MASIMO CORP
Form 10-K
February 26, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)
þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 29, 2018
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number 001-33642

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

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

(949) 297-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
Common Stock, par value $0.001	The Nasdaq Global Select Market

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

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ 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 þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ 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 þ 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. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer þ Accelerated filer ¨ Non accelerated filer ¨ Smaller reporting company ¨
Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2018, the last business day of the registrant’s most recently completed second fiscal quarter, as reported on the Nasdaq Global Select Market, was approximately $4.3 billion. Shares of stock held by officers, directors and 5 percent or more stockholders have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. At January 25, 2019, the registrant had 53,172,028 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K incorporate information by reference from the registrant’s proxy statement for the registrant’s 2019 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Financial Condition and Results of Operations" but appear throughout this Annual Report on Form 10-K. Examples of forward-looking statements include, but are not limited to, any projection or expectation of earnings, revenue or other financial items; the plans, strategies and objectives of management for future operations; factors that may affect our operating results, including accounting and tax estimates; our success in pending litigation; new products or services; the demand for our products; our ability to consummate acquisitions and successfully integrate them into our operations; future capital expenditures; effects of current or future economic conditions or performance; industry trends and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "opportunity," "plan," "potential," "predicts," "seek," "should," "will," or "v expressions and variations or negatives of these words. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which is subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause our actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed under Item 1A—"Risk Factors" in this Annual Report on Form 10-K. Furthermore, such forward-looking statements speak only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update or revise publicly any forward-looking statements to reflect events or circumstances after the date of such statements for any reason, except as otherwise required by law.

PART I

ITEM 1. BUSINESS

Overview

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

Our core business is Measure-through Motion and Low Perfusion® pulse oximetry monitoring, known as Masimo Signal Extraction Technology® (SET®) pulse oximetry. Our product offerings have expanded significantly over the years to also include noninvasive monitoring of blood constituents with an optical signature, optical organ oximetry monitoring, electrical brain function monitoring, acoustic respiration monitoring and exhaled gas monitoring. In addition, we have developed the Root™ patient monitoring and connectivity platform, the Radical-7® and Rad-97™ bedside and portable patient monitors and the Radius-7® wearable wireless patient monitor. We have also developed the Masimo Patient SafetyNet[1] supplemental remote patient surveillance and monitoring system, which currently allows up to 200 patients to be monitored and viewed simultaneously and remotely through a PC-based monitor or by care providers through their pagers, voice-over-IP phones or smartphones. As part of our hospital automation product suite, we recently launched UniView,™ an integrated display of real-time data and alarms from multiple Masimo and third-party devices, designed to reduce clinician cognitive overload, improve patient safety and promote data sharing and team coordination among multiple clinicians.

Our solutions and related products are based upon our proprietary Masimo SET® and rainbow® algorithms. These technologies are incorporated into a variety of product platforms designed to meet our customers' needs. In addition, we provide our technologies to OEMs in a form factor that is easy to integrate into their patient monitors, defibrillators, infant incubators and other devices.

Our technology is supported by a substantial intellectual property portfolio that we have built through internal development and, to a lesser extent, acquisitions and license agreements. We have also exclusively licensed from Cercacor Laboratories, Inc. (Cercacor) the right to certain OEM rainbow® technologies and to incorporate certain rainbow® technology into our products intended to be used by professional caregivers, including, but not limited to, hospital caregivers and alternate care facility caregivers.

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[1] The use of the trademark Patient SafetyNet is under license from the University HealthSystem Consortium.

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Conventional Pulse Oximetry

Pulse oximetry enables the noninvasive measurement of the oxygen saturation level of arterial blood (SpO_2), which delivers oxygen to the body's tissues. Pulse oximetry also measures pulse rate (PR), which, when measured by electrocardiogram (ECG), is called heart rate. Pulse oximeters use sensors attached to an extremity, typically the fingertip or certain core body sites. These sensors contain two light-emitting diodes that transmit red and infrared light from one side of the extremity through the tissue to a photodetector on the other side of the extremity. The photodetector in the sensor measures the amount of red and infrared light absorbed by the tissue. A microprocessor then analyzes the changes in light absorption to provide a continuous, real-time measurement of the amount of oxygen in the patient's arterial blood. Pulse oximeters typically give audio and visual alerts, or alarms, when the patient's arterial blood oxygen saturation level or pulse rate falls outside of a user-designated range. As a result, clinicians have the opportunity to assess patients who may need immediate treatment to prevent the serious clinical consequences of hypoxemia, or low arterial blood oxygen saturation levels, and hyperoxemia, or high arterial blood oxygen levels.

As one of the most common technologies used in and out of hospitals around the world, pulse oximetry has gained widespread clinical acceptance as a standard patient vital sign measurement because it can give clinicians a warning of possible hypoxemia or hyperoxemia. SpO_2 monitoring of oxygen saturation is critical because hypoxemia can lead to a lack of oxygen in the body's tissues, which can be toxic and result in organ damage or death. Pulse oximeters are used in a variety of critical care settings, including surgery, recovery rooms, intensive care units (ICUs), emergency departments and general care floors, as well as alternative care settings, such as long-term care facilities, physician offices and the home monitoring of patients with chronic conditions.

Clinicians also use pulse oximeters to monitor oxygen saturation in premature babies to ensure that appropriate oxygen saturation levels are maintained. In premature babies, oxygen saturation levels above clinically acceptable limits may lead to a condition known as retinopathy of prematurity (ROP), which, if left untreated, can lead to permanent eye damage or blindness. By ensuring that oxygen saturation levels in babies remain within clinically acceptable limits, clinicians believe they can lower the incidence of ROP.

Conventional pulse oximetry has limitations that can reduce its effectiveness and the quality of patient care. In particular, when using conventional pulse oximetry, oxygen saturation measurements can be distorted by motion artifact, or patient movement, and low perfusion, or low arterial blood flow at the measurement site. Motion artifact can cause conventional pulse oximeters to inaccurately measure the arterial blood oxygen saturation level, due mainly to the effect of movement-induced pulsations of venous blood, which is at a lower oxygen saturation than arterial blood. Low perfusion can also cause conventional pulse oximeters to report inaccurate measurements or, in some cases, no measurement at all. In addition, conventional pulse oximeters cannot distinguish oxygenated hemoglobin from dyshemoglobin, including the most prevalent forms of dyshemoglobins, carboxyhemoglobin and methemoglobin. As a result, conventional pulse oximeters may report falsely high oxygen levels when these dyshemoglobins are present in the blood. Furthermore, conventional pulse oximetry readings can also be impacted by bright light and electrical interference caused by the presence of electrical surgical equipment.

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

Lastly, because conventional pulse oximetry cannot consistently measure SpO_2 and pulse rate in the presence of motion artifact or low perfusion, its use is limited in lower acuity settings in the hospital, such as in general care areas, where a hospital's staff-to-patient ratio is significantly lower and the staff have less tolerance for false alarms. In addition, two-wavelength pulse oximeters cannot distinguish oxygenated hemoglobin from dyshemoglobin, including the most prevalent forms of carboxyhemoglobin and methemoglobin. As a result of these dyshemoglobins, pulse oximeters will report falsely high oxygen levels when they are present in the blood.

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Masimo SET® Pulse Oximetry

Masimo SET® was designed to overcome the primary limitations of conventional pulse oximetry by maintaining accuracy in the presence of motion artifact, low perfusion and weak signal-to-noise situations. Our Masimo SET® platform, which became available to U.S. hospitals in 1998, is the basis of our pulse oximetry products, and we believe represented the first significant technological advancement in pulse oximetry since its introduction in the early 1980s. Masimo SET® utilizes five signal processing algorithms, four of which are proprietary, in parallel to deliver high sensitivity and specificity in the measurement of arterial blood oxygen saturation levels. Sensitivity is the ability to detect true alarms and specificity is the ability to avoid false alarms. One of our proprietary processing algorithms, Discrete Saturation Transform®, separates the signal from noise in real time through the use of adaptive filtering and an iterative sampling technique that tests each possible saturation value for validity. Masimo SET® signal processing can therefore identify the venous blood and other "noise", isolate them and extract the arterial signal.

The performance of Masimo SET® pulse oximetry has been evaluated in more than 100 independent studies and thousands of clinical evaluations. We believe that Masimo SET® is trusted by clinicians to safely monitor in excess of approximately 100 million patients each year and has been chosen as the primary pulse oximeter technology used by nine of the top ten hospitals listed on the 2018-2019 U.S. News & World Report Best Hospitals Honor Roll.

Compared to conventional pulse oximeters, during patient motion and low perfusion, Masimo SET® provides measurements when other pulse oximeters cannot, significantly reduces false alarms (improved specificity), and accurately detects true alarms (improved sensitivity). Clinical studies have shown that the use of Masimo SET® pulse oximetry, in conjunction with modified clinical protocols, has helped clinicians reduce ROP in neonates and improve screening for newborns with critical congenital heart disease (CCHD). Clinical studies have also shown a reduction in rapid response activations and ICU transfers when Masimo SET® is used to continuously monitor patients on general wards. Additionally, researchers have found that the use of Masimo SET® is associated with reduced ventilator weaning time and arterial blood gas measurements in the ICU.

Our pulse oximetry technology is contained on a circuit board which can be placed inside a standalone pulse oximetry monitor, placed inside OEM multiparameter monitors, or included as part of an external "Board-in-Cable" solution that is plugged into a port on an OEM or other device. All of these solutions use our proprietary single-patient-use or reusable sensors and cables. We sell our products to end users through our direct sales force and through certain distributors, as well as to our OEM partners, for incorporation into their products. In 2013, we also began selling our pulse oximetry products in the consumer market.

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

Adhesive sensors are single-patient-use items, but the U.S. Food and Drug Administration (FDA) allows third parties to reprocess pulse oximetry sensors. In response to some hospitals' requests to implement environmentally friendly or "green" products, we offer sensor reprocessing as well as sensor recycling programs.

Masimo rainbow SET™ Platform

Since introducing Masimo SET®, we have continued to innovate by introducing noninvasive measurements that go beyond arterial blood oxygen saturation and pulse rate. In 2005, we introduced the Masimo rainbow SET™ platform, leveraging our Masimo SET® technology and incorporating licensed rainbow® technology to enable real-time monitoring of additional noninvasive measurements. Our rainbow SET™ platform includes our rainbow SET™ Pulse CO-Oximetry products, which we believe are the first devices cleared by the FDA to noninvasively and continuously monitor additional hemoglobin species that were previously only measurable using intermittent invasive procedures using multiple wavelengths of light. In addition to SpO_2, PR, perfusion index (Pi), Pleth Variability Index (PVi®) and respiration rate from the pleth (RRp®), rainbow® Pulse CO-Oximetry has the unique ability to measure and

distinguish oxygenated hemoglobins from the dyshemoglobins that are incapable of transporting oxygen, carboxyhemoglobin (SpCO®) and methemoglobin (SpMet®). Besides the ability to measure SpCO® and SpMet®, the Masimo rainbow SET™ platform also allows for the noninvasive and continuous monitoring of total hemoglobin concentration (SpHb®) as well as the monitoring of arterial oxygen saturation, in the presence of carboxyhemoglobin and methemoglobin, known as fractional arterial oxygen saturation ($SpfO_2$)™. Additionally, the rainbow SET™ platform also allows for the calculation of Oxygen Content (SpOC)™ and Oxygen Reserve Index™ (ORi)™. RRp®, $SpfO_2$™ and ORi™ have received CE Marking, but are not currently available for sale in the U.S.

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We believe that Masimo rainbow® Pulse CO-Oximetry products will become widely adopted for the noninvasive monitoring of these measurements. We also believe that the addition of acoustic respiration rate (RRa®), using our rainbow Acoustic Monitoring® technology, will strengthen the clinical demand for noninvasive and continuous monitoring using our rainbow® platform, especially in the growing general floor market.

Products with our MX circuit board contain our Masimo SET® pulse oximetry technology as well as circuitry to support rainbow® measurements. At the time of purchase, or at any time in the future, our customers and our OEMs' customers have the option of purchasing additional rainbow® software measurements, which allow the customer to incrementally expand their patient monitoring systems with a cost-effective solution. To date, over thirty-four companies have released rainbow SET™ equipped products or announced rainbow® integration plans.

Measurements

SpHb®

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

SpHb® is available as a continuous or a spot-check measurement. Continuous SpHb® monitoring provides real-time visibility into hemoglobin levels and the changes, or lack of changes, in hemoglobin levels, which can otherwise only be measured through intermittent, invasive blood testing. SpHb® monitoring is not intended to be used as the sole basis for making diagnosis or treatment decisions, but continuous SpHb® monitoring may help clinicians to trend hemoglobin in real time between invasive blood samples.

SpOC™

The oxygen content of blood is a function of both oxygen saturation and hemoglobin levels. SpOC™ provides a more complete picture of a patient's oxygenation status by combining noninvasive and continuous measurements of both hemoglobin and oxygen saturation levels into a single calculation.

SpCO®

Carbon monoxide (CO) is a colorless, odorless and tasteless gas that is undetectable by humans and is often unknowingly inhaled from combustion fumes, or during fires by victims and first responders. CO poisoning is the leading cause of accidental poisoning death in the U.S. and is responsible for up to 50,000 emergency department visits and 500 unintentional deaths annually. CO, when bound to hemoglobin cells, prevents those cells from carrying oxygen. Elevated CO levels may cause severe neurological damage, permanent heart damage or death. Screening for elevated CO levels in the emergency department is critical, as symptoms of CO poisoning in patients may be misdiagnosed because such symptoms are similar to the flu.

CO levels in the blood can be measured using a laboratory CO-Oximeter, which requires a patient or a patient's blood sample to be transported to a hospital with laboratory CO-Oximetry capability. Additional delays occur if a patient needs hyperbaric oxygen therapy, which often requires transfer to yet another medical center with hyperbaric capability. Outside the hospital, laboratory measurements of carboxyhemoglobin are not considered feasible. Historically, this meant that CO levels in the blood could not be assessed in environments in which such assessment would be very useful, such as in the home or as part of the medical evaluation of first responders potentially exposed to CO at the scene of a fire.

We believe that the greatest opportunity for SpCO® monitoring is in the EMS, fire and hospital emergency department settings, since elevated SpCO® levels may help indicate a need for invasive testing in patients with headaches or other non-specific symptoms of CO poisoning. While SpCO® is not intended to replace invasive carboxyhemoglobin tests, when used with other clinical variables, SpCO® may help clinicians identify elevated CO levels and help determine additional test and treatment options. Over the past few years, 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, have

educated their members on the benefits of noninvasive CO measurement when exposure is suspected or when an individual presents symptoms that could indicate elevated CO levels. In 2015, the National Fire Protection Association (NFPA), one of the world's authoritative sources on fire prevention and public safety, released updated Fire Rehabilitation Standard 1584, Standard on the Rehabilitation Process for Members During Emergency Operations and Training Exercises, requiring firefighters exposed to smoke at incident scenes and during training to be assessed for elevated CO levels.

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SpMet®

Methemoglobin in the blood leads to a dangerous condition known as methemoglobinemia, which occurs as a reaction to some common drugs used in hospitals and outpatient procedures. Methemoglobinemia reduces the amount of oxygen bound to hemoglobin for delivery to tissues and forces normal hemoglobin to bind more tightly to oxygen, releasing less oxygen to the tissues. Methemoglobinemia may go unrecognized or be subject to delayed diagnosis, 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 include benzocaine, a local anesthetic 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 Human Immunodeficiency Virus (HIV) patients. Warnings, cautions and alerts regarding the clinical significance and prevalence of methemoglobinemia have been generated by the FDA, the Veterans Administration, the Institute for Safe Medication Practices and the National Academy of Clinical Biochemistry. The American Academy of Pediatrics recommends monitoring methemoglobin levels in infants who receive nitric oxide therapy. While SpMet® is not intended to replace invasive methemoglobin tests, when used with other clinical variables, SpMet® may help clinicians identify elevated methemoglobin levels and help determine additional test and treatment options.

