MASIMO CORP
Form 10-K
February 17, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended January 2, 2010

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 ¨ 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, 2009, the last business day of the registrant s most recently completed second fiscal quarter, as reported on the NASDAQ Global Market, was approximately $1.18 billion.

At January 29, 2010, the registrant had 57,978,540 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 2010 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.

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MASIMO CORPORATION

FISCAL YEAR 2009 FORM 10-K ANNUAL REPORT

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or 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 the 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 that improve patient care. 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. Our Masimo SET platform has addressed many of the previous technology limitations and has been referred to by several industry sources as the gold standard in pulse oximetry. The benefits of Masimo SET have been validated in over 100 independent clinical and laboratory studies.

We develop, manufacture, and market a family of noninvasive blood constituent patient monitoring solutions that consists of a monitor or circuit board and our proprietary single-patient use and reusable sensors and cables. In addition, we offer remote monitoring and clinician notification solutions, such as the Masimo Patient SafetyNet. Our solutions and related products are based upon our proprietary Masimo SET algorithms. This software-based technology is incorporated into a variety of product platforms depending on our customers specifications. 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. We estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET was 640,000 units, based on an estimated 7 year field life assumption, as of January 2, 2010. 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 one billion, as of January 2, 2010, the largest component of which was the sale of sensors.

Our strategy is to utilize the reliability and accuracy of our Masimo SET platform, along with our Patient SafetyNet solutions, to facilitate the expansion of our pulse oximetry products into areas beyond critical care settings, including the general care areas of the hospital. Additionally, we have developed products that noninvasively monitor parameters beyond arterial blood oxygen saturation level and pulse rate, which create new market opportunities in both the critical care and non-critical care settings. In 2005, we launched our Masimo Rainbow SET platform utilizing 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 measure multiple parameters that previously required invasive or complicated procedures. In 2005, we launched Masimo 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 assess carbon monoxide poisoning status and help determine treatment and additional test options. In

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2006, we launched Masimo methemoglobin, or SpMet, allowing for the measurement of methemoglobin levels in the blood. Methemoglobin in the blood leads to a dangerous condition known as methemoglobinemia, which occurs as a reaction to some common drugs used in hospitals and in out patient procedures. When used with other clinical variables, SpMet may help clinicians assess methemoglobinemia status and help determine treatment and additional test options. In 2007, we launched Masimo PVI. Fluid administration is critical to optimizing fluid status, but traditional methods to guide fluid administration often fail to predict fluid responsiveness. When used with other clinical variables, PVI may help clinicians assess fluid status and help determine treatment options. In May 2008, we received FDA clearance for total hemoglobin, or SpHb, and began commercial release of our continuous monitoring total hemoglobin device in March 2009. Total 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. When used with other clinical variables, SpHb may help clinicians assess anemic status, help determine treatment and additional test options. In December 2009, we announced FDA clearance for Rainbow Acoustic Monitoring for continuous and noninvasive monitoring of respiration rate, or RRa. Respiration rate, which is the number of breaths per minute, is often the leading indicator of patient distress, but traditional methods are often considered inaccurate or not tolerated well by patients. When used with other clinical variables, RRa may help clinicians assess respiratory status and help determine treatment options. We believe that the use of products incorporating Rainbow technology will become widely adopted for the noninvasive monitoring of these parameters. In addition, we believe that we will develop and introduce additional parameters and products in the future based on our proprietary technology platforms.

Our technology is supported by a substantial intellectual property portfolio that we have built through internal development and, to a lesser extent, acquisitions and license agreements. As of January 2, 2010, we had 577 issued and pending patents worldwide. We have exclusively licensed from our development partner, Masimo Laboratories, Inc., or Masimo Labs, the right to incorporate Rainbow technology into our products intended to be used by professional caregivers, including, but not limited to, hospital caregivers and emergency medical services, or EMS, facility caregivers. On January 17, 2006, we settled a patent litigation dispute with Nellcor Puritan Bennett, Inc., a division of Tyco Healthcare (currently Covidien Ltd.). Under the terms of the settlement, Covidien Ltd., or Covidien, has agreed to discontinue the sale of its products found to infringe our patents and will pay us royalties at least through March 14, 2011 on the U.S. sales of its pulse oximetry products.

On August 13, 2007, we completed our initial public offering, or IPO, of common stock in which a total of 13,704,120 shares were sold, comprised of 10,416,626 shares sold by selling stockholders and 3,287,494 shares sold by us at an issue price of $17.00 per share. We raised a total of $55.9 million in gross proceeds from the IPO, or $47.8 million in net proceeds after deducting underwriting discounts and commissions of $3.9 million and estimated other offering costs of $4.2 million. Upon the closing of the IPO, all shares of convertible preferred stock outstanding automatically converted into an aggregate of 34,612,503 shares of common stock. The consolidated financial statements for the period ended December 29, 2007, including share and per share amounts, include the effects of the offering since it was completed prior to December 29, 2007.

Industry Background

Pulse oximetry has gained widespread clinical acceptance as a standard patient vital sign measurement because it can give clinicians an early warning of low arterial blood oxygen saturation levels, known as hypoxemia. Early detection is critical because hypoxemia can lead to a lack of oxygen in the body s tissues, which can result in 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 emergency medical services market.

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.

Pulse oximeters use sensors attached to an extremity, typically the fingertip. These sensors contain two light emitting diodes, or LEDs, that in a transmittance sensor 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.

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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 were 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 not ideal to allow for its use 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, all pulse oximeters cannot distinguish oxygenated hemoglobin from dyshemoglobin. The most prevalent forms of dyshemoglobins are carboxyhemoglobin and methemoglobin. As a result of these dyshemoglobins, pulse oximeters will report falsely high oxygen levels when they are present in the blood. Prior to Masimo noninvasive and continuous carboxyhemoglobin and methemoglobin monitors, lab-based tests were the only way to detect dyshemoglobins, but these tests are invasive and do not provide immediate or continuous results.

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. According to a Frost & Sullivan report dated March 2004, it was estimated that the U.S. pulse oximetry *sensor* market would increase to $622 million by 2010. According to a Frost & Sullivan report dated December 2008, it is estimated that the U.S. pulse oximetry *equipment* market would increase to $265 million by 2010. Based on these estimates, the total U.S. pulse oximetry market will be $887 million in 2010, with between 6% and 8% CAGR. Frost & Sullivan expects the growth in the U.S. pulse oximetry market to be driven by:

ongoing adoption of low perfusion, motion-tolerant technology;

aggressive awareness campaigns;

rising patient acuity, or severity of illnesses, which increases the need for monitoring in the intermediate and sub-acute settings;

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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.

Based on this Frost & Sullivan estimate for the U.S. market and other available estimates for markets outside the U.S., we estimate that the worldwide pulse oximetry market will be more than one billion dollars in 2010. According to the December 2008 Frost & Sullivan report, Masimo and Covidien each comprised 37.4% of the total U.S. pulse oximetry monitoring equipment market in 2008. According to a January 2009 market research report from iData, Masimo and Covidien had 43.5% and 38.3%, respectively, of the U.S. pulse oximetry monitoring equipment market. We believe we will continue to grow our U.S. market share amount as more hospitals convert to Masimo technology.

New Market Opportunities for Masimo SET

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 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 Masimo Patient SafetyNet identified patient distress earlier and decreasing 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, 87% of all hospital beds in the U.S. were located in non-critical care settings according to a study published in the Journal of Critical Care Medicine, 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 June 2007 Frost & Sullivan 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 and we plan to leverage the opportunity and expand our presence in this market.

New Market Opportunities for Masimo Rainbow SET

There are significant opportunities to expand Masimo s hospital and alternate care markets by enabling the measurement of additional noninvasive parameters beyond arterial blood oxygen saturation level and pulse rate.

Total Hemoglobin (SpHb®)

In May 2008, we received clearance from the FDA for our total hemoglobin monitoring technology and in September 2008, we began shipping, in a limited market release, these monitors and sensors. In March 2009, we commercially launched our continuous non-invasive total hemoglobin device. Hemoglobin is the part of a red blood cell that carries oxygen to the body and therefore a measurement of total hemoglobin is an indicator of the oxygen carrying capacity of the blood. 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

and 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. Blood transfusions are common, with up to 20% of surgical patients and 35% of ICU patients receiving one or more units of

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blood. Transfusions increase morbidity and mortality, associated with significant increases in short and long-term morbidity and mortality. Blood transfusions are also costly, with blood being one of the largest cost centers in a hospital. Each unit of blood is estimated to cost up to $500 to $1,000 for material alone, in addition to 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. 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.

A low or falling hemoglobin measurement also helps determine whether a patient has internal bleeding that requires further investigation. Significant bleeding occurs in up to 35% of surgical and critical care patients. Low hemoglobin identifies almost 90% of patients with bleeding, but traditional laboratory measurements are infrequent and delayed. Bleeding significantly increases the cost of treatment, according to multiple studies.

When used with other clinical variables, Masimo SpHb may help clinicians assess anemic status, 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 majority of anesthesiologists believed that SpHb would help prevent unnecessary transfusions and the majority of ICU physicians believed that SpHb could lead to significantly earlier bleeding detection. Capgemini also created a financial model and their study estimated that the average 500 bed hospital would save $468,000 annually by implementing SpHb and other Rainbow parameters. Because of the potential clinical and cost advantages of measuring total 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 diagnosis 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 15 million annual U.S. blood donations would be aided by the noninvasive and immediate assessment of hemoglobin.

Beginning in January 2010, the American Medical Association approved a Current Procedural Terminology, or CPT, code and Medicare implemented pricing on the Medicare Clinical Lab Fee Schedule for noninvasive hemoglobin, enabling U.S. hospitals and physician offices that perform testing to recover their costs, in addition to the clinical benefits they receive from this measurement.

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 assess carbon monoxide poisoning status 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, and recommended noninvasive carbon monoxide testing for Emergency Department and EMS 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.

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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.

We believe that the first and greatest opportunity for noninvasive blood carbon monoxide monitoring is in the EMS and emergency department settings. In the U.S. alone, there are 30,000 fire departments / EMS 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 by researchers at Johns Hopkins University in September 2004, there were 414 cases, or 19% of all patients reviewed, of acquired methemoglobinemia, at two hospitals over a 28-month period. 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 assess methemoglobinemia status 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.

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.

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, unnecessary 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, or CVP, monitoring often fail to predict fluid responsiveness, and newer methods are invasive, complicated, and/or costly.

When used with other clinical variables, Masimo PVI may help clinicians assess fluid status and help determine treatment options. PVI has been shown to predict fluid responsiveness in surgical and intensive care patients who are under mechanical ventilation. Mechanical ventilation means that a machine called a respirator is controlling patient breathing. PVI has also been shown to help clinicians improve fluid management by reducing 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 surgery and intensive care in hospitals, but it is also possible that future studies may reveal application in identifying dehydration or in optimizing fluid in cardiac conditions such as heart failure.

Acoustic Respiration Rate (RRa™)

We received FDA clearance for Rainbow Acoustic Monitoring of respiration rate in November 2009 and announced initial market release of the parameter in December 2009. We expect to continue limited market release activities throughout the first half of 2010 and are planning for full commercial launch in the second half of 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,

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which is considered unreliable. Masimo s noninvasive respiration rate parameter will be available in our Masimo Rainbow SET platforms with the launch of MX-3 Board, which was released in November 2009. These devices will be deployed through Masimo s acoustic respiration sensor on the patient s neck and connected to the bedside monitor with a special cable. Should the respiration rate change or stop, an alarm will be displayed on the device and in addition, can be sent to the Masimo Patient SafetyNet system. Patient SafetyNet can then notify the attending clinician or nurse of the condition, directly on the monitor or remotely via a pager.

When used with other clinical variables, RRa may help clinicians assess respiratory status and help determine treatment options. We believe this noninvasive measurement will become a key and important measurement in the general floor environment and may also have important applications in the post-anesthesia care unit as well as non-mechanically ventilated surgical patients.

Future Parameters

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

The Masimo Solution

Our innovative and proprietary technologies and products are 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 and 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 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 parameters 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 total hemoglobin, carboxyhemoglobin, methemoglobin, and PVI, which we refer to as Pulse CO-Oximetry. Along with the release of our Rainbow SET Pulse CO-Oximetry products, we have developed multi-wavelength sensors that have the ability to monitor multiple parameters with a single sensor. We believe that the use of Masimo Rainbow SET Pulse CO-Oximetry products will become widely adopted for the noninvasive monitoring of these parameters. We believe the addition of Rainbow Acoustic Monitoring for noninvasive and continuous monitoring of respiration rate (RRa) will strengthen the clinical demand for the Rainbow platform, especially in the growing general floor market.

Additionally, we market our Patient SafetyNet remote monitoring and clinician notification system for use with our Masimo SET pulse oximeters and Rainbow SET Pulse CO-Oximeters, which allow monitoring of the oxygen saturation and pulse rate of up to 80 patients simultaneously. We believe that the superior 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.

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Benefits of Our Products and Technology

We believe that our technology and products offer several key benefits, including:

Accurate, Real-Time Measurement. We believe that the Masimo SET platform has the ability to provide more accurate measurements with fewer missed events and false alarms than other pulse oximeters in the market place. Many of the top hospitals in the U.S., including seven of the top ten, according to U.S. News and World Reports Honor Roll for 2009, made Masimo SET their primary pulse oximetry platform.

Increased Quality of Patient Care. We believe that the proven accuracy and reliability of Masimo SET pulse oximetry allows for better clinical decisions, leading to fewer medical errors and better patient care. We believe that the noninvasive monitoring of carboxyhemoglobin will improve the quality of care based on the number of emergency room visits reported for carbon monoxide poisoning. We believe the noninvasive monitoring of methemoglobin will also improve patient care based on reported drug interactions that increase methemoglobin levels in the blood and that wireless remote-alarm and monitoring on the general care floor will reduce avoidable adverse events through earlier detection and intervention. We believe Masimo Rainbow SET will allow earlier and better clinical decisions in a variety of care areas.

Reduced Cost of Care. Several independent studies have shown that hospitals can reduce their costs as a result of using Masimo SET products. We believe that factors contributing to lower costs include a reduction in sensor usage as a result of more durable sensors, fewer invasive arterial blood gas procedures needed, less oxygen administration and a reduction in length of stay as the result of weaning patients off of ventilators more quickly. In addition, we expect that the noninvasive monitoring of carboxyhemoglobin and methemoglobin will help reduce the cost of care by reducing the need for invasive blood tests and limiting the costs from complications caused by incorrect diagnoses. We believe early detection of avoidable adverse events will contribute to lower length of stay because such events will be treated earlier before patients decompensate to critical levels. We believe earlier and better clinical decisions from Masimo Rainbow SET will allow for more cost-effective care and in some cases reimbursable procedures for hospitals and non-hospital providers.

Masimo SET Platform Allows for 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 EMS market. In addition, 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 Patient 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.

Upgradeable Rainbow 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 parameters. 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 parameter, which will allow the customer to expand their patient monitoring systems to monitor additional parameters with a cost-effective solution. The Rainbow platform enables breakthrough noninvasive measurement of parameters that previously required invasive testing, which may lead to earlier and better clinical decisions and decreased costs compared to standard care.

Our Strategy

Since inception, our mission has been to develop noninvasive blood constituent patient 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 from $155.5 million in 2006 to $300.1 million in 2009, representing a three year CAGR of 25%. This growth can be attributed to the increased access to pulse oximetry customers through our agreements with group purchasing organizations, or GPOs, and 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 $241.7 million, or 81%, of product revenue in 2009, from $104.0 million, or 67%, of product revenue in 2006.

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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 Masimo Patient SafetyNet, which enables continuous monitoring of up to 80 patients oxygen saturation, pulse rate, and with Rainbow SET, noninvasive hemoglobin and acoustic respiration rate.

Expand the use of Rainbow SET in the Hospital Setting. We believe the noninvasive measurement of Rainbow SET Pulse CO-Oximetry (total hemoglobin, carboxyhemoglobin, methemoglobin, PVI) and Rainbow Acoustic Monitoring (acoustic respiration rate), as well as future parameters, will provide an excellent opportunity to leverage existing customer relationships into new streams of revenue, 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 SET in the Non-Hospital Setting. We believe the noninvasive measurement of hemoglobin creates a significant opportunity in markets such as the physician office and blood donation centers, and noninvasive carboxyhemoglobin in the Fire/EMS market. To date, we have introduced a handheld product called Pronto and, in 2010, we expect to introduce a new handheld product called the Pronto-7 into the physician office and emergency department market. The Pronto-7 will allow users to simply and quickly measure hemoglobin, one of the most common invasive laboratory measurements taken in physician offices. We believe that the ability to noninvasively measure total hemoglobin will increase efficiency and improve clinical decision making in physician offices and emergency departments by enabling quick determination of total hemoglobin levels. The new Pronto-7 product will expedite the measurement process by quickly providing a non-invasive 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 Pulse CO-Oximetry Products Incorporating Licensed Rainbow Technology. We sold our first Masimo Rainbow SET 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 SET Pulse CO-Oximetry parameters 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 SET 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, through our license of Rainbow technology from Masimo Labs, we launched our Rainbow SET Pulse CO-Oximetry platform that enabled what we believe is the first FDA-cleared noninvasive monitoring of Carboxyhemoglobin, Methemoglobin, Hemoglobin and PVI, that previously required invasive testing. With Rainbow Acoustic Monitoring, we believe we have launched the first platform to enable noninvasive and continuous monitoring of respiration rate through an easy to use single patient adhesive acoustic sensor. We plan to continue to innovate and develop new technologies and products, internally and through our collaboration with Masimo Labs, for the noninvasive monitoring of other parameters.

Our future growth strategy is also closely tied to our focus on international expansion opportunities. Since 2005, we have generated between 74% and 81% of our product revenue in the U.S. Since 2006, we have been aggressively expanding our sales and marketing presence in Europe, Japan, Canada, Latin America and the rest of Asia. 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 will be able to develop 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.

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Our Products

We develop, manufacture and market a patient monitoring solution that incorporates a monitor or circuit board and sensors including both proprietary single-patient use and reusable sensors and 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)	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 (Pulse CO-Oximeters, Acoustic/Monitors, and Pulse Oximeters)	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. Rainbow and Non-Rainbow Sensors)	Extensive line of both single-patient use and reusable 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. Patient Safety Net)	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)	Rainbow parameters 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 and MS-2013.

Masimo Rainbow SET MX Circuit Boards. Our next-generation circuit board is the foundation for our Masimo Rainbow SET Pulse CO-Oximetry platform, utilizing technology licensed from Masimo Labs. The MX circuit boards measure arterial blood oxygen saturation levels and pulse rate, and have the circuitry to enable the measurement of total hemoglobin, oxygen content, carboxyhemoglobin, methemoglobin, PVI, and acoustic respiration rate, along with other potential parameters in the future. Customers can choose to buy additional parameters 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 parameters are developed, each new parameter may be available as a software upgrade to the existing system.

Monitors / Devices

Radical-7. We believe that the Radical-7 is the most advanced and versatile pulse oximeter available. The Radical-7 incorporates the MX circuit board, which enables Rainbow SET parameters, 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

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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 parameters 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 total 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.

Our 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 parameters such as total 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 Masimo Patient SafetyNet remote monitoring and clinician notification system. We began shipping the Rad-87 in July 2008.

Pronto. The Pronto is a handheld spot-check device, not a continuous monitoring device, using Masimo Rainbow SET technology, specifically designed to noninvasively provide total hemoglobin levels in both hospitals (i.e. emergency departments) and any remote setting such as physician offices or blood donation settings.

Rad-8. The Rad-8 is a bedside pulse oximeter featuring Masimo SET (but without Rainbow capability) with a low cost design and streamlined feature set, 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. 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 carboxyhemoglobin and methemoglobin in addition to oxygen saturation, pulse rate, perfusion and index. Its rugged and lightweight design makes it applicable for use in hospital and field settings, specifically for fire departments and EMS units.

Sensors

Sensors and Cables. We have developed one of the broadest lines of single-patient use and reusable sensors and cables. Masimo SET sensors are uniquely designed to reduce interference from physiological and non-physiological noise. Our proprietary technology platforms operate only with our proprietary sensor lines. However, through the use of adapter cables, we can connect our sensors to certain competitive 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. In addition, our LNOP single-patient use sensors offer several advantages over competitive disposable sensors, including a more durable tape material that is less likely to tear and an adhesive that can be easily rejuvenated with an alcohol swab. As a result, the sensor can be moved and reapplied multiple times during a patient s stay. Our LNOP single-patient neonatal adhesive sensors have been shown in independent, published studies to last approximately twice as long as the market-leading disposable sensor. Our reusable sensors, which include ear and forehead sensors, are primarily used for short-term hospital stays and spot checks. We currently sell over 40 different sensors for adults, children, infants and pre-term infants.

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

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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.

Masimo Rainbow SET Sensors. We believe we were the first to develop proprietary, multi-wavelength sensors for use with our Rainbow SET 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 total hemoglobin. Our licensed Rainbow SET sensors are the only sensors that are compatible with our licensed Rainbow SET products.

Remote-Alarm and Monitoring Solutions

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

Software

All of our monitors, including Radical-7 and certain future OEM products, which incorporate the MX board, will allow purchases of software for Rainbow parameters as well as other future parameters or features that can be field installed.

Geographic Information

We are a global company with a geographically diverse market presence. See Note 13 to our consolidated financial statements for financial information relating to the geographic areas in which we currently engage in business.

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, Japan, other parts of Asia, Latin America, Canada and Australia. We currently sell all of our products both directly to hospitals and the EMS market via our sales force, and certain distributors.

Our direct and distributor revenue accounted for 81% of our total product revenue in 2009. The primary focus of our sales representatives is to facilitate the conversion of competitor accounts to our Masimo SET pulse oximetry products. 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 SET Pulse CO-Oximetry and Rainbow Acoustic Monitoring products, including total hemoglobin, carboxyhemoglobin, methemoglobin, PVI and RRa. For the year ended January 2, 2010, Owens & Minor, one of our distributors, represented 14% of our total revenue and was the only customer that represented 10% or more of our revenue for the year ended January 2, 2010. Importantly, distributors such as Owens & Minor take and fulfill orders from our direct customers, many of whom have signed long-term sensor agreements with us. As a result, in the event a specific 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 six largest GPOs, based on the total volume of negotiated purchases. In return for the GPOs to put our products on contract, we have agreed to pay the GPOs a percentage of our revenue from their member hospitals. In fiscal 2009 and 2008, revenue from the sale of our pulse oximetry products to hospitals that are associated with GPOs amounted to $160.8 million and $132.1 million, respectively.

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Our marketing efforts are designed to build end-user awareness through 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. We expect to increase the size of our sales and marketing force worldwide during 2010, 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. (formerly Tyco Healthcare) 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. Although Covidien is still a competitor of ours, in 2006 we settled a patent infringement case against them following an appellate ruling which found that Covidien had infringed three of our patents. 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. On February 3, 2009, we filed a patent infringement suit against Phillips Electronics North America Corporation and Philips Medizin Systeme Böblingen Gmbh, which are affiliates of Philips Medical Systems, one of our OEM partners. Some of the remaining companies, including GE Medical Systems and Mindray Medical International Ltd., are also currently OEM partners of ours.

In November 2009, the Federal Appeals Court affirmed that Covidien violated antitrust laws through anticompetitive business practices related to the sale of its Nellcor pulse oximetry products. Specifically, the court ruled that Covidien s sole-source agreements and market-share based compliance pricing contracts were illegal. The court also ruled that above-cost bundling discounts when combined with sole-source or market-share-based pricing are illegal when such practices involve a significant portion of the market. We believe this ruling means that hospitals who are purchasing multiple Covidien products or in case of a MedAsset type bundle, including even other companies products, should no longer be threatened with price increases or rebate losses if they switch to Masimo.

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 parameters related to oxygenation and respiration, such as noninvasive and continuous hemoglobin and acoustic respiration rate;
- competitive pricing;
- sales and marketing capability;
- access to hospitals which are members of GPOs;
- access to OEM partners; and
- patent protection.

Masimo Laboratories, Inc.

Masimo Laboratories, Inc., or Masimo Labs, is an independent entity spun-off from us to our stockholders in 1998. Joe E. Kiani and Jack Lasersohn, members of our board of directors, are also members of the board of directors of Masimo Labs. Joe E. Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs.

We have a cross-licensing agreement with Masimo Labs 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 parameters.

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	End User Markets	
Parameters	**Professional Caregiver and EMS**	**Patient and Pharmacist**
Vital Signs[1]	Masimo	Masimo Labs
	(owns)	(non-exclusive license)
Non-Vital Signs[2]	Masimo	Masimo Labs
	(exclusive license)	(owns)

(1) Vital Signs parameters include 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 non- invasive 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 parameters, such as 3-D alarms, PVI and other features.

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

Our License to Masimo Labs. We granted Masimo Labs an exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET owned by us for the measurement of non-vital signs parameters and to develop and sell devices incorporating Masimo SET for monitoring non-vital signs parameters in the Labs Market. We also granted Masimo Labs a non-exclusive, perpetual and worldwide license, with sublicense rights, to use Masimo SET for the measurement of vital signs in the Labs Market. In exchange, Masimo Labs pays us a 10% royalty on the amount of vital signs sensors and accessories sold by Masimo Labs.

The Labs 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, EMS professionals or otherwise, provided the product is intended to be recommended, or resold, for use by the patient or pharmacist.

Masimo Labs License to Us. We exclusively licensed from Masimo Labs 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 total hemoglobin, which includes hematocrit. To date, we have developed and commercially released devices that measure carbon monoxide and methemoglobin 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 measurement of other non-vital signs parameters, 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 parameter.

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, EMS facility caregivers and vehicles where emergency medical services are provided.

Our license to Rainbow technology for these parameters in these markets is exclusive on the condition that we continue to pay Masimo Labs 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 measure non-vital signs parameters, sensors and accessories, rather than for measuring vital signs parameters, will be included in the 10% Rainbow royalty base. For multi-parameter devices, the Rainbow royalty base will include the percentage of the revenue based on the number of Rainbow-enabled parameters. For hospital contracts where we place equipment and enter into a sensor contract, we pay a royalty to Masimo Labs 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 payments, including $5.0 million per year starting in fiscal year 2010.

From Masimo Labs inception in 1998 through January 2, 2010, we paid Masimo Labs $26.1 million for both exclusive 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 parameters, including bilirubin for an additional $500,000 and blood glucose for an additional $2.5 million. As of January 2, 2010, feasibility on these parameters has not been attained. From its inception in 1998 through January 2, 2010, Masimo Labs has incurred a total of $20.6 million in expenses.

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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 Masimo Labs;
- the option to license technology developed by Masimo Labs 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 Masimo Labs;
- per product minimum royalties, to the extent less than the annual minimums, will be payable to Masimo Labs; and
- the minimum aggregate annual royalties for all licensed Rainbow parameters payable to Masimo Labs will increase to $15.0 million in 2010 for each year until the exclusive period of the agreement ends, plus up to $2.0 million per other Rainbow parameters.

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

- the sale of all or substantially all of either party 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 party;
- Joe E. Kiani, our Chief Executive Officer and the Chief Executive Officer of Masimo Labs, resigns or is terminated from his position with either party; and
- the merger or consolidation of either party with a non-affiliated third party.

Ownership of Improvements. Any improvements to Masimo SET or Rainbow technology made by Masimo Labs, by us, or jointly by Masimo Labs with us or with any third party that relates to non-vital signs monitoring, and any new technology acquired by Masimo Labs, is and will be owned by Masimo Labs. Any improvements to the Masimo SET platform or Rainbow technology made by Masimo Labs, by us, or jointly by Masimo Labs 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, in either case, 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 Masimo Labs and will be subject to the same license and option fees as if it had been developed by Masimo Labs. Also, we will not be reimbursed by Masimo Labs for our expenses relating to the development of any such technology.

Masimo Labs Services Agreement. We have also entered into a services agreement, or the Services Agreement, with Masimo Labs. Under this Services Agreement, we provide Masimo Labs with engineering services and accordingly charge Masimo Labs for these direct salary and payroll related expenses. In addition, at the end of each quarter, we charge Masimo Labs for its share of accounting, human resources, legal, facility and equipment costs, which we collectively refer to as indirect expenses. We expect Masimo Labs to continue to engage us for these services. However, pursuant to the Services Agreement, Masimo Labs may terminate the agreement by providing us 30 days notice, while we may terminate with 180 days notice to Masimo Labs.

