care worker through increased reliability, improved detection algorithms and the ability to reject false alarms; and
- adoption of pulse oximetry outside the hospital and in the faster growing alternate care market.

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. It is currently estimated that 87% of all U.S. hospital beds are located in non-critical care areas, where continuous patient monitoring is not widely used. A study published in July 2004 by *HealthGrades* showed that 264,000 hospital deaths over a three-year period were attributable to patient safety incidents, or generally preventable patient events in non-critical care areas. The study concluded that the failure to timely diagnose and treat patients accounted for over 70% of those deaths, suggesting that improved patient monitoring in non-critical care settings can alert clinicians of patient distress and help to improve patient care. A landmark study published in January 2010 by Dartmouth-Hitchcock Medical Center demonstrated that clinicians using Masimo SET® and SafetyNet™ identified patient distress earlier, which decreased rapid response team activations, ICU transfers, and ICU days.

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 non-critical care settings, 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 the November 2010 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 need oxygen therapy and Continuous Positive Airway Pressure. 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 Masimo 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 already 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 Philips, Atom Medical, Oridion, CareFusion and more. 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

Table of Contents

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 blood 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.

A low or falling hemoglobin measurement provides the primary indication for whether a patient receives a blood transfusion. The decision to transfuse often requires the physician to either make an educated guess or wait for hemoglobin lab results to confirm that it is necessary. Blood transfusions are common, with up to 20% of surgical patients and 35% of ICU patients receiving one or more units of blood. Transfusions have been shown in multiple studies to increase short and long-term morbidity and mortality. Blood transfusions are also costly, with blood being one of the highest cost items in a hospital. Each unit of blood is estimated to cost between $522 and $1,183, without including the additional cost of treatment associated with blood transfusion-related complications. It is known that some blood transfusions are unnecessary, especially when given in stable anemia or when bleeding is perceived but not significant. Experts advocate implementing restrictive transfusion practices and use of appropriate indicators for blood transfusion, and the Joint Commission recently introduced quality measures that encourage hospitals to track hemoglobin documentation prior to each unit of blood transfused.

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 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 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 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 infrequent and delayed.

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 large 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 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 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 2012, the Medicare reimbursement for SpHb® will be $7.10 per test when testing eligible patients.

5

Table of Contents

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.

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 study in March 2008 by Brown University, the 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. 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 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 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 2012, the Medicare reimbursement for SpCO® will be $7.10 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 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 ICU s.

Table of Contents

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 2012, the Medicare reimbursement for SpMet® will be $7.10 per day when testing eligible patients.

Pleth Variability Index (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.

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 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. Masimo s noninvasive respiration rate parameter is available in our Masimo rainbow® SET platforms with the launch of MX-3 board, which was released in November 2009. These devices with the RRa™ software and Masimo s acoustic respiration sensor 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 SafetyNet™ system. 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 in the gastrointestinal lab, as well as in the monitoring of non-mechanically ventilated patients during surgery.

Halo Index™

In October 2010, we debuted Halo Index™, which has received CE Marking in the European Union, but 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 SafetyNet™ remote monitoring and notification system, which facilitates simple and comprehensive assessment within a single index. In the future, we expect Halo Index™ will also be available as part of Masimo 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, we introduced In Vivo Adjustment™ (pending FDA 510(k) clearance in the U.S.) to the 2011 Radical-7™ that enables clinicians, for the first time, to adjust the noninvasive measurements of SpO_2, SpHb®, SpCO® and SpMet® to the

7

Table of Contents

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 brain function on a continuous basis 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® enables more individualized titration of sedation and faster emergence, while offering reliable monitoring during challenging conditions such as electrocautery.

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, Masimo developed the Pulse Oximetry ReSposable sensor system and began a limited market release in December 2010. The ReSposable sensor, part reusable and part disposable, combined 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. We expect to go to full market release in 2012 with ReSposable Pulse Oximetry Sensors.

8

Table of Contents

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, hemoglobin incapable of transporting oxygen, and allows for the rapid, noninvasive monitoring of hemoglobin, carboxyhemoglobin, methemoglobin, and pleth variability index, 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 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. SafetyNet™ offers a rich user interface with trending, and real time waveform capability at the central station and remote notification via pager or smart phones. 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 Masimo s commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture. 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, have been validated in low perfusion conditions .