PVi®

PVi® is a measure of the dynamic changes in the Pi that occur during the respiratory cycle. The calculation is accomplished by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. PVi® is displayed as a percentage. The lower the number, the less variability there is in Pi over a respiratory cycle. PVi® may show changes that reflect physiologic factors such as vascular tone, circulating blood volume and intrathoracic pressure excursions. When used with other clinical variables, PVi® may help clinicians assess fluid responsiveness in surgical and intensive care patients who are mechanically ventilated, and help determine other treatment options.

RPVi™

Rainbow® Pleth Variability Index (RPVi)™ is a multi-wavelength version of PVi® that is designed to provide enhanced specificity to changes in fluid volume compared to PVi®. Similar to PVi®, RPVi™ is displayed as a percentage and is calculated by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. The lower the number, the less variability there is in Pi over a respiratory cycle, which indicates more fluid in the body. RPVi™ has received the CE Mark, but is not currently available for sale in the U.S.

RRp®

Respiration rate is defined as the number of breaths per minute. Changes in respiration rate provide an early warning sign of deterioration in patient condition. A low respiration rate is indicative of respiratory depression and high respiration rate is indicative of patient distress. Current methods of monitoring respiration rate include end tidal carbon dioxide ($EtCO_2$) monitoring, which requires a nasal cannula be inserted in the patient's nose or a mask to be worn, and therefore has low patient compliance; and impedance monitoring, which is considered unreliable and requires the placement of ECG electrodes on the chest. RRp® allows clinicians to noninvasively and continuously measure and monitor respiration rate using a standard Masimo SET® pulse oximetry sensor or rainbow® Pulse CO-Oximetry sensor. RRp® is determined by the variations in the plethysmograph waveform due to respiration, although the measurement is not possible in all patients or conditions and may not immediately indicate changes in respiration rate. RRp® has received the CE Mark, as well as FDA 510(k) clearance when used in healthcare settings with the MightySat® Rx fingertip SET® pulse oximeter. RRp® is also available in the U.S. for use by consumers for general health and wellness purposes as part of our MightySat® fingertip pulse oximeter.

RRa®

Our sound-based monitoring technology, rainbow Acoustic Monitoring® (RAM®), enables RRa® and provides continuous and noninvasive monitoring of respiration rate. For patients requiring accurate and sensitive respiration rate monitoring, we believe that RRa® better detects pauses in breathing than respiration rate measurements from other technologies such as $EtCO_2$ monitoring and RRp®. RRa® also provides an important visual indication of

breathing through a displayed acoustic waveform. Multiple clinical studies have shown that the noninvasive measurement of acoustic respiration rate provides as good or better respiration rate monitoring accuracy as $EtCO_2$ monitoring, and can reliably detect episodes of respiratory pause, defined as the cessation of breathing for 30 seconds or more. When used with other clinical variables, RRa® may help clinicians assess respiratory depression and respiratory distress earlier and more often to help determine treatment options and potentially enable earlier interventions.

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$SpfO_2$™

Prior to our debut of $SpfO_2$,™ pulse oximeters could only measure and display functional SpO_2 oxygen saturation. Therefore, when patients had elevated carboxyhemoglobin and/or elevated methemoglobin, the displayed functional SpO_2 oxygen saturation overestimated the actual oxygen saturation value. $SpfO_2$,™ or fractional oxygen saturation, allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to functional oxygen saturation, and may also allow earlier interventions and more timely therapeutic decisions. $SpfO_2$™ has received CE Mark, but is not currently available for sale in the U.S.

ORi™

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

Other Noninvasive Measurements and Technologies

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

SedLine® Brain Function Monitoring

Brain function monitoring is most commonly used during surgery to help clinicians avoid over-titration and under-titration of anesthesia and sedation. SedLine® brain function monitoring technology measures the brain's electrical activity by detecting EEG signals. In contrast to whole-scalp EEG monitoring, which is used for diagnostic purposes, this form of EEG monitoring is often referred to as processed EEG monitoring or brain function monitoring. Brain function monitors display the patient's EEG waveforms, but these may be difficult for clinicians to interpret. With SedLine® technology, EEG signals are processed and displayed as a single number called the Patient State Index (PSi), which gives a continuous quantitative indication of the patient's depth of anesthesia and sedation. SedLine® brain function monitoring technology also displays raw EEG waveforms, the PSi trend and a Density Spectral Array view, which allows clinicians to compare EEG power in both sides of the brain over time to facilitate the detection of asymmetrical activity and agent-specific effects on the EEG signal.

SedLine® brain function monitoring technology is available on Root™ through the use of a Masimo Open Connect® (MOC-9®) connectivity port. The Root™ patient monitoring and connectivity platform integrates rainbow® and SET® measurements with measurement technologies, such as SedLine®.

NomoLine® Capnography and Gas Monitoring

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

In November 2017, we released the full family of NomoLine® capnography sampling lines to the U.S. market. NomoLine® sampling lines are available in more than 40 configurations of airway adapter sets and cannulas for use in a variety of clinical scenarios on both intubated and non-intubated adult, pediatric, infant and neonatal patients, in both low and high humidity configurations. NomoLine® capnography sampling lines are compatible with both Masimo and many third-party OEM monitors facilitating easy to use sidestream capnography and gas monitoring. NomoLine® capnography sampling lines have received FDA 510(k) clearance.

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O3® Regional Oximetry

O3® regional oximetry, also known as tissue or cerebral oximetry, uses near-infrared spectroscopy (NIRS) to provide continuous measurement of tissue oxygen saturation (rSO_2) to help detect regional hypoxemia, or oxygen deficits in specific tissues such as the brain, that pulse oximetry alone cannot detect under certain conditions. In addition, O3® sensors, in conjunction with our Root™ monitor, can automate the differential analysis of regional to central oxygen saturation derived from SET® pulse oximeters. O3® monitoring involves applying O3® regional oximetry sensors to the forehead and connecting the O3® MOC-9® module to a Root™ monitor through one of its three MOC-9® ports. O3® regional oximetry has received CE Mark and FDA 510(k) clearance for use in adult and pediatric patients.

Patient SafetyNet

Patient SafetyNet, our patient surveillance, remote monitoring and clinician notification solution, works in concert with our bedside and ambulatory monitoring devices to facilitate the supplemental monitoring of the oxygen saturation, pulse rate, perfusion index, hemoglobin, methemoglobin, and respiration rate of up to 200 patients simultaneously from a single server. Patient SafetyNet offers an intuitive and powerful user interface with trending, real-time waveform capability at a central station, as well as remote clinician notification via pager, Voice-over-IP phone or smart-phones. Patient SafetyNet also features an Adaptive Connectivity Engine™ (ACE) that enables two-way, HL-7 based connectivity to clinical/hospital information systems. The ACE significantly reduces the time and complexity to integrate and validate custom HL-7 implementations, and demonstrates our commitment to innovation that automates patient care with open, scalable, and standards-based connectivity architecture.

Patient SafetyNet Series 5000™, along with Iris® Connectivity, Iris Gateway®, Kite®, UniView™ and MyView® through the Root™ patient monitoring and connectivity platform, offers a new level of interoperability designed to enhance clinician workflows and reduce the cost of care in a variety of hospital settings, including operating rooms and the general care floors. Patient SafetyNet Series 5000™ with Iris® enables Root™ to assimilate data from all devices connected to the patient, thereby acting as a comprehensive in-room patient monitor and connectivity hub. Alarms and alerts for all devices are seamlessly forwarded to the patient's clinician and device data can be transferred to the patient's electronic medical record (EMR). The patient-centric user interface of the Patient SafetyNet Series 5000™ displays near real-time data from all devices with Kite®, providing a single unified dashboard of patient information. To simplify documentation of patient data, Root™ enables clinicians to easily verify and send patient vitals and Early Warning Scores (EWS), as well as all connected medical device information data, to the EMR directly from Root.™ An interface between the Patient SafetyNet Series 5000™ and the hospital admission, discharge and transfer (ADT) system allows clinicians to receive ADT information on Root™ for positive patient identification at the bedside. Clinicians can also manually enter additional data on the Root™ device, including temperature, blood pressure, level of consciousness, pain score and urine output.

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

MyView®

MyView® is a wireless, presence-detection system that enables the display of customized clinical profiles on Masimo devices, such as Root,™ Radical-7® and the Patient SafetyNet View Station. When a clinician approaches the device, a clinician-worn MyView® badge signals the device to display a preselected set of parameters and waveforms tailored to the individual clinician's preferences. MyView® gives clinicians the ability to receive and review medical device information in a manner that is most conducive to optimizing their workflow, while the presence mapping data collected by all the Masimo devices can provide insight into how clinicians spend time with patients. This provides nursing leadership and management the opportunity to examine analytical data on patient-clinician interactions and

optimize workflows across the unit, hospital and hospital system.

Patient SafetyNet Surveillance

Patient SafetyNet Surveillance is a software option that provides real-time video images of a patient's room, including the patient and connected monitoring devices, adding existing communication technology to central monitoring. Two-way audio is available to allow the caregiver to listen to and communicate with the patient. The system utilizes the existing hospital information technology network, precluding the installation of additional infrastructure.

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Trace™

Trace™ is a patient data visualization and reporting software designed for Masimo Root™ and Radical-7® monitors. Trace™ is the first data visualization and reporting software compatible with the full capabilities of the Masimo Root™ Patient Monitoring and Connectivity Platform, including Radical-7® and Radius-7® Pulse CO-Oximeters®, Root™ with integrated noninvasive blood pressure and temperature, and connected MOC-9® modules such as SedLine® brain function monitoring, NomoLine® capnography and O3® regional oximetry.

Third-Party Device Connectivity

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

The addition of Iris® connectivity to Root™ and Patient SafetyNet provides multiple advantages to hospitals, such as allowing standalone device information to be remotely viewed at a Patient SafetyNet view station, transmitted through notification systems to clinicians regardless of location or sent to electronic health record systems. This may enhance patient assessment, clinical workflows and decision support. In addition, bringing data from disparate devices together facilitates more integrated patient care, and provides a flexible and cost-effective platform, avoiding installation of separate costly systems and potentially reducing costs by leveraging existing network infrastructure.

Our Strategy

Our mission is to develop technologies that improve patient outcomes and reduce the cost of patient care. We intend to continue to grow our business and improve our market position by pursuing the following strategies:

- Continue to Expand our Market Share in Pulse Oximetry. We grew our product revenue to $829.9 million in 2018 from $599.3 million in 2015, representing a three-year compound annual growth rate of 11.5%. This growth can be attributed to continued expansion of our core SET® pulse oximeter customer base, higher revenues from rainbow® Pulse CO-Oximetry, NomoLine® capnography and other new technologies, and our expanding list of OEM partners. We supplement our direct sales to hospitals and other low-acuity healthcare facilities through various U.S. and international distributors. Combined sales through our direct and distributor sales channels increased to $718.6 million, or 86.6% of product revenue in 2018, from $508.2 million, or 84.8% of product revenue, in 2015. As the healthcare industry shifts toward hospitals, physicians and providers being rewarded by payers based on the quality and value of the services (as opposed to the volume of fee-for-service transactions), we expect to see more hospitals gravitate towards technologies like Masimo SET® that have a proven track record of improving patient care.
- Expand the Pulse Oximetry Market to Other Patient Care Settings. Many patients die due to unintended opioid overdoses after surgery while on general care floors. We believe the ability to continuously and accurately monitor patients outside of critical care settings, including the general, medical and surgical floors of the hospital, is currently an unmet medical need that has the potential to significantly improve patient care and increase the size of the pulse oximetry market. In addition, we believe the ability of Masimo SET® to accurately monitor and address the limitations of conventional pulse oximetry has enabled us, and will continue to enable us, to expand into non-critical care settings, and therefore, significantly expand the market for our products. To further support our expansion into the general care areas, we market Patient SafetyNet, which enables continuous monitoring of up to 200 patients' oxygen saturation, pulse rate and with rainbow SET,™ noninvasive hemoglobin and respiration rate. We believe that Patient SafetyNet, when combined with Masimo SET® pulse oximetry and RAM® or capnography, offers a clinically proven and cost-effective approach to continuous post-operative monitoring. Outside of the hospital setting, patients could die due to unintentional opioid overdose, even when opioids are being taken for short duration, such as after surgery, and as prescribed by a physician. We believe that in the home setting, accurate monitoring with Masimo SET® may help reduce the risk of opioid overdose by alerting family members and others when opioids have slowed a

patient's breathing and caused a significant drop in oxygen saturation.

- Expand the Use of rainbow® Technology in Hospital Settings. We believe the noninvasive measurement of rainbow® Pulse CO-Oximetry (SpHb®, SpCO®, SpMet®, PVi®, $SpfO_2$,™ SPOC™ and ORi™), rainbow Acoustic Monitoring® (RRa®), and the Halo Index,™ as well as future measurements, provide an excellent opportunity to help our customers improve patient care while reducing their overall cost of care.

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- Expand the Use of rainbow® Technology in Non-Hospital Settings. We believe the noninvasive measurement of hemoglobin, SpHb®, creates a significant opportunity in markets such as the physician office, emergency departments and blood donation centers; and the noninvasive measurement of carboxyhemoglobin, SpCO®, creates a significant opportunity in the fire/alternate care market.
- Expand the Use of Root™ in Hospital Settings. We believe Root™ represents a powerful new paradigm in patient monitoring because it enhances our rainbow® and SET® measurements with multiple specialty parameters, including SedLine® brain function monitoring, O3® regional oximetry, and NomoLine® capnography and gas monitoring, and enables open-architecture connectivity in an integrated, clinician-centric hub. Our Iris® integration platform for Root™ provides a conduit to the patient's EMR for a range of clinical devices that may otherwise remain disconnected, and therefore, unable to communicate their information. Iris® offers clinical utility and flexibility by collecting device information from multiple sources and making it available to clinicians in one networked place, akin to an airplane cockpit. Complementary innovations like the Radius-7® wearable, wireless monitor foster an environment of safety without sacrificing patient mobility or comfort. Radius-7® provides patients in medical-surgical units with mobility, allowing them to visit common areas and labs, all while being continuously monitored around the clock. Root™ is acuity-adaptable, meaning it can be configured for any care area, and is competitively priced.
- Utilize our Customer Base and OEM Relationships to Market Masimo rainbow SET™, O3®, SedLine® and Capnography Products Incorporating Licensed rainbow® Technology. We currently sell rainbow SET™ products through our direct sales force and distributors. We include our MX circuit boards in our pulse oximeters and also sell them to our OEM partners. Our MX circuit boards are equipped with circuitry to support rainbow® Pulse CO-Oximetry measurements that can be activated at time of sale or through a subsequent software upgrade. We believe that, over time, the clinical need for these measurements, along with our installed customer base, will help drive the adoption of our rainbow® Pulse CO-Oximetry products.
- Continue to Innovate and Maintain Our Technology Leadership Position. We invented and pioneered the first pulse oximeter to accurately measure arterial blood oxygen saturation level and pulse rate in the presence of motion artifact and low perfusion. In addition, we launched our rainbow SET™ platform that enabled what we believe is the first noninvasive monitoring of carboxyhemoglobin, methemoglobin and hemoglobin, as well as PVi®, all of which were previously only available with invasive and/or complicated testing. Furthermore, we believe that our introduction of RRa® with rainbow Acoustic Monitoring® technology represented the first platform to enable noninvasive and continuous respiration monitoring through an easy-to-use single-patient adhesive acoustic sensor. Finally, we believe that our recent introduction of ORi™ may provide advance warning of an impending hypoxic state, or an indication of an unintended hyperoxic state.

We plan to continue to innovate and develop new technologies and products, internally and through our collaboration with Cercacor, from whom we currently license certain rainbow® technologies.