Masimo Labs Expenses related to Pronto-7. In February 2009, we and Masimo Labs agreed that in order to accelerate the development of the technology supporting this product, Masimo Labs would re-direct a substantial amount of its engineering development activities to focus on this project for our benefit. Accordingly, we and Masimo Labs agreed that, effective during the year ended January 2, 2010, 50% of Masimo Labs engineering and engineering related expenses, and all third party engineering supplies expense related to Pronto-7 development, or $2.7 million would be charged to us. Both companies agreed to maintain this structure until we notify Masimo Labs 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 2010. Our research and development efforts focus primarily on continuing to enhance our technical expertise in pulse oximetry, enabling the noninvasive monitoring of other parameters and developing remote-alarm and monitoring solutions.

Although we and Masimo Labs each have separate research and development projects, we collaborate with Masimo Labs 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

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measurement of vital signs parameters, and Masimo Labs will have proprietary ownership of all technology related to the noninvasive measurement of non-vital signs parameters.

Our total research and development expenditures for 2009 were $31.7 million, which included $2.0 million related to expenses incurred by Masimo Labs pursuant to the Cross-Licensing Agreement. In 2008, our total research and development expenditures were $25.5 million, which included $2.4 million related to expenses incurred by Masimo Labs pursuant to the Cross-Licensing Agreement. In 2007, total research and development expenditures were $23.0 million, which included $1.9 million related to expenses incurred by Masimo Labs pursuant to the Cross-Licensing Agreement. We expect our research and development expenses to increase in 2010 and beyond as we expand our research and development force, enhance our existing products and technologies and develop new ones.

Intellectual Property

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

We have developed a patent portfolio internally, and to a lesser extent through acquisitions and licensing, that covers many aspects of our product offerings. As of January 2, 2010, we had 370 issued patents and 207 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. In addition, as of January 2, 2010, technology we licensed from our development partner, Masimo Labs, was supported by 62 issued patents and 96 pending applications in the U.S. and internationally. Some of our earliest patents begin to expire in 2011. Some of Masimo Labs earliest patents begin to expire in 2015. Additionally, as of January 2, 2010, we owned 41 U.S. registered trademarks and 128 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 Masimo Labs 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 measurement of vital signs parameters, and Masimo Labs will have proprietary ownership of all technology related to the noninvasive measurement of non-vital signs parameters. 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.

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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.

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, including our Masimo SET Software and Radical, but have determined that, in our view, based on FDA guidance as to when to submit a 510(k) notification for changes to a cleared device, new 510(k) clearances or PMA approvals are not required. 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 product is deemed a nonsignificant risk device eligible for more abbreviated 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 allow our OEM partners to reference our 510(k) FDA clearance for our Masimo SET circuit boards, sensors, cables and notification systems.

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

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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, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and 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 regulations, 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 governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

We must also register with the FDA as a medical device manufacturer and must 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 warning letter, injunction,

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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 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 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, EMS 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

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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.

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, 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 patient information, 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 patient information transmitted or stored electronically. We are not a covered entity but due to activities that we perform for or on behalf of covered entities, sometimes we are a business associate.

In certain circumstances, the HIPAA rules require covered entities to contractually bind us, as a business associate, to protect the privacy and security of health information 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 will be 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 health information 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, 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 health information 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

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that subject s health information 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 health information 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 patient information, 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 personal or patient information and these laws could create liability for us or increase our cost of doing business.

New health information 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 patient health information we could be subject to criminal or civil sanctions.

Third-Party Reimbursement

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

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. Effective January 1, 2007, however, reimbursement for certain pulse oximetry monitoring services, including those using our products, will no longer be packaged, but rather may receive a separate payment when no

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other separately payable services are provided. This could result in an increase in 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.

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, 2010, the maximum rates for noninvasive carboxyhemoglobin and methemoglobin testing under the Medicare laboratory fee schedule are $7.19 per service. The maximum rate for noninvasive hemoglobin testing also is $7.19. 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, health reform legislation currently being considered by the U.S. Congress 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. As of January 2, 2010, we had 1,548 employees and contract employees in manufacturing and quality worldwide. 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 excess 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 our 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.

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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 January 2, 2010, we had 2,199 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.

Executive Officers of the Registrant

Our executive officers, as of January 31, 2010, are set forth below:

Name	Age[1]	Position(s)
Joe E. Kiani	45	Chief Executive Officer & Chairman of the Board of Directors
Brian Campbell	44	Vice President, Operations
Jon Coleman	46	President, International
Mark P. de Raad	50	Executive Vice President, Chief Financial Officer and Corporate Secretary
Rick Fishel	52	President Americas and Worldwide OEM Business
Paul Jansen	39	Executive Vice President, Marketing
Yongsam Lee	45	Chief Information Officer
Michael O Reilly, M.D.	57	Executive Vice President, Medical Affairs
Stephen Paul	39	Executive Vice President of Acute Care Sales
Anand Sampath	43	Executive Vice President, Engineering

[1] As of January 31, 2010.

Joe E. 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 and chairman of the Medical Device Manufacturers Association (MDMA). Mr. Kiani holds a B.S.E.E. and an M.S.E.E. from San Diego State University.

Brian Campbell has served as our Vice President, Operations since October 2009. From August 2008 to October 2009, Mr. Campbell was Vice President of Operations of the Branded Products division of Hitachi Global Storage Technologies. He served as Senior Vice President of Worldwide Operations of Lantronix, a provider of internet connectivity and control solutions, from August 2006 to July 2008. From July 1989 to August 2006, he held progressive positions with Western Digital Corporation, most recently Vice President of Materials. Mr. Campbell holds a B.S. in Business Administration from the University of Arizona.

Jon Coleman has served as our President, International since August 2008. From October 2007 to August 2008, Mr. Coleman was President and Chief Executive Officer of You Take Control, Inc, a healthcare information technology 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

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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 and holds a B.S. in Accounting from the University of Santa Clara.

Rick Fishel has served as President Americas and Worldwide OEM Business since February 2009 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.

Paul Jansen has served as our Executive Vice President of Marketing since April 2008, and was our Vice President of Marketing from January 2008 to April 2008. From August 1997 through December 2007, he served as Vice President, Marketing & Clinical Development for CardioDynamics, a cardiac monitoring and diagnostics company. Mr. Jansen holds a B.S. in Planning from Iowa State University and an M.B.A. from Arizona State University.

Yongsam Lee has served as our Chief Information Officer since October 2009. From March 1996 to October 2001 and from April 2002 to October 2009, Mr. Lee held various positions with us, including 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.

Michael O Reilly, M.D. has served as our Executive Vice President, Medical Affairs since February 2008. Since April 2008, Dr. O Reilly has been a Professor of Anesthesiology and Perioperative Care at the University of California, Irvine. He was an Associate Professor from September 2002 to February 2008, and an Assistant Professor from September 1996 to August 2002, in Anesthesiology at the University of Michigan. He was also the Director of the Liver Transplant Anesthesiology at the University of Michigan and a member of various advisory boards. He has numerous publications in scientific journals, national and international invited presentations and earned various awards and grants. Dr. O Reilly holds an M.D. and M.S. in Cell Biology from the University of Vermont.

Stephen Paul has served as our Executive Vice President of Acute Care Sales since January 2010, and was our Vice President of U.S. Hospital Sales from February 2009 to January 2010 and our Western Area Vice President of Sales from March 2008 to February 2009. From April 1996 to February 2008, he held various positions, including Western Area Sales Director and Regional Sales Manager, with Boston Scientific, a developer, manufacturer and marketer of medical devices. Mr. Paul holds a B.A. in Political Science from University of California at Santa Barbara.

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

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Consequently, we are required to file reports and information with the 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.

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Risks Related to Our Revenues

We currently derive substantially all of our revenue from our Masimo 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, 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. 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. Our first product incorporating licensed Rainbow technology was made commercially available in September 2005. In September 2008, we began our limited market release of total hemoglobin, and focused on obtaining data and clinical feedback on the performance of the product in the hospital. In the first quarter of 2009, we commercially launched our total hemoglobin product for continuous and noninvasive monitoring in the hospital. We also have begun our limited market release of Rainbow Acoustic Monitoring and we expect to do full commercial launch in the second half of 2010. As with our total hemoglobin release, we have initially provided this new measurement to the market in a limited market release to allow us to evaluate the product s performance in the field. However, there can be no assurances of when we will roll it out fully.

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 and effectiveness of our products and their sales prices;
- reimbursement available through Centers for Medicare and Medicaid Services, or CMS, programs for using our products; and
- introduction and acceptance of competing products or technologies;

In order for any of our products to be accepted in the marketplace, we must demonstrate that they are effective and commercially beneficial. Even if customers accept these products, this acceptance may not result in sales if our competitors develop similar products that our customers prefer over ours. 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 Masimo Labs, which may impair our growth and adversely affect our financial condition and results of operations.

In May 1998, we created a newly-formed entity, Masimo Laboratories, Inc., or Masimo Labs, 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 Masimo Labs, 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 Masimo Labs:

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 measurement of non-vital signs measurements and to

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develop and sell devices incorporating Masimo SET for monitoring non-vital signs measurements in any product market in which a product is intended to be used by a patient or pharmacist rather than by a professional medical caregiver, which we refer to as the Labs Market, and

a non-exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET for measurement of vital signs in the Labs 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, total hemoglobin and bilirubin.

Under the Cross-Licensing Agreement, we are only permitted to sell devices utilizing Masimo SET for the measurement of non-vital signs measurements in markets where the product is intended to be used by a professional medical caregiver, including, but not limited to, hospital caregivers and emergency medical services, or EMS, 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 Masimo Labs 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 total 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.

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.

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for Masimo SET and licensed Rainbow technology. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. In particular, we may not be able to successfully commercialize our products for applications other than arterial blood oxygen saturation and pulse rate monitoring, including acoustic 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.

We depend on our 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 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 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 group purchasing organizations, or 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.

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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 January 2, 2010, January 3, 2009 and December 29, 2007, shipments of our pulse oximetry products to customers that are members of GPOs represented, were $160.8 million, $132.1 million and $101.0 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.

If we are unable to increase our sales, marketing and distribution capabilities or maintain or establish arrangements with third parties to sell, market and distribute our pulse oximetry and Rainbow technology products, our business, financial condition and results of operations could be adversely affected.

We have limited sales and marketing experience both in the U.S. and internationally and may not be successful in developing and implementing our business strategy. In addition, we currently have a small sales organization compared to many of our competitors. To increase our commercial capabilities, we need to:

- increase our sales and marketing forces;
- continue to maintain domestic and international OEM partners;
- ensure that distributors and OEM partners provide the technical and educational support customers need to use products incorporating Masimo SET and Rainbow technology successfully;
- promote monitoring systems using Masimo SET and Rainbow technology so that sales of those systems and our sensors increase; and
- be prepared to provide services, as necessary, to geographically dispersed users of monitoring systems using Masimo SET and Rainbow technology.

Failure to accomplish any of these requirements could have a material adverse effect on our business, financial condition and results of operations.

We currently plan to increase the size of our direct sales force to further market our products in the U.S. and internationally. Increasing our direct sales capabilities will be expensive and time consuming and we may not be able to further develop this capacity on a timely basis or at all. If we are unable to expand our sales and marketing capabilities, we will need to continue to contract with third parties to market, sell and distribute our approved products in the U.S. and internationally, which could cause our product revenue to be lower than if we directly marketed, sold and distributed our products. Furthermore, to the extent that we enter into co-promotion or other sales and marketing arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we are unable to maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate sufficient product revenue to be profitable.

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.

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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.

Recent deterioration in the credit markets and the financial services industry may negatively impact our business, results of operations, financial condition and liquidity.

Since 2008, the credit markets and the financial services industry have experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. While the ultimate outcome of these events cannot be predicted, they may have a material adverse effect on our liquidity, financial condition and results of operations if our customers ability to borrow money from their existing lenders, or to obtain credit from other sources to purchase our products under long term sensor agreements, were to be impaired. This credit market deterioration could affect our ability to acquire new customers for our products. In addition, the recent economic crisis could also adversely impact our suppliers ability to provide us with materials and components, either of which may negatively impact our ability to meet our customers requirements and grow our business.

We cannot guarantee that we will continue to experience the same collection rates that we have in the past, especially given the recent deterioration of the credit markets worldwide. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in our receivable collections and additional allowances may be required. These additional allowances could materially and adversely affect our financial results.

Our customers may reduce, delay or cancel purchases due to a variety of factors, such as lower hospital census levels, which could adversely affect our business, financial condition and results of operations.

As a result of the current worldwide economic environment, 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 to the overall economic environment, there are specific portions of our business, such as our OEM customers, who, due to their capital equipment sales model, could be impacted by the ongoing economic environment 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 total hemoglobin are sold with upfront license fees and more complex, and therefore, more expensive sensors could be impacted by hospital budget reductions.

The difficult economic environment and its impact on hospital budgets could also have other implications to our business, financial condition and results of operations. As an example, despite our agreements and our customers acknowledged preference for disposable single patient adhesive sensors due to performance and risk of contamination, our customers that are worried 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.

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

We also have a concentration of OEM, distribution and direct customers. If for any reason we were to lose our ability to sell to a specific group or class of customers, we would experience a significant reduction in revenue, which would adversely impact our operating results. Also, we cannot provide any assurance that we will retain our current customers or groups of customers or that we will be able to attract and retain additional customers in the future. For the years ended January 2, 2010, January 3, 2009 and December 29, 2007, one of our customers represented 14%, 12% and 11%, respectively, of our total revenue.

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. 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.

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Our royalty agreement with Covidien provides for a royalty rate schedule that could decline over the term of the settlement agreement. In addition, Covidien has the option to stop paying on March 14, 2011, which could significantly reduce our royalty revenue, total revenues and operating results due to not only the loss of royalties, but to the potential legal fees associated with a potential lawsuit resulting from Covidien s continued patent infringement of our technology.

In 2009, our royalties from the Covidien settlement totaled $49.0 million. 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, any decline in 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. Under the current settlement agreement, we earn royalties on Covidien s total U.S.-based pulse oximetry sales. The royalty rate in 2006 was nearly 20% if averaged over the entire year. The royalty rate for 2007 declined to 15%. In 2008, 2009 and through the remaining term of the settlement agreement, which will continue at least through March 14, 2011, the royalty rate is 13%, but may decline to 10%, subject to Covidien s ability to develop new products that avoid some of our current patent coverage as negotiated in the settlement agreement. As a result, our total revenues, gross margins, operating income and earnings per share could be significantly reduced as compared to prior periods if we are unable to generate sufficient revenues and gross margins to offset either the impact of declining royalty rates or declining sales of Covidien s pulse oximetry products in the U.S.

The current royalty agreement provides Covidien with the option to stop paying the royalty on March 14, 2011. In exchange for this royalty payment, we have provided Covidien the ability to ship its patent infringing product with our covenant not to sue Covidien as long as they are abiding by the terms of the agreement. Should Covidien decide to discontinue abiding by the terms of the current settlement agreement, including paying us the required royalty payment, then our royalty payments could decline to zero which would have a material impact on our royalty revenue, total revenues, gross margins, operating income and earnings per share. In addition, if Covidien chooses to discontinue abiding by the terms of the current settlement and to continue to ship its pulse oximetry technology, then it is likely that we would file a new patent infringement lawsuit against Covidien resulting in higher legal expenses which would increase our operating expenses thereby adversely impacting our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

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

Our success depends significantly on our ability to protect our rights to the technologies used in our products, including Masimo SET and licensed Rainbow technology. We rely on patent protection, trade secrets, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect our technology. 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. These proceedings could result in adverse decisions as to the claims included in our patents. Our issued and licensed patents and those that may be issued or licensed in the future may expire, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Some Masimo patents related to our Masimo SET algorithm technology begin to expire in March 2011. Additionally, upon expiration of our issued or licensed patents, we may lose some of our rights to exclude others from making, using, selling or importing products using the technology based on the expired 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. Our

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common law trademarks provide less protection than our 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. Whether a technology or product infringes a patent involves complex legal and factual issues and is often difficult to determine. We face the risk of claims that we have infringed on third parties intellectual property rights. Searching for existing intellectual property rights may not reveal important intellectual property and our competitors may also have filed for patent protection, which is not publicly-available information, or claimed trademark rights that have not been revealed through our availability searches. In addition, many of our employees were previously employed at other medical device companies. We may be subject to claims that our employees have disclosed, or that we have used, trade secrets or other proprietary information of our employees former employers. Our efforts to identify and avoid infringing on third parties intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement against us, even those without merit, could:

increase the cost of our products;

be expensive and time consuming to defend;

result in us being required to pay significant damages to third parties;

force us to cease making or selling products that incorporate the challenged intellectual property;

require us to redesign, reengineer or rebrand our products, product candidates and technologies;

require us to enter into royalty or licensing agreements in order to obtain the right to use a third party s intellectual property on terms that may not be favorable or acceptable to us;

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.

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. On February 3, 2009, we filed a patent infringement suit against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen Gmbh related to Philips FAST pulse oximetry technology and certain Philips patient monitors. Two patents at issue in this suit, related to our measure-through-motion technology, were successfully enforced in a previous suit by us against Nellcor. On June 15, 2009, Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen Gmbh answered our complaint and Philips Electronics North America Corporation filed antitrust and patent infringement counterclaims against us as well as counterclaims seeking declaratory judgments of invalidity on the patents asserted by us against Philips. On July 9, 2009, we filed our answer denying Philips counterclaims and asserting various defenses. We also asserted counterclaims against Philips for fraud, intentional interference with prospective economic advantage and for declaratory judgments of noninfringement and invalidity with respect to the patents asserted by Philips

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against us. Both Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen Gmbh are associated with Philips Medical Systems, an OEM partner of ours.

We believe that other competitors of ours, including some of our OEM partners, 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 pre-market approval, 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 usually takes from four to six months, although it can take longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain and generally takes from one to three years or even longer.

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 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. In that case, our ability to upgrade our products in a timely fashion could be limited. The withdrawal of existing 510(k) clearances or the inability to obtain new ones on a timely basis, or at all, could severely harm our business, financial condition and results of operations.

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, testing, production, component suppliers control, quality assurance, labeling, 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;

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delays in clearing or approving, or refusal to clear or approve, our products;

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

product recall or seizure;

orders for physician notification or device repair, replacement or refund;

interruption of production; and

operating restrictions.

Furthermore, our key component suppliers may not currently be, or may not continue to be, in compliance with applicable regulatory requirements. If any of these actions were to occur, it would harm our reputation and adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of our commercialized products in the event of material deficiencies or defects, in for example, design, labeling or manufacture. In the case of the FDA, the

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

From our inception through January 2, 2010, we initiated four voluntary recalls of our products, none of which was material to our operating results. Each of these recalls was reported to the FDA within the appropriate regulatory timeframes. Because of our dependence upon patient and physician perceptions, any negative publicity associated with these voluntary recalls could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

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

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

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

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

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

- the federal provisions of HIPAA established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

state laws analogous to each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental third-party payers, including commercial insurers, and state laws governing the privacy of certain health information.

We have certain arrangements with hospitals that may be affected by these laws. For instance, under our standard customer arrangements, we provide hospitals with free pulse oximetry monitoring devices in exchange for their agreement to purchase

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future pulse oximetry sensor requirements from us. In addition, we occasionally provide our customers with rebates in connection with their annual purchases. While we believe that these arrangements are structured such that we are currently in compliance with applicable federal and state health care laws, one or more of these arrangements may not meet the Federal Anti-Kickback Law s safe harbor requirements, which may result in increased scrutiny by government authorities that are responsible for enforcing these laws.

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

We are required to comply with federal and state laws governing the transmission, security and privacy of individually identifiable health information that we may obtain or have access to in connection with manufacture and sale of our products. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements. Our failure to comply may result in criminal and civil liability because the potential for enforcement action against business associates is greater as a result of HITECH.

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

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

Legislative and regulatory changes in the health care industry could have a negative impact on our financial performance. Furthermore, our business, financial condition, results of operations and cash flows could be significantly and adversely affected if certain types of health care reform programs are adopted in our key markets and other administration and legislative proposals are enacted into law.

Changes in the health care industry in the U.S. and elsewhere could adversely affect the demand for our products as well as the way in which we conduct our business. Significantly, the new administration and Congressional and state leaders have expressed a strong desire to reform the U.S. health care system. Recently, President Obama and members of Congress have proposed significant reforms. On November 7, 2009, the House of Representatives passed health reform legislation that would require most individuals to have health insurance, establish new regulations on health plans, create insurance pooling mechanisms and a government health insurance option to compete with private plans, and other expanded public health care measures. This legislation also would reduce Medicare spending on services provided by hospitals and other providers and would impose a 2.5 percent tax on the first taxable sale of any medical device.

On December 24, 2009, the Senate passed a similar health reform bill. The Senate bill includes a $2 billion annual fee or excise tax on the medical device manufacturing sector. Various health care reform proposals have also emerged at the state level. The House and Senate bills have not been conferenced, and it is unclear whether or when they will be enacted in part or in whole. We cannot predict what health care initiatives, if any, will be implemented at the federal or state level or the effect any future legislation or regulation will have on us. However, if the excise tax contained in the House or Senate health reform bills is enacted into law, our operating expenses resulting from such an excise tax and results of operations would be materially and adversely affected, if we can not pass the excise tax onto our customers.

In general, an expansion in government s role in the U.S. health care industry may lower reimbursements for our products, reduce demand for innovative products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly materially.

Furthermore, many private payors look to Medicare s coverage and reimbursement policies in setting their coverage policies and reimbursement amounts such that federal reforms could influence the private sector as well. Finally, many states also may attempt to reform their Medicaid programs such that either coverage for certain items or services may be narrowed or reimbursement for them could be reduced. These health care reforms may adversely affect our business.

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

In addition, the requirements or restrictions imposed on us or our products may change, either as a result of administratively adopted policies or regulations or as a result of the enactment of new laws. Such changes are particular possibilities in light of the 2008 elections in the U.S. There may be heightened scrutiny by federal and state regulators and legislators of the FDA s device approval process, the agency s efforts to assure the safety of marketed devices, and physician payments and promotional activities by manufacturers. Any new regulations or statutory provisions could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance.

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

Risks Related to Our Business and Operations

Masimo Labs has conducted most of the research and development of Rainbow technology and we are dependent upon Masimo Labs to develop improvements to Rainbow technology.

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

We will experience conflicts of interest with Masimo Labs with respect to business opportunities and other matters.

Prior to our initial public offering in August 2007, our stockholders owned approximately 99% of the outstanding shares of capital stock of Masimo Labs and we believe that as of January 2, 2010, a number of stockholders of Masimo Labs continued to own shares of our stock. Joe E. Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs. Jack Lasersohn, another member of our board of directors, also serves on the board of directors of Masimo Labs. Due to the interrelated nature of Masimo Labs with us, conflicts of interest will arise with respect to transactions involving business dealings between us and Masimo Labs, potential acquisitions of businesses or products, development of products and technology, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Masimo Labs. We cannot assure you that any conflict of interest will be resolved in our favor, or that with respect to our transactions with Masimo Labs we will negotiate terms that are as favorable to us as if such transactions were with an unaffiliated third party.

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

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

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We are required to pay royalties to Masimo Labs for all products sold that contain Rainbow technology, including certain annual minimum royalty payments, and this may impact our gross margins if we discontinue consolidating Masimo Labs within our financial statements.

The Cross-Licensing Agreement requires us to pay Masimo Labs a royalty for all products that we sell which include their proprietary Rainbow technology. This includes handheld, table-top and multi-measurement products that incorporate licensed Rainbow technology. Beginning in 2009, for hospital contracts where we place equipment and enter into a sensor contract, we will pay a royalty to Masimo Labs on the total sensor contract revenue based on the ratio of Rainbow enabled devices to total devices. The agreement also requires that we provide to Masimo Labs, at its request, up to 10% of our annual board and sensor production volume at our total manufactured cost. In addition to these specific royalty and product obligations, our Cross-Licensing Agreement requires that we pay Masimo Labs specific annual minimum royalty payments.

Currently, we are required to consolidate Masimo Labs within our financial statements. Accordingly, the royalties that we owe to Masimo Labs are eliminated in our consolidated financial statements presented within this Annual Report on Form 10-K and our other periodic reports and the gross profit margins reported in our consolidated financial results do not include the royalty expense that we pay to Masimo Labs. We are also obligated to include, and have included, Masimo Labs engineering and administrative expenses in our reported engineering and administrative expenses. If our financial statements were not consolidated with Masimo Labs, our reported cost of goods sold would increase and our reported engineering and administrative expenses would decrease. To date, the amount of royalty expense has approximated the amount of engineering and administrative expense and therefore, the net impact to our consolidated financial statements has not been significant. However, in the future, depending upon the success of Rainbow products and the royalties earned by Masimo Labs on those revenues, it is possible that the royalty expense will grow at a rate higher than the growth of engineering and administrative expenses. In the event the net impact on our consolidated results is material, we will reflect the amount of Masimo Labs income through our consolidated statement of income as an element of noncontrolling interest income. As a result, despite the current requirement to consolidate, any profit in our consolidated financial results that is attributable to Masimo Labs will be separately identified.

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

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

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

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

It is generally more expensive for us to make products that incorporate Rainbow technology than products that do not due to increased production costs and the royalties that we must pay to Masimo Labs. In order to successfully commercialize products incorporating Rainbow technology, we must be able to pass these higher costs on to the market. We cannot assure you that we will be able to sell products incorporating Rainbow technology at a price the market is willing to accept. If we cannot commercialize our products incorporating licensed Rainbow technology successfully, we may not be able to generate sufficient product revenue from these products to be profitable, which could adversely affect our business, financial condition and results of operations.

Rights provided to Masimo Labs in the Cross-Licensing Agreement may impede a change in control of our company.

In the event we undergo a change in control, we are required to immediately pay a $2.5 million fee to exercise an option to license technology developed by Masimo Labs for use in blood glucose monitoring. Under the Cross-Licensing Agreement, a

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change in control includes, but is not limited to, the resignation or termination of Joe E. Kiani from his position of Chief Executive Officer of either Masimo or Masimo Labs. Additionally, our per product royalties payable to Masimo Labs will become subject to specified minimums, and the minimum aggregate annual royalties for all licensed Rainbow measurements payable to Masimo Labs will increase to up to $15.0 million from $5.0 million currently for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, total hemoglobin and blood glucose, plus up to $2.0 million per other Rainbow measurements. Also, if the surviving or acquiring entity ceases to use Masimo as a company name and trademark following a change in control, all rights to the Masimo trademark will automatically be assigned to Masimo Labs. This could delay or discourage transactions involving an actual or potential change in control of us, including transactions in which our stockholders might otherwise receive a premium for their shares over our then-current trading price. In addition, our requirement to assign all future improvements for non-vital signs to Masimo Labs could impede a change in control of our company.

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

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

- delays or interruptions in manufacturing and shipping of our products;
- varying demand for and market acceptance of our technologies and products;
- the effect of competing technological and market developments resulting in lower selling prices or significant promotional costs;
- changes in the timing of product orders and the volume of sales to our OEM partners;
- actions taken by GPOs;
- delays in hospital conversions to our products and declines in hospital patient census;
- our legal expenses, particularly those related to litigation matters;
- changes in our product or customer mix;
- unanticipated delays or problems in the introduction of new products, including delays in obtaining clearance or approval from the FDA; and
- high levels of returns and repairs.

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

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

We face competition from other companies, many of which have substantially greater resources than we do and may be able to develop products perceived as more effective or easier to use than ours or are more readily accepted, or offer their products at lower prices than we can, which could adversely affect our business, financial condition and results of operations.

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. Our revenue and profit are significantly smaller than our primary competitors. A number of our competitors have substantially greater capital resources, larger customer bases, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours, and have established stronger reputations with our target customers and built relationships with GPOs and worldwide distribution channels that are more effective than ours. Competition could result in reductions in the price of our products, fewer orders for our products, a reduction of our

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gross margins and a loss of our market share. Reliance on clinical studies is an important means of demonstrating the effectiveness of products in our industry. If clinical studies supporting our competitors products are perceived to be accurate and reliable, market acceptance and sales of our products could be adversely impacted and we could lose market share to our competitors.