Reduced retinopathy of prematurity in very low birth weight neonates. In a study comparing the use of conventional pulse oximetry at one center and Masimo SET® at another, there was no significant decrease in retinopathy of prematurity using conventional pulse oximetry but there was a 58% reduction in the incidence of significant retinopathy of prematurity and a 40% reduction in the need for laser eye treatment with Masimo SET®.

Fewer arterial blood gas measurements, faster oxygen weaning time, and lower length of stay. 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. A landmark study published in January 2010 by Dartmouth-Hitchcock Medical Center demonstrated that clinicians using Masimo SET® and 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. 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 SafetyNet™ systems enable the Masimo SET® and rainbow® SET platforms to wirelessly and remotely monitor patients in the general care areas of the hospital that are not under the constant supervision of clinicians.

Table of Contents

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 risky and costly blood 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 critically-ill ventilated patients

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

SEDLine® Brain Function Monitoring

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

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 $406.5 million in 2011 from $259.6 million in 2008, representing a three year CAGR of 16.1%. 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 $342.9 million, or 84%, of product revenue in 2011, from $201.1 million, or 77%, of product revenue in 2008.

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 SafetyNet™, which enables continuous monitoring of up to 80 patients oxygen saturation, pulse rate, and with rainbow® SET, noninvasive hemoglobin and respiration rate.

Table of Contents

Expand the use of rainbow® technology in the Hospital Setting. We believe the noninvasive measurement of rainbow® Pulse CO-Oximetry (hemoglobin, carboxyhemoglobin, methemoglobin, pleth variability index) 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 Masimo s 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, 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 rainbow 4D™ technology, as, a noninvasive spot-check hemoglobin device, along with oxyhemoglobin, pulse rate, and perfusion index. With a touch screen for easy operation and wireless 802.11 and Bluetooth for printing and communication, the Pronto-7® is well suited for spot-check testing. The Pronto-7® allows users to simply and quickly perform a spot-check measurement of hemoglobin levels, one of the most common invasive laboratory measurements taken in physician offices. We believe that the ability to noninvasively measure hemoglobin will increase efficiency and improve clinical decision making in physician offices and emergency departments by enabling quick determination of hemoglobin levels. The new Pronto-7® product expedites the measurement process by quickly providing a noninvasive measurement thereby reducing the time required to take an invasive blood draw, create the labeling, sending the sample to the lab, waiting for the lab results (often not until the next day), and communicating 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 Pleth Variability Index, 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 generated between 71% and 76% of our product revenue in the U.S. 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 its 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.

Table of Contents

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.

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, uSpO2)	Signal processing apparatus for all Masimo SET® and licensed Masimo rainbow® SET technology platforms	Incorporated into our proprietary pulse oximeters and sold to OEM partners who incorporate our circuit boards into their patient monitoring systems
Monitors / Devices (e.g., Radical-7™, Pronto-7® and Rad-57™)	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
Sensors (e.g., SET®, rainbow® SEDLine and rainbow Acoustic Sensors™) and Cables	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	
Remote Alarm and Monitoring Solutions (e.g., Masimo 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™, Halo Index™ and In Vivo Adjustment™)	Rainbow® measurements and other proprietary features sold to installed monitors	Sold directly to end-users and through OEM partners who sell to end-users
Circuit Boards		

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

uSpO2 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 the ability to interface the uSpO2 cable/board to

12

Table of Contents

monitoring devices externally via an existing communications port in instances where internal integration of a traditional Masimo SET® technology board is not feasible. The uSpO2 cable/board provides full Masimo SET® Measure-Through Motion and Low Perfusion pulse oximetry found in other Masimo 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, 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.

Radical-7™ is a fully-equipped standalone Pulse CO-Oximeter™ with a detachable module, which functions as a battery-operated, handheld monitor. The handheld module can be connected with any other Radical-7™ base station, which allows Radical-7™ to stay with the patient, enabling continuous and reliable arterial blood oxygen saturation and blood constituent monitoring such as hemoglobin as patients are transported within the hospital. For example, 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 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 SafetyNet™ remote monitoring and clinician notification system. We began shipping the Rad-87® in July 2008.

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.

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

Table of Contents

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.

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.

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 s signal extraction technology.

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 frontal lobe.

Remote Alarm and Monitoring Solutions

Masimo SafetyNet™. 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.

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 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 Masimo 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.