Our future growth strategy is also closely tied to our focus on international expansion opportunities. Since 2007, we have continued to expand our sales and marketing presence in Europe, Asia, Asia Pacific, Middle East, Canada and Latin America. We have accomplished this by both additional staffing and adding or expanding sales offices in many of these territories. By centralizing a portion of our international operations, including sales management, marketing, customer support, planning, logistics and administrative functions, in Neuchâtel, Switzerland, we believe we have developed a more efficient and scalable international organization that is capable of being even more responsive to the business needs of our international customers under this centralized management structure.

Our Products and Markets

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

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

Patient Monitoring Solutions:		
Description:	Use:	Distribution Channel:
Circuit Boards and Modules (e.g., MX-3 (shown below), MX-5(shown below), MS-2011, MS-2013, MS-2040, uSpO2®, SedLine®, ISA™ and IRMA™)	• Signal processing apparatus for all Masimo technology platforms • Mainstream and sidestream capnography and gas monitoring	• Incorporated and sold to OEM partners who incorporate our circuit boards into their patient monitoring systems
Monitors and Devices (e.g., Radical-7®, Rad-97™ (both shown below), Rad-67™, Rad-87®, Rad-57®, Pronto-7®, Root™, Rad-8®, Rad-5® and Radius-7®)	• Bedside, handheld and wireless monitoring devices that incorporate Masimo SET® with and without licensed Masimo rainbow SET™ technology, noninvasive blood pressure and capnography.	• Sold directly to end-users and through distributors and in some cases to our OEM partners who sell to end-users

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Description:	Use:	Distribution Channel:
Patient Monitoring and Connectivity Platform (e.g., Root™, Radius-7® and Root™ with NIBP (shown below))	• Displays measurements from Masimo's Radical-7® (connected or hand carried) or Radius-7® (patient-worn) • Provides additional specialty measurements from Masimo or third-party-developed applications through Masimo Open Connect® (MOC-9®) • Integrates noninvasive blood pressure (NIBP) and temperature • Connects third-party devices such as IV pumps, ventilators, beds and other patient monitors to automate data transfer to the EMR	• Sold directly to end-users and through distributors
Sensors (e.g., SET®, rainbow® Pulse CO-Oximetry, rainbow Acoustic Monitoring® Sensors, RD SedLine®, TFA-1®, RD rainbow SET™ O3® Pediatric, RD rainbow Lite SET®, rainbow® DCI®-Mini (last four shown		

below))

- Extensive line of both single-patient, reusable and rainbow® sensors
- Patient cables, as well as adapter cables that enable the use of our sensors on certain competitors' monitors

- Sold directly to end-users and through distributors and to OEM partners who sell to end-users

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Description:	Distribution Channel:
Line Filters and Mainstream Adapters for Capnography and Gas Monitoring. (e.g., NomoLine® Cannula with EMMA® Capnograph with disposable adapter (shown below))	
• Line of disposables to measure gas parameters using mainstream and sidestream capnography	• Sold directly to end-users and through distributors and to OEM partners who sell to end-users
Remote Alarm and Supplemental Monitoring Solutions (e.g., Patient SafetyNet)	
• Network-linked, wired or wireless, multiple patient floor monitoring solutions	• Sold directly to end-users
• Standalone wireless alarm notification solutions	
Proprietary Measurements (e.g., SpHb®, SpCO®, SpMet®, PVi®, RRa®, ORi™, 3D Alarms® and	

Adaptive Threshold Alarm)

- rainbow® measurements and other proprietary features

- Sold directly to end-users and through OEM partners who sell to new and existing end-users

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Description:	Distribution Channel:
Connectivity (e.g., Iris® Connectivity, Connectivity Solutions and UniView™ (Shown below))	
• Software and hardware enabling third-party devices to connect through Patient SafetyNet and to document data in the EMR	• Sold directly to end-users

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Consumer Monitoring Solutions:

Devices (e.g. iSpO2®, MightySat® with PVi® and RRp®(shown below))	
• Fingertip pulse oximeter, or pulse oximeter cable and sensor for use with an iPhone, iPad, iPod touch and select Android smart phones	• Sold directly to consumers and through consumer retailers

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 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 measurements to the host monitor. The circuit boards and related software interface directly with our proprietary sensors to calculate SpO_2, PR and Pi. Our latest generation boards include the MS-2003, MS-2011, MS-2013 and MS-2040, with a typical power consumption of less than 45 milliwatts.

Masimo rainbow SET™ MX Circuit Boards. Our next-generation circuit board is the foundation for our Masimo rainbow® Pulse CO-Oximetry and rainbow Acoustic Monitoring® platform, utilizing certain technology that is licensed from Cercacor. The MX circuit boards offer full the functionality of our rainbow® technology, which includes noninvasive measurements for SpHb®, SpOC™, SpCO®, SpMet®, PVi® and RRa®, in addition to providing Measure-through Motion and Low Perfusion® SET® pulse oximetry measurements SpO_2, PR and Pi measurement capabilities of Masimo SET® pulse oximetry. Customers can choose to purchase additional measurements beyond SpO_2, PR and Pi at the time of sale or at any time in the future through a field-installed software upgrade.

Our MX-5 OEM circuit board deploys a technology platform that utilizes approximately half the power of previously available rainbow® circuit boards to deliver rainbow® Pulse CO-Oximetry noninvasive measurement performance. In addition to its lower power demands, the MX-5 adds dynamic power utilization to scale the MX-5's power draw based upon the combination of parameters being monitored to permit even longer battery run-times.

$uSpO_2$® Cable/Board. Our SET® technology-in-a-cable contains the low power (MS-2040) technology in a reduced size, allowing it to be embedded into patient cables as part of the sensor connector. This allows the $uSpO_2$® cable/board to interface with monitoring devices externally via an existing communications port in instances where internal integration of a traditional Masimo SET® technology board is not feasible. The $uSpO_2$® cable/board provides the same Masimo SET® Measure-through Motion and Low Perfusion® pulse oximetry found in our other products, with a typical power consumption of less than 45 milliwatts.

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Monitors / Devices

Root™. Root™ is a powerful patient monitoring and connectivity platform that integrates our rainbow® and SET® measurements with multiple additional specialty measurements through MOC-9® open architecture technology in an integrated, clinician-centric platform. The first MOC-9® technologies developed by Masimo were SedLine® brain function monitoring, NomoLine® capnography and gas monitoring and O3® regional oximetry. Root™ with NomoLine® capnography, SedLine® brain function monitoring, wireless communication and Iris® connectivity for third-party medical devices has received FDA 510(k) clearance. O3® regional oximetry has received CE Mark and FDA 510(k) clearance.

EWS for Root™ aggregates information from multiple vital signs and clinical observations to generate a score that represents the potential degree of patient deterioration. There are several EWS protocols, such as the Pediatric Early Warning Score (PEWS), Modified Early Warning Score (MEWS) and National Early Warning Score (NEWS). These various scores require vital signs contributors such as oxygen saturation, pulse rate, respiration rate, body temperature and systolic blood pressure along with contributors input by clinicians, such as level of consciousness, use of supplemental oxygen and urine output. The weighting and number of contributors differ depending upon which EWS protocol is used. Root™ can be customized for various predefined EWS protocols, or hospitals can configure their own set of required contributors, and their relative weights, to create an EWS unique to their care environment.

Our MOC-9® partnerships enable third parties to utilize Root's™ open architecture and built-in connectivity to independently develop, obtain regulatory approvals, and commercialize their own external MOC-9® module. Alternatively, third parties can develop Masimo Open Connect Control (MOC-C)™ applications for Root™ using the MOC-9® software development kit (SDK). While we support the development efforts of our MOC® partners as needed, and help increase awareness of the availability of non-Masimo MOC-9® modules and MOC-C™ applications, our MOC-9® partners use their existing distribution channels to sell their MOC-9® modules or MOC-C™ applications to customers.

In July 2018, we announced the Vital Signs Check application for Root™. Vital Signs Check is an integrated patient data collection and workflow application that augments Root's™ versatility by helping to streamline hospital vital signs testing and optimize patient data management through automated patient association, centralized data collection, and immediate electronic charting at the bedside.

Radical-7®. The Radical-7® Pulse CO-Oximeter® is a wireless touchscreen device that incorporates our MX circuit board to allow upgradable rainbow SET™ measurements and offers three-in-one capability. The Radical-7® can be used as:

- a standalone device for bedside monitoring;
- a detachable, battery-operated handheld unit for easy portable monitoring;
- an integrated device as part of the Root™ patient monitoring and connectivity platform; and
- a monitor interface via SatShare®, a proprietary technology allowing our products to work with certain competitor products, to upgrade existing conventional multiparameter patient monitors to Masimo SET® while displaying rainbow® measurements on the Radical-7® itself.

With its wide-ranging flexibility, Radical-7® can continuously monitor a patient from the ambulance, to the emergency room, to the operating room, to the general floor and beyond, until the patient is discharged. Radical-7® delivers the accuracy and reliability of Masimo rainbow SET™ with multi-functionality, ease of use and the availability of measurement upgrades for existing monitors.

Radius-7®. Radius-7® for the Root™ patient monitoring and connectivity platform is the first and only wearable, wireless monitor with rainbow SET™ technology, enabling continuous monitoring and early identification of clinical deterioration while still allowing patients the freedom of movement. With Bluetooth® and Wi-Fi wireless connectivity, Radius-7® with Root™ can alert clinicians at the bedside or remotely, through Masimo Patient SafetyNet, of critical changes in a patient's SpO_2 and PR, even during states of motion and low perfusion, as well as RRa® and additional rainbow SET™ measurements. Radius-7® with Root™ has received both CE Mark and FDA 510(k) clearance.

Rad-97™. Rad-97™ is a versatile standalone Pulse CO-Oximeter® that features a 1080p HD color display with user-friendly multi-touch navigation and Measure-through Motion and Low Perfusion® SET® that can be used to

measure SpO_2, PR, PVi® and Pi. rainbow SET™ measurements such as SpHb®, SpOC™, SpCO®, SpMet® and RRa® can also be enabled. Rad-97™ is the smallest Masimo bedside device currently capable of monitoring the full rainbow SET™ platform. Rad-97™ has received CE Mark. In September 2017, we announced FDA 510(k) clearance and full market release of Rad-97™, including an additional Rad-97™ configuration with integrated NomoLine® capnography. Rad-97™ has also received FDA 501(k) clearance for home use, bringing hospital-grade technology to the home in a single integrated device that is a monitoring, connectivity and telecommunications hub.

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An optional integrated camera allows remote clinicians to interact with patients at home over live audio and video. With its built-in enterprise Wi-Fi capability, Rad-97™ has the ability to connect wirelessly from the home to supplemental patient monitoring systems, including Patient SafetyNet, facilitating automatic data transfer to hospital EMR systems.

Rad-97™ NIBP. Rad-97™ NIBP includes an integrated port that allows clinicians to connect a blood pressure cuff inflation hose directly to the device. Designed for reliability and patient comfort, Rad-97™ NIBP is compatible with both disposable and reusable cuffs for a variety of patient types. Rad-97™ NIBP enables clinicians to measure arterial blood pressure for adult, pediatric and neonatal patients, with three measurement modes: spot-check, automatic interval (which measures blood pressure routinely, at a desired interval) and stat interval (which continually measures blood pressure for a desired duration). In March 2017, we announced the CE Mark of the Rad-97™ NIBP. In September 2017, we announced FDA 510(k) clearance and full market release of Rad-97™ NIBP.

Rad-67™. Rad-67™, our handheld Pulse CO-Oximeter®, is a compact, portable spot-check device that offers Measure-through Motion and Low Perfusion® SET® pulse oximetry and upgradeable rainbow® noninvasive monitoring technology. With the universal reusable rainbow® DCI®-mini sensor, Rad-67™ features Next Generation SpHb® technology. In June 2017, we announced the limited market release of the Rad-67™. The Rad-67™ with next generation SpHb® technology has received the CE Mark, but is not currently available for sale in the U.S.

Rad-57®. Rad-57® is a fully featured handheld Pulse CO-Oximeter® that provides continuous, noninvasive measurement of SpO_2, PR, PVi® and Pi with the ability to upgrade to SpHb®, SpCO®, SpMet® and SpOC. Its rugged and lightweight design makes it applicable for use in hospital and field settings, specifically for fire departments and emergency medical service units.

Rad-8®. Rad-8® is a bedside pulse oximeter featuring Masimo SET® (without the ability to update to rainbow® technology) in a low cost design and with a streamlined feature set.

Rad-5®/Rad-5v®. Rad-5® and Rad-5v® were Masimo's first dedicated lightweight, user-configurable, handheld pulse oximeters to provide Masimo SET® SpO_2, PR and Pi measurement (without the ability to upgrade to rainbow® technology).

Rad-G™. Rad-G™ is a low-cost, rugged, handheld pulse oximetry device with a rechargeable battery and LCD display. It uses Measure-through Motion and Low Perfusion® SET® pulse oximetry technology to measure SpO_2, PR, Pi and RRp®. Rad-G™ was designed primarily for use in pneumonia screening and spot-checking of SpO_2 in low-resource settings. Rad-G™ is not currently available for sale in the U.S.

Pronto®. Pronto® is a handheld noninvasive multiparameter testing device that uses Masimo rainbow SET™ technology to provide spot-check measurement of SpO_2, PR, Pi and SpHb® in both hospitals (i.e., emergency departments) and remote settings such as physician offices.

SatShare®. Our SatShare® technology enables a conventional monitor to receive continuous measurement updates using Masimo SET® through a simple cable connection from the back of Radical-7® to the sensor input port on 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 the more accurate monitoring capabilities using Masimo SET®, as well as other additional functionality, in a cost-effective manner. SatShare® technology has facilitated many hospital-wide conversions of previously installed competitor monitors to Masimo SET®. In addition, Masimo rainbow SET™ measurements such as SpHb® are available to clinicians on the Radical-7® itself while the device is being used in SatShare® mode.

MightySat® Rx. MightySat® Rx is a fingertip pulse oximeter that incorporates Masimo Measure-through Motion and Low Perfusion® SET® technology, which measures and displays SpO_2, PR and Pi with the option to add PVi® and RRp®. The MightySat® Rx (without RRp®) has received CE Mark and FDA 510(k) clearance. In February 2017, we announced the CE Mark of the RRp® measurement on the MightySat® Rx fingertip pulse oximeter.

$iSpO_2$ Rx™. The $iSpO_2$ Rx™ pulse oximeter combines a fingertip sensor, cable and pulse oximeter in a lightweight, portable device that connects directly to a smart device for displaying measurements. $iSpO_2$ Rx™ uses Measure-through Motion and Low Perfusion® SET® technology to measure SpO_2, PR and Pi. The Masimo Professional Health app, available for both iOS® and Android devices, allows clinicians to track, trend and download patient data. $iSpO_2$ Rx™

has received the CE Mark, but is not currently available for sale in the U.S.

SedLine® MOC-9® Module. Our SedLine® MOC-9® module for Root™ is an EEG-based continuous brain function monitor that provides information about a patient's response to anesthesia. Our Next Generation SedLine® enhances PSi to make it less susceptible to EMG interference and to improve performance in low-power EEG cases.

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O3® MOC-9® Module. Our O3® MOC-9® module for Root™ uses NIRS to detect regional hypoxemia by continuously measuring tissue oxygen saturation (rSO_2), automating the differential analysis of regional to central oxygen saturation.

NomoLine® Capnography and Gas Monitoring. Our gas analyzers, IRMA™ and ISA,™ are available through Root™ MOC-9® modules via OEM integration or through an emergency capnometer (EMMA®). These analyzers enable our customers to benefit from CO_2, N_2O, O_2 and anesthetic agent monitoring in many hospital environments.

uSpO_2® Cable/Board. Our SET® technology-in-a-cable contains our low power (MS-2040) technology in a reduced size, allowing it to be embedded into patient cables as part of the sensor connector.

Sensors

Sensors and Cables. We have developed one of the broadest lines of single-patient-use (disposable), reusable and rainbow® sensors and cables. In total, we have over 100 different types of sensors designed to meet virtually every clinical need. Masimo SET® sensors are uniquely designed to reduce interference from physiological and non-physiological noise. Our proprietary technology platforms operate only with our proprietary sensor lines. However, through the use of adapter cables, our sensors can be connected to certain competitor pulse oximetry monitors. We sell our sensors and cables to end-users directly or through our distributors and OEM partners.