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

We are highly dependent on our senior management, especially Joe E. Kiani, our Chief Executive Officer, and other key officers. We are also heavily dependent on our engineers and field sales team, including sales representatives and clinical specialists. Our success will depend on our ability to retain our current management, engineers and field sales team, and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management, engineers and field sales personnel is intense and we may not be able to retain our personnel. In addition, some of our key personnel hold stock options with an exercise price that is greater than our recent closing prices, which may minimize the retention value of these options. The loss of the services of members of our key personnel could prevent the implementation and completion of our objectives, including the development and introduction of our products. In general, our officers may terminate their employment at any time without notice for any reason. We carry key person life insurance on only Mr. Kiani, who is also the Chief Executive Officer of Masimo Labs. Mr. Kiani devotes most of his time to us.

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

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

- difficulties in integrating any acquired companies, personnel, products and other assets into our existing business;
- delays in realizing the benefits of the acquired company, products or other assets;
- diversion of our management s time and attention from other business concerns;
- limited or no direct prior experience in new markets or countries we may enter;
- higher costs of integration than we anticipated; and
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions.

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

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

In the fourth quarter of 2008, we implemented a new international business structure designed to better serve and support our growing international business. By centralizing our international operations, including sales management, marketing, customer support, planning, logistics and administrative functions, we believe we will be able to develop a more efficient and scalable international organization capable of being even more responsive to the business needs of our international customers all under one centralized management structure. We commenced

the implementation of an international business structure to align our operations with the business needs of our non-U.S. customers and we believe that we may, in the long run, also benefit from certain operational benefits and achieve a lower overall tax rate. However, there can be no assurance that our efforts will produce any anticipated operational benefits or provide an overall lower tax rate. Realization of the expected benefits will depend on a number of factors, including our future business results and profitability, the effectiveness and timing of our implementation of our international business structure, changes in U.S. or international tax law and the geographic composition of our pre-tax income. Legislative action may be taken by the U.S. Congress which, if ultimately enacted, could adversely affect our effective tax rate and/or require us to take further action, at potentially significant expense, to seek to preserve our effective tax rate. We cannot predict the outcome of any specific legislative proposals. However, if proposals were enacted that had a negative effect on our international business structure, we could be subjected to increased taxation and/or potentially significant expense.

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

We derive a portion of our net sales from international operations. In the years ended January 2, 2010 and January 3, 2009, 25.8% and 25.1%, respectively, of our product revenue was derived from our international operations. In addition, we purchase a portion of our raw materials and components on the international market. The sale and shipping of our products across international borders, as well as the purchase of materials and components from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and we would be exposed to potentially significant penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, manufacturing and sales activities. Any material decrease in our international sales would adversely affect our business, financial condition and results of operations.

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

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- a shortage of high-quality sales people and distributors;
- loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- pricing pressure that we may experience internationally;
- laws and business practices favoring local companies;
- political instability and actual or anticipated military or political conflicts;

longer payment cycles; and

difficulties in enforcing or defending intellectual property rights.

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

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

We market our products in certain foreign markets through our subsidiaries and other international distributors. The related sales agreements may provide for payments in a foreign currency. Accordingly, our operating results are subject to fluctuations in foreign currency exchange rates. When the U.S. dollar weakens against these currencies, the dollar value of foreign-currency denominated revenue and expense increases, and when the dollar strengthens against these currencies, the dollar value of foreign-currency denominated revenue and expense decreases. We are exposed to foreign currency risk on outstanding foreign currency denominated receivables and payables. Changes in exchange rates may adversely affect our results of operations. Our primary foreign currency exchange rate exposures are with the Euro, the Japanese yen, the British pound, the Canadian dollar and the Australian dollar against the U.S. dollar.

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We currently do not hedge against our foreign currency exchange rate risks and therefore believe our exposure to these risks may be higher than if we entered into hedging transactions, including forward exchange contracts or similar instruments. If we decide in the future to enter into forward foreign exchange contracts to attempt to reduce the risk related to foreign currency exchange rates, these contracts may not mitigate the potential adverse impact on our financial results due to the variability of timing and amount of payments under these contracts. In addition, these types of contracts may themselves cause financial harm to us and have inherent levels of counterparty risk over which we would have no control.

We manufacture our products at two locations and any disruption in these manufacturing facilities could adversely affect our business, financial condition and results of operations.

To date, we have relied on our manufacturing facilities in Irvine, California and Mexicali, Mexico. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since our Irvine, California facility is located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods and similar events. In the event that one of our facilities was affected by a natural or man-made disaster, we would be forced to rely on third-party manufacturers if we could not shift production to our other manufacturing facility. Our insurance for damage to our property and the disruption of our business from casualties may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If we are forced to seek alternative facilities, we may incur additional costs and we may experience a disruption in the supply of our products until those facilities are available. We are also vulnerable to disruptions which may occur as a result of local, regional and worldwide health risks, including but not limited to outbreaks of Avian and Swine flu. Such disruptions may include the inability to manufacture and distribute our products due to the direct effects of illness on individuals or due to constraints on supply and distribution that may result from either voluntary or government imposed restrictions. Any disruption or delay at our manufacturing facilities could have an adverse impact on our ability to produce sufficient inventory of our products or may require us to incur additional expenses in order to produce sufficient inventory, and could impair our ability to meet the demand of our customers and our customers may cancel orders or purchase products from our competitors, which could adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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accordance with the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. Any failure to maintain the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business, negatively impact the trading price of our stock, and adversely affect investors confidence in our company and our ability to access capital markets for financing.

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

The manufacture and sale of products using Masimo SET and licensed Rainbow technology expose us to product liability claims and product recalls, including, but not limited to, those that may arise from unauthorized off-label use, which is use of a device in a manner outside the measurement or measurements cleared by the FDA, or malfunction of, or design flaws or manufacturing defects in, our products or the use of our products with incompatible components or systems. Any losses that we may suffer from product liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our technology and products, together with the corresponding diversion of the attention of our key employees, may subject us to significant damages and could adversely affect our business, financial condition and results of operations. We cannot be certain that our product liability insurance will be sufficient to cover any or all damages or claims. Furthermore, we may not be able to obtain or maintain insurance in the future at satisfactory rates or in adequate amounts to protect us against any product liability claims.

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

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

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

Risks Related to Our Stock

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

There has been significant volatility in the market price and trading volume of equity securities, which is often unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our stock. From January 4, 2009 to January 2, 2010, our closing stock price ranged from $22.13 to $31.08. You may not be able to resell your shares at or above the price you paid for them due to fluctuations in the market price of our stock caused by changes in our operating performance or prospects and other factors.

Some specific factors, in addition to the other risk factors identified above, that may have a significant effect on our stock market price, many of which we cannot control. These include but are not limited to:

- actual or anticipated fluctuations in our operating results or future prospects;
- our announcements or our competitors announcements of new products;
- the public s reaction to our press releases, our other public announcements and our filings with the SEC;

strategic actions by us or our competitors, such as acquisitions or restructurings;

new laws or regulations or new interpretations of existing laws or regulations applicable to our business;

changes in accounting standards, policies, guidance, interpretations or principles;

changes in our growth rates or our competitors growth rates;

developments regarding our patents or proprietary rights or those of our competitors;

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our inability to raise additional capital as needed;

concern as to the efficacy of our products;

changes in financial markets or general economic conditions;

sales of stock by us or members of our management team, our Board of Directors or certain institutional stockholders; and

changes in stock market analyst recommendations or earnings estimates regarding our stock, other comparable companies or our industry generally.

In particular, the current decline of the financial markets and related factors beyond our control, including the credit and mortgage crisis in both the U.S. and worldwide, may cause our stock price to decline rapidly and unexpectedly.

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

As of January 2, 2010, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned 12.0% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, the stockholders may be able to exercise a significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have some control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of us or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our stock. In addition, these stockholders, some of whom have representatives sitting on our board of directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes in control of us, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

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

As of January 2, 2010, an aggregate of 12,249,845 shares of our stock were reserved for future issuance under our three equity incentive plans, 8,125,871 of which were subject to options outstanding as of that date at a weighted average exercise price of $18.21 per share. To the extent outstanding options are exercised, our existing stockholders may incur dilution. We rely heavily on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

Future resales of our stock, including those by our insiders, may cause our stock price to decline.

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

In March 2009, we registered an aggregate of 4,657,660 shares reserved under our equity plans under a Registration Statement on Form S-8. All shares issued pursuant to a Registration Statement on Form S-8 can be freely sold in the public market upon issuance, subject to restrictions on our affiliates under Rule 144. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our stock.

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

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our amended and restated certificate of incorporation authorizes our board of directors to issue up to five million shares of blank check preferred stock. As a result, without further stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it

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more difficult for a third party to acquire us. In addition, our amended and restated certificate of incorporation provides for a staggered board of directors, whereby directors serve for three year terms, with one third of the directors coming up for reelection each year. A staggered board will make it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

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

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

We may elect to not declare cash dividends on our stock, or may elect to only pay dividends on an infrequent or irregular basis, and any return on your investment may be limited to the value of our stock.

Our board of directors may from time to time declare, and we may pay, dividends on our outstanding shares in the manner and upon the terms and conditions provided by law. However, we may elect to retain all future earnings for the operation and expansion of our business, rather than paying cash dividends on our stock. Any payment of cash dividends on our stock will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our board of directors. In the event our board of directors declares any dividends, there is no assurance with respect to the amount, timing or frequency of any such dividends.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease 155,800 square feet of space in Irvine, California, for our corporate headquarters, product manufacturing, research and development, warehousing and distribution operations. The leases covering this space expire in September 2014.

We also lease 95,600 square feet of space in Mexicali, Mexico, for the manufacture of our sensors and accessories under a shelter labor agreement with Industrial Vallera de Mexicali, S.A. de C.V., or IVEMSA. IVEMSA is a Mexican maquiladora, which is a shelter services provider incorporated in Mexico that is licensed to operate factories and plants in Mexico. The shelter program allows foreign companies to manufacture in Mexico without being required to organize and operate their own subsidiary, for example, as a Mexican corporation. As a result, the risks of labor liability, ownership of facilities and legal presence of foreign corporations in Mexico are avoided. We entered into the agreement with IVEMSA to establish and run a facility to manufacture our sensors and accessory products. IVEMSA leases the space directly from the owner of the property under an agreement that expires in August 2014.

On January 1, 2009, we entered into a five year lease for 7,000 square feet of office space for our international headquarters in Neuchatel, Switzerland. This office space is focused on operations including sales, marketing, customer service and other administrative functions. In addition, we lease 6,900 square feet in Limonest, France to support our sales and marketing functions. We also lease 3,700 square feet of space in Tokyo, Japan, which we use for sales, marketing, customer service and administrative functions, as well as maintaining product inventory. In addition, we lease 10,000 square feet of space in Montreal, Canada, which we use primarily for research, development, sales and marketing activities. We also maintain small sales offices in Europe, Asia, Australia and the United Kingdom. We believe that our existing facilities are adequate to meet our needs and that existing needs and future growth can be accommodated by leasing alternative or additional space.

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ITEM 3. LEGAL PROCEEDINGS

In May 2002, we filed a lawsuit against Tyco Healthcare, parent company of Nellcor, in the U.S. District Court for the Central District of California, alleging damage to our business as a result of the anti-competitive business practices of Tyco Healthcare. Specifically, we alleged that we had incurred damages as a result of a series of illegal exclusionary and anti-competitive acts by Tyco Healthcare that were designed to maintain its monopoly in the pulse oximetry market in violation of federal antitrust laws.

In March 2005, a jury found that Tyco Healthcare s use of sole-source contracts, product bundling and market share-based compliance pricing contracts, among other conduct, violated the federal antitrust laws and awarded damages on that basis. Tyco Healthcare filed post-trial motions requesting that the District Court either override the jury decision or grant a new trial. In March 2006, the District Court upheld a portion of the jury verdict and vacated the remaining verdict. In addition, the District Court vacated the jury s damages award and granted Tyco Healthcare a new trial on damages. After a retrial of damages to the court, on July 2, 2007, the District Court entered its final judgment awarding us damages which were trebled as is mandatory under federal antitrust law to $43.5 million and denying our request for a permanent injunction with respect to Tyco Healthcare s business practices found to be anti-competitive. We and Tyco Healthcare each filed a notice of appeal from the judgment. We sought reinstatement of the jury s verdict on bundling and an affirmance of the liability findings concerning sole-source and market share-based compliance contracts. We also asked the appellate court to increase the amount of damages awarded by the trial court.

On November 2, 2009, we announced that the Ninth Circuit Court of Appeals has affirmed the 2006 Federal District Court decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its Nellcor pulse oximetry products. The 2006 decision found that Tyco had unlawfully maintained monopoly power in violation of Section 2 of the Sherman Act, and that Tyco s sole-source agreements and market-share based compliance pricing contracts were unlawful restraints of trade in violation of Section 1 of the Sherman Act and unlawful exclusionary dealing arrangements in violation of Section 3 of the Clayton Act. The Ninth Circuit also held that above-cost bundling discounts when combined with sole-source or market-share-based pricing can be anticompetitive when such practices involve a significant portion of the market.

On January 11, 2010, we completed negotiations to resolve the merits of our antitrust litigation with Covidien and, as a result, we retained $30.1 million from a payment from Covidien, following the Ninth Circuit Court of Appeals October 2009 affirmance of a Federal District Court decision that Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products.

On February 3, 2009, we filed a patent infringement suit against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen Gmbh related to Philips FAST pulse oximetry technology and certain Philips patient monitors. The suit was brought in the U.S. District Court for the District of Delaware. Two patents at issue in this suit, related to our measure-through-motion technology, were successfully enforced in our previous suit against Covidien. On June 15, 2009, Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen Gmbh answered our complaint and Philips Electronics North America Corporation filed antitrust and patent infringement counterclaims against us as well as counterclaims seeking declaratory judgments of invalidity on the patents asserted by us against Philips. We believe that we have good and substantial defenses to the antitrust and patent infringement claims asserted by Philips. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

On April 24, 2009, we sent a letter to Hygia Health Services, Inc., or Hygia, demanding that Hygia cease and desist from reprocessing used Masimo sensors. In response to that cease and desist letter, on May 5, 2009, Hygia filed a Declaratory Judgment action against us in the District Court for the Northern District of Alabama, Southern Division. On May 28, 2009, we filed our counterclaims, alleging patent and trademark infringement, unfair competition, false designation of origin and injury to business reputation. Hygia filed its reply to our counterclaims, denying the allegations, and has alleged that our patents are unenforceable. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

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

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We did not submit any matters to a vote of our stockholders during the quarter ended January 2, 2010.

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PART II

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

Market Information

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

	Price Range	
	High	**Low**
Fiscal 2009:		
First Quarter	$ 30.28	$ 22.35
Second Quarter	$ 31.00	$ 22.70
Third Quarter	$ 28.44	$ 22.13
Fourth Quarter	$ 31.08	$ 26.21
Fiscal 2008:		
First Quarter	$ 39.50	$ 25.86
Second Quarter	$ 35.00	$ 25.06
Third Quarter	$ 41.95	$ 33.49
Fourth Quarter	$ 38.51	$ 22.04

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

As of January 29, 2010, the closing price of our stock on the NASDAQ Global Market was $27.76 per share, and the number of stockholders of record was 74. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our stock is held of record through brokerage firms in street name.

Stock Performance Graph

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

The following stock performance graph compares total stockholder returns for Masimo Corporation from the date of our initial public offering of August 8, 2007 through January 2, 2010 against the NASDAQ Market Composite Index and NASDAQ Medical Equipment Index, assuming a $100 investment made on August 8, 2007. Each of the two comparative measures of cumulative total return assumes reinvestment of dividends. The stock performance shown on the graph below is not necessarily indicative of future price performance.

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Dividend Policy

We have not paid any cash dividends on our common stock since our initial public offering. Future determination as to the payment of cash (or stock) dividends will depend upon many factors, including our financial condition and results of operations, the capital requirements of our businesses and any other relevant factors deemed relevant by our board of directors. As of January 2, 2010, there were no contractual restrictions that prohibit us from paying cash or stock dividends on our common stock.

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ITEM 6. SELECTED FINANCIAL DATA

The following tables reflect selected financial data derived from our consolidated financial statements for each of the last five years. The consolidated statement of income data for the years ended January 2, 2010, January 3, 2009 and December 29, 2007 and the consolidated balance sheet data as of January 2, 2010 and January 3, 2009 are derived from our audited consolidated financial statements included in this Form 10-K. The consolidated statement of income data for the years ended December 31, 2006 and 2005, and the consolidated balance sheet data as of December 29, 2007, December 31, 2006, and 2005 are derived from our audited consolidated financial statements not included in this Form 10-K. Historical results are not necessarily indicative of future results. The selected financial data set forth below should be read in conjunction with our consolidated financial statements, the related notes and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007	Year ended December 31, 2006	Year ended December 31, 2005
	(in thousands, except share information)				
Statement of Income Data[1]:					
Revenue:					
Product	$ 300,143	$ 259,592	$ 200,186	$ 155,542	$ 107,890
Royalty	48,972	47,482	56,100	68,796	
Total revenue	349,115	307,074	256,286	224,338	107,890
Cost of goods sold	100,313	89,454	73,606	61,640	42,717
Gross profit	248,802	217,620	182,680	162,698	65,173
Operating expenses:					
Research and development	31,701	25,495	22,960	24,875	8,548
Selling, general and administrative	134,577	120,069	91,234	91,384	42,807
Patent litigation expenses (proceeds) [2]				(262,605)	1,736
Purchased in-process research and development					2,800
Antitrust litigation	298	706	1,537	109	278
Total operating expenses	166,576	146,270	115,731	(146,237)	56,169
Operating income	82,226	71,350	66,949	308,935	9,004
Non-operating income (expense):					
Interest income	178	2,305	2,361	6,741	224
Interest expense	(75)	(753)	(2,475)	(1,824)	(1,851)
Other	(149)	(511)	1,287	551	(8)
Total non-operating income (expense)	(46)	1,041	1,173	5,468	(1,635)
Income before provision for (benefit from) income taxes	82,180	72,391	68,122	314,403	7,369
Provision for (benefit from) income taxes	28,158	40,464	25,867	132,577	(26,012)
Net income including noncontrolling interest	54,022	31,927	42,255	181,826	33,381
Preferred stock dividend				(77,785)	
Accretion of preferred stock			(4,837)	(7,985)	(8,278)
Undistributed income attributable to preferred stockholders			(14,339)	(34,275)	(19,599)
Net income attributable to noncontrolling interest	(794)				
Net income attributable to Masimo Corporation	$ 53,228	$ 31,927	$ 23,079	$ 61,781	$ 5,504
Net income per common share attributable to Masimo Corporation stockholders[3]:					

Basic	$ 0.92	$ 0.57	$ 0.71	$ 3.79	$ 0.57	
Diluted	$ 0.88	$ 0.53	$ 0.60	$ 3.04	$ 0.42	
Weighted-average number of common shares:						
Basic Two Class method	N/A	N/A	16,654,586	16,319,898	9,717,882	

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	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007	Year ended December 31, 2006	Year ended December 31, 2005
Diluted Two Class method	N/A	N/A	20,732,872	20,302,872	13,102,611
Basic Single Class method	57,602,646	56,320,712	54,660,216	N/A	N/A
Diluted Single Class method	60,170,848	60,190,335	59,829,198	N/A	N/A

(1) Pursuant to authoritative accounting guidance, Masimo Labs is consolidated within our financial statements. Accordingly, all inter-company royalties, option and licensing fees, and other charges between us and Masimo Labs have been eliminated in the consolidation. Also, all direct engineering expenses that have been incurred by us and charged to Masimo Labs have not been eliminated and are included as research and development expense in our consolidated statements of income. For additional discussion of accounting for Masimo Labs, see Note 3 to the Consolidated Financial Statements.

(2) In January 2006, we entered into a settlement agreement with Nellcor (currently Covidien) under which we agreed to settle all pending patent litigation with them. In return, Nellcor agreed to pay us $263.0 million for damages incurred through January 2006.

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

	January 2, 2010	January 3, 2009	December 29, 2007	December 31, 2006	December 31, 2005
	(in thousands, except dividends declared per common share)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 189,043	$ 146,910	$ 96,733	$ 55,382	$ 14,172
Working capital	229,947	166,595	121,831	30,125	34,213
Total assets	356,345	293,348	235,511	159,073	100,589
Long term debt, including current portion	231	622	31,041	21,042	29,060
Convertible preferred stock					143,959
Total stockholders equity (deficit)	289,688	219,498	150,105	56,990	(101,082)
Dividends declared per common share[4]				4.09	

(4) Dividends declared as a result of a one-time patent litigation settlement with Covidien in 2006. The dividends were declared for the same amount per share to both common and preferred stockholders, assuming the conversion of all outstanding shares of preferred stock into common stock on a 1:1 basis.

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

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

Overview

We are a global medical technology company that develops, manufactures, and markets noninvasive patient monitoring products that improve patient care. 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. 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. Low perfusion can also cause the failure of the conventional pulse oximeter to obtain an accurate measurement. Conventional pulse oximetry readings can also be impacted by bright light and electrical interference from the presence of electrical surgical equipment. Published independent research shows that over 70% of the alarms were false outside the operating room using conventional pulse oximetry. Our Masimo SET platform has addressed many of the previous technology limitations. The benefits of Masimo SET have been validated in over 100 independent clinical and laboratory studies.

We develop, manufacture and market a family of noninvasive blood constituent patient monitoring solutions that consists of a monitor or circuit board and our proprietary single-patient use and reusable sensors and cables. In addition, we offer remote-monitoring and clinician notification solutions. Although our Masimo SET platform is only operable with our proprietary sensors, our sensors have the capability to work with certain competitor pulse oximeters through the use of our adapter cables. In 2005, we launched our Masimo Rainbow SET Pulse CO-Oximetry platform utilizing licensed Rainbow technology from Masimo Labs, which enables the noninvasive and continuous measurement of not only arterial blood oxygen saturation level and pulse rate, but also carboxyhemoglobin, or carbon monoxide levels in the blood, methemoglobin (2006) saturation levels in the blood and total hemoglobin (2008), or the oxygen-carrying component of red blood cells. Also, in 2007 we launched PVI, which is a measurement that quantifies changes in the plethysmographic waveform over the respiration cycle. Along with the release of our Masimo Rainbow SET Pulse CO-Oximetry products, we have developed multi-wavelength sensors that have the ability to monitor multiple parameters with a single sensor. In November 2009, we received FDA clearance for Rainbow Acoustic Monitoring for continuous and noninvasive monitoring of respiration rate, or RRa, which is the number of breaths per minute. In December 2009, we announced initial market release of the parameter and expect to continue limited market release activities throughout the first half of 2010 and are planning for full commercial launch in the second half of 2010. While RRa is a Rainbow platform parameter, it is not licensed from Masimo Labs, but rather directly owned by us. We have focused on building our U.S. and international sales and marketing infrastructure to market our products to end-users, such as hospitals, and OEM partners for incorporation into their patient-monitoring products. We market our pulse oximetry products to hospitals and the alternate care market through our direct sales force, and market our circuit boards to our OEM partners. Today, the primary focus of our hospital sales force is to facilitate the conversion of hospitals to our Masimo SET or Masimo Rainbow SET products. In the U.S., we typically enter into long-term sales contracts with hospitals, pursuant to which we ship and install our pulse oximeters at no cost to the hospital in exchange for a commitment to purchase a minimum number of sensors from us over a specified period of time. With the introduction of Masimo Rainbow SET Pulse CO-Oximetry, we have established a small sales force to concentrate on the alternate care market. Over the past year, we have expanded our sales and marketing staffing levels. We supplement our direct sales with sales through our distributors, who, within the U.S., function as inventory or fulfillment houses for our hospital customers. During 2009, we generated product revenue of $300.1 million, representing a compound annual growth rate, or CAGR, of 24.5% for the three years ended January 2, 2010. During this period, direct and distributor sales have increased to $241.7 million, or 80.5%, of product revenue for 2009, from $201.1 million, or 77.5%, of product revenue for 2008.

The building of our installed base of pulse oximeters and pulse oximeter circuit boards generates recurring sales of our sensors, primarily single-patient use sensors. A user of one of our pulse oximeters or our OEMs pulse oximeters can obtain the benefit of the Masimo SET or Masimo Rainbow SET only by using our proprietary sensors that are designed for our system. We currently estimate that our worldwide installed base was 640,000 units, based on an estimated 7 year field life assumption, as of January 2, 2010, up from 567,000 units as of January 3, 2009. We estimate our installed base to be the number of pulse oximeters and pulse oximeter circuit boards that we have shipped in the past seven years. In the event we increase this assessment period beyond seven years in the future, our estimated installed base may increase. We expect our worldwide installed base to continue to increase as we expand our market share and expand the pulse oximetry market to other patient care settings.

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Masimo Laboratories, Inc.

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

Under the Cross-Licensing Agreement, we granted Masimo Labs 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 measurement 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, the Labs Market, rather than a professional medical caregiver. We also granted Masimo Labs a non-exclusive, perpetual and worldwide license, with sublicense rights to use all Masimo SET for the measurement of vital signs in the Labs Market.

We exclusively license from Masimo Labs the right to make and distribute products in the professional medical caregiver markets, or the Masimo Market, that utilize Rainbow technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation and total hemoglobin, which includes hematocrit. To date, we have developed and commercially released devices that measure carbon monoxide, methemoglobin and total hemoglobin using licensed Rainbow technology. We also have the option to obtain the exclusive license to make and distribute products that utilize Rainbow technology for the measurement of other non-vital signs parameters, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver.

From May 1998 through May 2009, Masimo Labs contracted the services of our employees for the development of Rainbow technology. We paid Masimo Labs for the option to market and develop products based on Masimo Labs technology in defined markets. Through December 2005, we had paid Masimo Labs $7.5 million in option fees and nearly all these option fees were used by Masimo Labs to repay us for the services that we had provided to Masimo Labs. In addition, through December 2009, we exercised three licenses, for $2.5 million each, for the right to market products based on the new carbon monoxide, methemoglobin and total hemoglobin parameter technologies developed by Masimo Labs. Effective January 1, 2007, we entered into a Services Agreement with Masimo Labs to govern the general and administrative services we currently provide to Masimo Labs.

The Cross-Licensing Agreement requires us to pay certain royalties on products incorporating the licensed Rainbow technology. The royalty is up to 10% of the Rainbow royalty base, which will include handhelds, tabletop and multi-parameter devices. We are also subject to certain specific annual minimum aggregate royalty payments. These minimum aggregate royalty payments were $4.0 million for 2009, $3.5 million for 2008 and $3.2 million for 2007. In 2010 and each year thereafter, the minimum aggregate royalty payment is $5.0 million. In addition, in connection with a change in control, as defined in the Cross-Licensing Agreement, the minimum aggregate annual royalties for all licensed Rainbow parameters payable to Masimo Labs will increase to $15.0 million per year in 2010, and each year thereafter, and up to $2.0 million per year for each additional Rainbow parameter.

In order to accelerate the product development of our total hemoglobin spot check measurement device, in February 2009, we agreed to fund additional Masimo Labs engineering expenses. Specifically, these expenses included third party engineering materials and supplies expense as well as 50% of total Masimo Labs engineering and engineering related payroll expenses from April 2009 until completion of the product development efforts. These expenses totaled $2.7 million in 2009.

Pursuant to authoritative accounting guidance, Masimo Labs is consolidated within our financial statements for all periods presented. To date, we have been required to consolidate since we were deemed to be the primary beneficiary of Masimo Labs activities. This determination was based on the obligation to absorb the expected losses, as well as exercising significant influence over the operations and decision making of Masimo Labs. Accordingly, all inter-company royalties, option and license fees and other charges between us and Masimo Labs as well as all intercompany payables and receivables have been eliminated in the consolidation. Also, all direct engineering expenses that have been incurred by us and charged to Masimo Labs have not been eliminated and are included as research and development expense in our consolidated statements of income. For the foreseeable future, we anticipate that we will continue to consolidate Masimo Labs pursuant to the current authoritative accounting guidance; however, in the event that we no longer have (1) the power to direct the activities that most significantly impact Masimo Labs economic performance and (2) the right to receive benefits or obligation to absorb losses which could be significant to Masimo Labs, we may discontinue consolidating Masimo Labs. If we discontinue consolidating Masimo Labs, our reported cost of goods sold will increase by the amount of royalties paid to Masimo Labs which are currently eliminated upon consolidation. In addition, our reported research and development and general and administrative expenses will decrease by the amounts directly incurred by Masimo Labs or incurred by us and charged to Masimo Labs. For additional discussion of Masimo Labs, see Note 3 to the Consolidated Financial Statements.