14

Table of Contents

X-Cal™

In 2011, Masimo implemented a technology called X-Cal™ in its 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 SET® pulse oximetry sensor, patient cable, and instrument 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 Masimo s quality and performance controls, and are not tested or warrantied to work within a Masimo system;

- Masimo designs its sensors and cables to last well beyond their warranty and customer feedback indicates Masimo sensors and cables last significantly longer than competing products, but cable and sensor reliability may still be compromised when used beyond their expected life, 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 third-party reprocessed sensors tested fail to meet Masimo s performance specifications.

Masimo offers its 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 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.

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 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, methemoglobin, pleth variability index, acoustic respiration rate, and Halo Index™.

Our direct and distributor revenue accounted for 84% of our total product revenue in 2011. For the year ended December 31, 2011, 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 31, 2011. 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 to put our products on contract, we

Table of Contents

have agreed to pay the GPOs a percentage of our revenue from their member hospitals. In 2011 and 2010, revenue from the sale of our pulse oximetry products to hospitals that are associated with GPOs amounted to $223.8 million and $183.8 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 2012, 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 which 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;
- 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	
Measurements	**Alternate Care Market**	**Patient and Pharmacist**
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.

Table of Contents

(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. 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 the exclusive license 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 market, 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 products used to monitor non-vital signs measurements, sensors and accessories, rather than for monitoring vital signs measurements, 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.

We are also subject to certain specific annual minimum aggregate royalty payment obligations, which increased to $5.0 million per year payment starting in 2010.

From Cercacor s inception in 1998 through December 31, 2011, we paid Cercacor $36.1 million for both exclusive licensing options and minimum royalty payments. We have 180 days after proof of feasibility to exercise the above-referenced option to obtain a license to the remaining non-vital signs measurements, including bilirubin for an additional $500,000 and blood glucose for an additional $2.5 million. As of December 31, 2011, feasibility on these measurements has not been attained. From its inception in 1998 through December 31, 2011, Cercacor has incurred a total of $29.2 million in 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.

Table of Contents

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

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

Ownership of Improvements. Any improvements to Masimo SET® or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third party that relates to non-vital signs monitoring, and any new technology acquired by Cercacor, is and will be owned by Cercacor. Any improvements to the Masimo SET® platform or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third party that relates to vital signs monitoring, and any new technology acquired by us, is and will be owned by us. However, for both non-vital signs and vital signs monitoring, any improvements to the technology, excluding acquired technology, will be assigned to the other party and 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. From July 2010 through December 2011, Cercacor continued to assist us with other product development efforts and charged us accordingly. For the year ended December 31, 2011, the total funding for these additional Cercacor expenses was $2.5 million. Both companies have agreed to maintain this structure 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 2012. 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 2011 were $38.4 million, which included $3.4 million related to expenses incurred by Cercacor pursuant to the Cross-Licensing Agreement. In 2010, our total research and development expenditures were $36.0 million, which included $1.7 million related to expenses incurred by Cercacor. In 2009, our total research and development expenditures were $31.7 million, which included $2.0 million related to expenses incurred by Cercacor. We expect our research and development expenses to increase in 2012 and beyond as we expand our research and development force, enhance our existing products and technologies and develop new product

candidates.

Table of Contents

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 31, 2011, we had 364 issued patents and 239 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. In addition, as of December 31, 2011, technology we licensed from our development partner, Cercacor, was supported by 125 issued patents and 185 pending applications in the U.S. and internationally. Some of our earliest patents began to expire in 2011. Some of Cercacor s earliest patents begin to expire in 2015. Additionally, as of December 31, 2011, we owned 41 U.S. registered trademarks and 114 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 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 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 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.

19

Table of Contents

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.

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 believe that our Original Equipment Manufacturer, or 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)s.

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;

Table of Contents

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;

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 action 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 constitutes 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 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

Table of Contents

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.

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. 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, has 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 and 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 antikickback 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 of a manufacturer s products from reimbursement under government programs, and imprisonment.

22

Table of Contents

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: health care fraud and false statements related to healthcare matters. The health care fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. 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 this statute is a felony and may result in fines and imprisonment.

The FCPA 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 elaborate 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 a majority 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. Due to the very recent enactment of HITECH and expected implementing regulations, we are unable to predict what the extent of the impact on our business will be, but these new HITECH requirements may require us to incur additional costs and may restrict our business operations.