Our single-patient-use sensors offer several advantages over reusable sensors, including improved performance, cleanliness, increased comfort and greater reliability. Our reusable sensors are primarily used for short-term, spot-check monitoring.

RD SET,™ RD rainbow SET,™ and RD rainbow Lite SET®. Our RD family of sensors is designed to maximize patient comfort, optimize clinician workflow and reduce material waste. RD sensors are lightweight with no moving parts and a flat, soft cable with smooth edges. RD sensors are available in fold-over and wrap-around styles for a variety of patient types and clinical scenarios.

SofTouch™ Sensors. SofTouch™ sensors are designed with less or no adhesive for patients with compromised skin conditions. SofTouch™ sensors are available as single-patient sensors for newborns and multi-site reusable sensors for pediatrics and adults.

Trauma and Newborn Sensors. We have developed two specialty sensor lines, for trauma and resuscitation situations, as well as for newborns. These sensors contain an identifier that automatically sets the pulse oximeter to its maximum sensitivity and fastest settings, and allow for quick application, even in wet and slippery environments. Additionally, we introduced low-profile sensors LNCS® and M-LNCS® Neo, NeoPt and Inf sensors to monitor oxygen saturation in newborns. These sensors are smaller and thinner, making them significantly more comfortable for patients and easier for clinicians to apply.

Blue® Sensors. We believe our Blue® Sensors are the first FDA-cleared sensors to accurately monitor arterial blood oxygen saturation levels in cyanotic infants and children with abnormally low oxygen saturation levels.

E1® Ear Sensor. We believe that our E1® Ear Sensor is the first single-patient-use ear sensor that can be placed securely in the ear conchae, allowing clinicians to combine Masimo SET® performance and central monitoring to provide quick access and responsive assessment of oxygenation. The E1® Ear Sensor is designed for field emergency medical services utilization.

TFA-1® Adhesive Forehead Sensor. We designed our TFA-1® forehead sensor for hospitals desiring forehead monitoring using a disposable sensor. TFA-1® combines Masimo SET® performance with quick access and responsive oxygenation assessment, and has received FDA 510(k) clearance.

rainbow® Sensors. We developed these proprietary, multi-wavelength sensors for use with our rainbow® Pulse CO-Oximetry products. In contrast to traditional sensors that only have the capability to monitor SpO_2, and PR, our rainbow® sensors can also monitor SpCO®, SpMet® and SpHb®. Our licensed rainbow SET™ sensors are the only sensors that are compatible with our licensed rainbow SET™ products. Rainbow® sensors are available in single-patient-use, and reusable spot-check sensor types.

The rainbow® DCI®-mini is the first noninvasive hemoglobin spot-check sensor for infants and small children (weight 3 to 30 kg). Paired with our handheld Pronto® or Rad-67™ devices, the rainbow® DCI®-mini sensors are designed to help clinicians quickly and easily spot-check hemoglobin levels in infants and small children, which may facilitate the

identification of anemia. When paired with Rad-67,™ the rainbow® DCI®-mini enables Next Generation SpHb® measurements. The rainbow® DCI®-mini has received CE Mark in Japan and Europe, but is not currently available for sale in the U.S. The rainbow® Super DCI®-mini sensor allows for the ability to measure SpHb®, SpCO®, SpMet® and SpO_2 on the same noninvasive reusable sensor. The rainbow® Super DCI®-mini has received CE Mark in Japan and Europe, but is not currently available for sale in the U.S.

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rainbow Acoustic® Sensors. We believe we were the first to market a continuous respiration rate monitoring technology based on an acoustic sensor placed on the patient's neck. Our rainbow Acoustic® sensors detect the sounds associated with breathing and convert the sounds into continuous respiration rate using proprietary signal processing that is based on Masimo SET®. RAS-45, our single-use acoustic respiration sensor for RAM®, is designed to facilitate placement on and improve attachment to the neck. RAS-45 operates with Masimo MX circuit boards to measure RRa® and display an acoustic respiration wave form. Like the RAS-125c sensor, RAS-45 operates with Masimo MX technology boards to measure RRa®, display the acoustic respiration wave form and optionally allow clinicians to listen to the sound of breathing. Both the RAS-45 and RAS-125c are available in CE marked countries and the U.S. for adult and pediatric patients who weigh more than 10 kg. In September 2018, we received FDA 510(k) clearance for the RAS-45 for infant and neonatal patients. With this new clearance, acoustic respiration rate measurement is now available for all patients, including neonates, in the U.S. The RAS-45 for infant and neonatal patients has not received CE mark.

SedLine® Sensor. Used with the SedLine® MOC-9® module for the Root™ patient monitoring and connectivity platform, the SedLine® sensor is a disposable sensor that collects EEG data for our SedLine® monitor. In 2017, we introduced RD SedLine® sensors, which feature a repositioned, color-coded sensor-cable connection that lies comfortably on the patient's head and soft foam pads to reduce discomfort upon application to the patient.

O3® Sensors. Used with the O3® MOC-9® module for the Root™ patient monitor, each O3® sensor contains four light-emitting diodes and two detectors to continuously measure rSO_2. In May 2017, we announced FDA 510(k) clearance for our pediatric application of O3® regional oximetry with the O3® pediatric sensor, making O3® regional oximetry monitoring available in the U.S. for both adult patients and pediatric patients weighing more than 5 kg (11 lbs) and less than 40 kg (88 lbs).

Reprocessed Sensors. We offer customers the option of using Masimo reprocessed sensors, the only sensor reprocessing solution that maintains new Masimo sensor performance specifications.

Remote Alarm and Monitoring Solutions

Masimo Patient SafetyNet. Patient SafetyNet is a supplemental remote monitoring and clinician notification system that routes bedside-generated alarms through a server to a qualified clinician's handheld paging device in real-time. Each system can support up to 200 bedside monitors and can either be integrated into a hospital's existing IT infrastructure or operate as a stand-alone wireless network. In March 2018, we announced Replica,™ an application for smart phones and tablets that works in conjunction with Patient SafetyNet.™ Replica™ allows clinicians to view continuous monitoring data for multiple patients, as well as view and respond to alarms and alerts, all from their smart phones, regardless of location.

Proprietary Measurements and Features

All of our monitors shipped since January 2006, including Radical-7® and certain future OEM products, that incorporate the MX circuit board will allow purchases of software for rainbow® measurements, as well as other future measurements. Our current rainbow® measurements include SpHb®, SpCO®, SpMet®, SpOC™ ORi,™ Pi, PR, PVi®, RPVi,™ RRp® and $SpfO_2$,™ as well as rainbow Acoustic Monitoring®, RRa®.

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

Eve,™ our newborn screening software application for our Radical-7® Pulse CO-Oximeter®, is designed to help clinicians more effectively and efficiently screen newborns for CCHD. In the Radical-7® Pulse CO-Oximeter®, Eve™ automates the screening steps with animated instruction, including sensor application, measurement selection and screening result determination. Eve™ is intended to provide consistent application of the screening protocol to reduce method-and operator-induced variability and improve efficiency by automating the data capture and comparison

between readings. Eve™ has received CE Mark, but is currently not available for sale in the U.S.

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X-Cal®

Sensor and cable failures can prevent pulse oximeters from providing the patient safety advantages that continuous pulse oximetry monitoring is intended to provide. Our X-Cal® technology enhances patient safety and improves clinician efficiency by preserving system quality, performance and reliability and reducing the chances of bad or inferior sensors and cables being used on patients. X-Cal® technology enhances the benefits of Masimo's pulse oximetry by incorporating the means to track the expected monitoring life of our sensors and cables and provides appropriate user messaging on the host monitor.

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

- Patient safety may be compromised by using imitation Masimo sensors and cables because they are not produced with comparable components, do not provide proper shielding from ambient interferences, create electrostatic noise caused by motion, do not have our quality and performance controls, and are not tested or warranted to work within a Masimo system;
- We design our sensors and cables to last well beyond their warranty period and customer feedback indicates our sensors and cables last significantly longer than competing products, but cable and sensor reliability may still be compromised when used beyond their intended life, affecting patient care and causing clinicians and biomedical engineers to spend time troubleshooting intermittent cable and sensor issues; and
- We believe that third-party reprocessed pulse oximetry sensors introduce challenges in the clinical environment due to potential quality issues. In fact, we believe that most third-party reprocessed sensors do not indicate that they are capable of performing in the same conditions as Masimo Measure-through Motion and Low Perfusion® sensors or in neonatal applications, key performance requirements available with Masimo SET® sensors. To the best of our knowledge, no third-party company has attempted to reprocess rainbow SET™ sensors.

Connectivity

Iris® connectivity on Root™ allows third-party devices, such as intravenous pumps and ventilators, to connect to Root™ enabling display of measurements and notification on the Root™ monitor, with the ability to document results in the EMR through Masimo Patient SafetyNet.

Iris Gateway® bridges the gap between device data generated at the patient bedside and documentation in patient data management systems by automatically transferring data from medical devices to EMRs, improving productivity and reducing the likelihood of transcription errors.

Kite® provides a supplemental display of data from a Masimo device on a compatible smart television and allows clinicians to configure the display differently than that of the connected Masimo device. Kite® integrates into existing hospital infrastructures where a supplementary display may be beneficial, such as the operating room.

UniView™ provides a supplemental, integrated display of real-time data and alarms from multiple Masimo and third-party devices. UniView™ is designed to reduce clinician cognitive overload and promote data sharing among multiple clinicians, helping them to spot trends and coordinate care.

Data Analysis & Reporting

Trace™ is the first data visualization and reporting software compatible with the full capabilities of the Root™ patient monitoring and connectivity platform, including Radical-7® and Radius-7® Pulse CO-Oximeters®, Root™ with integrated noninvasive blood pressure and temperature, and connected MOC-9® modules such as SedLine® brain function monitoring, ISA™ and ISA™ OR+ capnography, and O3® regional oximetry. Trace™ can create insightful, easy-to-read patient reports that include parameter trends, histograms, event annotations, and key statistics. Trace™ can communicate with Masimo devices via high-speed wired or wireless connections, with the ability to transfer up to 96 hours of patient data.

Consumer Products

MightySat®, our fingertip pulse oximeter for personal use provides SpO_2, PR and Pi measurements for health and wellness applications. MightySat®, which is also available with RRp® and PVi®, provides measurements in a compact, battery-powered design with a large color screen that can be rotated for real-time display of the measurements. Bluetooth® wireless functionality enables measurement display via a free, downloadable Masimo Personal Health application on iOS® and Android mobile devices, as well as the ability to trend and communicate

measurements, including the Apple Health Kit. MightySat® is available through consumer retailers and directly from Masimo, and is intended for general health and wellness use only. MightySat® is not intended for medical use.

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$iSpO_2$® is a personal use pulse oximeter that combines a fingertip sensor, cable and pulse oximeter in a lightweight, portable device that connects directly to a smart device for displaying measurements. $iSpO_2$® uses Measure-through Motion and Low Perfusion® SET® technology to measure SpO_2, PR and Pi. The Masimo Personal Health app, available for both iOS® and Android devices, allows users to track, trend and download their data, as well as share it with the Apple Health app. $iSpO_2$® is available through consumer retailers and directly from Masimo and is intended for general health and wellness use only. $iSpO_2$® is not intended for medical use.

Cercacor Laboratories, Inc.

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

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

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

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

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

Our License to Cercacor. We granted Cercacor an exclusive, perpetual and worldwide license, with sublicense rights, to use our Masimo SET® technology, including all improvements, for the monitoring of non-vital signs measurements and to develop and sell devices incorporating Masimo SET® for monitoring non-vital signs measurements in the "Cercacor Market". The Cercacor Market consists of any product market in which a product is intended to be used by a patient or pharmacist rather than a professional medical caregiver regardless of the particular location of the sale, including sales to doctors, hospitals, alternate care market professionals or otherwise, provided the product is intended to be recommended, or resold, for use by the patient or pharmacist. We also granted Cercacor a non-exclusive, perpetual and worldwide license, with sublicense rights, to use Masimo SET® for the measurement of vital signs in the Cercacor Market. In exchange, Cercacor pays us a 10% royalty on the amount of vital signs sensors and accessories sold by Cercacor.

Cercacor's License to us. We exclusively license from Cercacor the right to make and distribute products in the "Masimo Market" that utilize rainbow® technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation, and hemoglobin, which includes hematocrit. The Masimo Market consists of any product market where the product is intended to be used by a professional medical caregiver, including hospital caregivers, surgicenter caregivers, paramedic vehicle caregivers, doctors' offices caregivers, alternate care facility caregivers and vehicles where alternative care services are provided. We also have the option to obtain exclusive licenses to make and distribute products in the Masimo Market that utilize rainbow® technology for the monitoring of

other non-vital signs measurements, including blood glucose. We have 180 days after proof of feasibility to exercise the above-referenced option to obtain a license for the measurement of blood glucose for an additional $2.5 million and licenses for other non-vital signs measurements for an additional $0.5 million each. The licenses are exclusive until the later of 20 years from the grant of the applicable license or the expiration of the last patent included in the rainbow® technology related to the applicable measurements. To date, we have developed and commercially released devices that measure carbon monoxide, methemoglobin and hemoglobin using licensed rainbow® technology. We also make and distribute products that monitor respiration rate via rainbow Acoustic Monitoring®, which is a Masimo-developed rainbow® technology and, therefore, is not required to be licensed from Cercacor.

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Our license to use rainbow® technology for these measurements in these markets is exclusive on the condition that we continue to pay Cercacor royalties on our products incorporating rainbow® technology, subject to certain minimum aggregate royalty thresholds, and that we use commercially reasonable efforts to develop or market products incorporating the licensed rainbow® technology. The royalty is up to 10% of the rainbow® royalty base, which includes handhelds, tabletop and multiparameter devices. Handheld products incorporating rainbow® technology carry a 10% royalty rate. For other products, only the proportional amount attributable to that portion of our devices used to monitor non-vital signs measurements, rather than to monitor vital signs measurements, and sensors and accessories for measuring only non-vital sign parameters are included in the 10% rainbow® royalty base. For multiparameter devices, the rainbow® royalty base includes the percentage of the revenue based on the number of rainbow®-enabled measurements. For hospital contracts where we place equipment and enter into a sensor contract, we pay a royalty to Cercacor on the total sensor contract revenue based on the ratio of rainbow®-enabled devices to total devices. During the year ended December 29, 2018 and going forward, we are subject to certain specific annual minimum aggregate royalty payment obligations of $5.0 million per year.

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

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

For purposes of the Cross-Licensing Agreement, a change in control includes any of the following with respect to us or Cercacor:

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

Ownership of Improvements. Any improvements to Masimo SET® or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third-party that relates to non-vital signs monitoring, and any new technology acquired by Cercacor, is and will be owned by Cercacor. Any improvements to the Masimo SET® platform or rainbow® technology made by Cercacor, by us, or jointly by Cercacor with us or with any third-party that relates to vital signs monitoring, and any new technology acquired by us, is and will be owned by us. However, for both non-vital signs and vital signs monitoring, any improvements to the technology, excluding acquired technology, will be assigned to the other party and will be subject to the terms of the licenses granted under the Cross-Licensing Agreement. Any new non-vital signs monitoring technology utilizing Masimo SET® that we develop will be owned by Cercacor and will be subject to the same license and option fees as if it had been developed by Cercacor. Also, we will not be reimbursed by Cercacor for our expenses relating to the development of any such technology.

Other Agreements with Cercacor. We have also entered into various other agreements with Cercacor, including an Administrative Services Agreement, a Consulting Services Agreement and a Sublease Agreement. See Note 3 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on these agreements and other transactions with Cercacor.