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Sedline, Inc.

SEDLine, Inc., or SEDLine, a privately held entity that was formed in December 2009, is a company with the mission to expand the scope and applications for neuromonitoring. SEDLine manufactures and sells brain function monitoring devices to hospitals. We made loans to SEDLine totaling $3.0 million during 2009. Pursuant to authoritative accounting guidance, it was determined that we are the primary beneficiary of SEDLine for 2009 and therefore required to consolidate SEDLine s financial results within our financial statements. For additional discussion of SEDLine, see Note 3 to the Consolidated Financial Statements.

Royalty Revenue

As part of our patent litigation settlement agreement with Covidien, we granted them a covenant not to sue on certain new products and they agreed to pay us royalties on its total U.S. pulse oximetry revenue at least through March 14, 2011. We recognize this royalty revenue based on the royalty rate per the settlement agreement multiplied by our estimate of Covidien s U.S. pulse oximetry revenue for each quarter. This estimate is adjusted prospectively when we receive the Covidien royalty report, approximately 60 days after the end of each quarter. Per our settlement agreement, the 2008 royalty rate declined from the 2007 rate, but will remain consistent through March 14, 2011, unless Covidien is able to develop new products that avoid some of our current patent coverage as negotiated in the settlement agreement.

Results of Operations

The following table provides a comparison of our earnings per share calculated under the GAAP based two class method, and the non-GAAP if converted method for the entire year ended December 29, 2007, as compared to our earnings per share for the years ended January 2, 2010 and January 3, 2009.

Upon the closing of our initial public offering on August 13, 2007, all outstanding shares of our prior Series A through Series G convertible preferred stock were converted into an aggregate of 34,612,503 shares of common stock. Therefore, effective August 13, 2007, we transitioned from computing earnings per share from the two class method to the if converted method, pursuant to authoritative accounting guidance. Net income for the year ended December 29, 2007 was allocated between the periods during which two classes of equity securities were outstanding and during which a single class of equity securities was outstanding based on the respective number of days. For the year ended December 29, 2007, two classes of equity securities were outstanding for 224 days and a single class of equity securities was outstanding for 139 days, or 61.7% and 38.3% of the total days in the year end reporting period, respectively.

We believe that the following non-GAAP earnings per share information for 2007 is relevant and useful information that can be used by analysts, investors and other interested parties to assess our performance on a comparable basis to future reported earnings per share. Accordingly, we are disclosing this information to permit additional analysis of our performance (in thousands, except share data):

	Year Ended January 2, 2010 As Reported	Year Ended January 3, 2009 As Reported	Year Ended December 29, 2007	
			As Reported	Non-GAAP
Net income attributable to common stockholders:				
Net income two class method	N/A	N/A	$ 26,075	
Accretion of preferred stock	N/A	N/A	(4,837)	
Income attributable to preferred stockholders	N/A	N/A	(14,339)	
Net income attributable to common stockholders	N/A	N/A	$ 6,899	
Basic net income per common share:				
Weighted average common shares outstanding two class method	N/A	N/A	16,654,586	
Basic earnings per share for period during which two classes of equity securities were outstanding	N/A	N/A	$ 0.41	
Net income for period during which single class of equity securities was outstanding	$ 53,228	$ 31,927	$ 16,180	$ 42,255

Weighted average common shares outstanding	single class	57,602,646	56,320,712	54,660,216	52,611,674
Basic net income per share for period during which single class of equity securities was outstanding		$ 0.92	$ 0.57	$ 0.30	
Basic net income per common share		**$ 0.92**	**$ 0.57**	**$ 0.71**	**$ 0.80**

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	Year Ended January 2, 2010 As Reported	Year Ended January 3, 2009 As Reported	Year Ended December 29, 2007 As Reported	Non-GAAP
Diluted net income per common share:				
Weighted average common shares outstanding two class method	N/A	N/A	16,654,586	
Diluted common share equivalent: stock options	N/A	N/A	4,078,286	
	N/A	N/A	20,732,872	
Diluted earnings per share for period during which two classes of equity securities were outstanding	N/A	N/A	$ 0.33	
Net income for period during which single class of equity securities was outstanding	$ 53,228	$ 31,927	$ 16,180	$ 42,255
Weighted average common shares outstanding single class[(1)]	57,602,646	56,320,712	54,660,216	52,611,674
Diluted common share equivalent: stock options	2,568,202	3,869,623	5,168,982	4,615,833
	60,170,848	60,190,335	59,829,198	57,227,507
Diluted net income per share for period during which single class of equity securities was outstanding	$ 0.88	$ 0.53	$ 0.27	
Diluted net income per common share	**$ 0.88**	**$ 0.53**	**$ 0.60**	**$ 0.74**

(1) Weighted average shares outstanding used to compute basic net income per share after conversion of convertible preferred stock; one class of common shares was outstanding for the period from August 13, 2007 to December 29, 2007.

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

	Year ended January 2, 2010		Year ended January 3, 2009		Year ended December 29, 2007	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(in thousands, except percentages)					
Revenue:						
Product	$ 300,143	86.0%	$ 259,592	84.5%	$ 200,186	78.1%
Royalty	48,972	14.0	47,482	15.5	56,100	21.9
Total revenue	349,115	100.0	307,074	100.0	256,286	100.0
Cost of goods sold	100,313	28.7	89,454	29.1	73,606	28.7
Gross profit	248,802	71.3	217,620	70.9	182,680	71.3
Operating expenses:						
Research and development	31,701	9.1	25,495	8.3	22,960	9.0
Selling, general and administrative	134,577	38.5	120,069	39.1	91,234	35.6
Antitrust litigation	298	0.1	706	0.2	1,537	0.6
Total operating expenses	166,576	47.7	146,270	47.6	115,731	45.2
Operating income	82,226	23.6	71,350	23.3	66,949	26.1

Non-operating income (expense):						
Interest income	178	0.1	2,305	0.8	2,361	0.9
Interest expense	(75)		(753)	(0.2)	(2,475)	(1.0)
Other	(149)		(511)	(0.2)	1,287	0.5
Total non-operating income (expense)	(46)	0.1	1,041	0.4	1,173	0.4
Income before provision for income taxes	82,180	23.5	72,391	23.6	68,122	26.5
Provision for income taxes	28,158	8.1	40,464	13.2	25,867	10.0
Net income including noncontrolling interests	54,022	15.4	31,927	10.4	42,255	16.5
Accretion of preferred stock					(4,837)	(1.9)
Undistributed income attributable to preferred stockholders					(14,339)	(5.6)
Net income attributable to noncontrolling interests	(794)	(0.2)				
Net income attributable to common stockholders	$ 53,228	15.2%	$ 31,927	10.4%	$ 23,079	9.0%

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Comparison of the Year ended January 2, 2010 to the Year ended January 3, 2009

Revenue. Total revenue increased $42.0 million, or 13.7%, to $349.1 million for the year ended January 2, 2010 from $307.1 million for the year ended January 3, 2009.

Product revenue increased $40.5 million, or 15.6%, to $300.1 million in the year ended January 2, 2010, from $259.6 million for the year ended January 3, 2009. This increase was primarily due to an increase in our installed base of pulse oximeter circuit boards and pulse oximeters to 640,000 units, based on an estimated 7 year field life assumption, at January 2, 2010, from 567,000 units at January 3, 2009. Product revenue generated by our direct and distribution sales channels increased $40.6 million, or 20.2%, to $241.7 million from $201.1 million, while revenues from our OEM channel remained unchanged at $58.4 million. Contributing to the year over year increase in product revenues were increased sales of our Rainbow products which rose by 45.7% to $19.5 million for the year ended January 2, 2010 from $13.4 million for the year ended January 3, 2009. Our U.S. product revenue increased $28.3 million, or 14.6%, to $222.7 million in the year ended January 2, 2010, from $194.4 million for the year ended January 3, 2009. Additionally, our non-U.S. product revenue increased $12.2 million, or 18.7%, to $77.4 million in the year ended January 2, 2010, from $65.2 million for the year ended January 3, 2009.

Our royalty revenue increased $1.5 million, or 3.1%, to $49.0 million for the year ended January 2, 2010 from $47.5 million for the year ended January 3, 2009, based on actual royalties received and estimated Covidien U.S. pulse oximetry sales in the fourth quarter of 2009.

Cost of Goods Sold. Cost of goods sold increased $10.8 million, or 12.1%, to $100.3 million for the year ended January 2, 2010, from $89.5 million for the year ended January 3, 2009. Our gross margin increased to 71.3% for the year ended January 2, 2010, from 70.9% for the year ended January 3, 2009. Excluding royalties, product gross profit margins increased by 1.1% to 66.6% for the year ended January 2, 2010 from 65.5% for the year ended January 3, 2009. This increase was primarily due to a favorable product mix, including the impact of increased Rainbow product revenues, greater sensor sales and lower manufacturing costs resulting from the efficiencies derived from higher production levels. We incurred $4.0 million and $3.5 million in Masimo Labs royalty expenses for the years ended January 2, 2010 and January 3, 2009, respectively, which have been eliminated in our consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 65.2% and 64.2% for the years ended January 2, 2010 and January 3, 2009, respectively.

Research and Development. Research and development expenses increased $6.2 million, or 24.3%, to $31.7 million for the year ended January 2, 2010, from $25.5 million for the year ended January 3, 2009. This increase was mainly due to $2.8 million of additional engineering supplies and clinical trials research expense related to new product development, $1.0 million of increased payroll and payroll related costs associated with increased research and development staffing levels and an increase of $720,000 for additional outside service expense related to new product development. In addition, the reduction in expenses related to capitalized software development costs was $162,000 during the year ended January 2, 2010, as compared to an $844,000 reduction during the year ended January 3, 2009. Share-based payment expense, which is included in payroll and payroll related costs, was $2.5 million and $2.2 million for the years ended January 2, 2010 and January 3, 2009, respectively. Included in these total research and development expenses are $2.0 million and $2.4 million of engineering expenses incurred by Masimo Labs for the years ended January 2, 2010 and January 3, 2009, respectively.

Selling, General and Administrative. Selling, general and administrative expenses increased $14.5 million, or 12.1%, to $134.6 million for the year ended January 2, 2010, from $120.1 million in the year ended January 3, 2009. This increase was primarily due to increased payroll and related expenses of $12.4 million as a result of an increase in selling, general and administrative staffing to 522 at January 2, 2010 from 415 at January 3, 2009. In addition, expenses related to new product samples increased $2.3 million during the year ended January 2, 2010 and travel and related expenses increased $1.7 million primarily due to additional sales representatives and their increased travel activities. These increases were partially offset by a reduction of $1.2 million in marketing related tradeshow expenses during the year ended January 2, 2010 as compared to January 3, 2009. Share-based payment expense, which is included in payroll and payroll related costs, was $7.7 million and $5.2 million for the years ended January 2, 2010 and January 3, 2009, respectively. Included in these total selling, general and administrative expenses are $1.2 million and $805,000 of activities performed by Masimo Labs for the years ended January 2, 2010 and January 3, 2009, respectively.

Non-operating income (expense). Non-operating expense was $46,000 for the year ended January 2, 2010, as compared to non-operating income of $1.0 million the year ended January 3, 2009. This net change of $1.1 million was primarily due to the decline in interest income of $2.1 million resulting from the significant decline in interest rates earned on our invested cash. This decline was partially offset by lower interest expense of $678,000 resulting from the repayment of long-term debt balances in March 2008. The foreign currency losses were $236,000 during the year ended January 2, 2010, compared to

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currency losses of $414,000 during the year ended January 3, 2009. The foreign currency losses, primarily resulting from the weakening of the U.S. dollar as compared to the Canadian dollar, were partially offset by foreign currency gains primarily resulting from the weakening of the U.S. dollar compared to the Euro and Australian dollar.

Provision for Income Taxes. Our provision for income taxes was $28.2 million for the year ended January 2, 2010, compared to $40.5 million for the year ended January 3, 2009. Our effective tax rate decreased to 34.3% in 2009 from 55.9% in 2008. This decrease in tax provision and effective tax rate was due primarily to the implementation of a new international business structure in 2008, designed to ultimately align our operations, in a cost efficient manner, with the business needs of our non-U.S. customers, and which included a tax charge related to the prepayment of licensing commercial rights to utilize pre-existing intangibles. Our future effective income tax rate will depend on various factors, including profits (losses) before taxes, changes to tax law, and the geographic composition of pre-tax income.

Comparison of the Year ended January 3, 2009 to the Year ended December 29, 2007

Revenue. Total revenue increased $50.8 million, or 19.8%, to $307.1 million for the year ended January 3, 2009 from $256.3 million for the year ended December 29, 2007.

Product revenue increased $59.4 million, or 29.7%, to $259.6 million in the year ended January 3, 2009, from $200.2 million for the year ended December 29, 2007. This increase was primarily due to an increase in our installed base of pulse oximeter circuit boards and pulse oximeters to 567,000 units at January 3, 2009, from 470,000 units at December 29, 2007. Product revenue generated by our direct and distribution sales channels increased $57.4 million, or 40.0%, to $201.1 million from $143.7 million, while revenues from our OEM channel increased $2.0 million, or 3.5%, to $58.5 million from $56.5 million. Contributing to the year over year increase in product revenues were increased sales of our Rainbow products which rose by 92.0% to $13.4 million for the year ended January 3, 2009 from $7.0 million for the year ended December 29, 2007. Our U.S. product revenue increased $41.9 million, or 27.5%, to $194.4 million in the year ended January 3, 2009, from $152.5 million for the year ended December 29, 2007. Additionally, our non-U.S. product revenue increased $17.5 million, or 36.6%, to $65.2 million in the year ended January 3, 2009, from $47.7 million for the year ended December 29, 2007.

Our royalty revenue decreased $8.6 million, or 15.4%, to $47.5 million for the year ended January 3, 2009 from $56.1 million for the year ended December 29, 2007, primarily due to the expected decline in the 2008 royalty rate from 15% to 13% under the terms of our settlement agreement with Covidien.

Cost of Goods Sold. Cost of goods sold increased $15.9 million, or 21.5% to $89.5 million for the year ended January 3, 2009, from $73.6 million for the year ended December 29, 2007. Our gross margin decreased to 70.9% for the year ended January 3, 2009, from 71.3% for the year ended December 29, 2007. This decrease in gross margin was primarily due to the expected $8.4 million decrease in Covidien royalty revenue. Excluding royalties, product gross profit margins increased by 2.3% to 65.5% for the year ended January 3, 2009 from 63.2% for the year ended December 29, 2007. This increase was primarily due to the impact of increased Rainbow products revenues and lower manufacturing costs resulting from the efficiencies derived from higher production levels. We incurred $3.5 million and $3.2 million in Masimo Labs royalty expenses for the years ended January 3, 2009 and December 29, 2007, respectively, which have been eliminated in our consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 64.2% and 61.7% for the years ended January 3, 2009 and December 29, 2007, respectively.

Research and Development. Research and development expenses increased $2.5 million, or 11.0%, to $25.5 million for the year ended January 3, 2009, from $23.0 million for the year ended December 29, 2007. This increase was mainly due to $3.1 million of increased payroll and payroll related costs associated with increased research and development staffing levels. This increase in payroll and payroll related costs was partially offset by a reduction in capitalized software development costs of $570,000, net of amortization. Share-based payment expense, which is included in payroll and payroll related costs, was $2.2 million and $670,000 for the years ended January 3, 2009 and December 29, 2007, respectively. Included in these total research and development expenses are $2.4 million and $1.9 million of engineering expenses incurred by Masimo Labs for the years ended January 3, 2009 and December 29, 2007, respectively.

Selling, General and Administrative. Selling, general and administrative expenses increased $28.9 million, or 31.6%, to $120.1 million for the year ended January 3, 2009, from $91.2 million in the year ended December 29, 2007. This increase was primarily due to increased payroll and related expenses of $14.6 million as a result of an increase in staffing to 415 at January 3, 2009 from 360 at December 29, 2007. Additionally, travel and related expenses increased $4.6 million primarily due to additional sales representatives and their increased travel activities. Also, professional fees increased $3.4 million mainly due to increases in expenses related to the implementation of our new international business structure, Sarbanes-

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Oxley Act compliance efforts and other activities related to tax compliance, audit and financial reporting. Tradeshow and related marketing expenses rose by $1.8 million due to additional tradeshows during 2008 as compared to 2007, while legal expenses increased $1.2 million related to the Shaklee litigation which concluded in 2008. Share-based payment expense, which is included in payroll and payroll related costs, was $5.2 million and $3.0 million for the years ended January 3, 2009 and December 29, 2007, respectively. Included in these total selling, general and administrative expenses are $805,000 and $530,000 of activities performed by Masimo Labs for the years ended January 3, 2009 and December 29, 2007, respectively.

Non-operating income. Non-operating income declined to $1.0 million for the year ended January 3, 2009, from $1.2 million for the year ended December 29, 2007. This decline in income was due to the increase in other expense of $1.8 million for the year ended January 3, 2009, which resulted primarily from a $1.6 million change in foreign currency transaction gain (loss). The foreign currency loss was $414,000 during the year ended January 3, 2009, as compared to $1.2 million of currency gain during the year ended December 29, 2007, resulting from the strengthening of the U.S. dollar as compared to the Euro, British pound and Australian dollar for most of 2008. This increase in other expense was partially offset by a decrease in interest expense of $1.7 million, as a result of the payoff of $26.7 million in debt during the year ended January 3, 2009.

Provision for Income Taxes. Our provision for income taxes was $40.5 million for the year ended January 3, 2009, compared to $25.9 million for the year ended December 29, 2007. Our effective tax rate increased to 55.9% in 2008 from 38.0% in 2007. This increase in tax provision and effective tax rate was due primarily to the implementation of a new international business structure, designed to ultimately align our operations, in a cost efficient manner, with the business needs of our non-U.S. customers. The tax charges related to expenses for sharing in the costs of our ongoing research and development efforts as well as the prepayment of licensing commercial rights to utilize pre-existing intangibles. Absent this implementation, our effective tax rate would have been 35.3% for 2008; that rate being reduced as compared to 2007 due primarily to increased research and development related tax credits.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the sale of equity securities. Through January 2, 2010, we raised $81.7 million through seven preferred stock private equity financings, $47.8 million from our August 2007 initial public offering and $29.2 million from the exercise of stock options.

As of January 2, 2010, we had cash and cash equivalents of $132.1 million, of which $119.0 million was invested in U.S. Treasury bills, $1.7 million was in money market accounts with major financial institutions and $11.4 million was in checking accounts. These U.S. Treasury bills are classified as cash equivalents since they are highly liquid investments, with a maturity of three months or less at the date of purchase. We carry cash equivalents at cost which approximates fair value. We also had short-term investments of $57.0 million as of January 2, 2010, which were comprised of U.S. Treasury bills with maturities of more than three months, but less than one year.

In 2009, 2008 and 2007, we received $48.8 million, $49.9 million and $43.5 million, respectively, in cash receipts from Covidien for royalties pursuant to our settlement agreement. We expect to continue to receive a royalty based on Covidien s U.S. pulse oximetry products sales, through at least the term of the royalty agreement, which is March 14, 2011. The royalty rate is currently 13%, but may decline to 10%, subject to Covidien s ability to develop new products or technologies that avoid some of our current patent coverage as negotiated in our settlement agreement with Covidien.

Cash Flows from Operating Activities. Cash provided by operating activities was $47.1 million in 2009. This consists primarily of our net income of $54.0 million, resulting from continued growth and profitability of our business. Additionally, share-based payment expense was $10.7 million due to the continued granting of stock options, and depreciation and amortization was $6.0 million in 2009. These increases were partially offset by decreased income taxes payable of $10.2 million resulting from the 2009 payment of the prior year tax charge related to the prepaid license arising from our international business structure. Also, accounts receivable increased $9.0 million due to business growth, and inventory increased $3.9 million pursuant to our policy of having sufficient inventory to meet customer demand.

Cash provided by operating activities was $78.2 million in 2008. This consists primarily of our net income of $31.9 million, resulting from continued growth and profitability of our business. Income tax benefits from the exercise of stock options was $17.2 million, resulting from significant stock option exercises during 2008. Income taxes payable increased by $12.8 million as the result of increased operating income and a higher effective tax rate in 2008 which was primarily due to the implementation of a new international business structure. Additionally, share-based payment expense was $7.7 million and depreciation and amortization was $5.7 million in 2008. Also, other liabilities increased $4.1 million due to increased unrecognized tax liability. These increases to cash flow from operating activities were partially offset by an increase of $6.2 million in accounts receivable due to business growth which was partially offset by continued improvement in the timing of

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cash receipts and a $5.6 million increase in inventory pursuant to our policy of having sufficient inventory to meet customer demand.

Cash Flows from Investing Activities. Cash used in investing activities for 2009 was $64.5 million primarily due to the purchase of short-term investments of $57.0 million. These investment purchases were as a result of a change in our investment policy in 2009 to slightly longer term investments with a higher yield. In addition, property and equipment purchases were $3.6 million to support the growth of the business, and intangible assets increased $1.9 million relating primarily to capitalized legal expenses associated with our patent related activities. Cash paid for acquisitions was $2.0 million in 2009.

Cash used in investing activities for 2008 was $9.4 million primarily consisting of $6.9 million in purchases of property and equipment and $2.5 million for the increase in intangible assets relating primarily to capitalized legal expenses associated with our patent related activities. The property and equipment purchases included manufacturing equipment and tools of $3.7 million, leasehold improvements of $1.2 million and $1.0 million for additional construction in process, all in order to support the growth of the business.

Cash Flows from Financing Activities. Cash provided by financing activities in 2009 was $2.3 million. This primarily consists of proceeds from issuance of stock of $2.6 million as a result of the exercise of stock options. These proceeds were partially offset by $450,000 of debt repayments in 2009. Unless we obtain additional third party financing, we anticipate that our current debt payments will be minimal in the future.

Cash used by financing activities in 2008 was $18.8 million. This primarily consists of debt repayments of $30.4 million throughout 2008, including $26.7 million, or the entire then outstanding balance on one financing arrangement. This was partially offset by proceeds from issuance of stock of $9.8 million and $1.9 million of excess tax benefit from share-based payment arrangements, due to exercises of stock options in 2008.

Future Liquidity Needs. In the future, in addition to funding our working capital requirements, we anticipate our primary use of cash to be the equipment that we provide to hospitals under our long-term sensor purchase agreements. We anticipate additional capital purchases related to expanding our worldwide international operations including manufacturing, sales, marketing and other areas of necessary infrastructure growth. Our focus on international expansion will also require both continuing and incremental investments in facilities and infrastructure in the Americas, Europe and Asia. We also anticipate possible uses of cash for the acquisition of technologies or the acquisition of technology companies. The amount and timing of our actual investing activities will vary significantly depending on numerous factors, such as the progress of our product development efforts, our timetable for international sales operations and manufacturing expansion and both domestic and international regulatory requirements. Despite these capital investment requirements, we anticipate that our existing cash and cash equivalents, as well as short-term investments, will be sufficient to meet our working capital requirements, capital expenditures, and operations for at least the next 12 months.

Current Financing Arrangements. As of January 2, 2010, other than capital leases, we did not have any other long term borrowings. The capital lease amounts represent principal and interest due on leased office equipment.

Contractual Obligations. The following table summarizes our outstanding contractual obligations as of January 2, 2010 and the effect those obligations are expected to have on our cash liquidity and cash flow in future periods (in thousands):

	Payments Due By Period				
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Operating Leases[1]	$ 2,483	$ 4,356	$ 3,693	$	$ 10,532
Purchase Commitments[2]	23,597	557			24,154
Capital Leases (including interest)[3]	72	111	68		251
Total Contractual Obligations	$ 26,152	$ 5,024	$ 3,761	$	$ 34,937

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

(3) Leased office equipment.

Other obligation: As of January 2, 2010, the liability for uncertain tax positions including interest was $8.7 million. Due to the high degree of uncertainty regarding the timing of potential cash flows associated with these liabilities, we are unable to make a reasonably reliable estimate of the amounts and periods in which these liabilities might be made.

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In addition to these contractual obligations, we have the following annual minimum royalty commitments to Masimo Labs, as of January 2, 2010 (in thousands):

	Payments Due By Period			
	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Minimum royalty commitment to Masimo Labs	$ 5,000	$ 10,000	$ 10,000	[1]

(1) Subsequent to 2014, the royalty arrangement requires a $5.0 million minimum annual royalty payment unless the agreement is amended, restated or terminated.

Masimo Labs is consolidated within our financial statements for all periods presented. Accordingly, all inter-company royalties, option and license fees and other charges between us and Masimo Labs have been eliminated in the consolidation. For additional discussion of Masimo Labs, see Note 3 to the Consolidated Financial Statements.

Off-Balance Sheet Arrangements

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

Critical Accounting Estimates

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

Inventory/Reserves for Excess or Obsolete Inventory

Inventories are stated at the lower of cost or market. Cost is determined using a standard cost method, which approximates FIFO (first-in, first-out). Inventory valuation allowances are recorded for materials that have become obsolete or are no longer used in current production and for inventory that has a market value less than the carrying value in inventory. We generally purchase raw materials in quantities that we anticipate will be fully used within one year. However, changes in operating strategy and customer demand, and frequent unpredictable fluctuations in market values for such materials can limit our ability to effectively utilize all of the raw materials purchased and sold through resulting finished goods to customers for a profit. We regularly monitor potential inventory excess, obsolescence and lower market values compared to standard costs and, when necessary, reduce the carrying amount of our inventory to its market value. Specific reserves are maintained to reduce the carrying value of inventory items on hand that we know may not be used in finished goods. A general inventory reserve is also maintained based on our estimate of future limitations on our ability to utilize the inventory on hand. Our inventory reserve was $5.2 million at both January 2, 2010 and January 3, 2009, respectively. If our estimates for potential inventory losses prove to be too low, then our future earnings will be affected when the related additional inventory losses are recorded.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is used to state trade receivables at a net estimated realizable value. We rely on prior experience to estimate the amount that we expect to collect on the gross receivables outstanding, which cannot be known with exact certainty as of the time of issuance of this report. We maintain a specific allowance for customer accounts that we know may not be collectible due to customer liquidity issues. We also maintain a general allowance for future collection losses that arise from customer accounts that do not indicate an inability, but may be unable, to pay.

Although such losses have historically been within our expectations and the allowances we have established, we cannot guarantee that we will continue to experience the same loss rates that we have in the past, especially given the recent deterioration of the credit markets of the worldwide economy. A significant change in the liquidity or financial condition of our customers could cause

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unfavorable trends in our receivable collections and additional allowances may be required. Our accounts receivable balance was $38.9 million and $30.7 million, net of allowances for doubtful accounts of $2.0 million and $1.3 million at January 2, 2010 and January 3, 2009, respectively.

Share-Based Payment

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

During the year ended December 29, 2007 and the nine months ended September 27, 2008, we did not have sufficient information available that was indicative of future exercise and post-vesting behavior to estimate the expected term. As a result, we adopted the simplified method of estimating the expected term of a stock option. Under this method, the expected term is presumed to be the mid-point between the vesting date and the contractual end of the term. The use of the simplified method requires our option plan to be consistent with a plain vanilla plan. Subsequent to September 27, 2008, we had sufficient Company specific and available external information to estimate our expected term and therefore we did not rely on the simplified method. As we obtain more historical data as a publicly traded company, we expect to rely increasingly on Company specific information for our estimate of expected term.

Additionally, during the year ended December 29, 2007 and the nine months ended September 27, 2008, we did not have sufficient information available regarding the historic volatility for our shares. As a result, we estimated volatility based on a peer group of companies, which collectively provides a reasonable basis for estimating volatility. Subsequent to September 27, 2008 and after we had been publicly traded for more than one year, we were able to use Company specific as well as peer group information to estimate the volatility of our shares. As we obtain more historical data as a publicly traded company, we expect to rely increasingly on Company specific information for our estimate of volatility.