The HIPAA standards also apply to the use and disclosure of PHI for research, and 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 PHI and these laws could create liability for us or increase our cost of doing business.

Table of Contents

New PHI standards, 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 PHI 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.

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 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. This could result in changes to Medicare payments to our customers for the use of our products in the hospital outpatient setting.

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.

24

Table of Contents

Our success with rainbow® SET technologies in U.S. care areas with reimbursable test procedures, such as hospital emergency department, 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, 2011, the maximum rates for noninvasive carboxyhemoglobin, methemoglobin and hemoglobin testing under the Medicare laboratory fee schedule are $7.06 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, recently enacted health care reform legislation could affect future Medicare payment for these services.

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.

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 25,000 square foot International Organization for Standardization 13485:2003 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 allows 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.

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

Employees

As of December 31, 2011, we had 2,548 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.

25

Table of Contents

Executive Officers of the Registrant

Our executive officers, as of January 31, 2012, are set forth below:

Name	Age[1]	Position(s)
Joe Kiani	47	Chief Executive Officer & Chairman of the Board of Directors
Tony Allan	46	Chief Operating Officer
Jon Coleman	48	President, Worldwide Sales, Marketing and Clinical Research
Mark P. de Raad	52	Executive Vice President, Chief Financial Officer and Corporate Secretary
Rick Fishel	54	President, Worldwide OEM Business and Corporate Development
Yongsam Lee	47	Chief Information Officer and Executive Vice President, Regulatory Affairs
Anand Sampath	45	Executive Vice President, Engineering

[1] As of January 31, 2012.

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.

Tony Allan has served as our Chief Operating Officer since May 2010. From August 1995 to May 2010, he held various positions, including Vice President of Global Business Units, Instrumentation and Medical Sector and Senior Business Unit Director with Jabil Circuit Inc., an electronics design, manufacturing and product solutions company. Mr. Allan holds a Post Graduate diploma in Quality Engineering from Paisley University and a H.N.D. Engineering from Glasgow College.

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. 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.

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.

Table of Contents

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 Securities and Exchange Commission, or 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.

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;

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.

Table of Contents

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 market 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.

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

Table of Contents

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 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 31, 2011, January 1, 2011 and January 2, 2010, shipments of our pulse oximetry products to customers that are members of GPOs represented $223.8 million, $183.8 million and $160.8 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.

Table of Contents

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.

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.

Medical device reprocessors that reprocess our single-use sensors and then resell them to hospitals at a cost lower than our new sensors may adversely affect our business, financial condition and results of operations.

Certain medical device reprocessors have been collecting our used single-use sensors from hospitals and then reprocessing, repackaging and reselling those sensors to hospitals at a price lower than our new sensors. Over the past two years, there has been an increase in our customer s awareness of these programs and willingness to consider purchasing some of their sensor requirements from these third party reprocessors. These reprocessed sensors may lead to confusion with our authorized products, reduce our revenue and harm our customer relationships. In addition, this may increase time and expense spent investigating and addressing performance issues with the reprocessed sensors, and enforcing our proprietary rights and contracts against the reprocessors.

Despite our agreements and our customers acknowledged preference for disposable single patient adhesive sensors due to performance and risk of contamination, our customers who are concerned about finances could take desperate measures such as switching from disposable sensors to reusable sensors. In addition, our customers could also begin purchasing third party recycled sensors, rather than our new sensors, in an attempt to reduce their overall operating costs.

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. 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, which may result in reduced customer demand for our products and cause our revenue to decline.

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 31, 2011, January 1, 2011 and January 2, 2010, our royalties from the Covidien settlement agreement totaled $32.5 million, $49.0 million and $49.0 million each year, 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.

Table of Contents

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 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;

Table of Contents

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;

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 as described in Part 1, Item 3 of this Annual Report on Form 10-K, and Note 12 to the consolidated financial statements. Both Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH are associated with Philips Medical Systems, an OEM partner of ours. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

We believe that other competitors of ours, including GE Medical Systems and Mindray Medical International Ltd., may be infringing at least one of our patents. Our failure to pursue any potential claim could result in the loss of our proprietary rights and harm our position in the marketplace. Therefore, we may be forced to pursue litigation to enforce our rights. 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, 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

Table of Contents

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. It is believed that this study may result in formal changes to the FDA s 510(k) clearance review and approval processes which could potentially lengthen the review process of any future application of ours even further.

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.

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 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.

Table of Contents

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.