As a result of changes in the capital structure of Cercacor, as well as certain of its contractual relationships with us, we completed a re-evaluation of the authoritative consolidation guidance during the year ended December 31, 2016 and determined that, although Cercacor remains a variable interest entity, we are no longer its primary beneficiary. Based on such determination, we discontinued consolidating Cercacor within our consolidated financial statements effective

as of January 3, 2016. See Note 3 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information.

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Government Regulation

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

U.S. Food and Drug Administration (FDA) Premarket Clearance and Approval Requirements

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

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

Although an applicant may initially choose whether to submit a 510(k) notification for clearance, a PMA for approval or a de novo classification request, the FDA decides which pathway is appropriate based upon the classification of the device. Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's general regulatory controls (General Controls) for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation (QSR), facility registration and product listing, reporting of adverse medical events and malfunctions, reporting of corrections and removals, and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Only specified Class I devices, including devices with software, are subject to the design controls requirements of the QSR; other Class I devices are exempt from design control requirements. Some Class I devices are also exempt from many of the good manufacturing practice requirements of the QSR by regulation. While most Class I devices are exempt from the 510(k) premarket notification process, some Class I devices also require 510(k) clearance by the FDA.

Class II devices are subject to the FDA's General Controls, including the Design Control requirements of the QSR, and other special controls deemed necessary by the FDA to provide reasonable assurance of 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, although some Class II devices are exempt from the premarket notification requirement. The majority of our current regulated devices are classified as Class II devices, while only a few are classified as Class I devices.

To obtain 510(k) clearance, a company must submit a premarket notification demonstrating substantial equivalence between the proposed device and a legally marketed "predicate" device. A "predicate device" is a legally marketed device that (i) was legally marketed prior to May 28, 1976, for which the FDA has not yet called for submission of a PMA application; (ii) has been reclassified by the FDA from Class III to Class II or Class I; (iii) has been cleared through the 510(k) premarket notification process; or (iv) previously has been determined to be exempt from the 510(k) process. The proposed device is substantially equivalent to the predicate device if the proposed device has the same intended use and the same technological characteristics as the predicate device, or, if the proposed device has different technological characteristics, the proposed device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness. After a device receives 510(k) clearance, any modification that could

significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, requires a new 510(k) clearance or, if the modified device is not substantially equivalent to the unmodified device, could require a PMA approval or de novo classification. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review this decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, PMA approval or de novo classification, the agency may retroactively require the manufacturer to seek 510(k) clearance, PMA approval or de novo classification. The FDA can also require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance, PMA approval or de novo classification is obtained.

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Class III devices are those deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or those devices deemed not substantially equivalent to a legally marketed predicate device. Due to the risk level associated with Class III devices, the FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of the device. These Class III devices must be approved through the PMA approval process during which the manufacturer must provide reasonable assurance of safety and effectiveness for the intended use(s) of the device to the FDA's satisfaction. A PMA application must be supported by valid scientific evidence, including extensive preclinical (including bench tests and laboratory and animal studies) and clinical studies as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. As part of the PMA application review, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the FDA's QSRs. If the FDA approves the PMA, it may place restrictions on the device or the labeling or require additional clinical studies, monitoring or other post-market requirements. If the FDA's evaluation of the PMA application or the manufacturing facility is not favorable, the FDA may deny approval of the PMA application or issue a "not approvable" letter. The FDA may also require additional clinical trials, which can delay the PMA approval process by several years or otherwise make obtaining PMA approval infeasible. 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 or de novo classification request. Clinical trials involving a "significant risk" device require FDA approval of an Investigational Device Exemption (IDE) application, unless the proposed study is deemed to be exempt from the IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, protocols for the proposed clinical trials and other information demonstrating that the device is appropriate for use with humans in a clinical study. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards (IRBs) at the clinical trial sites. Submission of an IDE application does not give assurance that the FDA will issue the IDE. If the IDE application is approved, there can be no assurance the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. If the study meets the requirements for a non-significant risk study, it may be eligible for compliance with "abbreviated" IDE requirements, which include a subset of the requirements applicable to significant risk medical devices studies. Sponsors of non-significant risk studies must obtain IRB approval but are not required to obtain FDA approval of an IDE application. Sponsors of both significant risk and non-significant risk trials must comply with the FDA's regulations, including the requirement that informed consent be obtained from each subject, and with clinical trial reporting regulations that require submission of information about certain clinical trials to a public database maintained by the National Institutes of Health. 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, approval or classification of the device.

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

We market our iSpO2® pulse oximeter and MightySat® fingertip pulse oximeter for general health and wellness use. We are marketing these products in accordance with the FDA's current policy and enforcement discretion which indicates that pulse oximeters that are not intended for medical purposes can be marketed directly to consumers without first obtaining 510(k) clearance. We cannot assure you that the FDA will not change its policy regarding the regulation of these products. If the FDA changes its policy, we may be required to seek 510(k) clearance to market

these pulse oximeters. We also may be required to cease marketing and/or recall the products until we obtain new 510(k) clearances.

The regulatory regime is subject to change by Congress or the FDA. For example, in December 2016, Congress enacted the 21st Century Cures Act (Cures Act), which contained several provisions related to the review and approval of new medical technologies. Along with other changes, the Cures Act established a statutory program for "breakthrough" devices, defined as devices intended to treat or diagnose a life-threatening or irreversibly debilitating disease that represents a breakthrough technology, devices that have no approved/cleared alternatives, devices that offer significant advantages over approved/cleared alternatives, or devices where the availability of such device is in the best interest of patients. The FDA will apply additional resources to help speed the approval or clearance of devices that are designated as breakthrough devices. The Cures Act also included provisions related to the "least burdensome" principle and expanded the number of patients that could be treated using a device approved under a Humanitarian Device Exemption, among other provisions. Furthermore, in August 2017, Congress enacted the FDA Reauthorization Act of 2017 (FDARA).

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Although FDARA principally reauthorized the FDA user fee programs, it also included, among other things, provisions that establish processes for the initial classification and reclassification of accessory devices, i.e., devices used with a parent device.

User Fees

Unless a specific exemption or waiver applies, 510(k) submissions, de novo classification requests, and PMA applications are subject to user fees. The PMA and de novo classification user fees are significantly higher than the user fees for 510(k) notifications. The FDA was reauthorized to assess medical device user fees through fiscal year 2022 pursuant to FDARA.

Pervasive and Continuing FDA Regulation

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

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- unique device identification (UDI) registration, which identifies medical devices through their distribution and use;
- QSRs and current good manufacturing practices (GMPs), which require manufacturers, including third-party manufacturers, to follow stringent design control, testing, change control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process, including requirements for packaging, labeling and record keeping, complaint handling, corrective and preventive actions and internal auditing;
- labeling control and advertising regulations, including FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses or indications;
- for 510(k)-cleared devices, clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change or modification in intended use of one of our cleared devices;
- for any future PMA approved products, approval of product modifications that affect the safety or effectiveness of the device;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device 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;
- for any future PMA approved products, post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of its conditions of approval, governing laws and/or regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

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

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

- an FDA Form 483, which is issued by the FDA at the conclusion of an inspection when an investigator has observed any conditions that may constitute potential violations of the FDCA and related Acts;
- a public warning letter that notifies a company of potential violations of the FDCA;
- fines and monetary civil penalties against us and/or OEM partners;
- delays in clearing or approving, or refusal to clear or approve, our products;
-

withdrawal or suspension of clearances and/or approvals of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

- product recall;

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- product detention or seizure;
- interruption of production;
- refusal to provide Certificates to Foreign Governments (CFGs), which may be necessary to permit the export of devices from the U.S. to other countries;
- operating restrictions;
- injunctions (including those agreed to in a consent decree); and
- criminal prosecution.

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

Advertising and Promotion

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission (FTC) and by federal and state regulatory and enforcement authorities, including the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and various state attorneys general. Although physicians are permitted to use their medical judgment to use medical devices for indications other than those cleared or approved by the FDA, we may not promote our products for such "off-label" uses and can only market our products for cleared or approved uses.

Other companies' promotional activities for their FDA-regulated products have been the subject of FTC enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. FTC enforcement actions often result in consent decrees that constrain future actions. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

Import and Export Requirements

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

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

Foreign countries often require, among other things, a CFG for export. To obtain a CFG, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities were in compliance with the FDA's QSR regulations at the time of the last FDA inspection.

Foreign Regulation Regarding Clearance and Approval

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

In particular, marketing of medical devices in the European Union (EU) is subject to compliance with the Medical Devices Directive 93/92/EEC (MDD). A medical device may be placed on the market within the EU only if it conforms to certain "essential requirements" and bears the CE Mark. The most fundamental and essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the essential performance(s) intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

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Manufacturers must demonstrate that their devices conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. The classification rules are mainly based on three criteria: the length of time the device is in contact with the body, the degree of invasiveness and the extent to which the device affects the anatomy. Conformity assessment procedures for all but the lowest risk classification of device involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Manufacturers usually have some flexibility to select a notified body for the conformity assessment procedures for a particular class of device and to reflect their circumstances, e.g., the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer's quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE Mark. Application of the CE Mark allows the general commercializing of a product in the EU. The product can also be subjected to local registration requirements depending on the country. We maintain CE Marking on all of our products that require such markings as well as local registrations as required.

In May 2017, the EU adopted a new Medical Devices Regulation (EU) 2017/745 (MDR), which will repeal and replace the MDD with effect from May 26, 2020. The MDR clearly envisages, among other things, stricter controls of medical devices, including strengthening of the conformity assessment procedures, increased expectations with respect to clinical data for devices and pre-market regulatory review of high-risk devices. The MDR also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2020 may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU.

Medical Device Tax

The Affordable Care Act (ACA) also imposed a significant new tax on medical device makers in the form of a 2.3% excise tax on U.S. medical device sales, with certain exemptions (MDET). For the year ended January 2, 2016, we recorded $6.9 million in medical device taxes that were included in selling, general and administrative expenses. The MDET is currently suspended through December 31, 2019. The tax may be reimposed on medical device makers beginning on January 1, 2020 if the suspension is not re-extended or the medical device tax is not permanently repealed.

Conflict Minerals and Supply Chain

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

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

Environmental

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

materials and wastes. Products that we sell in Europe are subject to regulation in EU markets under the Restriction of Hazardous Substances Directive (RoHS). RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in EU member states. In addition, the EU's Regulation-Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products.

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

Health Care Fraud and Abuse

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

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

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

The Physician Payment Sunshine Act (Sunshine Act), which was enacted by Congress as part of the ACA, requires medical device companies to track and publicly report, with limited exceptions, all payments and transfers of value to physicians and teaching hospitals in the U.S. Companies are required to track payments made and to report such payments to the government by March 31 of each year. Several states have similar requirements.

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

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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. Therefore, our risk of being found in violation of these laws is increased by the fact that some of these laws are broad and open to interpretation.

Privacy and Security of Health and Other Personal Information

Numerous federal, state and international laws and regulations, including HIPAA and General Data Protection Regulation (GDPR), govern the collection, use and disclosure of patient-identifiable, protected health information (PHI) and other personal information. In the U.S., HIPAA applies to covered entities, which include most healthcare facilities that purchase and use our products, and their business associates. The HIPAA Privacy Rule restricts the use and disclosure of PHI, and requires covered entities and their business associates to safeguard that information and to provide certain rights to individuals with respect to that information. The HIPAA Security Rule establishes detailed requirements for safeguarding PHI transmitted or stored electronically. Although we are not a covered entity, we are sometimes deemed to be a business associate of covered entities due to activities that we perform for or on behalf of covered entities, such as training customers on the use of our products or investigating product performance. As business associates, we are subject to many of the requirements of HIPAA and could be directly subject to HIPAA civil and criminal enforcement and the associated penalties for violation of the Privacy, Security and Breach Notification Rules.

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

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

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

Third-Party Reimbursement

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

The Centers for Medicare & Medicaid Services (CMS) is the federal agency responsible for administering the Medicare program. Along with its contractors, CMS establishes the coverage and reimbursement policies for the Medicare program. Because a large percentage of our products are used in the treatment of 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.

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

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

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

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

Our success with rainbow SET™ technologies in U.S. settings of care with reimbursable monitoring procedures, such as hospital emergency departments, hospital procedure labs, and the physician office may largely depend on the ability of providers to receive reimbursement for such procedures. While private insurance payers often follow Medicare coverage and payment, we cannot be certain of this and, in many cases, cannot control the coverage or payment rates that private insurance payers put in place. In addition, the potential amendment, repeal or judicial invalidation of the ACA, and/or the enactment of other legislation or regulations, could affect future payment for services involving the use of our products.

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

Other U.S. and Foreign Regulation

We and our OEM partners also must comply with numerous federal, state and local laws, as well as laws in other jurisdictions, 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.

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, Medtronic plc (Medtronic, formerly Covidien Ltd.), currently holds a substantial share of the pulse oximetry market.

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Medtronic sells its own brand of Nellcor pulse oximeters to end-users, sells pulse oximetry modules to other monitoring companies on an OEM basis, and licenses to certain OEMs the right to make their pulse oximetry platforms compatible with their sensors. We also face substantial competition from larger medical device companies, including companies that develop products that compete with our proprietary Masimo SET® and our OEM partners. We believe that a number of companies have announced products that claim to offer motion-tolerant accuracy. Pursuant to the terms of the Third Amendment to Settlement Agreement and Release of Claims effective September 2016, Medtronic discontinued paying royalties to us for its sales after October 6, 2018. In addition, some of our patents have expired and other will expire over time in accordance with the laws of the jurisdiction in which they were issued.

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

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

Sales and Marketing

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

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

For the year ended December 29, 2018, two just-in-time distributors, Owens & Minor and Cardinal Health, represented approximately 10.0% and 12.5%, respectively, of our total revenue. These were the only two customers that represented 10% or more of our revenue for the year ended December 29, 2018. Importantly, these two distributors take and fulfill orders from our direct customers, many of which have signed long-term sensor purchase agreements with us. As a result, in the event a specific just-in-time distributor is unable to fulfill these orders, the orders would be redirected to other distributors or fulfilled directly by us.

Additionally, we sell certain of our products through our OEM partners who both incorporate our boards into their monitors and resell our sensors to their customers' installed base of Masimo SET® products. Our OEM agreements allow us to expand the availability of Masimo SET® through the sales and distribution channels of each OEM partner. To facilitate clinician awareness of Masimo SET® installations, all of our OEM partners have agreed to place the Masimo SET® logo prominently on their instruments.

In order to facilitate our U.S. direct sales to hospitals, we have signed contracts with what we believe to be the five largest national GPOs in the U.S., based on the total volume of negotiated purchases. In return for the GPOs putting our products on contract, we have agreed to pay the GPOs a percentage of our revenue from their member hospitals. In 2018 and 2017, revenue from the sale of our pulse oximetry products to hospitals that are associated with GPOs amounted to $470.5 million and $417.0 million, respectively.

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

Intellectual Property

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

We have developed a patent portfolio internally, and, to a lesser extent, through acquisitions and licensing, that covers many aspects of our product offerings. As of December 29, 2018, we had 644 issued patents and 353 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. Our patents expire in accordance with the laws of the particular jurisdiction in which they were issued, which sometimes change. Additionally, as of December 29, 2018, we owned 81 U.S. registered trademarks and 248 foreign registered trademarks, as well as trade names that we use in conjunction with the sale of our products. Our trademarks are perpetually renewable.

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

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

Research and Product Development

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

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

Manufacturing

Our strategy is to manufacture products in-house when it is efficient and cost-effective for us to do so. We currently manufacture our bedside and handheld pulse oximeters, our full line of disposable and reusable sensors and most of our patient cables in-house or through captive contract maquiladora operations. We maintain an approximate 70,700 square foot manufacturing facility in Irvine, California, and two separate manufacturing facilities in Mexicali and San Luis Rio Colorado, Mexico that have combined square footage of approximately 216,900 square feet, all three of which are International Organization for Standardization (ISO) 13485:2016 certified. We also maintain an approximate 86,500 square foot facility in Hudson, New Hampshire, a portion of which is used to manufacture advanced light emitting diodes and other advanced component-level technologies. In addition, we maintain an ISO 13485:2016 certified facility approximating 16,400 square feet in Danderyd, Sweden, a portion of which is used to manufacture ultra-compact mainstream and sidestream capnography and gas monitoring technologies. We will continue to utilize third-party contract manufacturers for products and subassemblies that can be more efficiently manufactured by these parties, such as our circuit boards. We monitor our third-party manufacturers and perform inspections and product tests at various steps in the manufacturing cycle to ensure compliance with our specifications.