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

Share-based payment expense amounted to $10.7 million for the year ended January 2, 2010, $7.7 million for the year ended January 3, 2009 and $3.9 million for the year ended December 29, 2007. The fair market value of our stock may also increase the cost of future stock option grants. To the extent that the fair market value of our stock increases, the overall cost of granting these options will also increase. For further details regarding our share-based payments see Note 11 of our consolidated financial statements.

Revenue Recognition and Deferred Revenue

We derive revenue primarily from four sources: (i) direct sales of pulse oximetry and related products to end user hospitals, emergency medical response organizations and other direct customers; (ii) direct sales of pulse oximetry and related products to distributors who then typically resell to end user hospitals, emergency medical response organizations and other direct customers; (iii) direct sales of integrated circuit boards and sensors to OEM customers who both incorporate our embedded software technology into their multi-parameter monitoring devices and, resell our sensors; (iv) long-term sales contracts to end user hospitals in which we may provide up front monitoring equipment at no charge in exchange for a multi-year sensor purchase commitment.

We enter into agreements to sell pulse oximetry and related products and services as well as multiple deliverable arrangements that include various combinations of products and services. While the majority of our sales transactions contain standard business terms and conditions, there are some transactions that contain non-standard business terms and conditions. As a result, contract interpretation is sometimes required to determine the appropriate accounting including: (i) whether an arrangement exists; (ii) how the arrangement consideration should be allocated among the deliverables if there are multiple deliverables; (iii) if fair value can be determined for each deliverable based on vendor specific objective evidence, or VSOE; (iv) when to recognize revenue on the deliverables; and (v) whether undelivered elements are essential to the functionality of the delivered elements. In situations where VSOE of fair value does not exist for certain undelivered elements, the contract product

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revenue and corresponding cost of goods sold are deferred until either the element is delivered, VSOE of fair value is established, or the obligation to deliver the element no longer exists. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

Accounting for Income Taxes

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

Management s judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We continue to monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly. At January 2, 2010, we had $33.0 million of net operating loss carryforwards from our foreign jurisdictions which begin to expire in 2015. Also, we had $9.1 million of net operating losses from various states, which will begin to expire in 2012, of which $4.2 million, or $150,000 after tax effect, will be recorded in stockholders equity when realized. We believe that it is more likely than not that the deferred tax assets related to foreign net operating losses will not be realized. A valuation allowance has been provided on such loss carryforwards.

Our consolidated income tax provision or benefit and the net deferred tax assets include Masimo Labs income taxes provision or benefit and deferred tax assets. For income tax purposes, Masimo Labs is not a member of our consolidated group and files its separate federal and California income tax returns.

On January 1, 2007, we adopted an accounting standard which prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As of January 2, 2010 and January 3, 2009, the balance of gross unrecognized tax benefits was $8.1 million and $7.3 million, respectively. The amount of unrecognized benefits which, if ultimately recognized, could favorably affect the tax rate in a future period was $6.9 million and $6.1 million as of January 2, 2010 and January 3, 2009, respectively. Both amounts are net of any federal and/or state benefits and the remaining balance relates to timing differences. It is reasonably possible that the amount of unrecognized tax benefits in various jurisdictions may decrease up to $2.0 million in the next 12 months due to the expiration of statutes of limitation.

Interest and penalties related to unrecognized tax benefits are recognized in income tax expense. At January 2, 2010, we had accrued $669,000 for the payment of interest.

We conduct business in multiple jurisdictions, and as a result, one or more of our subsidiaries files income tax returns in the U.S. federal, various state, local and foreign jurisdictions. Due to the generation of net operating loss carryforwards, all years since 1994 are open for examination by major taxing authorities.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update 2009-13, or ASU No. 09-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements* . ASU No. 09-13 modifies the requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. This update shall be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Earlier application as of the beginning of our fiscal year is permitted, provided we have not previously issued financial statements for any period within that year. We are currently evaluating what impact this update will have on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update 2009-14, or ASU No. 09-14, *Software (Topic 985): Certain Revenue Arrangements That Include Software Elements* . ASU No. 09-14 modifies the software revenue recognition guidance to exclude from its scope tangible products that contain both software and non-software components that function together to deliver a product s essential functionality. ASU No. 09-14 is effective for fiscal years beginning after June 15, 2010 and may be applied retrospectively or prospectively for new or

materially modified arrangements. Earlier application as of the beginning of our fiscal year is permitted, provided we have not previously issued financial statements for any period within that year. We are currently evaluating what impact this update will have on our consolidated financial statements.

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In December 2009, the FASB issued Accounting Standards Update 2009-17, or ASU No. 09-17, *Consolidations (Topic 810) - Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*, which codifies FASB Statement No. 167, Amendments to FASB Interpretation No. 46(R). ASU No. 09-17 represents a revision to former FASB Interpretation No. 46 (Revised December 2003), *Consolidation of Variable Interest Entities*, and changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity s purpose and design and the reporting entity s ability to direct the activities of the other entity that most significantly impact the other entity s economic performance. ASU No. 09-17 is effective for fiscal years beginning after November 15, 2009. Early application is not permitted. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

In January 2010, the FASB issued Accounting Standards Update 2010-06, or ASU No. 10-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements*. ASU No. 10-06 requires an entity to disclose separately the amounts of significant transfers in and out of Level 1 and 2 fair value measurements, and describe the reasons for the transfers. Also, it requires additional disclosure regarding purchases, sales, issuances and settlements of Level 3 measurements. ASU No. 10-06 is effective for interim and annual periods beginning after December 15, 2009, except for the additional disclosure of Level 3 measurements, which is effective for fiscal years beginning after December 15, 2010. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense we must pay with respect to our various outstanding debt instruments. Our risk associated with fluctuation in interest expense is limited to our outstanding capital lease arrangements, which have fixed interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest-sensitive financial instruments at January 2, 2010. Declines in interest rates over time will, however, reduce our interest income and expense while increases in interest rates will increase our interest income and expense.

Foreign Currency Exchange Rate Risk

A majority of our assets and liabilities are maintained in the United States in U.S. dollars and a majority of our sales and expenditures are transacted in U.S. dollars. We transact with foreign customers in currencies other than the U.S. dollar. These foreign currency revenues, when converted into U.S. dollars, can vary depending on average exchange rates during a respective period. In addition, we are exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of income as incurred. Certain of our foreign sales support subsidiaries transact in their respective country s local currency, which is also their functional currency. As a result, expenses of these foreign subsidiaries when converted into U.S. dollars can vary depending on average monthly exchange rates during a respective period. Certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses. These foreign currency gains or losses are included in our statements of income as incurred. In addition, any other transactions between us or our subsidiaries and a third party, denominated in a currency different from the functional currency, are a foreign currency transaction. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of income as incurred and are converted to U.S. dollars at average exchange rates for a respective period.

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

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

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the periods presented, and we do not anticipate that it will have a material adverse effect in the future.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Annual Report. We recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated by the SEC under the Exchange Act. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of January 2, 2010.

Grant Thornton LLP, the independent registered public accounting firm that audited the financial statements included in this Form 10-K, has issued an attestation report on the effectiveness of our internal control over financial reporting as of January 2, 2010. This report, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of January 2, 2010, is included herein.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended January 2, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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ITEM 9B. OTHER INFORMATION
None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE
The information required by this item concerning our directors, compliance with Section 16 of the Exchange Act and our code of ethics that applies to our principal executive officer, principal financial officer and principal accounting officer is incorporated by reference from the information set forth in the sections under the headings Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Election of Directors Information Regarding the Board of Directors and Corporate Governance in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders to be held in 2010, or the 2010 Proxy Statement.

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

ITEM 11. EXECUTIVE COMPENSATION
The information required by this item is incorporated by reference from the information in the 2010 Proxy Statement under the heading Compensation of Executive Officers.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS
The information required by this item is incorporated by reference from the information in the 2010 Proxy Statement under the headings Equity Compensation Plan Information and Security Ownership of Certain Beneficial Owners and Management.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE
The information required by this item is incorporated by reference from the information in the 2010 Proxy Statement under the headings Transactions with Related Persons and Election of Directors Information Regarding the Board of Directors and Corporate Governance.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES
The information required by this item is incorporated by reference from the information in the 2010 Proxy Statement under the heading Ratification of Selection of Independent Auditors Principal Accountant Fees and Services.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES
(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

Exhibit Number	Description of Document
2.1(1)	Asset Purchase Agreement, dated December 21, 2005, between the Registrant, Masimo Canada ULC and Andromed Inc. (Exhibit 2.1)
2.1(a)(1)	List briefly identifying the contents of schedules omitted from Exhibit 2.1 (Exhibit 2.1(a))
3.1(1)	Amended and Restated Certificate of Incorporation (Exhibit 3.2)

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Exhibit Number	Description of Document
3.2(2)	Certificate of Designation of Series A Junior Participating Preferred Stock (Exhibit 3.1)
3.3(6)	Amended and Restated Bylaws adopted on October 9, 2008 (Exhibit 3.1)
4.1(1)	Form of Common Stock Certificate (Exhibit 4.1)
4.2(1)	Fifth Amended and Restated Registration Rights Agreement made and entered into as of September 14, 1999 between the Registrant and certain of its stockholders (Exhibit 4.2)
4.3(2)	Rights Agreement, dated November 9, 2007, between the Registrant and Computershare Trust Company, N.A., as Rights Agent (Exhibit 4.1)
4.4(4)#	Masimo Retirement Savings Plan (Exhibit 4.7)
10.1(1)#	Form of Indemnity Agreement between the Registrant and its officers and directors (Exhibit 10.1)
10.2(1)#	Employment Agreement, dated July 19, 2007, between Joe E. Kiani and the Registrant (Exhibit 10.2)
10.3(7)#	Amendment No. 1 to Employment Agreement, dated December 31, 2008, between Joe E. Kiani and the Registrant (Exhibit 10.3)
10.4(1)#	Offer Letter, dated February 15, 1996, between Yongsam Lee and the Registrant (Exhibit 10.7)
10.5(7)#	Offer Letter, dated May 21, 2004, between Rick Fishel and the Registrant (Exhibit 10.13)
10.6(1)#	Offer Letter, dated June 9, 2006, between Mark P. de Raad and the Registrant (Exhibit 10.9)
10.7(1)#	Offer Letter, dated March 30, 2007, between Anand Sampath and the Registrant (Exhibit 10.8)
10.8(7)#	Offer Letter, dated December 19, 2007, between Michael O Reilly and the Registrant (Exhibit 10.12)
10.9(7)#	Offer Letter, dated December 27, 2007, between Paul Jansen and the Registrant (Exhibit 10.11)
10.10(7)#	Offer Letter, dated July 23, 2008, between Jon C. Coleman and the Registrant (Exhibit 10.9)
10.11(1)#	Executive Annual Cash Bonus Award Plan, effective January 1, 2007 (Exhibit 10.40)
10.12(1)#	Executive Multi-Year Cash Bonus Award Plan, effective January 1, 2008 (Exhibit 10.41)
10.13(7)#	CEO and Executive Officer Equity Award Compensation Policy, effective January 4, 2008 (Exhibit 10.53)
10.14(7)#	Amended and Restated 2007 Severance Protection Plan and Summary Plan Description, effective December 31, 2008 (Exhibit 10.54)
10.15(3)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Mark P. de Raad (Exhibit 10.2)
10.16(3)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Yongsam Lee (Exhibit 10.3)
10.17(7)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Rick Fishel (Exhibit 10.57)
10.18(1)#	Third Amended and Restated 1996 Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan of the Registrant, as amended, and forms of agreements related thereto (Exhibit 10.31)
10.19(1)#	2004 Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan of the Registrant, as amended, and forms of agreements related thereto (Exhibit 10.32)
10.20(1)#	2007 Stock Incentive Plan of the Registrant, and forms of agreements related thereto (Exhibit 10.33)

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Exhibit Number	Description of Document
10.21(1)+	Purchase Agreement, dated July 26, 2001, between Jabil Circuit, Inc. and the Registrant (Exhibit 10.15)
10.22(1)	ADSP-2136X Sharc ROM Agreement, dated July 19, 2004, between Analog Devices Inc. and the Registrant (Exhibit 10.36)
10.23(7)+	Manufacturing and Purchase Agreement, dated October 2, 2008, by and between Analog Devices, Inc. and the Registrant (Exhibit 10.21)
10.24(1)	Manufacturing and Purchase Agreement, dated August 19, 2005, between Dowa Mining Co., Ltd. and the Registrant (Exhibit 10.10)
10.25(1)+	Supply Agreement, dated February 22, 2002, between Wintek Electro-Optics Corporation and the Registrant (Exhibit 10.24)
10.26(1)+	Shelter Labor Services Agreement, dated December 27, 2000, between Industrial Vallera de Mexicali, S.A. de C.V. and the Registrant (Exhibit 10.11)
10.27(5)+	Lease Agreement effective as of September 1, 2007, by and among Industrias Asociadas Maquiladoras, S.A. de C.V., Industrial Vallera de Mexicali, S.A. de C.V. and the Registrant, as guarantor (Exhibit 10.1)
10.28(1)+	Pulse Oximetry & Related Products Capital Equipment Supplier Agreement, dated December 16, 2005, between Novation, LLC (Novation) and the Registrant, as amended (the Novation Agreement) (Exhibit 10.22)
10.29(7)+	Letter Amendment to Exhibit A of the Novation Agreement, dated January 31, 2007, between Novation and the Registrant (Exhibit 10.28)
10.30(7)+	Letter Amendment to Exhibit A of the Novation Agreement, dated June 13, 2007, between Novation and the Registrant (Exhibit 10.29)
10.31(7)+	Letter Amendment to Exhibit A of the Novation Agreement, dated May 1, 2008, between Novation and the Registrant (Exhibit 10.30)
10.32(7)	Extension and Amendment of the Novation Agreement, dated December 4, 2008, between Novation and the Registrant (Exhibit 10.31)
10.33(8)+	Letter Amendment to Exhibit A of the Pulse Oximetry & Related Products Capital Equipment Supplier Agreement, dated January 2, 2009, between Novation, LLC and the Registrant (Exhibit 10.30)
10.34(8)+	Group Purchasing Agreement Capital Equipment, effective June 1, 2009, by and between Premier Purchasing Partners, L.P. and the Registrant (Exhibit 10.32)
10.35(9)++	Lease Agreement, relating the premises at 40 Parker, effective as of November 1, 2009, between the Registrant and Northwestern Mutual Life Insurance Company (Exhibit 10.1)
10.36(1)+	Standard Industrial/Commercial Multi-Tenant Lease-Net, dated February 8, 2006, between The Northwestern Mutual Life Insurance Company and the Registrant (Exhibit 10.21)
10.37(9)++	Amendment No. 1 to Lease Agreement, relating the premises at 50 Parker, dated April 30, 2009, between the Registrant and Northwestern Mutual Life Insurance Company (Exhibit 10.3)
10.38(9)++	Lease Agreement, relating the premises at 60 Parker, effective as of August 1, 2009, between the Registrant and Northwestern Mutual Life Insurance Company (Exhibit 10.2)
10.39(1)	Settlement Agreement and Release of Claims, dated January 17, 2006, between Masimo Laboratories, Inc., Nellcor Puritan Bennett, Inc., Mallinckrodt, Inc., Tyco Healthcare Group LP, Tyco International Ltd., Tyco International (US) Inc. and the Registrant (Exhibit 10.30)
10.40(1)+	Amended and Restated Cross-Licensing Agreement, effective January 1, 2007, between Masimo Laboratories, Inc. and the Registrant (Exhibit 10.34)

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Exhibit Number	Description of Document
10.41(1)	Services Agreement, effective January 1, 2007, between Masimo Laboratories, Inc. and the Registrant (Exhibit 10.35)
10.42(1)	Contribution and Assignment Agreement, dated January 1, 2005, between Masimo Americas, Inc. and the Registrant (Exhibit 10.16)
10.43(1)	Sales and Distribution Agreement, dated January 1, 2005, between Masimo Americas, Inc. and the Registrant (Exhibit 10.17)
10.44(1)	Occupancy Agreement, dated January 1, 2005, between Masimo Americas, Inc. and the Registrant (Exhibit 10.18)
10.45(1)	Management Services Agreement, dated January 1, 2005, between Masimo Americas, Inc. and the Registrant (Exhibit 10.19)
10.46(7)	Cost Sharing Agreement, effective September 29, 2008, by and between Masimo International Holdings and the Registrant (Exhibit 10.48)
10.47(7)	Buy-in License Agreement, effective September 29, 2008, by and between Masimo International Holdings and the Registrant (Exhibit 10.49)
10.48(7)	Assignment and Assumption of Cost Sharing Agreement and Buy-in License Agreement, effective November 21, 2008, by and between Masimo International Holdings and Masimo International Technologies SARL (Exhibit 10.50)
21.1*	List of Registrant s subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Joe E. Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Mark P. de Raad, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Joe E. Kiani, Chief Executive Officer, and Mark P. de Raad, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the exhibits to the Company s Registration Statement on Form S-1 (No. 333-142171), originally filed on April 17, 2007. The number given in parenthesis indicates the corresponding exhibit number in such Form S-1, as amended.
(2) Incorporated by reference to the exhibits to the Company s Current Report on Form 8-K, filed on November 9, 2007. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
(3) Incorporated by reference to the exhibits to the Company s Current Report on Form 8-K, filed on January 17, 2008. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
(4) Incorporated by reference to the exhibit to the Company s Registration Statement on Form S-8, filed on February 11, 2008. The number given in parenthesis indicates the corresponding exhibit number in such Form S-8.
(5) Incorporated by reference to the exhibit to the Company s Current Report on Form 8-K, filed on June 5, 2008. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
(6) Incorporated by reference to the exhibit to the Company s Current Report on Form 8-K, filed on October 10, 2008. The number given in parenthesis indicates the corresponding exhibit number in such Form 8-K.
(7) Incorporated by reference to the exhibit to the Company s Annual Report on Form 10-K, filed on March 4, 2009. The number given in parenthesis indicates the corresponding exhibit number in such Form 10-K.
(8) Incorporated by reference to the exhibit to the Company s Quarterly Report on Form 10-Q, filed on May 6, 2009. The number given in parenthesis indicates the corresponding exhibit number in such Form 10-Q.
(9) Incorporated by reference to the exhibit to the Company s Quarterly Report on Form 10-Q, filed on November 4, 2009. The number given in parenthesis indicates the corresponding exhibit number in such Form 10-Q.
* Filed herewith.
# Indicates management contract or compensatory plan.

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+ The SEC has granted confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

++ Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
Pursuant to Item 601(b)(2) of Regulation S-K, the schedules to this agreement have been omitted. A list identifying the contents of the omitted schedules is included as Exhibit 2.1(a). The Registrant agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.

(b) Exhibits

See Item 15(a)(3) above.

(c) Financial Statement Schedules

See Item 15(a)(2) above.

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SIGNATURES

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

Date: February 16, 2010 By: /s/ Joe E. Kiani
Joe E. Kiani

Chairman of the Board & Chief Executive Officer

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

SIGNATURE	TITLE(S)	DATE
/s/ Joe E. Kiani	Chairman of the Board & Chief Executive Officer	February 16, 2010
Joe E. Kiani	(Principal Executive Officer)	
/s/ Mark P. de Raad	Executive Vice President & Chief Financial Officer	February 16, 2010
Mark P. de Raad	(Principal Financial and Accounting Officer)	
/s/ Steven Barker, M.D., Ph.D.	Director	February 16, 2010
Steven Barker, M.D., Ph.D.		
/s/ Edward L. Cahill	Director	February 16, 2010
Edward L. Cahill		
/s/ Robert Coleman, Ph.D.	Director	February 16, 2010
Robert Coleman, Ph.D.		
	Director	
Sanford Fitch		
/s/ Jack Lasersohn	Director	February 16, 2010
Jack Lasersohn		

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Masimo Corporation

We have audited the accompanying consolidated balance sheets of Masimo Corporation as of January 2, 2010 and January 3, 2009, and the related consolidated statements of income, stockholders equity and cash flows for each of the three years in the period ended January 2, 2010. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Masimo Corporation as of January 2, 2010 and January 3, 2009, and the results of its operations and its cash flows for each of the three years in the period ended January 2, 2010, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Masimo Corporation s internal control over financial reporting as of January 2, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 16, 2010 expressed an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ GRANT THORNTON LLP

Irvine, California

February 16, 2010

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Masimo Corporation

We have audited Masimo Corporation s internal control over financial reporting as of January 2, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Masimo Corporation s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on Masimo Corporation s internal control over financial reporting based on our audit.

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

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

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

In our opinion, Masimo Corporation maintained, in all material respects, effective internal control over financial reporting as of January 2, 2010, based on criteria established in *Internal Control Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Masimo Corporation as of January 2, 2010 and January 3, 2009, and the related consolidated statements of income, stockholders equity and cash flows for each of the three years in the period ended January 2, 2010 and our report dated February 16, 2010 expressed an unqualified opinion on those consolidated financial statements.

/s/ GRANT THORNTON LLP

Irvine, California

February 16, 2010

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MASIMO CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except share amounts)

	January 2, 2010	January 3, 2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 132,054	$ 146,910
Short-term investments	56,989	
Accounts receivable, net of allowance for doubtful accounts of $1,972 and $1,300 at January 2, 2010 and January 3, 2009, respectively	38,897	30,715
Royalties receivable	11,500	11,375
Inventories	31,559	27,400
Prepaid expenses	3,742	3,908
Prepaid income taxes	1,705	872
Deferred tax assets	11,585	10,511
Other current assets	1,357	551
Total current assets	289,388	232,242
Deferred cost of goods sold	28,163	28,431
Property and equipment, net	11,682	12,979
Deferred tax assets	11,500	8,781
Restricted cash	593	577
Intangible assets, net	9,829	7,410
Goodwill	448	448
Other assets	4,742	2,480
Total assets	$ 356,345	$ 293,348
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 16,716	$ 15,914
Accrued compensation	17,793	15,607
Accrued liabilities	9,754	5,566
Income taxes payable	477	10,862
Deferred revenue	14,641	17,233
Current portion of long-term debt		395
Current portion of capital lease obligation	60	70
Total current liabilities	59,441	65,647
Deferred revenue	270	213
Capital lease obligation, less current portion	171	157
Other liabilities	6,775	7,833
Total liabilities	66,657	73,850
Commitments and contingencies		
Stockholders equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized at January 2, 2010 and January 3, 2009; 0 shares issued and outstanding at January 2, 2010 and January 3, 2009		
	58	57

Common stock, $0.001 par value, 100,000,000 shares authorized at January 2, 2010 and January 3, 2009; 57,876,450 and 57,326,527 shares issued and outstanding at January 2, 2010 and January 3, 2009, respectively		
Treasury stock, 156,240 shares at January 2, 2010 and January 3, 2009	(1,209)	(1,209)
Additional paid-in capital	195,690	179,666
Accumulated other comprehensive income (loss)	63	(7)
Retained earnings	94,112	40,884
Total Masimo Corporation stockholders equity	288,714	219,391
Noncontrolling interest	974	107
Total stockholders equity	289,688	219,498
Total liabilities and stockholders equity	$ 356,345	$ 293,348

The accompanying notes are an integral part of these consolidated financial statements.

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MASIMO CORPORATION

CONSOLIDATED STATEMENTS OF INCOME

(in thousands, except share information)

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Revenue:			
Product[1]	$ 300,143	$ 259,592	$ 200,186
Royalty	48,972	47,482	56,100
Total revenue	349,115	307,074	256,286
Cost of goods sold	100,313	89,454	73,606
Gross profit	248,802	217,620	182,680
Operating expenses:			
Research and development	31,701	25,495	22,960
Selling, general and administrative	134,577	120,069	91,234
Antitrust litigation	298	706	1,537
Total operating expenses	166,576	146,270	115,731
Operating income	82,226	71,350	66,949
Non-operating income (expense):			
Interest income	178	2,305	2,361
Interest expense	(75)	(753)	(2,475)
Other	(149)	(511)	1,287
Total non-operating income (expense)	(46)	1,041	1,173
Income before provision for income taxes	82,180	72,391	68,122
Provision for income taxes	28,158	40,464	25,867
Net income including noncontrolling interests	54,022	31,927	42,255
Accretion of preferred stock			(4,837)
Undistributed income attributable to preferred stockholders			(14,339)
Net income attributable to noncontrolling interests	(794)		
Net income attributable to Masimo Corporation	$ 53,228	$ 31,927	$ 23,079
Net income per common share attributable to Masimo Corporation stockholders:			
Basic	$ 0.92	$ 0.57	$ 0.71
Diluted	$ 0.88	$ 0.53	$ 0.60
Weighted-average number of common shares:			
Basic Two class method	N/A	N/A	16,654,586
Diluted Two class method	N/A	N/A	20,732,872
Basic Single class method	57,602,646	56,320,712	54,660,216
Diluted Single class method	60,170,848	60,190,335	59,829,198

(1) Includes related party product revenue of $0, $0 and $20,421 for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively. See Note 4.

The following table presents details of the share-based payment expense (Note 11) that is included in each functional line item in the consolidated statements of income above (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Cost of goods sold	$ 413	$ 257	$ 264
Research and development	$ 2,541	$ 2,236	$ 670
Selling, general and administrative	$ 7,720	$ 5,223	$ 2,958

The accompanying notes are an integral part of these consolidated financial statements.

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MASIMO CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share amounts)

	Masimo Corporation Stockholders										
	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Deficit)	Noncontrolling Interest	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at December 31, 2006	11,537,501	$ 88,328	16,565,532	$ 17	114,600	$ (628)	$	$ (317)	$ (30,439)	$ 29	$ 56,990
Stock options exercised			268,343				831				831
Income tax benefit from exercise of stock options							204				204
Conversion of preferred stock to common stock	(11,537,501)	(93,165)	34,612,503	35			93,130				
Issuance of common stock in initial public offering			3,287,494	3			47,846				47,849
Accretion of redemption value on convertible preferred stock		4,837					(2,596)		(2,241)		
Cumulative impact of change in accounting for uncertainties in income taxes									(618)		(618)
Compensation related to stock option grants to employees							3,465			10	3,475
Repurchase of common stock from employees			(41,640)		41,640	(581)	417				(164)
Comprehensive income (loss):											
Net income									42,255		42,255
Foreign currency translation adjustment								(717)			(717)
Total comprehensive income, net of											41,538

tax									
Balance at December 29, 2007	54,692,232	55	156,240	(1,209)	143,297	(1,034)	8,957	39	150,105
Stock options exercised	2,634,295	2			9,753				9,755
Income tax benefit from exercise of stock options					19,090				19,090
Compensation related to stock option grants to employees					7,526			68	7,594
Comprehensive income:									
Net income							31,927		31,927
Foreign currency translation adjustment						1,027			1,027
Total comprehensive income, net of tax									32,954
Balance at January 3, 2009	57,326,527	57	156,240	(1,209)	179,666	(7)	40,884	107	219,498
Stock options exercised	549,923	1			2,574				2,575
Income tax benefit from exercise of stock options					2,973				2,973
Compensation related to stock option grants to employees					10,477			73	10,550
Comprehensive income:									
Net income							53,228	794	54,022
Foreign currency translation adjustment						70			70
Total comprehensive income, net of tax									54,092
Balance at January 2, 2010	$ 57,876,450	$ 58	156,240	$ (1,209)	$ 195,690	$ 63	$ 94,112	$ 974	$ 289,688

The accompanying notes are an integral part of these consolidated financial statements.