We also do full functional testing of our circuit boards.

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

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

Employees

As of December 29, 2018, we had approximately 1,500 full-time employees and approximately 3,000 dedicated contract personnel worldwide.

Address

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

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ITEM 1A. RISK FACTORS

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

Risks Related to Our Revenues

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

We are highly dependent upon the continued success and market acceptance of our proprietary Masimo SET® technology that serves as the basis of our primary product offerings. Continued market acceptance of products incorporating Masimo SET® will depend upon us continuing to provide evidence to the medical community that our products are cost-effective and offer significantly improved performance compared to conventional pulse oximeters. Health care providers that currently have significant investments in competitive pulse oximetry products may be reluctant to purchase our products. If hospitals and other health care providers do not believe our Masimo SET® platform is cost-effective, safe or more accurate or reliable than competitive pulse oximetry products, they may not buy our products in sufficient quantities to enable us to generate revenue growth from the sale of these products. In addition, allegations regarding the safety and effectiveness of our products, whether or not substantiated, may impair or impede the acceptance of our products.

Some of our products 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.

Many of our noninvasive measurement technologies are considered disruptive. These technologies have performance levels that we believe are acceptable for many clinical environments but may be insufficient in others. In addition, these technologies may perform better in some patients and settings than others. Over time, we hope to continue to improve the performance of these technologies and educate the clinical community on how to properly evaluate them. If we are successful in these endeavors, we expect these technologies will become more useful in more environments and will become more widely adopted. We are continuing to invest in sales and marketing resources to achieve market acceptance of these products, but are unable to guarantee that our technologies will achieve general market acceptance.

The degree of market acceptance of these products will depend on a number of factors, including:

- perceived clinical benefits from our products;
- perceived cost effectiveness of our products;
- perceived safety and effectiveness of our products;
- reimbursement available through government and private health care programs for using some of our products; and
- introduction and acceptance of competing products or technologies.

If our products do not gain market acceptance or if our customers prefer our competitors' products, our potential revenue growth would be limited, which would adversely affect our business, financial condition and results of operations.

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

Since 1998, we have been a party to a cross-licensing agreement with Cercacor, (as amended, the Cross-Licensing Agreement), under which we granted Cercacor:

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

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- a non-exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET® technology owned by us for measurement of vital signs in the Cercacor Market.

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

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

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

The medical device industry is intensely competitive and is significantly affected by new product introductions and other market activities of industry participants. A number of our competitors have substantially greater capital resources, larger product portfolios, larger customer bases, larger sales forces and greater geographic presence, have established stronger reputations with specific customers, and have built relationships with Group Purchasing Organizations and other hospital purchasing groups (collectively, GPOs) that may be more effective than ours. Our Masimo SET® platform faces additional competition from companies developing products for use with third-party monitoring systems, as well as from companies that currently market their own pulse oximetry monitors. In addition, competitors with larger product portfolios than ours are engaging in bundling practices, whereby they offer increased discounts to hospitals that purchase their requirements for a variety of different products from the competitor, including products that we do not offer.

Rapid product development and technological advances within the medical device industry place 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 our existing technologies. 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, such as for respiration rate, hemoglobin, carboxyhemoglobin and methemoglobin monitoring.

If we do not successfully adapt our products and applications both within and outside these measurements, we could lose revenue opportunities and customers. Furthermore, one or more of our competitors may develop products that are substantially equivalent to our U.S. Food and Drug Administration (FDA) cleared products, or those of our original equipment manufacturer (OEM) partners, in which case a competitor of ours may use our products or those of our OEM partners as predicate devices to more quickly obtain FDA clearance of their competing products. Competition could result in pressure from our customers to reduce the price of our products and place fewer orders for our products, which could, in turn, cause a reduction in our revenues and product gross margins, thereby adversely impacting our business, financial condition and results of operations.

Some of the world’s largest technology companies that have not historically operated in the healthcare or medical device space, such as Apple, Alphabet, Samsung and others, have developed or may develop products and technologies that may compete with our current or future products and technologies. These companies have substantially greater capital, research and development, and sales resources than we have. If we are unable to successfully compete against them, our financial performance could decline.

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

We are, and will continue to be, dependent upon our domestic and international OEM partners for a portion of our revenue through their marketing, selling and distribution of certain of their products that incorporate our technologies. Although we expect that our OEM partners will accept and actively market, sell and distribute products that incorporate our technologies, they may not do so. Because products that incorporate our technologies may represent a relatively small percentage of business for some of our OEM partners, they may have less incentive to promote these products over other products that do not incorporate these technologies.

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In addition, some of our OEM partners offer products that compete with ours and also may be involved in intellectual property disputes with us. Therefore, we cannot guarantee that our OEM partners, or any company that may acquire any of our OEM partners, will vigorously promote products incorporating our technologies. The failure of our OEM partners to successfully market, sell or distribute products incorporating our technologies, the termination of OEM agreements, the loss of OEM partners or the inability to enter into future OEM partnership agreements would have a material adverse effect on our business, financial condition and results of operations.

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

Our ability to sell our products to hospitals depends, in part, on our relationships with GPOs. Many existing and potential customers for our products are members of GPOs. GPOs negotiate pricing arrangements and contracts with medical supply manufacturers and distributors that may include provisions for sole sourcing and bundling, which generally reduce product purchasing decisions available to the hospitals.

These negotiated prices are made available to a GPO's members. If we are not one of the providers selected by a GPO, the GPO's 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 such GPO for the duration of such contractual arrangement. Shipments of our pulse oximetry products to customers that are members of GPOs represented more than 80% of our U.S. product sales for the year ended December 29, 2018. Our failure to renew our contracts with GPOs may cause us to lose market share and could have a material adverse effect on our business, financial condition and results of operations. In addition, if we are unable to develop new relationships with GPOs, our competitive position would likely suffer and our opportunities to grow our revenues and business would be harmed.

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 lack of adequate coverage and reimbursement for our products or the procedures in which our products are used may deter customers from purchasing our products.

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

We do not control payer decision-making with respect to coverage and payment levels for our products. Additionally, we expect many payers to continue to explore cost-containment strategies (e.g., comparative and cost-effectiveness analyses, so-called "pay-for-performance" programs implemented by various public government health care programs and private third-party payers, and expansion of payment bundling initiatives, and other such methods that shift medical cost risk to providers) that may potentially impact coverage and/or payment levels for our current products or products we develop in the future.

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.

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations or financial condition.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payers to curb these costs have resulted in a consolidation trend in the healthcare

industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This has resulted in, and will likely continue to result in, greater pricing pressures and the exclusion of certain suppliers from important market segments as GPOs, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals.

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We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to impact the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and adversely impact our business, financial condition and results of operations.

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

Our customers are facing growing levels of uncertainties, including variations in overall hospital census for paying patients and the impact of such census variations on hospital budgets. As a result, many hospitals are reevaluating their entire cost structure, including the amount of capital they allocate to medical device technologies and products. Such developments could have a significant negative impact on our OEM customers who, due to their traditionally larger capital equipment sales model, could see declines in purchases from their hospital customers. This, in turn, could reduce our board sales to our OEM customers.

In addition, certain of our products, including our rainbow® measurements such as carbon monoxide, methemoglobin and hemoglobin, that are sold with upfront license fees and more complex and expensive sensors, could also be impacted by hospital budget reductions.

States and other local regulatory authorities may issue guidelines regarding the appropriate scope and use of our products from time to time. For example, some of our noninvasive monitoring devices may be subject to authorization by individual states as part of the Emergency Medical Services (EMS) scope of practice procedures. A lack of inclusion into scope of practice procedures may limit adoption.

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

We have a concentration of OEM, distribution and direct customers. For example, sales to two just-in-time distributors each represented more than 10% of our product sales for the year ended December 29, 2018. We cannot provide any assurance that we will retain our current customers, groups of customers or distributors, or that we will be able to attract and retain additional customers in the future. If for any reason we were to lose our ability to sell to a specific group or class of customers, or through a distributor, we could experience a significant reduction in revenue, which would adversely impact our operating results.

Our sales could also be negatively affected by any rebates, discounts or fees that are required by, or offered to, GPOs and customers, including wholesalers or distributors. Additionally, some of our just-in-time distributors have been demanding higher fees, which we may be forced to pay in order to continue to offer products to our customers or which may force us to distribute our products directly to our customers. The loss of any large customer or distributor, or an increase in distributor fees, could have a material adverse effect on our business, financial condition and results of operations.

Our royalty and other revenue has historically consisted primarily of royalties received from Medtronic plc (Medtronic, formerly Covidien Ltd.) related to its U.S. sales, and more recently, revenue from non-recurring engineering (NRE) services for a certain OEM customer. However, Medtronic is not required to pay royalties to us on any sales occurring after October 6, 2018. In addition, we have completed the majority of our contracted NRE services and expect to complete the remaining NRE services next year. We currently do not expect to replace this royalty and NRE services revenue with revenue from other sources, and such loss of revenue will have an adverse effect on our future results of operations.

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

We believe that other organizations are manufacturing and selling imitation Masimo sensors. In addition, certain medical device reprocessors have been collecting our used single-patient-use sensors from hospitals and then reprocessing, repackaging and reselling those sensors to hospitals. These imitation and third-party reprocessed sensors are sold at lower prices than new Masimo sensors. Our experience with both these imitation sensors and third-party

reprocessed sensors is that they provide inferior performance, increased sensor consumption, reduced comfort and a number of monitoring problems. Notwithstanding these limitations, some of our customers have indicated a willingness to purchase some of their sensor requirements from these imitation manufacturers and third-party reprocessors in an effort to reduce their sensor costs.

These imitation and reprocessed sensors have led and may continue to lead to confusion with our genuine Masimo products; have reduced and may continue to reduce our revenue; and, in some cases, have harmed and may continue to harm our reputation if customers conclude incorrectly that these imitation or reprocessed sensors are original Masimo sensors.

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In addition, we have expended a significant amount of time and expense investigating issues caused by imitation and reprocessed sensors, troubleshooting problems stemming from such sensors, educating customers about why imitation and reprocessed sensors do not perform to their expectations, enforcing our proprietary rights against the imitation manufacturers and reprocessors, and enforcing our contractual rights under our customer contracts.

In response to these imitation sensors and third-party reprocessors, we have incorporated X-Cal® technology into certain products to ensure our customers get the performance they expect by using genuine Masimo sensors and that such sensors do not continue to be used beyond their useful life. However, some customers may object to the X-Cal® technology, potentially resulting in the loss of customers and revenues.

We also offer our own Masimo reprocessed sensors, which meet the same performance specifications as our new Masimo sensors, to our customers. Reprocessed sensors sold by us are also offered at a lower price and, therefore, may reduce certain customer demand for our new sensors. As a result, increased sales of our own Masimo reprocessed sensors may result in lower revenues, which could negatively impact 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. Our utilization of patent protection, trade secrets and a combination of copyright and trademark laws, as well as nondisclosure, confidentiality and other contractual arrangements, to protect our intellectual property afford us only limited protection and may not adequately protect our rights or permit us to gain or maintain any competitive advantage.

Our patents related to Masimo SET® algorithm technology began to expire in 2011. Certain other patents related to our ProCal sensor technology began to expire in 2015. Additionally, upon the expiration of other issued or licensed patents, we may lose some of our rights to exclude competitors from making, using, selling or importing products using the technology based on the expired patents. Furthermore, in recent years, the U.S. Supreme Court has ruled on several patent cases and several laws have been enacted that, in certain situations, potentially narrows the scope of patent protection available and weakens the rights of patent owners. There can be no assurance that we will be successful in securing additional patents on commercially desirable improvements, that such additional patents will adequately protect our innovations or offset the effect of expiring patents, or that competitors will not be able to design around our patents.

In addition, third parties may challenge our issued patents through procedures such as Inter-Partes Review (IPR). In many IPR challenges, the U.S. Patent and Trademark Office (PTO) cancels or significantly narrows issued patent claims. IPR challenges could increase the uncertainties and costs associated with the maintenance, enforcement and defense of our issued and future patents and could have a material adverse effect on our business, financial condition and results of operations.

We also utilize unpatented proprietary technology and know-how and often rely on confidentiality agreements and intellectual property assignment agreements with our employees, OEM partners, independent distributors and consultants to protect such unpatented proprietary technology and know-how. 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.

We rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Common law trademarks provide less protection than registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

The laws of foreign countries may not adequately protect our intellectual property rights.

Intellectual property protection laws in foreign countries differ substantially from those in the U.S. If we fail to apply for intellectual property protection in foreign countries, 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.

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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.

Searching for existing intellectual property rights may not reveal important intellectual property and our competitors may also have filed for patent protection, which may not be publicly-available information, or claimed trademark rights that have not been revealed through our searches. In addition, some 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:

- be expensive and time consuming to defend and result in payment of significant damages to third parties;
- force us to stop making or selling products that incorporate the intellectual property;
- require us to redesign, reengineer or rebrand our products, product candidates and technologies;
- require us to enter into royalty agreements that would increase the costs of our products;
- 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; and
- 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;

any of which could 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. As a result, we may initiate litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert management's attention from implementing our business strategy.

We believe that the success of our business depends, in 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 positions related to some of our pulse oximetry signal processing patents that resulted in various settlements, most recently in 2016, and in view of some of the new market entrants, may be required to engage in additional litigation to protect our intellectual property in the future. In addition, we believe that an individual, who previously held a high level technical position with us, misappropriated our intellectual property for the benefit of himself and other companies. 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 successful or 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 U.S., which could severely harm our business.

Unless an exemption applies, each medical device that we wish to market in the U.S. must first undergo premarket review pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA) by receiving clearance of a 510(k) premarket notification, receiving clearance through the de novo review process, or obtaining approval of a premarket approval (PMA) application. Even if regulatory clearance or approval of a product is granted, the FDA may clear or approve our products only for limited indications for use. Additionally, the FDA may not 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 traditional FDA 510(k) clearance process for our products has generally taken between three to six months. However, our more recent experience and interactions with the FDA, along with information we have received from other medical device manufacturers, suggests that, in some cases, the FDA is requiring applicants to provide additional or different information and data for 510(k) clearance than it had previously required, and that the FDA may not rely on approaches that it had previously accepted to support 510(k) clearance. As a result, we have experienced lengthier FDA 510(k) review periods over the past few years, which have delayed the 510(k) clearance

process for our products.

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To support our product applications to the FDA, we frequently are required to conduct clinical testing of our products. Such clinical testing must be conducted in compliance with FDA requirements pertaining to human research. Among other requirements, we must obtain informed consent from human subjects and approval by institutional review boards before such studies may begin. We must also comply with other FDA requirements such as monitoring, record-keeping, reporting and the submission of information regarding certain clinical trials to a public database maintained by the National Institutes of Health. In addition, depending on the risk posed by a study, we may be required to obtain the FDA's approval of the study under an Investigational Device Exemption (IDE). Compliance with these requirements can require significant time and resources. If the FDA determines that we have not complied with such requirements, the FDA may refuse to consider the data to support our applications or may initiate enforcement actions.

Even though 510(k) clearances have been obtained, if safety or effectiveness problems are identified with our pulse oximeters incorporating Masimo SET® and licensed rainbow® technology, patient monitor devices, sensors, cables and other products, we may need to initiate a recall of such 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 or de novo review processes. The process of obtaining a de novo classification or PMA approval is much more costly, lengthy and uncertain than the process for obtaining 510(k) clearance. De novo classification generally takes six months to one year from the time of submission of the de novo request, although it can take longer. Approval of a PMA generally takes one to three years from the time of submission of the PMA, but may be longer.

We sell consumer versions of our $iSpO_2$® and MightySat® pulse oximeters that are not intended for medical use. Some of our products or product features may also be exempted from the 510(k) process and/or other regulatory requirements in accordance with specific FDA guidance and policies, such as the FDA guidance related to mobile medical applications. In addition, some of our products or product features may not be subject to device regulation pursuant to Section 520(o) of the FDCA, which excludes certain software functions from the statutory definition of a device. If the FDA changes its policy or concludes that our marketing of these products is not in accordance with its current policy and/or Section 520(o) of the FDCA, we may be required to seek clearance or approval of these devices through the 510(k), de novo or PMA processes.

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

Our OEM partners are required to obtain their own FDA clearances in the U.S. for most products incorporating Masimo technologies. The FDA clearances we have obtained may not make it easier for our OEM partners to obtain clearances of products incorporating these technologies, or the FDA may not grant clearances on a timely basis, if at all, for any future products incorporating Masimo technologies that our OEM partners propose to market.

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

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

In addition to the FDA, from time to time we are subject to inspections by the California Food and Drug Branch, international regulatory authorities, and other similar governmental agencies. The standards used by these regulatory authorities are complex and may differ from those used by the FDA.

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

- warning letters or untitled letters issued by the FDA;

- fines, civil penalties, in rem forfeiture proceedings, injunctions, consent decrees and criminal prosecution;
- import alerts;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawals or suspensions of clearance or approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

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- product recalls or seizures;
- orders for physician notification or device repair, replacement or refund;
- interruptions of production or inability to export to certain foreign countries; and
- operating restrictions.

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

Failure to obtain regulatory authorizations in foreign jurisdictions may 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 generally 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 or different product testing than required to obtain FDA clearance. FDA clearance does not ensure new product registration/licensing by foreign regulatory authorities, and we may be unable to obtain foreign regulatory registration/licensing on a timely basis, if at all.

In addition, clearance by one foreign regulatory authority does not ensure clearance by any other foreign regulatory authority or by the FDA. If we fail to receive necessary approvals to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, financial condition and results of operations could be adversely affected.

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

We have made modifications to our devices in the past and we may make additional modifications in the future. Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness or that could constitute a major change in its intended use would require a new 510(k) clearance or possibly a de novo review or PMA. 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. For device modifications that we conclude do not require a new 510(k), we may be required to recall and to stop marketing the modified devices if the FDA disagrees with our conclusion and requires new clearances or approvals for the modifications, which could have an adverse effect on our business, financial condition and results of operations.

Federal regulatory reforms may impact our ability to develop and commercialize our products and technologies.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of medical devices. For example, in August 2017, Congress enacted the FDA Reauthorization Act of 2017 (FDARA). FDARA reauthorized the FDA to collect device user fees, including a new user fee for de novo classification requests, and contained substantive amendments to the device provisions of the FDCA. Among other changes, FDARA required that the FDA update and revise its processes for scheduling inspections of device establishments, communicating about those inspections with manufacturers and providing feedback on the manufacturer’s responses to Form 483s. The statute also required that the FDA study the impact of device servicing, including third party servicers, and creates a new process for device sponsors to request classification of accessory devices as part of the PMA application for the parent device or to request a separate classification of accessory devices.

In addition, the FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business or products. Future regulatory changes could make it more difficult for us to obtain or maintain approval to develop and commercialize our products and technologies.

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

Under the FDA medical device reporting regulations, we are required to report to the FDA any incident in which a product of ours may have caused or contributed to a death or serious injury or in which a product of ours

malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in the European Union (EU) are legally required to report any serious or potentially serious incidents involving devices produced or sold by the manufacturer to the relevant authority in those jurisdictions where any such incident occurred.

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The FDA and similar foreign regulatory 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. The FDA must find that there is a reasonable probability that the device would cause serious adverse health consequences or death in order to require a recall. The standard for recalling deficient products may be different in foreign jurisdictions. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found or they become aware of a safety issue involving a marketed product. A government-mandated or voluntary recall by us or by one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.

We may initiate certain field actions, such as a correction or removal of our products in the future. Any correction or removal initiated by us to reduce a health risk posed by our device, or to remedy a violation of the FDCA caused by the device that may present a risk to health, must be reported to the FDA. If the FDA subsequently determines that a report was required for a correction or removal of our products that we did not believe required a report, we could be subject to enforcement actions.

Any recalls of our products or enforcement actions would divert managerial and financial resources and could have an adverse effect on our financial condition and results of operations. In addition, given our dependence upon patient and physician perceptions, any negative publicity associated with any recalls could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Promotion of our products using claims that are off-label, unsubstantiated, false or misleading could subject us to substantial penalties.

Obtaining 510(k) clearance permits us to promote our products for the uses 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. While we may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. If the FDA determines that our products were promoted for off-label use or that false, misleading or inadequately substantiated promotional claims have been made by us or our OEM partners, it could request that we or our OEM partners modify those promotional materials or take regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our communications, including promotional or training materials, to constitute promotion of an uncleared or unapproved use. If not successfully defended, enforcement actions related to off-label promotion could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In any such event, our reputation could be damaged, adoption of our products could be impaired and we could be subject to extensive fines and penalties.

Additionally, we must have adequate substantiation for the claims we make for our products. If any of our claims are determined to be false, misleading or deceptive, our products could be considered misbranded under the FDCA or in violation of the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act alleging that our marketing materials are false or misleading.

The regulatory environment governing information, cybersecurity and privacy laws is increasingly demanding and continues to evolve.

Personal privacy and data security have become significant issues in the U.S. Europe and in many other jurisdictions where we offer our products. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future.

Certain U.S. laws govern the transmission, security and privacy of individually identifiable information that we may obtain or have access to in connection with the operation of our business, including the conduct of clinical research trials or other research studies that may provide us with access to sensitive health and other personal information. We may be required to make costly system modifications to comply with these data privacy and security requirements. In addition, if we do not properly comply with applicable laws and regulations related to the protection of this

information, we could be subject to criminal or civil sanctions. Internationally, the General Data Protection Regulation (GDPR) has recently taken effect in the European Economic Area (EEA) and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. Furthermore, other international jurisdictions, including South Korea, China and Australia, have also implemented laws relating to data privacy and protection. Although we believe that we are complying with the GDPR and similar laws, these laws are still relatively new. Therefore, as international data privacy and protection laws continue to evolve, and as new regulations, interpretive guidance and enforcement information becomes available, we may incur incremental costs to modify our business practices to comply with these requirements. In addition, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents.

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Violations of these laws, or allegations of such violations, could subject us to cash and non-cash penalties for noncompliance, disrupt our operations, involve significant management distraction and result in a material adverse effect on our business, financial condition and results of operations.

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

Health care fraud and abuse laws potentially applicable to our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the purchase, order or recommendation of an item or service reimbursable under a federal health care program (such as the Medicare or Medicaid programs);
- the federal False Claims Act and other federal laws which prohibit, among other things, knowingly and willfully presenting, or causing to be presented, claims for payment from Medicare, Medicaid, other government payers or other third-party payers that are false or fraudulent;
- 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 governmental programs and non-governmental third-party payers, including commercial insurers; and
- the Physician Payments Sunshine Act (Sunshine Act), which requires medical device companies to track and publicly report, with limited exceptions, all payments and transfers of value to physicians and teaching hospitals in the U.S. If we fail to comply with the data collection and reporting obligations imposed by the Sunshine Act, we may be subject to substantial civil monetary penalties.

If we are found to have violated any such laws or other similar governmental regulations, including their foreign counterparts, that are directly or indirectly applicable to us, 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 such action, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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

Changes in the health care industry in the U.S. and abroad could adversely affect the demand for our products and the way in which we conduct our business. For example, the Patient Protection and Affordable Care Act (the ACA), enacted in 2010, required most individuals to have health insurance, established new regulations on health plans, created insurance-pooling mechanisms and reduced Medicare spending on services provided by hospitals and other providers. The ACA also imposed significant new taxes on medical device makers in the form of a 2.3% excise tax on U.S. medical device sales, as well as related compliance and reporting obligations. This medical device excise tax (MDET) has been temporarily suspended by Congress on a number of occasions, and most recently through December 31, 2019. The MDET may be reimposed on medical device makers beginning on January 1, 2020 if such suspension is not re-extended or the MDET is not permanently repealed.

Additionally, the long-term viability of the ACA, and its impact on our business and results of operations, remains uncertain. There have also been recent U.S. Congressional actions to repeal and replace the ACA, and future actions are expected. For example, on December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the 2017 Tax Act) was signed into law. The 2017 Tax Act, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage effective January 1, 2019. Although we cannot predict the ultimate content or timing of any healthcare reform legislation, potential changes resulting from any amendment, repeal or replacement of these programs, including any reduction in the future availability of healthcare insurance benefits, decrease the number of people who are insured, which could adversely affect our business and future results of operations.

Our medical devices and business activities are subject to rigorous regulation by the FDA and other federal, state and international governmental authorities. These authorities and members of Congress have been increasing their scrutiny over the medical device industry. In recent years, Congress, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and the Department of Defense have issued subpoenas and other requests for information to medical device manufacturers, primarily related to financial arrangements with health care providers, regulatory compliance and marketing and product promotional practices. Furthermore, certain state governments have enacted legislation to limit and/or increase transparency of interactions with health care providers, pursuant to which we are required by law to disclose payments and other transfers of value to health care providers licensed by certain states.

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We anticipate that the government will continue to scrutinize our industry closely, and any new regulations or statutory provisions could result in delays or increased costs during the periods of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance.

Risks Related to Our Business and Operations

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

Prior to our initial public offering in August 2007, our stockholders owned 99% of the outstanding shares of capital stock of Cercacor, and we believe that a number of our stockholders, including certain of our directors and executive officers, continue to own shares of Cercacor stock. Joe Kiani, our Chairman and Chief Executive Officer (CEO), is also the Chairman and CEO of Cercacor.

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

We will be required to assign to Cercacor and pay Cercacor for the right to use certain products and technologies we develop that relate to the monitoring of non-vital sign parameters, including improvements to Masimo SET®.

Under the Cross-Licensing Agreement, if we develop certain products or technologies that relate to the noninvasive monitoring of non-vital sign parameters, including improvements to Masimo SET® for the noninvasive monitoring of non-vital sign parameters, we would be required to assign these developments to Cercacor and then license the technology back from Cercacor in consideration for upfront payments and royalty obligations to Cercacor. Therefore, these products and technologies would be deemed to have been developed or improved exclusively by Cercacor. In addition, we will not be reimbursed by Cercacor for our expenses relating to the development or improvement of any such products or technologies, which expenses may be significant. As a result of these terms, we may not generate any revenue from the further development of certain products and technologies for the monitoring of non-vital sign parameters, including improvements to Masimo SET®, which could adversely affect our business, financial condition and results of operations.

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

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

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

As a result of the royalties that we must pay to Cercacor, it is generally more expensive for us to make products that incorporate licensed rainbow® technology than products that do not include licensed rainbow® technology.

We cannot assure you that we will be able to sell products incorporating licensed rainbow® technology at a price the market is willing to accept. If we cannot commercialize our products incorporating licensed rainbow® technology successfully, we may not be able to generate sufficient product revenue from these products to be profitable, which

could adversely affect our business, financial condition and results of operations.

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

We may experience significant fluctuations in our quarterly and annual results and may not maintain our current levels of profitability in the future.

Our operating results have fluctuated in the past and are likely to fluctuate in the future. Many of the countries in which we operate, including the U.S. and several of the members of the EU, have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors. In addition, continuing strength and growth in the U.S. economy has raised the probability of inflationary pressures and future interest rate hikes that have not been experienced in the U.S. for more than a decade. Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions.

In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition. Our 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. If our operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly.

Future changes in accounting pronouncements and tax laws, or the interpretation thereof, could have a significant impact on our reported results, and may affect our historical reporting of previous transactions.

New accounting pronouncements or taxation rules, and evolving interpretations thereof, have occurred and are likely to occur in the future. For example, in recent years, the Financial Accounting Standards Board (FASB) issued new accounting standards that impact our reporting of revenue and expenses, including Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers (ASC 606) and ASC Topic 842, Leases (ASC 842). Changes made by these new accounting standards not only apply prospectively, but depending on the method of adoption, may also recast previously reported results. In addition, the 2017 Tax Act, which took effect on January 1, 2018, included a number of changes to existing tax law impacting businesses including, among other things, a permanent reduction in the corporate income tax rate from 35% to 21%, a one-time transition tax on the "deemed repatriation" of cumulative undistributed foreign earnings as of December 31, 2017 and changes in the prospective taxation of the foreign operations of U.S. multinational companies. Moreover, Congressional leaders have recognized that the process of adopting extensive tax legislation in a short amount of time without hearings and substantial time

for review is likely to have led to drafting errors, issues needing clarification and unintended consequences that will have to be reviewed in subsequent tax legislation or addressed in future tax regulations. We continue to evaluate the impact of ASC 606, ASC 842 and the 2017 Tax Act on our business, financial condition and results of operations. For additional information related to the impact of new accounting pronouncements and the 2017 Tax Act, please see Notes 2 and 18, respectively, to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

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

The methods, estimates and judgments that we use in applying our accounting policies are, by their nature, subject to substantial risks, uncertainties and assumptions. Factors may arise over time that lead us to change our methods, estimates and judgments, the impact of which could significantly affect our results of operations. See “Critical Accounting Estimates” contained in Part II, Item 7 of this Annual Report on Form 10-K for additional information about these methods, estimates and judgments.

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

We are highly dependent on our senior management, especially Joe Kiani, our CEO, and other key officers. We are also heavily dependent on our engineers and field sales team, including sales representatives and clinical specialists. The loss of the services of members of our key personnel or the inability to attract and retain qualified personnel in the future could prevent the implementation and completion of our objectives, including the development and introduction of our products. In general, our key personnel may terminate their employment at any time and for any reason without notice, unless the individual is a participant in our 2007 Severance Protection Plan, in which case the individual has agreed to provide us with six months’ notice if such individual decides to voluntarily resign.

We are involved, and may become involved in the future, in disputes and other legal or regulatory proceedings that, if adversely decided or settled, could materially and adversely affect our business, financial condition and results of operations.

We are, and may in the future become, party to litigation, regulatory proceedings or other disputes. In general, claims made by or against us in disputes and other legal or regulatory proceedings can be expensive and time consuming to bring or defend against, requiring us to expend significant resources and divert the efforts and attention of our management and other personnel from our business operations. These potential claims may include but are not limited to personal injury and class action lawsuits, intellectual property claims and regulatory investigations relating to the advertising and promotional claims about our products and employee claims against us based on, among other things, discrimination, harassment or wrongful termination. Any one of these claims, even those without merit, may divert our financial and management resources that would otherwise be used to benefit the future performance of our operations. Any adverse determination against us in these proceedings, or even the allegations contained in the claims, regardless of whether they are ultimately found to be without merit, may also result in settlements, injunctions or damages that could have a material adverse effect on our business, financial condition and results of operations.

Changes to government immigration regulations may materially affect our workforce and limit our supply of qualified professionals, or increase our cost of securing workers.

We recruit professionals on a global basis and must comply with the immigration laws in the countries in which we operate, including the U.S. Some of our employees are working under Masimo-sponsored temporary work visas, including H1-B visas. Statutory law limits the number of new H1-B temporary work permit petitions that may be approved in a fiscal year. Furthermore, there is a possibility that the current U.S. immigration visa program may be significantly overhauled. Any resulting changes to this visa program could impact our ability to recruit, hire and retain qualified skilled personnel. If we are unable to obtain work visas in sufficient quantities or at a sufficient rate for a significant period of time, our business, operating results and financial condition could be adversely affected.

The risks inherent in operating internationally, including the purchase, sale and shipment of our components and products across international borders, may adversely impact our business, financial condition and results of operations.