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MASIMO CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Cash flows from operating activities:			
Net income including noncontrolling interest	$ 54,022	$ 31,927	$ 42,255
Adjustments to reconcile net income including noncontrolling interest to net cash provided by operating activities:			
Depreciation and amortization	5,979	5,745	5,263
Share-based payment	10,674	7,716	3,892
Loss on disposal of property and equipment	5	91	
Provision for (benefit from) doubtful accounts	733	108	(25)
Provision for obsolete inventory	232	1,352	1,155
Provision for warranty costs	2,220	1,646	1,482
Provision (benefit) for deferred income taxes	(3,566)	447	2,696
Income tax benefit from exercise of stock options granted prior to January 1, 2006	2,758	17,201	60
Excess tax benefits from share-based payment arrangements	(215)	(1,889)	(144)
Changes in operating assets and liabilities:			
Increase in accounts receivable	(8,982)	(6,244)	(3,269)
(Increase) decrease in royalties receivable	(125)	2,491	(12,577)
(Increase) decrease in accounts receivable from related parties		3,053	(953)
Increase in inventories	(3,929)	(5,588)	(7,021)
(Increase) decrease in deferred cost of goods sold	309	(2,232)	(4,306)
(Increase) decrease in prepaid expenses	197	(54)	(1,727)
(Increase) decrease in prepaid income taxes	(833)	2,376	(3,247)
(Increase) decrease in other assets	(3,065)	1,163	(2,210)
Increase in accounts payable	777	1,847	4,345
Increase (decrease) in accounts payable to related parties		(583)	99
Increase in accrued compensation	1,926	3,121	53
Increase (decrease) in accrued liabilities	1,935	(2,485)	19
Increase (decrease) in income taxes payable	(10,169)	12,754	(1,110)
Increase (decrease) in deferred revenue	(2,518)	111	2,784
Increase (decrease) in other liabilities	(1,244)	4,104	1,309
Net cash provided by operating activities	47,121	78,178	28,823
Cash flows from investing activities:			
Purchases of property and equipment	(3,636)	(6,852)	(5,325)
Purchase of short-term investments	(56,989)		
Increase in intangible assets	(1,851)	(2,523)	(1,641)
Increase in restricted cash	(15)	(67)	
Cash paid for acquisitions	(1,981)		(187)
Net cash used in investing activities	(64,472)	(9,442)	(7,153)
Cash flows from financing activities:			
Proceeds from initial public offering, net of proceeds			47,849
Proceeds from issuance of long-term debt			20,075
Repayments on long-term debt	(450)	(30,436)	(10,158)

Proceeds from issuance of common stock	2,575	9,755	831
Excess tax benefits from share-based payment arrangements	215	1,889	144
Dividends paid		(13)	(37,350)
Purchase of treasury stock			(581)
Net cash provided by (used in) financing activities	2,340	(18,805)	20,810
Effect of foreign currency exchange rates on cash	155	246	(1,129)
Net increase (decrease) in cash and cash equivalents	(14,856)	50,177	41,351
Cash and cash equivalents at beginning of period	146,910	96,733	55,382
Cash and cash equivalents at end of period	$ 132,054	$ 146,910	$ 96,733
Supplemental disclosure of cash flow information:			
Cash paid for:			
Interest	$ 78	$ 872	$ 2,355
Income taxes	$ 39,075	$ 4,783	$ 25,911
Noncash investing and financing activities:			
Accretion of redemption value of convertible preferred stock	$	$	$ 4,837
Assets acquired under capital leases	$ 59	$ 17	$ 83

The accompanying notes are an integral part of these consolidated financial statements.

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MASIMO CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Company

Masimo Corporation, or the Company, is a global medical technology company that develops, manufactures and markets noninvasive patient monitoring products that improve patient care. The Company 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. The Company has also developed Masimo Rainbow SET products which measure multiple blood parameters, including carboxyhemoglobin, methemoglobin, PVI and total hemoglobin, and acoustic respiration rate. The Company develops, manufactures and markets a family of patient monitoring solutions which incorporate a monitor or circuit board and sensors, including both proprietary single-patient use and reusable sensors and cables. The Company considers both the pulse oximetry device (monitor or circuit board) and its sensors and cables to be products as defined in its statements of income. The Company sells to hospitals and the emergency medical services, or EMS, market through its direct sales force and distributors, and markets its circuit boards containing the Company s proprietary algorithm and software architecture to original equipment manufacturer, or OEM, partners.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Masimo Corporation, Masimo Laboratories, Inc. and SEDLine, Inc. which have been consolidated pursuant to authoritative guidance issued by the Financial Accounting Standards Board, or FASB. In addition, these consolidated financial statements include the accounts of Masimo Corporation s wholly-owned subsidiaries, Masimo Americas, Inc., Masimo Europe Ltd., Masimo Japan K.K., Masimo Canada ULC, Masimo Australia Pty. Ltd., Masimo Holdings L.P., Masimo International Sarl, Masimo International Technologies Sarl, Masimo China Medical Technology Co., Ltd., Masimo Hong Kong Limited and Masimo Asia Pacific PTE. Ltd., and Masimo Österreich GmbH. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates include: determination of accounts receivable allowances, inventory reserves, warranty reserves, rebate reserves, valuation of the Company s stock options, distributor channel inventory, royalty revenues, deferred revenue, property tax and uncertain income tax positions. Actual results could differ from those estimates.

Fair Value Measurements

Effective December 30, 2007, the Company adopted the authoritative guidance for fair value measurements issued by the FASB. This guidance defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. In February 2008, the FASB provided a one year deferral of the effective date for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Effective January 4, 2009, the Company adopted the authoritative guidance for non-financial assets and liabilities.

This guidance describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1 Quoted prices in active markets for *identical* assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for *similar* assets or liabilities; quoted prices in markets that are not active; or other inputs that can be corroborated by observable market data for

substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Effective December 30, 2007, the Company adopted FASB guidance that allowed an entity the irrevocable option to elect fair value for the initial and subsequent measurement for specified financial assets and liabilities on a contract-by-contract basis.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company did not elect the fair value option under this statement as to specific assets or liabilities. Therefore, through January 2, 2010, the Company has not recognized the net change in fair value of its financial assets and liabilities.

The estimated fair values of the Company s financial instruments, which include cash and cash equivalents, short-term investments, accounts receivable, accounts payable, accrued liabilities and income taxes payable, approximate their carrying values due to their short maturities. These items are classified as either Level 1 or Level 2 inputs.

Cash equivalents consist of highly liquid investments, with a maturity of three months or less when acquired, including U.S. Treasury bills and money market funds. The Company records these U.S. Treasury bills at cost and continues to carry those amounts at cost, which approximates fair value. The cost and fair value of the U.S. Treasury bills classified as cash equivalents at January 2, 2010, excluding accrued interest, were both $119.0 million. The fair value is based on quoted market prices in active markets for identical assets, a level 1 input.

The Company records money market funds at cost and continues to carry those amounts at cost which equals fair value. The fair value is based on quoted market prices in active markets for identical assets, a level 1 input. As of January 2, 2010, the cost and fair value of the Company s money market funds was equal to $1.7 million.

Short-term investments, totaling $57.0 million, consist of U.S. Treasury bills with a maturity between three months and one year at the date of purchase. These amounts are stated at cost which approximates fair value and is based on quoted market prices in active markets for identical assets, a level 1 input.

Fiscal Periods

The Company follows a conventional 52/53 week fiscal year and fiscal 2007 was designated as a 52 week fiscal year. Under a conventional 52/53 week fiscal year, a 52 week year includes four quarters of 13 fiscal weeks while a 53 week fiscal year includes three 13 week quarters and one 14 week quarter. Under the Company s fiscal year policy, each quarter and the year end will end on the Saturday corresponding to either the 13 or 14 week quarter. As a result of the adoption of the 52/53 week convention in fiscal 2007, the Company s first, second and third quarters ended on Saturday, March 31, June 30 and September 29, 2007, respectively, and its fiscal year ended on Saturday, December 29, 2007.

In fiscal 2008, the Company was on a 53 week fiscal calendar in which its first, second and third quarters ended on Saturday, March 29, June 28 and September 27, 2008, respectively. The Company s 2008 fiscal year ended on Saturday, January 3, 2009. For fiscal 2008, the first three quarters were 13 week quarters and the fourth fiscal quarter was a 14 week quarter. The additional week in fiscal 2008 did not have a significant impact on the Company s results of operations.

In fiscal 2009, the Company was on a 52 week fiscal calendar in which the Company s first, second and third quarters ended on Saturday, April 4, July 4 and October 3, 2009, respectively, and its fiscal year ended on Saturday, January 2, 2010. Each quarter in 2009 was a 13 week quarter.

Similar to fiscal 2009, fiscal 2010 will be a 52 week fiscal calendar in which the Company s first, second and third quarters will end on Saturday, April 3, July 3 and October 2, 2010, respectively, and its fiscal year will end on Saturday, January 1, 2011. Each quarter in 2010 will be a 13 week quarter.

Reclassifications

Certain amounts in the consolidated financial statements for prior periods have been reclassified to conform with current period presentation.

Cash and Cash Equivalents

As of January 2, 2010, the Company s cash balance was $11.4 million, comprised of checking and savings accounts. Additionally, the Company had cash equivalents of $120.7 million, consisting of $119.0 million of U.S. Treasury bills with a maturity of three months or less at the date of

purchase, and $1.7 million of money market funds, which are all highly liquid investments and readily convertible into known amounts of cash. As of January 3, 2009, the Company had $146.9 million in cash and cash equivalents. This was comprised of $125.5 million in U.S. Treasury bills with a maturity of three months or less, $13.6 million in money market funds and $7.8 million in checking and savings accounts balances. Interest income on cash and cash equivalents is accrued and recognized monthly.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Short-term investments

Short-term investments, which are held to maturity, consist of U.S. Treasury bills with a maturity between three months and one year when acquired. These amounts are stated at cost which approximates fair value. As of January 2, 2010, the Company had $57.0 million in short-term investments. During the year ended January 2, 2010, there were no realized gains or losses recognized. The Company did not have any short-term investments as of January 3, 2009.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of trade receivables recorded upon recognition of revenue for product revenues, reduced by reserves for estimated bad debts and returns. Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Credit is extended based on evaluation of the customer s financial condition. Collateral is not required. The allowance for doubtful accounts is determined based on historical write-off experience, current customer information and other relevant factors, including specific identification of past due accounts, based on the age of the receivable in excess of the contemplated or contractual due date. Accounts are charged off against the allowance when the Company believes they are uncollectible.

Changes in the allowance for doubtful accounts for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, were as follows (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Allowance for doubtful accounts, beginning of period	$ 1,300	$ 1,370	$ 1,625
Provision for (benefit from) doubtful accounts	733	108	(25)
Write off of uncollectible accounts	(61)	(178)	(230)
Allowance for doubtful accounts, end of period	$ 1,972	$ 1,300	$ 1,370

The accounts receivable balance was $38.9 million and $30.7 million, net of allowances for doubtful accounts.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a standard cost method, which approximates FIFO (first in, first out) and includes material, labor and overhead. Inventory reserves are recorded for inventory items that have become excess or obsolete or are no longer used in current production and for inventory that has a market price less than the carrying value in inventory.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets, which range from three to five years. Leasehold improvements are amortized over the lesser of the lease term or the estimated useful life of the improvements. Normal repair and maintenance costs are expensed as incurred, whereas significant improvements that materially increase values or extend useful lives are capitalized and depreciated over the remaining estimated useful lives of the related assets. Upon sale or retirement of depreciable assets, the related cost and accumulated depreciation or amortization are removed from the accounts and any gain or loss on the sale or retirement is recognized in income. For the years ended January 2, 2010, January 3, 2009 and December 29, 2007, depreciation of property and equipment, which includes amortization of equipment under capital leases, was $5.1 million, $5.0 million and $4.6 million, respectively.

Intangible Assets and Goodwill

Intangible assets consist primarily of patents and trademarks, and goodwill resulting from the acquisition of Andromed, Inc. in 2005. Costs related to patents and trademarks, which include legal and application fees, are capitalized and amortized over the estimated useful lives using the straight-line method. Patent and trademark amortization commences once final approval of the patent or trademark has been obtained. Patent costs are amortized over the lesser of 10 years or the patent s remaining legal life, which assumes renewals, and trademark costs over 17 years, and their associated amortization cost is included in general and administrative expense. For intangibles purchased in an asset acquisition or business combination, which mainly include patents and trademarks, the useful life is determined in the same manner as noted above. For the years ended January 2, 2010, January 3, 2009 and December 29, 2007, amortization of patents and trademarks was $708,000, $584,000 and $594,000, respectively. As of January 2, 2010 and January 3, 2009, the total costs of patents not yet amortizing was $3.2

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million and $2.7 million, respectively. As of January 2, 2010 and January 3, 2009, the total costs of trademarks not yet amortizing was $148,000 and $180,000, respectively. Costs to renew intangibles are capitalized and amortized over the remaining useful life of the intangible. For the year ended January 2, 2010, total renewal costs capitalized for patents and trademarks were $370,000 and $48,000, respectively. As of January 2, 2010, the weighted average number of years until the next renewal is 2 years for patents, and 6 years for trademarks.

The Company s policy is to renew its patents and trademarks. Management continually evaluates the amortization period and carrying basis of patents and trademarks to determine whether any events or circumstances warrant a revised estimated useful life or reduction in value. Capitalized application costs are charged to operations when it is determined that the patent or trademark will not be obtained or is abandoned.

Impairment

The impairment evaluation for goodwill is conducted annually as of the balance sheet date or more frequently if events or changes in circumstances indicate that an asset might be impaired. The evaluation is performed using a two-step process. In the first step, the estimated fair value of the reporting unit is compared with its carrying amount, including goodwill. Since the Company has one reporting unit, the estimated fair value of goodwill is determined by the Company s stock market valuation compared to its net assets, excluding goodwill. If the estimated fair value is less than the carrying amount, then a second step must be completed in order to determine the amount of the goodwill impairment. In the second step, the implied fair value of the goodwill is determined by allocating the fair value of all of the reporting unit s assets and liabilities other than goodwill in a manner similar to a purchase price allocation. The resulting implied fair value of the goodwill that results from the allocation is then compared to the carrying amount of the goodwill and an impairment charge is recorded for the difference.

The Company reviews long lived assets and identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted operating cash flow expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair value of the asset. Long-lived assets to be disposed of are reported at the lower of carrying amount or fair value less costs to sell.

No impairment of goodwill, intangible assets, or other long lived assets was recorded during the years ended January 2, 2010, January 3, 2009 or December 29, 2007.

Restricted Cash

In May 2004, the Company entered into a facilities sublease which required the Company to deliver an irrevocable standby letter of credit in the amount of $450,000 to the sub-landlord. In connection with the letter of credit issued by Comerica Bank, the Company was required to deposit $450,000 into a restricted account. In December 2005, the Company entered into a facilities lease in France which required the Company to deliver an irrevocable standby letter of credit in the amount of 43,000 ($61,000 as of January 2, 2010 and $60,000 as of January 3, 2009) to the landlord. In connection with the letter of credit issued by Banque Nationale de Paris, the Company was required to deposit 43,000 into a restricted account. In December 2008 and July 2009, the Company entered into facilities leases in Switzerland which required the Company to deposit CHF 22,000 ($20,000 as of January 2, 2010 and January 3, 2009) and CHF 17,000 ($16,000 as of January 2, 2010), respectively, in a restricted bank account on behalf of the landlord. Additionally, in January and July 2008, the Company was required to deposit $9,000 and $37,000, respectively, into restricted bank accounts by governmental agencies. All of these amounts are shown as restricted cash on the accompanying consolidated balance sheets.

Income Taxes

The Company accounts for income taxes in accordance with current authoritative accounting guidance, whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered. The Company evaluates the need to establish a valuation allowance for deferred tax assets based on positive and negative evidence including past operating results, the amount of existing temporary differences to be recovered and expected future taxable income. A valuation allowance to reduce the deferred tax assets is established when it is more likely

than not that some or all of the deferred tax assets will not be realized.

On January 1, 2007, the Company adopted an accounting standard which prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken

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in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities.

Revenue Recognition and Deferred Revenue

The Company follows the current authoritative guidance for software revenue recognition. Based on these requirements, the Company recognizes revenue when: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable and (iv) collectibility is reasonably assured. Revenue from the sale of the Company s products is generally recognized when title and risk of loss transfers to the customer upon shipment, the terms of which are shipping point or destination. The Company uses contracts and customer purchase orders to determine the existence of an arrangement. The Company uses shipping documents and/or third-party proof of delivery to verify that title has transferred. The Company assesses whether the fee is fixed or determinable based upon the terms of the agreement associated with the transaction. To determine whether collection is probable, the Company assesses a number of factors but primarily relies upon past transaction history with the customer, if available.

The Company derives revenue primarily from four sources: (i) direct sales of pulse oximetry and related products to end user hospitals, emergency medical response organizations and other direct customers; (ii) direct sales of pulse oximetry and related products to distributors who then typically resell to end user hospitals, emergency medical response organizations and other direct customers; (iii) direct sales of integrated circuit boards and sensors to OEM customers who both incorporate the Company s embedded software technology into their multi-parameter monitoring devices and, resell the Company s sensors; (iv) long-term sales contracts to end user hospitals in which the Company may provide up front monitoring equipment at no charge in exchange for a multi-year sensor purchase commitment.

The Company enters into agreements to sell pulse oximetry and related products and services as well as multiple deliverable arrangements that include various combinations of products and services. While the majority of the Company s sales transactions contain standard business terms and conditions, there are some transactions that contain non-standard business terms and conditions. As a result, contract interpretation is sometimes required to determine the appropriate accounting including: (i) whether an arrangement exists; (ii) how the arrangement consideration should be allocated among the deliverables if there are multiple deliverables; (iii) if fair value can be determined for each deliverable based on vendor specific objective evidence, or VSOE; (iv) when to recognize revenue on the deliverables; and (v) whether undelivered elements are essential to the functionality of the delivered elements. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

The Company s sales under long-term sales contracts are generally structured such that the Company agrees to provide up-front and at no charge certain monitoring equipment, installation, training and ongoing warranty support in exchange for the hospital s agreement to purchase sensors over the term of the agreement, which ranges from three to six years. The Company has determined that its patented algorithm and software architecture, which resides within the monitors, is more than incidental to the product as a whole. The Company has also determined that the non-software deliverables (i.e. sensors, adapter cables, etc.) are considered essential to the functionality of the delivered elements. Furthermore, no payments are due to the Company from the hospital customer until sensors are shipped or delivered to the hospital at fixed prices per sensor over the term of the arrangement. Accordingly, the Company does not recognize any revenue when the monitoring and related equipment is delivered to the hospitals and installation and training is complete. The Company recognizes revenue for all of the delivered elements, on a pro-rata basis, as the sensors are delivered under the long-term sales contract. The cost of the monitoring equipment initially placed at the hospitals is deferred and amortized to cost of goods sold over the life of the underlying long-term sensor contract. In the event that the monitoring equipment is delivered over a period of time, revenue is deferred and recognized on a proportional basis relative to the number of units of the monitoring equipment delivered over time.

In situations where VSOE of fair value does not exist for certain undelivered elements, the entire contract product revenue and corresponding cost of goods sold are deferred until either the element is delivered, VSOE of fair value is established, or the obligation to deliver the element no longer exists. During the years ended January 2, 2010, January 3, 2009 and December 29, 2007, $1.2 million, $3.6 million and $4.5 million, respectively, of contract product revenue was deferred related to contracts for which VSOE of fair value was not established for undelivered specified hardware upgrade rights. Related deferred costs of $451,000, $1.3 million and $1.5 million were deferred in the same 2009, 2008 and 2007 periods, respectively. During the years ended January 2, 2010, January 3, 2009 and December 29, 2007 previously deferred revenue of $7.4 million, $3.5 million, and $2.0 million, respectively, was recognized related to such contracts with specified hardware upgrade rights. Related deferred costs of $2.8 million, $1.3 million, and $718,000 were expensed during the same 2009, 2008 and 2007 periods, respectively.

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The Company provides certain end-user hospitals with the ability to purchase sensors under rebate programs. Under these programs, the end user hospitals may earn rebates based on their purchasing activity. The Company estimates and provides allowances for these programs at the time of sales as a reduction to revenue.

Sales to the Company s distributors are recognized on the sell-through method. The Company s distributors purchase primarily sensor products which they then resell to hospitals that are typically fulfilling their purchase obligation to the Company under the end-user hospital s long-term sensor sales contract. Upon shipment to the distributor, revenue is deferred until the Company s commitment to its end-user hospital is fulfilled, which occurs when the sensors are sold by the distributor to the end-user hospital.

Certain of the Company s distributors purchase products at specified distributor pricing and then may resell the product to end-user hospitals with whom the Company has separate pricing agreements. Where distributor prices are higher than end-user hospital contracted prices, the Company provides rebates to these distributors for the difference between distributor prices and end-user hospital prices. The Company estimates and provides allowances for the rebate programs at the time of sales as a reduction to revenue and accounts receivable.

In general, customers do not have a right of return for credit or refund. However, the Company allows returns under certain circumstances. At the end of each period, the Company estimates and accrues for these returns as a reduction to revenue and accounts receivable. The Company estimates returns based on several factors, including contractual limitations and past returns history.

In September 2005, the U.S. Federal Court of Appeals ruled that Mallinckrodt, Inc., now part of Covidien (formerly Tyco Healthcare), and one of its subsidiaries, Nellcor Puritan Bennett, Inc., collectively referred to as Nellcor, infringed Masimo patents and ordered the lower court to enjoin Nellcor s infringing products. On January 17, 2006, the Company settled all existing patent litigation with Covidien. Under terms of the agreement, in exchange for the Company s covenant not to sue Covidien on future sales of its new products, Covidien agreed to pay the Company royalties on its total U.S. pulse oximetry revenue at least through March 14, 2011, which the Company records as royalty revenue. The Covidien royalties are recognized by the Company based on U.S. sales of Covidien s infringing products reported to the Company by Covidien. The Company recognizes royalty revenue based on the royalty rate per the settlement agreement multiplied by its estimate of Covidien s sales for each quarter. This estimate is adjusted prospectively when the Company receives the Covidien royalty report, approximately 60 days after the end of the quarter. At January 2, 2010 and January 3, 2009, the Company has recorded a royalty receivable of $11.5 million and $11.4 million, respectively, related to estimated royalty payments owed by Covidien to the Company.

Taxes Collected From Customers and Remitted to Governmental Authorities

Pursuant to authoritative guidance, the Company s policy is to present taxes collected from customers and remitted to governmental authorities on a net basis.

Product Warranty Expense

The Company provides a product warranty against defects in material and workmanship for a period ranging from six months to one year, depending on the product type. In the case of long-term sales agreements, the Company typically warranties the products for the term of the agreement, which ranges from three to six years. In traditional sales activities, including direct and OEM sales, the Company establishes an accrual for the estimated costs of the product warranty at the time of revenue recognition. Estimated product warranty expenses are recorded as an accrued liability, with a corresponding provision to cost of sales. In end-user hospital contracts, revenue related to an extended product warranty is recognized over the life of the contract, while the product warranty costs related to the end-user hospital contracts are expensed as incurred.

Changes in the product warranty accrual were as follows (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Warranty accrual, beginning of period	$ 334	$ 649	$ 599
Provision for warranty costs	2,220	1,646	1,482
Warranty expenditures	(2,200)	(1,961)	(1,432)
Warranty accrual, end of period	$ 354	$ 334	$ 649

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Shipping and Handling Costs and Revenue

All shipping and handling costs are expensed as incurred and are recorded as a component of cost of sales. Charges for shipping and handling billed to customers are included as a component of product revenue in accordance with authoritative accounting guidance.

Advertising Costs

Advertising costs are expensed as incurred. These costs are included in selling, general and administrative expense in the accompanying consolidated statements of income. Advertising costs for the years ended January 2, 2010, January 3, 2009, and December 29, 2007 were $5.7 million, $7.7 million and $6.4 million, respectively.

Research and Development

Costs related to research and development activities are expensed as incurred. These costs include personnel costs, materials, depreciation and amortization on associated tangible and intangible assets and an allocation of facility costs, all of which are directly related to research and development activities.

Software Development Costs

In accordance with authoritative accounting guidance, costs related to the research and development of new software products and enhancements to existing software products are expensed as incurred until technological feasibility of the product has been established, at which time such costs are capitalized, subject to expected recoverability. For the years ended January 2, 2010 and January 3, 2009, the Company capitalized $162,000 and $844,000 of software development costs, respectively. The capitalized costs are amortized over the estimated life of the products, or seven years. The Company amortized $201,000, $116,000 and $58,000 for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively. The Company had unamortized software development costs of $1.1 million and $1.2 million at January 2, 2010 and January 3, 2009, respectively, which is included within intangible assets on the accompanying consolidated balance sheets.

Foreign Currency Translation

The Company s international headquarters is in Switzerland, and its functional currency is the U.S. dollar. The Company has several foreign sales support subsidiaries that maintain foreign offices, of which the most significant are in Japan and Europe. The functional currencies of these subsidiaries are the Japanese yen and Euro, respectively. The Company also has subsidiaries in Canada, Australia, Singapore, Hong Kong and China. The functional currencies of these subsidiaries are the Canadian dollar, Australian dollar, Singapore dollar, Hong Kong dollar and Chinese yuan, respectively.

The Company transacts with foreign customers in currencies other than the U.S. dollar. Therefore, it experiences realized and unrealized foreign currency gains or losses on foreign denominated receivables. In addition, certain intercompany transactions give rise to realized and unrealized foreign currency gains or losses. Also, any other transactions between the Company or its subsidiaries and a third party, denominated in a currency different from the functional currency, are foreign currency transactions. Realized and unrealized foreign currency gains or losses are included in the Company s statements of income as incurred and are converted to U.S. dollars at average exchange rates for a respective period. These transaction gains or (losses) were $(236,000), $(414,000) and $1.2 million for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively.

Assets and liabilities of foreign subsidiaries, whose functional currency is not the U.S. dollar, are translated into U.S. dollars at the rate of exchange at the balance sheet date. Statement of income amounts are translated at the average monthly exchange rates for the respective periods. Translation gains and losses are included as a component of accumulated other comprehensive income (loss) within stockholders equity.

Comprehensive Income (Loss)

Authoritative accounting guidance establishes requirements for reporting and disclosure of comprehensive income (loss) and its components. Comprehensive income (loss) includes foreign currency translation adjustments that have been excluded from net income and is presented in the accompanying consolidated statements of stockholders equity.

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Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) included in the Company s consolidated statements of stockholders equity consists only of foreign currency translation adjustments. The change in accumulated other comprehensive income (loss) is summarized as follows (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Other comprehensive income (loss), beginning of period	$ (7)	$ (1,034)	$ (317)
Foreign currency translation adjustment	70	1,027	(717)
Tax benefit (expense)			
Other comprehensive income (loss), end of period	$ 63	$ (7)	$ (1,034)

Segment Information

The Company uses the management approach in determining reportable business segments. The management approach designates the internal organization used by management for making operating decisions and assessing performance as the source for determining the Company s reportable segments. Based on this assessment, management has determined it operates in one reportable business segment, which is comprised of patient monitoring and related products.

Net Income Per Common Share

Basic net income per common share is computed by dividing net income attributable to Masimo Corporation for the period by the weighted average number of common shares outstanding during the period. Net income attributable to Masimo Corporation in 2007 is calculated in accordance with the accounting guidance on earnings per share which establishes standards regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder of such securities to participate in dividends and earnings of the Company. Pursuant to accounting guidance, the two-class method of computing basic earnings per share is required when an entity has participating securities. Dividends must be calculated for the participating security on undistributed earnings and are a reduction in the net income attributable to common shareholders. The Company s Series A through G preferred stock were participating securities as they had the right to dividends in the event dividends were declared on common stock. Assumed dividends on undistributed earnings were allocated as if the entire net income were distributed and were based on the relationship of the weighted average of common shares outstanding and the weighted average of common shares outstanding if the preferred stock were converted into common stock.

Upon closing of the Company s initial public offering on August 13, 2007, all of the outstanding convertible preferred shares were converted into common shares. Therefore, subsequent to this stock conversion, the Company used the if-converted method to calculate earnings per share. Accordingly, for the year ended December 29, 2007, the Company calculated net income per share using the two-class method for the first 224 days of the period and the if-converted method for the remainder of the period. Income was allocated between these periods on a straight-line basis over the number of days of the respective periods.

Diluted net income per common share is computed by dividing the net income attributable to common stockholders for the period by the weighted average number of common and potential common shares outstanding during the period, if the effect of potential common shares is dilutive. Potential common shares include incremental shares of common stock issuable upon the exercise of stock options and warrants. Employee stock options to purchase approximately 3,601,961, 1,894,181 and 572,175, shares for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively, were outstanding, but were not included in the computation of diluted earnings per share because their effect would have been antidilutive. A reconciliation of the numerator and denominator used in the calculation of basic and diluted net

income per common share follows (in thousands, except share and per share data):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Net income attributable to common stockholders:			
Net income two class method	N/A	N/A	$ 26,075
Accretion of preferred stock	N/A	N/A	(4,837)
Undistributed income attributable to preferred stockholders	N/A	N/A	(14,339)
Net income attributable to common stockholders (A)	N/A	N/A	$ 6,899

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	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Basic net income per common share:			
Weighted average common shares outstanding two class method (B)	N/A	N/A	16,654,586
Basic earnings per share for period during which two classes of equity securities were outstanding (A/B)	N/A	N/A	$ 0.41
Net income for period during which single class of equity securities was outstanding (C)	$ 53,228	$ 31,927	$ 16,180
Weighted average common shares outstanding single class[1] (D)	57,602,646	56,320,712	54,660,216
Basic net income per share for period during which single class of equity securities was outstanding (C/D)	$ 0.92	$ 0.57	$ 0.30
Basic net income per common share	**$ 0.92**	**$ 0.57**	**$ 0.71**
Diluted net income per common share:			
Weighted average common shares outstanding two class method	N/A	N/A	16,654,586
Diluted common share equivalent: stock options	N/A	N/A	4,078,286
Total diluted common share and share equivalents two class (E)	N/A	N/A	20,732,872
Diluted earnings per share for period during which two classes of equity securities were outstanding (A/E)	N/A	N/A	$ 0.33
Net income for period during which single class of equity securities was outstanding (F)	$ 53,228	$ 31,927	$ 16,180
Weighted average common shares outstanding single class[1]	57,602,646	56,320,712	54,660,216
Diluted common share equivalent: stock options	2,568,202	3,869,623	5,168,982
Total diluted common share and share equivalents single class (G)	60,170,848	60,190,335	59,829,198
Diluted net income per share for period during which single class of equity securities was outstanding (F/G)	$ 0.88	$ 0.53	$ 0.27
Diluted net income per common share	**$ 0.88**	**$ 0.53**	**$ 0.60**

(1) Weighted average shares outstanding used to compute basic net income per share after conversion of convertible preferred stock; one class of common shares was outstanding for the period from August 13, 2007 to December 29, 2007.

Share-Based Payment

On January 1, 2006, the Company began to expense the estimated fair value of employee stock options and similar awards based on the fair value of the award on the date of grant, in accordance with the current authoritative accounting guidance. The cost is recognized over the period during which an employee is required to provide services in exchange for the award, which is usually the vesting period. The Company adopted the accounting standard using the prospective transition method that applies to awards granted, modified or canceled subsequent to the date of

adoption. Prior periods were not revised for comparative purposes.

Options granted prior to January 1, 2006, were accounted for using the intrinsic value method and using the minimum value method for its pro forma disclosures, unless such options are modified, repurchased or cancelled. The cash flows related to the reduction of income taxes paid as a result of the deduction triggered by employee exercise of stock options granted or modified prior to January 1, 2006 will continue to be presented as an operating cash flow.

New Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update 2009-13, or ASU No. 09-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements* . ASU No. 09-13 modifies the requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. This update shall be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Earlier application as of the beginning of the Company s fiscal year is

MASIMO CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

permitted, provided it has not previously issued financial statements for any period within that year. The Company is currently evaluating what impact this update will have on its consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update 2009-14, or ASU No. 09-14, *Software (Topic 985): Certain Revenue Arrangements That Include Software Elements*. ASU No. 09-14 modifies the software revenue recognition guidance to exclude from its scope tangible products that contain both software and non-software components that function together to deliver a product s essential functionality. ASU No. 09-14 is effective for fiscal years beginning after June 15, 2010 and may be applied retrospectively or prospectively for new or materially modified arrangements. Earlier application as of the beginning of the Company s fiscal year is permitted, provided it has not previously issued financial statements for any period within that year. The Company is currently evaluating what impact this update will have on its consolidated financial statements.

In December 2009, the FASB issued Accounting Standards Update 2009-17, or ASU No. 09-17, *Consolidations (Topic 810) Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*, which codifies FASB Statement No. 167, Amendments to FASB Interpretation No. 46(R). ASU No. 09-17 represents a revision to former FASB Interpretation No. 46 (Revised December 2003), *Consolidation of Variable Interest Entities*, and changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity s purpose and design and the reporting entity s ability to direct the activities of the other entity that most significantly impact the other entity s economic performance. ASU No. 09-17 is effective for fiscal years beginning after November 15, 2009. Early application is not permitted. The Company does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

In January 2010, the FASB issued Accounting Standards Update 2010-06, or ASU No. 10-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements*. ASU No. 10-06 requires an entity to disclose separately the amounts of significant transfers in and out of Level 1 and 2 fair value measurements, and describe the reasons for the transfers. Also, it requires additional disclosure regarding purchases, sales, issuances and settlements of Level 3 measurements. ASU No. 10-06 is effective for interim and annual periods beginning after December 15, 2009, except for the additional disclosure of Level 3 measurements, which is effective for fiscal years beginning after December 15, 2010. The Company does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

3. Variable Interest Entities (VIEs)

Masimo Laboratories, Inc.

Masimo Laboratories, Inc., or Masimo Labs, is an independent entity spun off from the Company to its stockholders in 1998. The Company is a party to a cross-licensing agreement with Masimo Labs, which was recently amended and restated effective January 1, 2007, or the Cross-Licensing Agreement, that governs each party s rights to certain intellectual property held by the two companies. Under the Cross-Licensing Agreement, the Company exclusively licenses from Masimo Labs the right to make and distribute products in the professional medical caregiver markets, or the Masimo Market, that utilize Rainbow technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation, and total hemoglobin, which includes hematocrit. To date, the Company has developed and commercially released devices that measure carbon monoxide, methemoglobin and total hemoglobin using licensed Rainbow technology. The Company also has the option to obtain the exclusive license to make and distribute products that utilize Rainbow technology for the measurement of other non-vital signs parameters, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver.

From May 1998 through May 2009, Masimo Labs contracted the services of the Company s employees for the development of Rainbow technology. The Company paid Masimo Labs for the option to market and develop products based on Masimo Labs technology in defined markets. Through December 2005, the Company had paid Masimo Labs $7.5 million in option fees and nearly all these option fees were used by Masimo Labs to repay the Company for the services that the Company had provided to Masimo Labs. In addition, through September 2009, the Company exercised three licenses, for $2.5 million each, for the right to market products based on the new carbon monoxide, methemoglobin and total hemoglobin parameter technologies developed by Masimo Labs. Effective January 1, 2007, the Company entered into a Services

Agreement with Masimo Labs to govern the general and administrative services the Company currently provides to Masimo Labs.

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The Cross-Licensing Agreement requires the Company to pay certain royalties on products incorporating the licensed Rainbow technology. The royalty is up to 10% of the Rainbow royalty base, which will include handhelds, tabletop and multi-parameter devices. Beginning in 2009, for hospital contracts where Masimo places equipment and enters into a sensor contract, the Company will pay a royalty to Masimo Labs on the total sensor contract revenues based on the ratio of Rainbow enabled devices to total devices.

The Company is also subject to certain specific annual minimum aggregate royalty payments. These minimum aggregate royalty payments were $4.0 million for 2009, $3.5 million for 2008 and $3.2 million for 2007. In 2010 and each year thereafter, the minimum aggregate royalty payment is $5.0 million. In addition, in connection with a change in control, as defined in the Cross-Licensing Agreement, the minimum aggregate annual royalties for all licensed Rainbow parameters payable to Masimo Labs will increase to $15.0 million for 2010, and each year thereafter, and up to $2.0 million per year for each additional Rainbow parameter.

In order to accelerate the product development of the Company s total hemoglobin spot check measurement device, in February 2009, the Company agreed to fund additional Masimo Labs engineering expenses. Specifically, these expenses included third party engineering materials and supplies expense as well as 50% of total Masimo Labs engineering and engineering related payroll expenses from April 2009 until completion of the product development efforts. These expenses totaled $2.7 million in 2009.

Pursuant to authoritative accounting guidance, Masimo Labs is consolidated within the Company s financial statements for all periods presented. The Company is required to consolidate since it was deemed to be the primary beneficiary of Masimo Labs activities. This determination was based on the obligation to absorb the expected losses, as well as exercising significant influence over the operations and decision making of Masimo Labs. Accordingly, all inter-company royalties, option and license fees and other charges between the Company and Masimo Labs as well as all intercompany payables and receivables have been eliminated in the consolidation. Also, all direct engineering expenses that have been incurred by the Company and charged to Masimo Labs have not been eliminated and are included as research and development expense in its consolidated statements of income.

SEDLine, Inc.

SEDLine, Inc., or SEDLine, a privately held entity that was formed in December 2009, is a company with the mission to expand the scope and applications for neuromonitoring. This entity manufactures and sells brain function monitoring devices to hospitals. The Company made loans to SEDLine totaling $3.0 million during 2009. These loans, which are secured by the assets of SEDLine, bear an initial interest rate of 7% and may be converted into equity upon certain events. These loans, if converted to equity, would entitle the Company to a 39% ownership in SEDLine. Pursuant to an investment agreement with SEDLine, the Company is obligated to provide additional loans up to $1.5 million subject to SEDLine achieving certain product development milestones. Concurrent with the investment agreement, the Company and SEDLine entered into a Merger Agreement, whereby the Company has the option to acquire SEDLine at certain pre-determined valuations. Also, in December 2009, the Company purchased two patents from SEDLine for $500,000. Pursuant to authoritative accounting guidance, it was determined that the Company is the primary beneficiary of SEDLine for 2009 and therefore is required to consolidate SEDLine s financial statements within the Company s financial statements.

In December 2009 and concurrent with the Company s loan to SEDLine, SEDLine purchased the assets of its neuromonitoring business from another company for $1.6 million. SEDLine had no revenue and de minimis expenses in 2009. The Company has not been required to collateralize any of SEDLine s obligations, and creditors of SEDLine have no recourse to the general credit of the Company.

For the foreseeable future, the Company anticipates that it will continue to consolidate each VIE pursuant to the current authoritative accounting guidance; however, in the event that the Company no longer has (1) the power to direct the activities that most significantly impact the VIE s economic performance and (2) the right to receive benefits or obligation to absorb losses which could be significant to the VIE, the Company may discontinue consolidating either entity.

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Below are condensed consolidating schedules of the Balance Sheets as of January 2, 2010 and January 3, 2009, and Statements of Income for the years ended January 2, 2010, January 3, 2009 and December 29, 2007 reflecting Masimo Corporation, Masimo Labs, SEDLine and related eliminations (in thousands).

	January 2, 2010						January 3, 2009			
Balance Sheets:	**Corp**	**Labs**	**Labs Elim**	**SEDLine**	**SEDLine Elim**	**Total**	**Corp**	**Labs**	**Labs Elim**	**Total**
ASSETS										
Cash and cash equivalents	$ 129,841	$ 464	$	$ 1,749	$	$ 132,054	$ 146,684	$ 226	$	$ 146,910
Short-term investments	56,989					56,989				
Accounts receivable, net	50,397	363	(363)			50,397	42,090			42,090
Inventories	30,687	245		627		31,559	27,400			27,400
Prepaid expenses	5,370	77				5,447	4,623	157		4,780
Deferred tax asset, current	10,406	1,179				11,585	9,336	1,175		10,511
Other current assets	1,357					1,357	551	3,002	(3,002)	551
Deferred cost of goods sold	28,163					28,163	28,431			28,431
Property and equipment, net	11,087	575		20		11,682	12,566	413		12,979
Deferred tax asset, long term	11,043	457				11,500	8,196	585		8,781
Intangible assets, net	13,373	1,883	(6,031)	604		9,829	12,771	1,045	(6,406)	7,410
Other assets, long term	8,747	2,966	(2,930)		(3,000)	5,783	3,472	33		3,505
Total assets	$ 357,460	$ 8,209	$ (9,324)	$ 3,000	$ (3,000)	$ 356,345	$ 296,120	$ 6,636	$ (9,408)	$ 293,348
LIABILITIES										
Accounts payable	$ 15,702	$ 1,014	$	$	$	$ 16,716	$ 15,776	$ 138	$	$ 15,914
Accrued liabilities and compensation	27,466	444	(363)			27,547	23,920	255	(3,002)	21,173
Income taxes payable	459	18				477	10,862			10,862
Deferred revenue, current	14,641	375	(375)			14,641	17,233	375	(375)	17,233
Current portion of long-term debt	60					60	465			465
Deferred revenue, long-term	270	5,656	(5,656)			270	213	6,031	(6,031)	213
Long term debt, less current portion	171			3,000	(3,000)	171	157			157
Other liabilities	9,705		(2,930)			6,775	7,830	3		7,833
STOCKHOLDERS EQUITY (DEFICIT)										
Common stock	58	10	(10)			58	57	10	(10)	57
Treasury stock	(1,209)					(1,209)	(1,209)			(1,209)
Additional paid in capital	195,690	170	(170)			195,690	179,666	97	(97)	179,666
Accumulated other comprehensive income (loss)	63					63	(7)			(7)
Retained earnings (deficit)	94,384	522	(794)			94,112	41,157	(273)		40,884

Total Masimo Corporation stockholders equity (deficit)	288,986	702	(974)			288,714	219,664	(166)	(107)	219,391
Noncontrolling interest			974			974			107	107
Total stockholders equity (deficit)	288,986	702				289,688	219,664	(166)		219,498
Total liabilities and stockholders equity (deficit)	$ 357,460	$ 8,209	$ (9,324)	$ 3,000	$ (3,000)	$ 356,345	$ 296,120	$ 6,636	$ (9,408)	$ 293,348

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Year ended January 2, 2010				Year ended January 3, 2009				Year ended December 29, 2007			
Statement of Income:	**Corp**	**Labs**	**Labs Elim**	**Total**	**Corp**	**Labs**	**Elim**	**Total**	**Corp**	**Labs**	**Elim**	**Total**
Total revenue	$ 349,115	$ 4,375	$ (4,375)	$ 349,115	$ 307,074	$ 3,875	$ (3,875)	$ 307,074	$ 256,286	$ 3,527	$ (3,527)	$ 256,286
Cost of good sold	104,313		(4,000)	100,313	92,954		(3,500)	89,454	76,760		(3,154)	73,606
Gross profit (loss)	244,802	4,375	(375)	248,802	214,120	3,875	(375)	217,620	179,526	3,527	(373)	182,680
Operating expenses:												
Research and development	29,656	2,045		31,701	23,065	2,430		25,495	21,065	1,895		22,960
Selling, general and administrative	133,781	1,171	(375)	134,577	119,264	1,180	(375)	120,069	90,702	905	(373)	91,234
Antitrust litigation	298			298	706			706	1,537			1,537
Total operating expenses	163,735	3,216	(375)	166,576	143,035	3,610	(375)	146,270	113,304	2,800	(373)	115,731
Operating income	81,067	1,159		82,226	71,085	265		71,350	66,222	727		66,949
Non-operating income (expense)	(46)			(46)	1,038	3		1,041	1,173			1,173
Income before provision for (benefit from) income taxes	81,021	1,159		82,180	72,123	268		72,391	67,395	727		68,122
Provision for (benefit from) income taxes	27,793	365		28,158	40,483	(19)		40,464	25,555	312		25,867
Net income including noncontrolling interest	53,228	794		54,022	31,640	287		31,927	41,840	415		42,255
Accretion of preferred stock									(4,837)			(4,837)
Undistributed income attributable to preferred stockholders									(14,339)			(14,339)
Net income attributable to noncontrolling interest			(794)	(794)								
Net income attributable to Masimo Corporation	$ 53,228	$ 794	$ (794)	$ 53,228	$ 31,640	$ 287	$	$ 31,927	$ 22,664	$ 415	$	$ 23,079

Note: SEDLine s Statement of Income is not separately disclosed for the year ended January 2, 2010, since it did not have any revenues and its expenses were de minimis.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Related Party Transactions

For the year ended December 29, 2007, two of the Company s customers and one third-party vendor were stockholders of the Company, and were considered to be related parties. They were not considered to be related parties during the year ended January 3, 2009 or January 2, 2010, as a result of their disposal of Masimo common stock in 2008.

Sales to these two customers for the year ended December 29, 2007 was $20.4 million. Also, the Company purchased certain inventory from one of the stockholders referred to in the preceding paragraph. Total purchases from this stockholder for the year ended December 29, 2007 was $2.4 million.

The Company made payments of $3.6 million for the year ended December 29, 2007 to one of the Company s stockholders noted above for legal services.

As of January 2, 2010 and January 3, 2009, the Company had amounts due from employees of $242,000 and $239,000, respectively. These amounts are classified in other assets in the accompanying consolidated balance sheets.

The Company s Chief Executive Officer has been a member of the board of directors of Saba Software, Inc., a human capital development and management solutions provider, since 1997. The Company has paid Saba Software $16,000, $84,000 and $51,000 for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively, for various software products and services.

5. Inventories

Inventories consist of the following (in thousands):

	January 2, 2010	January 3, 2009
Raw materials	$ 18,259	$ 17,678
Work in-process	3,949	2,001
Finished goods	9,351	7,721
Total	$ 31,559	$ 27,400

Finished goods inventory held by distributors was $1.8 million and $1.7 million as of January 2, 2010 and January 3, 2009, respectively.

6. Property and Equipment

Property and equipment, net consists of the following (in thousands):

	January 2, 2010	January 3, 2009
Machinery and equipment	$ 14,924	$ 13,537
Tooling	6,809	5,979
Computer equipment	5,595	5,338
Furniture and office equipment	2,236	2,088

Vehicles	45	45
Leasehold improvements	5,264	3,513
Demonstration units	2,744	2,853
	37,617	33,353
Accumulated depreciation and amortization	(26,034)	(21,467)
Construction-in-progress	99	1,093
Total	$ 11,682	$ 12,979

The gross value of furniture and office equipment under capital lease obligations was $272,000 and $446,000 as of January 2, 2010 and January 3, 2009, respectively, with accumulated amortization of $90,000 and $264,000, respectively.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Intangible Assets

Intangible assets, net consist of the following (in thousands):

	January 2, 2010	January 3, 2009
Cost		
Patents	$ 11,140	$ 8,074
Trademarks	940	833
Capitalized software development costs	1,563	1,401
Covenant not to compete	40	40
Total cost	13,683	10,348
Accumulated amortization		
Patents	(3,171)	(2,510)
Trademarks	(221)	(174)
Capitalized software development costs	(429)	(229)
Covenant not to compete	(33)	(25)
Total accumulated amortization	(3,854)	(2,938)
Net carrying amount	$ 9,829	$ 7,410

For the years ended January 2, 2010, January 3, 2009 and December 29, 2007, total amortization expense was $917,000, $708,000 and $660,000, respectively.

Estimated amortization expense for each of the fiscal years are as follows (in thousands):

2010	$ 1,049
2011	957
2012	875
2013	785
2014	734
Thereafter	5,429
Total	$ 9,829

During the year ended January 2, 2010, the Company acquired patents in the amount of $1.5 million, which are being amortized over a weighted average amortization period of 9.6 years.

8. Long-Term Debt and Capital Lease Obligations

Long-term debt consists of the following (in thousands):

	January 2, 2010	January 3, 2009
Financing arrangements	$	$ 395
Total debt		395
Less current portion of long-term debt		(395)
Long-term portion	$	$

During the year ended January 2, 2010, the Company paid off its entire long-term debt balance. There are no additional amounts available for future borrowing under this arrangement. As of January 3, 2009, the Company had an arrangement with a third party medical equipment financing company, which allowed for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements.

Capital lease obligations consist of the following (in thousands):

	January 2, 2010	January 3, 2009
Capital lease obligations	$ 231	$ 227
Less current portion of capital lease obligations	(60)	(70)
Long-term portion	$ 171	$ 157

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The Company currently has six capital leases outstanding, all for office equipment. The interest rates on these capital leases range from 5.2% to 8.8%. These capital leases mature on various dates between March 2011 and May 2014.

Future maturities of capital lease obligations for each of the fiscal years are as follows (in thousands):

2010	$ 60
2011	50
2012	47
2013	46
2014	28
Total	$ 231

9. Other Liabilities, Long-Term

Other long-term liabilities consist of the following (in thousands):

	January 2, 2010	January 3, 2009
Unrecognized tax benefit	$ 6,632	$ 7,206
Deferred rent, long-term	79	49
Other	64	578
Total other liabilities, long-term	$ 6,775	$ 7,833

The unrecognized tax benefit relates to the Company s long-term portion of tax liability, under recent authoritative accounting guidance which became effective on January 1, 2007. This guidance prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. See Note 14 for further details.

10. Stockholders Equity

Stock Split

In May 2007 and June 2007, the Company s Board of Directors and stockholders, respectively, approved a forward stock split of the Company s common stock at a ratio of three shares for every one share previously outstanding. The forward stock split was effective on June 25, 2007. As a result of the stock split, the conversion price of each outstanding share of the Company s preferred stock was reduced to one-third of the pre-stock split conversion price of such preferred stock, and effectively increased the conversion ratio to three shares of common stock for one share of preferred stock. All common stock share and per share data included in these consolidated financial statements reflect the forward stock split.

Convertible Preferred Stock

Upon the closing of the IPO in 2007, all 11,537,501 outstanding shares of convertible preferred stock, Series A through G, automatically converted into an aggregate of 34,612,503 shares of common stock. Also, the convertible preferred stockholders rights to receive annual

cumulative dividends and the related accretion were eliminated. Voting rights of the preferred stockholders was eliminated.

Initial Public Offering

In August 2007, the Company completed its IPO of common stock in which a total of 13,704,120 shares were sold and issued, comprised of 10,416,626 shares sold by selling stockholders, 1,500,000 shares sold by the Company at the initial closing and 1,787,494 shares sold by the Company pursuant to the underwriters full exercise of their over-allotment option, at an issue price of $17.00 per share.

Series A Junior Participating Preferred Stock and Stockholder Rights Plan

On November 8, 2007, the Company authorized and declared a dividend of one preferred stock purchase right, or a Right, for each outstanding share of its common stock to stockholders of record at the close of business on November 26, 2007, or the Record Date. Each Right entitles the registered holder to purchase from the Company one one-thousandth of one share of the Company s Series A junior participating preferred stock, par value $0.001 per share, at a purchase price equal to $136.00 per Right, subject to adjustment. In addition, one Right will be issued with each share of common stock that becomes outstanding

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after the Record Date, and prior to the earliest of the distribution date, the date the Rights are redeemed, or the Final Expiration Date of November 8, 2017. In connection with the stockholder rights plan described herein, the Board designated 100,000 shares of preferred stock as Series A junior participating preferred stock, as set forth in the Certificate of Designation of Series A Junior Participating Preferred Stock.

Until a Right is exercised, the holder of such Right will have no rights as a stockholder of the Company, beyond those as an existing stockholder, including, without limitation, the right to vote or to receive dividends. Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the common stock. The Rights have certain anti-takeover effects. The Rights will cause dilution to a person or group that attempts to acquire the Company in a transaction which the Board does not approve is in the best interests of the Company and its stockholders, as discussed in detail below.

In the event that a person or group of affiliated or associated persons has acquired beneficial ownership of 15% or more of the Company s outstanding common stock, or Acquiring Person, each holder of a Right, other than the Acquiring Person, will thereafter have the right to receive, upon exercise, common stock having a market value equal to two times the exercise price of the Right.

The shares of Series A junior preferred stock issuable upon exercise of the Rights have the following characteristics: they are not redeemable; the holders of preferred stock are entitled, when, as and if declared, to minimum preferential quarterly dividend payments of an amount equal to (i) $1.00 per share or (ii) 1,000 times the aggregate per share amount of all cash dividends and 1,000 times the aggregate per share amount of all non-cash dividends or other distributions; the holders of preferred stock are entitled, in the event of a liquidation, dissolution or winding up, to a minimum preferential payment equal to $1,000 per share, plus all accrued and unpaid dividends, provided that the holders shall be entitled to receive 1,000 times the aggregate payment made per common share; the holders of preferred stock are entitled to 1,000 votes per share, voting together with the common stock; and the holders of preferred stock are entitled, in the event of a merger, consolidation or other transaction in which outstanding shares of common stock are converted or exchanged, to receive 1,000 times the amount received per share of common stock.

11. Share-Based Payment

The Company s 1989 Incentive Stock Option, Nonqualified Stock Option, and Restricted Stock Purchase Plan, or the 1989 Plan, provided for the issuance of options to purchase up to 3,000,000 shares of the Company s common stock to eligible officers, key employees, non-employee directors and consultants of the Company at prices not less than the fair market value of the Company s common stock on the date the option is granted, as determined by the Board. The options vested annually over five years using the straight-line method, unless otherwise provided, and expire five or ten years from the date of grant. The 1989 Plan terminated on September 26, 1999.

In May 1996, the Company adopted the 1996 Incentive Stock Option, Nonqualified Stock Option, and Restricted Stock Purchase Plan, or the 1996 Plan, which initially provided for the issuance of options to purchase up to 600,000 shares of the Company s common stock, to eligible officers, key employees, non-employee directors and consultants of the Company at prices not less than the fair market value of the Company s common stock on the date the option is granted, as determined by the Board. The options vested annually over five years using the straight-line method, unless otherwise provided, and expire ten years from the date of grant. The Board voted in October 1999 to amend the 1996 Plan to increase the number of shares authorized for issuance to include the unissued options from the 1989 Plan prior to its expiration, as well as any additional options that would become available through future forfeitures. The Board approved increases in the number of shares available for grant under the 1996 Plan to 3,600,000 shares in December 1997, to 4,200,000 shares in August 1999, to 7,200,000 shares in March 2000, and to 9,450,000 shares in March 2003. The Company terminated the 1996 Plan on May 4, 2006.

In April 2004, the Company adopted the 2004 Incentive Stock Option, Nonqualified Stock Option, and Restricted Stock Purchase Plan, or the 2004 Plan, which initially provided for the issuance of options to purchase up to 3,000,000 shares of the Company s common stock, plus any shares available under the prior year stock option plans, including shares that become available due to forfeitures at prices not less than the fair market value of the Company s common stock on the date the option is granted, as determined by the Board. The options generally vest annually over five years using the straight-line method, unless otherwise provided, and expire ten years from the date of grant. The Board approved increases in the number of shares available for grant under the 2004 Plan to 4,500,000 shares on February 6, 2006, to 6,000,000 shares on November 1, 2006 and to 7,500,000 shares on May 24, 2007. The Company may terminate the 2004 Plan at any time. If not terminated sooner, the 2004 Plan will automatically terminate on April 29, 2014.

On August 7, 2007, in connection with the Company s IPO, the 2007 Stock Incentive Plan, or the 2007 Plan, became effective. Under the 2007 Plan, 3,000,000 shares of common stock are reserved for future issuance, plus any shares available

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under the prior year stock option plans, including shares that become available due to forfeitures at prices not less than the fair market value of the Company s common stock on the date the option is granted. The options generally vest annually over five years using the straight-line method, unless otherwise provided, and expire ten years from the date of grant. The Company may terminate the 2007 Plan at any time. If not terminated sooner, the 2007 Plan will automatically terminate on August 7, 2017.

The number and weighted average exercise price of options issued and outstanding under all stock option plans, at exercise prices ranging between $1.34 and $41.51 per share, are as follows:

	Year ended January 2, 2010		Year ended January 3, 2009		Year ended December 29, 2007	
	Shares	Average Exercise Price	Shares	Average Exercise Price	Shares	Average Exercise Price
Options outstanding, beginning of period	7,329,474	$ 15.97	8,321,191	$ 7.53	7,691,388	$ 4.95
Granted	1,675,450	$ 25.30	2,493,000	$ 32.05	1,676,150	$ 19.40
Canceled	(326,130)	$ 27.24	(850,422)	$ 18.53	(776,504)	$ 9.14
Expired	(3,000)	$ 1.33		$	(1,500)	$ 1.00
Exercised	(549,923)	$ 4.68	(2,634,295)	$ 3.70	(268,343)	$ 3.10
Options outstanding, end of period	8,125,871	$ 18.21	7,329,474	$ 15.97	8,321,191	$ 7.53
Options exercisable, end of period	3,491,917	$ 10.46	2,760,046	$ 6.18	4,052,329	$ 3.48
Options available for grant, end of period	4,123,974		834,234		5,396,076	

The weighted-average fair value of options granted was $11.66 for the year ended January 2, 2010, $13.70 for the year ended January 3, 2009 and $9.01 for the year ended December 29, 2007. At January 2, 2010, an aggregate of 12,249,845 shares of stock were reserved for future issuance under the plans.

Effective January 1, 2007, the fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions used for grants:

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Risk-free interest rate	1.2% to 3.1%	1.1% to 3.8%	3.4% to 4.8%
Expected term	5.3 years to 5.5 years	5.3 years to 6.5 years	6.5 years
Estimated volatility	40.7% to 55.1%	36.6% to 53.4%	36.7% to 41.6%
Expected dividends	0%	0%	0%

As a non-public company prior to August 13, 2007, the date of completion of its IPO, the Company estimated the current price of the underlying shares based on valuations established by the Board. Historically, the Board has used various sources to establish the value of the Company s stock. As a publicly traded entity, the Company relies on daily reported close prices of the Company s shares.

The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with a remaining term approximately equal to the expected life of the Company s stock options.

During the year ended December 29, 2007 and the nine months ended September 27, 2008, the Company did not have sufficient information available which is indicative of future exercise and post-vesting behavior to estimate the expected term. The Company adopted the simplified

method of estimating the expected term of a stock option, as permitted by Staff Accounting Bulletin 107. Under this method, the expected term is presumed to be the mid-point between the vesting date and the contractual end of the term. The use of the simplified method requires the Company s option plan to be consistent with a plain vanilla plan. Subsequent to September 27, 2008, the Company had sufficient Company specific and available external information to estimate its expected term and therefore did not rely on the simplified method. As the Company obtains more historical data as a publicly traded company, it expects to rely increasingly on Company specific information for its estimate of expected term.

Additionally, during the year ended December 29, 2007 and the nine months ended September 27, 2008, the Company did not have sufficient information available regarding the historic volatility for its shares. As a result, the Company estimated volatility based on a peer group of companies, which collectively provided a reasonable basis for estimating volatility. Subsequent to September 27, 2008, and after the Company had been publicly traded for more than one year, it was able to

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use Company specific as well as peer group information to estimate the volatility of its shares. As the Company obtains more historical data as a publicly traded company, it expects to rely increasingly on Company specific information for its estimate of volatility. The changes in the method of estimating the expected term and the volatility did not have a material impact on the results of operations.

The Company s Board of Directors may from time to time declare, and the Company may pay, dividends on its outstanding shares in the manner and upon the terms and conditions provided by law. Any determination to declare and pay dividends will be made by the Company s Board of Directors and will depend upon the Company s results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by the Board of Directors. In the event a dividend is declared, there is no assurance with respect to the amount, timing or frequency of any such dividends. Based on this uncertainty and unknown frequency, for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, no dividend rate was used in the assumptions to calculate the share-based payment expense.

The Company is required to develop an estimate of the number of stock options that will be forfeited due to employee turnover. Adjustments in the estimated forfeiture rates can have a significant effect on its reported share-based payment, as it recognizes the cumulative effect of the rate adjustments for all expense amortization in the period the estimated forfeiture rates were adjusted. The Company estimates and adjusts forfeiture rates based on a periodic review of recent forfeiture activity and expected future employee turnover. Adjustments in the estimated forfeiture rates could also cause changes in the amount of expense that it recognizes in future periods.

The Company recorded share-based payment expense of $10.7 million, $7.7 million and $3.9 million during the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively. The related deferred tax asset was $7.2 million as of January 2, 2010 and $3.7 million as of January 3, 2009. The Company has elected to recognize share-based payment expense on a straight-line basis over the requisite service period for the entire award.

As of January 2, 2010, there was $49.6 million of total unrecognized share-based payment expense related to unvested options granted or modified on or after January 1, 2006. That expense is expected to be recognized over a weighted average period of 3.6 years as of January 2, 2010. The total fair market value on the respective vesting dates of all options vesting during 2009 and 2008, aggregated $25.8 million and $21.9 million, respectively.

The aggregate intrinsic value of options outstanding, with an exercise price greater than their fair market values, as of January 2, 2010 was $103.9 million. The aggregate intrinsic value of options exercisable, with an exercise price greater than their fair market values, as of January 2, 2010 was $71.2 million. The aggregate intrinsic value of options exercised during 2009, 2008 and 2007 was $12.2 million, $75.0 million and $4.1 million, respectively. The intrinsic value is calculated as the difference between the market value of the Company s stock on the date of exercise or the respective period end, as appropriate, and the exercise price of the options. The weighted average remaining contractual term of options outstanding as of January 2, 2010 was 6.6 years. The weighted average remaining contractual term of options exercisable as of January 2, 2010 was 4.9 years. No options were granted to consultants and no amount of deferred compensation was amortized to expense during the years ended January 2, 2010, January 3, 2009 and December 29, 2007.

The schedule below reflects the number and weighted average exercise price of outstanding and exercisable options segregated by exercise price ranges:

	January 2, 2010			January 3, 2009		
	Options Outstanding		Options Exercisable	Options Outstanding		Options Exercisable
Range of Exercise Prices	Number of Options	Average Remaining Contractual Life	Number of Options	Number of Options	Average Remaining Contractual Life	Number of Options

$1.34 to $4.00	1,907,197	3.58	1,720,123	2,315,509	4.50	1,858,531
$4.67 to $12.00	1,293,396	6.37	843,816	1,444,995	7.34	604,935
$12.87 to $16.00	940,488	7.37	354,348	1,008,600	8.36	194,180
$22.50 to $28.99	2,078,700	9.08	128,470	564,470	9.44	20,760
$29.12 to $31.99	1,344,950	8.17	265,860	1,289,800	9.11	9,300
$32.09 to $38.30	191,400	8.51	55,080	293,600	9.52	400
$38.44 to $41.51	369,740	8.52	124,220	412,500	9.47	71,940
Total	8,125,871	6.97	3,491,917	7,329,474	7.26	2,760,046

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The weighted-average exercise price of all options outstanding as of January 2, 2010 and January 3, 2009, was $18.21 and $15.97 per option, respectively.

The Company repurchased 41,640 shares of common stock from former employees for $581,000 during the year ended December 29, 2007. These shares were recorded in treasury stock, using the cost method, and are available for reissue. The difference between the repurchase prices and the original option exercise prices totaled $417,000 and was recorded as an operating expense for the year ended December 29, 2007. No shares were repurchased during the years ended January 2, 2010 or January 3, 2009.

12. Commitments and Contingencies

Leases

The Company leases its manufacturing and headquarters facilities in the U.S. under non-cancelable operating leases that expire in September 2014. The Company also leases its manufacturing facilities in Mexico and offices in Europe, Asia and Australia under operating lease agreements, almost all of which are non-cancelable, expiring at various dates through August 2014. The Company also entered into a lease agreement for its international headquarters in Switzerland. Certain leases contain pre-determined price escalations and in some cases renewal options. The Company recognizes the lease costs using a straight line method based on total lease payments. The Company also received certain leasehold improvement incentives totaling $650,000 for its manufacturing and headquarters facilities in the U.S. These leasehold improvement incentives have been recorded as deferred rent and are being amortized as a reduction to rent expense on a straight-line basis over the life of the lease. As of January 2, 2010 and January 3, 2009, rent expense accrued in excess of the amount paid and the remaining unamortized leasehold improvement incentive aggregated $100,000 and $282,000, respectively. The Company also leases automobiles in Europe and Japan that are classified as operating leases and expire at various dates through October 2010. The majority of these leases are non-cancelable. The Company also has capital leases outstanding for office equipment all of which are non-cancelable.

Future minimum lease payments under operating and capital leases for each of the following fiscal years are as follows (in thousands):

	As of January 2, 2010		
	Operating Leases	Capital Leases	Total
2010	$ 2,483	$ 72	$ 2,555
2011	2,122	58	2,180
2012	2,234	53	2,287
2013	2,204	49	2,253
2014	1,489	19	1,508
Thereafter			
Total	$ 10,532	$ 251	$ 10,783

Rental expense related to operating leases for the years ended January 2, 2010, January 3, 2009 and December 29, 2007 was $3.2 million, $3.3 million and $2.2 million, respectively. Included in the future minimum capital lease payments as of January 2, 2010 is interest aggregating $20,000.

Employee Benefit Plan

In fiscal year 1996, the Company adopted the Masimo Retirement Savings Plan, or the Plan, which is a 401(k) plan covering all of the Company s full-time U.S. employees who meet certain eligibility requirements. In general, the Company matches 100% of an employee s contribution up to 3% of the employee s compensation, subject to a maximum amount. The Company may also contribute to the Plan on a

discretionary basis. The Company contributed $1.2 million, $1.1 million and $977,000 to the plan for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively, all in the form of matching contributions.

Employment and Severance Agreement

As of January 2, 2010, the Company had an employment agreement with one of its key employees that provides for an aggregate annual base salary of $686,400 plus other benefits, with annual increases at the discretion of its Compensation Committee. The agreement with the Company, which was restated effective July 14, 2009, also provides for an annual bonus based on the Company s attainment of certain objectives and goals. The agreement had an initial term of three years, with automatic renewal, unless either the Company or the executive notifies the other party of non-renewal of the agreement. Also,

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under this employment agreement, the key employee may be entitled to receive certain salary, equity, tax, medical and life insurance benefits if he is terminated by the Company, terminates his employment for good reason under certain circumstances or there is a change in control of the Company.

On January 11, 2008, the Company entered into a severance plan participation agreement with three of its executive officers. The participation agreements, or Agreements, are governed by the terms and conditions of the Company s 2007 Severance Protection Plan, or Severance Plan, which became effective on July 19, 2007 and was amended effective December 31, 2008. Under the Agreements, the executive officer may be entitled to receive certain salary, equity, medical and life insurance benefits if he is terminated by the Company without cause or terminates his employment for good reason under certain circumstances. The executive officers are also required to give the Company six months advance notice of their resignation under certain circumstances.

On February 18, 2009, the Company entered into a limited severance plan participation agreement with another three of its executive officers. The limited participation agreements, or Limited Agreements, are governed by the terms and conditions of the Severance Plan. Under the Limited Agreements, fifty percent of the executive officer s unvested and outstanding stock options will immediately vest if he is terminated by the Company upon a change in control under certain circumstances. The executive officers are also required to give the Company six months advance notice of their resignation under certain circumstances.

Purchase Commitments

Pursuant to contractual obligations with vendors, the Company had $24.2 million of purchase commitments as of January 2, 2010, of which at least $23.6 million is expected to be purchased within 1 year. The remaining $557,000 may be purchased within the next 1 to 2 years. The Company does not have any purchase commitments for more than 2 years. These purchase commitments were made for certain inventory items to secure better pricing and to ensure the Company will have raw materials when necessary.

Concentrations of Risk

The Company is exposed to credit loss for the amount of cash deposits with financial institutions in excess of federally insured limits. As of January 2, 2010, the Company had $11.4 million of bank balances of which $3.2 million was covered by the Federal Deposit Insurance Corporation limit. The Company invests its excess cash deposits in U.S. Treasury bills and money market accounts with major financial institutions. As of January 2, 2010, the Company had $176.0 million, including cash equivalents and short-term investments, in U.S. Treasury bills which are backed by the U.S. federal government and $1.7 million in money market accounts.

While the Company and its contract manufacturers rely on sole source suppliers for certain components, steps have been taken to minimize the impact of a shortage or stoppage of shipments, such as maintaining excess inventory and designing products that may be easily modified to use a different component. There can be no assurance that a shortage or stoppage of shipments of the materials or components that the Company purchases will not result in a delay in production, or adversely affect the Company s business.

The Company s ability to sell its products to U.S. hospitals depends in part on its relationships with Group Purchasing Organizations, or GPOs. Many existing and potential customers for the Company s products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO s affiliated hospitals and other members. For the years ended January 2, 2010, January 3, 2009 and December 29, 2007, revenue from the sale of the Company s pulse oximetry products to customers affiliated with GPOs amounted to $160.8 million, $132.1 million and $101.0 million, respectively, representing, 94.7%, 92.8% and 89.4%, respectively, of its revenue from sales to U.S. hospitals.

For the years ended January 2, 2010, January 3, 2009 and December 29, 2007, one customer represented 14%, 12% and 11%, respectively, of total revenue. This particular customer was a distributor, which takes and fulfills orders from the Company s direct customers, many of whom have signed long-term sensor agreements with the Company. In the event this distributor was unable to fulfill these orders, the orders would be redirected to other distributors of the Company s or fulfilled directly by the Company.

Two customers represented 6% and 6% of accounts receivable at January 2, 2010 and 10% and 7% of accounts receivable at January 3, 2009.

Litigation

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In May 2002, the Company filed a lawsuit against Tyco Healthcare, parent company of Nellcor, in the U.S. District Court for the Central District of California, alleging damage to the Company s business as a result of the anti-competitive business practices of Tyco Healthcare. Specifically, the Company alleges that it had incurred damages as a result of a series of illegal exclusionary and anti-competitive acts by Tyco Healthcare that were designed to maintain its monopoly in the pulse oximetry market in violation of federal antitrust laws.

In March 2005, a jury found that Tyco Healthcare s use of sole-source contracts, product bundling and market share-based compliance pricing contracts, among other conduct, violated the federal antitrust laws and awarded damages on that basis. Tyco Healthcare filed post-trial motions requesting that the District Court either override the jury decision or grant a new trial. In March 2006, the District Court upheld a portion of the jury verdict and vacated the remaining verdict. In addition, the District Court vacated the jury s damages award and granted Tyco Healthcare a new trial on damages. After a retrial of damages to the court, on July 2, 2007, the District Court entered its final judgment awarding the Company damages which were trebled as is mandatory under federal antitrust law to $43.5 million and denying the Company s request for a permanent injunction with respect to Tyco Healthcare s business practices found to be anti-competitive. The Company and Tyco Healthcare each filed a notice of appeal from the judgment. The Company sought reinstatement of the jury s verdict on bundling and an affirmance of the liability findings concerning sole-source and market share-based compliance contracts. The Company also asked the appellate court to increase the amount of damages awarded by the trial court.

On October 28, 2009, the Ninth Circuit Court of Appeals affirmed the district court s decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its Nellcor pulse oximetry products. The court found that Tyco had unlawfully maintained monopoly power in violation of Section 2 of the Sherman Act, and that Tyco s sole-source agreements and market-share based compliance pricing contracts were unlawful restraints of trade in violation of Section 1 of the Sherman Act and unlawful exclusive dealing arrangements in violation of Section 3 of the Clayton Act. The court also affirmed the district court s damages award. (See Note 15)

On February 3, 2009, the Company 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 Philips patient monitors. The suit was brought in the U.S. District Court for the District of Delaware. Two patents at issue in this suit, related to the Company s measure-through-motion technology, were successfully enforced in its previous suit against Nellcor. On June 15, 2009, Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen Gmbh answered the Company s complaint and Philips Electronics North America Corporation filed antitrust and patent infringement counterclaims against the Company as well as counterclaims seeking declaratory judgments of invalidity on the patents asserted by the Company against Philips. The Company believes that it has good and substantial defenses to the antitrust and patent infringement claims asserted by Philips. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

On April 24, 2009, the Company sent a letter to Hygia Health Services, Inc., or Hygia, demanding that Hygia cease and desist from reprocessing used Masimo sensors. In response to that cease and desist letter, on May 5, 2009, Hygia filed a Declaratory Judgment action against the Company in the District Court for the Northern District of Alabama, Southern Division. On May 28, 2009, the Company filed its counterclaims, alleging patent and trademark infringement, unfair competition, false designation of origin and injury to business reputation. Hygia filed its reply to the Company s counterclaims, denying the allegations, and has alleged that the Company s patents are unenforceable. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

From time to time, the Company may be involved in litigation relating to claims arising out of its operations in the normal course of business. The Company believes that it currently is not a party to any legal proceedings which, individually or in the aggregate, would have a material adverse effect on its consolidated financial position, results of operations, or cash flows.

13. Segment Information and Enterprise Reporting

The Company s chief decision maker, the Chief Executive Officer, reviews financial information presented on a consolidated basis, accompanied by disaggregated information about revenues by geographic region for purposes of making operating decisions and assessing financial performance. Accordingly, the Company considers itself to be in a single reporting segment, specifically patient monitoring and related products. The Company does not assess the performance of its geographic regions on other measures of income or expense, such as depreciation and amortization, operating income or net income. In addition, the Company s assets are primarily located in the U.S. and are not allocated to any

specific region. The

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Company does not produce reports for, or measure the performance of, its geographic regions on any asset-based metrics. Therefore, geographic information is presented only for revenues.

The following schedule presents an analysis of the Company s product revenue based upon the geographic area to which the product was shipped (in thousands):

	Year ended January 2, 2010		Year ended January 3, 2009		Year ended December 29, 2007	
Geographic Area by Destination						
North and South America	$ 229,940	77%	$ 200,491	77%	$ 156,169	78%
Europe, Middle East and Africa	41,459	14	37,684	15	28,247	14
Asia and Australia	28,744	9	21,417	8	15,770	8
Total product revenue	$ 300,143	100%	$ 259,592	100%	$ 200,186	100%

Sales to customers located in the U.S. were $222.7 million, $194.4 million and $152.5 million, for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively.

14. Income Taxes

The components of income (loss) before provision for (benefit from) income taxes are as follows (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
United States	$ 76,344	$ 104,156	$ 67,008
Foreign	5,836	(31,765)	1,114
Total	$ 82,180	$ 72,391	$ 68,122

The following table presents the current and deferred provision (benefit) for income taxes (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Current:			
Federal	$ 26,952	$ 36,011	$ 20,654
State	4,081	3,699	2,449
Foreign	691	307	68
	31,724	40,017	23,171

Deferred:			
Federal	(2,208)	2,176	2,747
State	(1,251)	(1,447)	(51)
Foreign	(107)	(282)	
	(3,566)	447	2,696
Total	$ 28,158	$ 40,464	$ 25,867

Included in the 2009, 2008 and 2007 current tax provisions above are $872,000, $4.1 million and $1.7 million, respectively, of tax and accrued interest related to uncertain tax positions for each year.

The temporary differences that give rise to the deferred tax provision (benefit) consist of (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Property and equipment	$ 846	$ (358)	$ (114)
Capitalized research and development costs	95	754	(217)
Tax credits	(781)	(1,603)	(241)
Deferred revenue	926	4,818	1,046
Acquired intangibles	119	88	101

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	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Net operating losses	343	2,437	1,787
Accrued liabilities	(867)	(1,686)	52
Share-based payment	(3,467)	(2,033)	(1,121)
State taxes and other	(165)	666	2,941
Change in valuation allowance	(615)	(2,636)	(1,538)
Total	$ (3,566)	$ 447	$ 2,696

The reconciliation of the U.S. federal statutory tax rate to the Company s effective tax rate is as follows:

	Year ended January 2, 2010	Year ended January 3, 2009	Year ended December 29, 2007
Statutory regular federal income tax rate	35.0%	35.0%	35.0%
State provision, net of federal benefit	2.2	2.0	2.3
Nondeductible items	0.3	0.8	0.9
Foreign tax rate differential	(1.7)	0.2	(0.5)
Prepaid licensing		19.6	
Tax credits	(1.4)	(2.2)	(0.5)
Other	(0.1)	0.5	0.8
Total	34.3%	55.9%	38.0%

The provision for income taxes was $28.2 million, or an effective rate of 34.3%, during the year ended January 2, 2010 compared to $40.5 million, or an effective tax rate of 55.9%, during the year ended January 3, 2009. The effective tax rate differs from the statutory U.S. federal income tax rate of 35.0% primarily due to state taxes, permanent differences between financial pre-tax income and taxable income, the mix of income across the jurisdictions in which the Company does business and research related tax credits. The effective rate in 2009 differs from 2008 due primarily to the implementation of a new international business structure in 2008, designed to ultimately align the Company s operations, in a cost efficient manner, with the business needs of its non-US customers, and which include a tax charge relating to the prepayment of licensing commercial rights to utilize pre-existing intangibles.

The components of the deferred tax assets are as follows (in thousands):

	January 2, 2010	January 3, 2009
Deferred tax assets:		
Property and equipment	$ 565	$ 1,411
Tax credits	3,769	2,845
Deferred revenue	3,231	4,156
Acquired intangibles	857	975
Net operating losses	1,870	2,092
Accrued liabilities	7,195	6,246
Share-based payment	7,201	3,734

Other	965	934
Total	25,653	22,393
Valuation allowance	(1,998)	(2,492)
Total deferred tax assets	23,655	19,901
State taxes and other	(570)	(609)
Net deferred tax assets	$ 23,085	$ 19,292
Current net deferred tax asset	11,585	10,511
Long-term net deferred tax asset	11,500	8,781
Net deferred tax assets	$ 23,085	$ 19,292

At January 2, 2010, the Company has $33.0 million of net operating loss carryforwards from its foreign jurisdictions which will begin to expire in 2015. Also, the Company has $9.1 million of net operating losses from various states, which will begin to expire in 2012, of which $4.2 million, or $150,000 after tax effect, will be recorded in stockholders equity when realized.

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The Company has state research and development credits of $2.3 million which will carryforward indefinitely. Additionally, the Company has $477,000 of investment tax credit on research and development expenditures from its operations in Canada which will begin to expire in 2018. Management believes that it is more likely than not that the deferred tax assets related to foreign net operating loss carryforwards will not be realized. In making this determination, the Company considers all available positive and negative evidence, including scheduled reversals of liabilities, projected future taxable income, tax planning strategies and recent financial performances. A valuation allowance has been provided on such loss carryforwards.

During the years ended January 2, 2010, January 3, 2009 and December 29, 2007, the Company recorded a tax benefit of $3.0 million, $19.1 million and $204,000, respectively, from the exercise of non-qualified stock options and incentive stock options as a reduction of its income tax liability and an increase in stockholders equity. The tax benefit results from the difference between the fair value of the Company s stock on the exercise dates and the exercise price of the option.

The Company has not provided for income taxes on undistributed earnings of foreign subsidiaries as such earnings are intended to be permanently reinvested in those operations. As of January 2, 2010, the Company s foreign subsidiaries have cumulative losses. Net deferred tax assets in the foreign subsidiaries relate primarily to net operating losses and are offset in full by valuation allowances.

Included in the Company s consolidated income tax provision of $28.2 million, $40.5 million and $25.9 million for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively, are the following related to Masimo Labs: current income tax provision of $244,000, current income tax provision of $163,000, and current income tax benefit of $36,000, respectively, and deferred income tax provision of $125,000, deferred tax benefit of $182,000, and deferred income tax provision of $348,000, respectively. The temporary differences that give rise to the deferred tax provision of $125,000, deferred tax benefit of $182,000, deferred income tax provision of $348,000, respectively, are mainly research and development credits, share-based payment expense and deferred revenue for the years ended January 2, 2010, January 3, 2009 and December 29, 2007, respectively.

Masimo Labs deferred tax asset balance as of January 2, 2010 and January 3, 2009 was $1.6 million and $1.8 million, respectively, which consists of deferred revenue, fixed assets and intangibles, share-based payment and research and experimentation credit carryforwards, which begin to expire in 2024. Management of Masimo Labs believes that it is more likely than not that part of deferred tax assets related to research and experimentation credit will not be realized. In making this determination, Masimo Labs considers all available positive and negative evidence, including scheduled reversals of liabilities, projected future taxable income, tax planning strategies and recent financial performances. For the years ended January 2, 2010 and January 3, 2009, a valuation allowance of $400,000 has been provided on such credit carryforwards.

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

The adoption of this standard resulted in a reduction of the Company s beginning retained earnings as of January 1, 2007, of $618,000. As of the adoption date, the balance of gross unrecognized tax benefits is $3.6 million.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits for the years ended January 2, 2010 and January 3, 2009 (in thousands):

	Year ended January 2, 2010	Year ended January 3, 2009
Unrecognized tax benefits, beginning of period	$ 7,298	$ 3,340
Increase from tax positions in prior period	3	73
Decrease from tax positions in prior period	(27)	(176)

Increase from tax positions in current period	850	4,061
Settlements		
Lapse of statute of limitations.	(30)	
Unrecognized tax benefits, end of period	$ 8,094	$ 7,298

The amount of unrecognized benefits which, if ultimately recognized, could favorably affect the tax rate in a future period was $6.9 million and $6.1 million as of January 2, 2010 and January 3, 2009, respectively. Both amounts are net of any federal and/or state benefits, and the remaining balance relates to timing differences. It is reasonably possible that the amount

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of unrecognized tax benefits in various jurisdictions may decrease up to $2.0 million in the next 12 months due to the expiration of statutes of limitation.

Interest and penalties related to unrecognized tax benefits are recognized in income tax expense. For years ended January 2, 2010, January 3, 2009 and December 29, 2007, the Company had accrued $669,000, $446,000 and $211,000, respectively, for the payment of interest.

The Company conducts business in multiple jurisdictions, and as a result, one or more of the Company s subsidiaries files income tax returns in the U.S. federal, various state, local and foreign jurisdictions. Due to the generation of net operating loss carryforwards, all years since 1994 are open for examination by major taxing authorities.

15. Subsequent Events

On January 11, 2010, the Company completed negotiations to resolve the merits of its antitrust litigation with Covidien and, as a result, the Company retained $30.1 million from a payment from Covidien, following the Ninth Circuit Court of Appeals October 2009 affirmance of a Federal District Court decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products. The decision found that Covidien had unlawfully maintained monopoly power in violation of Section 2 of the Sherman Act, and that Covidien s sole-source agreements and market-share based compliance pricing contracts constituted unlawful restraints of trade in violation of Section 1 of the Sherman Act and unlawful exclusive dealing in violation of Section 3 of the Clayton Act. The Ninth Circuit also stated that above-cost bundling discounts when combined with sole-source or market-share based compliance contracts can be anticompetitive when such practices involve a significant portion of the market. The suit was originally filed by the Company in 2002. The judgment against Covidien for the antitrust violations was for $43.5 million; however, the total payment, after reimbursement for legal fees, costs, and interest was $59.0 million. The portion of the total payment from Covidien that was not retained by the Company was paid to the law firm that handled the trial for the Company.

The Company evaluated all events and transactions that occurred from the balance sheet date of January 2, 2010 through the consolidated financial statements issue date of February 16, 2010. During this period, other than the event noted above, there were no events or transactions occurring which require recognition or disclosure in the consolidated financial statements.

16. Quarterly Financial Data (unaudited)

The following tables contain selected unaudited Consolidated Statements of Operations data for each quarter of 2009 and 2008 (in thousands, except per share data):

	Quarter ended			
Fiscal 2009	**April 4, 2009**	**July 4, 2009**	**October 3, 2009**	**January 2, 2010**
Total revenue	$ 85,492	$ 83,569	$ 87,441	$ 92,613
Gross profit	60,747	59,995	62,243	65,817
Operating income	20,086	19,948	20,840	21,352
Net income attributable to Masimo Corporation	13,021	13,092	13,055	14,060
Net income per share attributable to Masimo Corporation Stockholders:				
Basic [(1)]	$ 0.23	$ 0.23	$ 0.23	$ 0.24
Diluted [(1)]	$ 0.22	$ 0.22	$ 0.22	$ 0.23

	Quarter ended			
Fiscal 2008	**March 29, 2008**	**June 28, 2008**	**September 27, 2008**	**January 3, 2009**

Total revenue	$ 71,110	$ 74,766	$ 78,132	$ 83,066
Gross profit	49,989	53,363	55,739	58,529
Operating income	13,994	16,740	20,506	20,110
Net income (loss) attributable to Masimo Corporation[2]	8,791	10,601	13,065	(530)
Net income (loss) per share attributable to Masimo Corporation Stockholders:				
Basic	$ 0.16	$ 0.19	$ 0.23	$ (0.01)
Diluted [1]	$ 0.15	$ 0.18	$ 0.22	$ (0.01)

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(1) The sum of the quarterly basic and diluted net income per share amounts for the year ended January 2, 2010 and the diluted net income (loss) for the year ended January 3, 2009 do not equal the annual related per share amounts due to differences in the weighted average shares outstanding between the quarterly and annual computations.

(2) During the quarter ended January 3, 2009, the Company incurred an income tax expense of $20.5 million, or 102.7% of income before provision for income taxes. This increase in tax expense was due to the implementation of an international restructuring during the quarter ended January 3, 2009 offset by benefit from increased research and development tax credits. The tax charges related to expenses for sharing in the costs of ongoing research and development efforts as well as the prepayment of licensing commercial rights to utilize pre-existing intangibles.