We currently derive approximately 30% of our net sales from international operations. In addition, we purchase a portion of our raw materials and components from international sources. The sale and shipment 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, including those related to conflict minerals. Compliance with such regulations is costly and we could be exposed to potentially significant penalties if we are found not to be in compliance with such regulations. Any failure to comply with applicable legal and regulatory obligations could

impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, manufacturing and sales activities. Any material decrease in our international sales would adversely affect our business, financial condition and results of operations.

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In June 2016, the United Kingdom (UK) held a referendum pursuant to which voters elected to leave the EU, commonly referred to as Brexit. Although the long-term effects of Brexit will depend on any agreements the UK makes to retain access to the EU markets, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for medical device companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. Additionally, Brexit may increase the possibility that other countries may decide to leave the EU in the future.

In addition, our international 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;
- the 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;
- compliance with foreign tax laws, regulations and requirements;
- pricing pressure;
- changes in foreign currency exchange rates;
- laws and business practices favoring local companies;
- political instability and actual or anticipated military or political conflicts;
- financial and civil unrest worldwide;
- outbreaks of illnesses, pandemics or other local or global health issues;
- the inability to collect amounts paid by foreign government customers to our appointed foreign agents;
- longer payment cycles, increased credit risk and different collection remedies with respect to receivables; and
- difficulties in enforcing or defending intellectual property rights.

The U.S. government has recently initiated substantial changes in U.S. trade policy and U.S. trade agreements, including the initiation of tariffs on certain foreign goods. In response to these tariffs, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U.S. goods. In addition, the U.S. is negotiating or has entered into new trade agreements that could affect adversely us, including the United States-Mexico-Canada Agreement, which if adopted, would replace the North American Free Trade Agreement. A trade war, trade barriers or other governmental actions related to tariffs, international trade agreements, import or export restrictions or other trade policies could adversely impact demand for our products, our costs, customers, suppliers and/or the U.S. economy or certain sectors thereof and, therefore, adversely affect our business, financial condition and results of operations.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from promising or making improper payments to non-U.S. officials for the purpose of obtaining an advantage to secure or retain business. Because of the predominance of government-sponsored health care systems around the world, many of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. We have adopted policies and practices that help us ensure compliance with these anti-bribery laws. However, such policies and practice may require us to invest in additional monitoring resources or forgo certain business opportunities in order to ensure global compliance with these laws.

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. As a result, events that result in global economic uncertainty could significantly affect our results of operations in the form of gains and losses on foreign currency transactions and potential devaluation of the local currencies of our customers

relative to the U.S. Dollar.

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While a majority of our sales are transacted in U.S. Dollars, some of our sales agreements with foreign customers provide for payment in currencies other than the U.S. Dollar. These foreign currency revenues, when converted into U.S. Dollars, can vary depending on average exchange rates during a respective period. Similarly, certain of our foreign subsidiaries transact business in their respective country's local currency, which is also their functional currency. In addition, certain production costs related to our manufacturing operations in Mexico are denominated in Mexican Pesos. As a result, expenses of these foreign subsidiaries and certain production costs, when converted into U.S. Dollars, can vary depending on average monthly exchange rates during a respective period.

We are also exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables and payables, as well as cash deposits. When converted to U.S. Dollars, these receivables, payables and cash deposits can vary depending on the monthly exchange rates at the end of the period. In addition, certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses based on the currency underlying such intercompany transactions. Accordingly, our operating results are subject to fluctuations in foreign currency exchange rates.

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

We currently do not hedge our foreign currency exchange rate risk. As a result, changes in foreign exchange rates could have a material adverse effect on our business, financial condition and results of operations. For additional information related to our foreign currency exchange rate risk, please see Quantitative and Qualitative Disclosures about Market Risk in Part II, Item 7(a) of this Annual Report on Form 10-K.

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

We rely on manufacturing facilities in California, New Hampshire, Mexico and Sweden that may be affected by natural or man-made disasters. Earthquakes are of particular significance since some of our facilities are located in earthquake-prone areas. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist or terrorist organizations, epidemics, communication failures, fire, floods and similar events. Our facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial time to repair if significant damage were to result from any of these occurrences.

If one of our manufacturing 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 facilities. Furthermore, our insurance for damage to our property and the disruption of our business from casualties may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If the lease for any of our leased facilities is terminated, we are unable to renew any of our leases or we are otherwise forced to seek alternative facilities, or if we voluntarily expand one or more of our manufacturing operations to new locations, we may incur additional transition costs and experience a disruption in the supply of our products until the new facilities are available and operating. Additionally, we have occasionally experienced seasonality among our manufacturing workforce, and if we continue to experience such seasonality or other workforce shortages or otherwise have issues retaining employees at our manufacturing facilities, we may not be able to meet our customers' demands.

Our manufacturing facilities in Mexico are authorized to operate under the Mexican Maquiladora, or IMMEX program. The IMMEX program allows us to import certain items from the U.S. into Mexico duty-free, provided that such items, after processing, are exported from Mexico within a stipulated timeframe. Maquiladora status, which is renewed periodically, is subject to various restrictions and requirements, including compliance with the terms of the IMMEX program and other local regulations. Failure to comply with the IMMEX program regulations, including any changes thereto, could increase our manufacturing costs and adversely affect our business, operating results and financial condition.

If we do not accurately forecast customer demand, we may hold suboptimal inventory levels that could adversely affect our business, financial condition and results of operations.

If we are unable to meet the demand of our customers, our customers may cancel orders or purchase products from our competitors, which could reduce our revenue and gross profit margin. Conversely, if product demand decreases, we may be unable to timely adjust our manufacturing cost structure, resulting in excess capacity, which would lower gross product margins. Similarly, if we are unable to forecast demand accurately, we could be required to record charges related to excess or obsolete inventory, which would also lower our gross margin.

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If we are unable to obtain key materials and components from sole or limited source suppliers, we will not be able to deliver our noninvasive patient monitoring solutions to customers.

We depend on certain sole or limited source suppliers for key materials and components, including digital signal processor chips and analog-to-digital converter chips, for our noninvasive patient monitoring solutions. Manufacturing problems may occur related to these and other outside sources if these suppliers fail to develop and ship products and components to us on a timely basis, or provide us with products and components that do not meet our quality standards and required quantities. In addition, from time to time there have been industry-wide shortages of certain components that we use in our noninvasive blood constituent patient monitoring solutions. We may also experience price increases for materials or components, with no guarantee that such increases can be passed along to our customers, which could adversely impact our gross margins.

If any of these problems occur, we may be unable to obtain substitute sources for these products and components on a timely basis or on terms acceptable to us, which could harm our ability to manufacture our own products and components profitably or on time.

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 adversely affected.

We are required to prepare and disclose certain information under the Securities Exchange Act of 1934 in a timely manner and meet our reporting obligations in their entirety, and our failure to do so 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.

If we fail to maintain adequate internal controls over financial reporting, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with the Sarbanes-Oxley Act. Moreover, any failure to maintain compliance with the requirements of Section 404 of the Sarbanes-Oxley Act or any material weakness in our internal control environment could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business, negatively impact the trading price of our stock, and adversely affect investors' confidence in our company and our ability to access capital markets for financing.

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

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

For example, the Dodd-Frank Act includes provisions regarding "conflict minerals" (generally tin, tantalum, tungsten and gold) that are mined in the Democratic Republic of Congo and adjoining countries (the DRC region), and in June 2016, the EU adopted its own regulation on conflict minerals that covers the sourcing of conflict minerals from anywhere in the world. The provisions of the Dodd-Frank Act require us to undertake comprehensive due diligence to determine whether conflict minerals used in our products, including any portion of our products manufactured by third parties, financed or benefited armed groups in the DRC region. The rules also require us to file conflict mineral reports with the SEC annually. We have incurred, and expect to continue to incur, additional costs to comply with these rules, including costs related to determining the source of origin of conflict minerals used in our products. Given the complexity of our supply chain, we may face difficulties if our suppliers are unwilling or unable to verify the origin of all conflict minerals used in our products.

In addition, stockholder litigation surrounding executive compensation and disclosure of executive compensation has increased with the passage of the Dodd-Frank Act. Furthermore, our stockholders may not continue to approve our advisory vote on named executive officer compensation that is required to be voted on by our stockholders annually

pursuant to the Dodd-Frank Act. If we are involved in a lawsuit related to compensation matters or any other matters not covered by our directors' and officers' liability insurance, we may incur significant expenses in defending against such lawsuits, or be subject to significant fines or required to take significant remedial actions, each of which could adversely affect our business, financial condition and results of operations.

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

Our products are predominantly used in patient care and expose us to product liability claims and product recalls, including, but not limited to, those that may arise from unauthorized off-label use, malfunctions, design flaws or manufacturing defects related to our products or the use of our products with incompatible components or systems. We cannot be certain that our product liability insurance will be sufficient to cover any or all damages for product liability claims that may be brought against us in the future. Furthermore, we may not be able to obtain or maintain insurance in the future at satisfactory rates or in adequate amounts to protect us against any product liability claims. Additionally, the laws and regulations regarding product liability are constantly evolving, both through the passage of new legislation at the state and federal levels and through new interpretations of existing legislation. For example, in February 2017, the Washington Supreme Court determined that, under the Washington Product Liability Act, medical device manufacturers have a duty to warn hospitals of any potential risks posed by their products. As the legal and regulatory landscape surrounding product liability change, we may become exposed to greater liability than currently anticipated.

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.

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 several businesses since our inception and we may acquire additional businesses in the future. Future acquisitions may require debt or equity financing, which could be dilutive to our existing stockholders or reduce our earnings per share. Even if we complete acquisitions, there are many factors that could affect whether such acquisition will be beneficial to our business, including, without limitation:

- payment of above-market prices for acquisitions and higher than anticipated acquisition costs;
- issuance of common stock as part of the acquisition price or a need to issue stock options or other equity to newly-hired employees of target companies, resulting in dilution of ownership to our existing stockholders;
- reduced profitability if an acquisition is not accretive to our business over either the short-term or the long-term;
- 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;
- regulatory challenges;
- cybersecurity and compliance related issues;
- 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;
- unanticipated issues dealing with unfamiliar suppliers, service providers or other collaborators of the acquired company;
- higher costs of integration than we anticipated;
- write-downs or impairments of goodwill or other intangible assets associated with the acquired company;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions;
- negative impacts on our relationships with our employees, clients or collaborators;
- litigation or other claims in connection with the acquisition; and
- changes in the overall financial model as certain acquired companies may have a different revenue, gross profit margin or operating expense profile.

Further, our ability to benefit from future acquisitions depends on our ability to successfully conduct due diligence, negotiate acceptable acquisition terms, evaluate prospective acquisitions and bring acquired technologies and/or products to market at acceptable margins and operating expense levels. Our failure in any of these tasks could result in unforeseen liabilities associated with an acquired company, acquiring a company on unfavorable terms or selecting and eventually acquiring a suboptimal acquisition target. 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. If we do not achieve the anticipated benefits of an acquisition as rapidly as expected, or at all, investors or analysts may not perceive the same benefits of the acquisition as we do.

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If these risks materialize, our stock price could be materially adversely affected. 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.

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

Certain manufacturing processes for our products may involve the storage, 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 certain environmental laws, as well as certain other laws and regulations, that restrict the materials that can be used in our products or in our manufacturing processes. For example, products that we sell in Europe are subject to regulation in the EU markets under the Restriction of the Use of Hazardous Substances Directive (RoHS). RoHS prohibits companies from selling products that contain certain hazardous materials in EU member states. In addition, the EU's Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products. Compliance with such regulations may be costly and, therefore, we may incur significant costs to comply with these laws and regulations.

In addition, new environmental laws may further affect how we manufacture our products, how we use, generate or dispose of hazardous materials and waste, or further affect what materials can be used in our products. Any required changes to our operations may increase our manufacturing costs, detrimentally impact the performance of our products, add greater testing lead-times for product introductions or have other similar effects.

In connection with 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. The risk of accidental injury to our employees or contamination from these materials cannot be eliminated, and we could be held liable for any resulting damages, the related liability for which could exceed our reserves. We do not specifically insure against environmental liabilities. If an enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action on terms favorable to us.

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

Increased global cybersecurity vulnerabilities, cybersecurity threats, and sophisticated and targeted cybersecurity attacks pose a risk to the security of Masimo's and our customers', partners', suppliers' and third-party service providers' products, systems and networks, including the confidentiality, availability and integrity of any underlying information and data. Our ability to effectively manage and maintain our internal business information, and to ship products to customers and invoice them on a timely basis, depends significantly on our enterprise resource planning system and other information systems. Portions of our information technology systems may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In addition, interfaces between our products and our customers' computer networks could provide additional opportunities for cybersecurity attacks on us and our customers. The techniques used to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. Cybersecurity attacks in particular are evolving and include, but are not limited to, threats, malicious software, ransom ware, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of confidential or otherwise protected information and corruption of data. As a result, there can be no assurance that our protective measures will prevent or detect security breaches that could have a significant impact on our business, reputation, financial condition and results of operations.

The failure of these systems to operate or integrate effectively with other internal, customer, supplier or third-party service provider systems and to protect the underlying information technology system and data integrity, including from cyber-attacks, intrusions or other breaches or unauthorized access of these systems, or any failure by us to remediate any such attacks or breaches, may also result in damage to our reputation or competitiveness, delays in product fulfillment and reduced efficiency of our operations, and could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, financial condition

and results of operations.

From time to time, we may carry out strategic initiatives that could negatively impact our business, financial condition and results of operations.

We expect to continue to carry out strategic initiatives and investments that we believe are necessary to grow our revenues and expand our business, both in the U.S. and abroad. For example, we have continued to invest in international expansion programs designed to increase our worldwide presence and take advantage of market expansion opportunities around the world. Although we believe these initiatives and investments continue to be in the long-term best interests of Masimo and our stockholders, there are no assurances that such initiatives and investments will yield favorable results for us.

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Accordingly, if these initiatives and investments are not successful, our business, financial condition and results of operations could be adversely affected.

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

Our Credit Agreement dated December 17, 2018 (Credit Facility) with JPMorgan Chase Bank, N.A., as Administrative Agent and a Lender, and Bank of the West, a Lender, contains various affirmative covenants and restrictions that limit our ability to engage in specified types of transactions, including:

- incurring specified types of additional indebtedness (including guarantees or other contingent obligations);
- paying dividends on, repurchasing or making distributions in respect of our common stock or making other restricted payments, subject to specified exceptions;
- making specified investments (including loans and advances);
- selling or transferring certain assets;
- creating certain liens;
- consolidating, merging, selling or otherwise disposing of all or substantially all of our assets; and
- entering into certain transactions with any of our affiliates.

In addition, under our Credit Facility, we are required to satisfy and maintain specified financial ratios and other affirmative covenants. Our ability to meet those financial ratios and affirmative covenants could be affected by events beyond our control and, therefore, we cannot be assured that we will be able to continue to satisfy these requirements. A breach of any of these ratios or covenants could result in a default under our Credit Facility. Upon the occurrence of an event of default, the Lenders could elect to declare all amounts outstanding under the Credit Facility immediately due and payable, terminate all commitments to extend further credit and pursue legal remedies for recovery, all of which could adversely affect our business and financial condition. As of December 29, 2018, we had no amounts outstanding under the Credit Facility and were in compliance with all applicable covenants. See Note 13 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on our Credit Facility.

We may experience conflicts of interest with respect our CEO’s role in the Patient Safety Movement Foundation.

Joe Kiani, our Chairman and CEO, founded the Patient Safety Movement Foundation in 2012 with the aim of eliminating preventable deaths caused by medical errors. Conflicts of interest issues may arise between our business and customers and the objectives of the Patient Safety Movement Foundation. Recommendations and other actions encouraged by the Patient Safety Movement Foundation may not favor our products. Additionally, some hospitals and other healthcare providers may disagree with the Patient Safety Movement Foundation’s actions or recommendations and disfavor Masimo products because of Mr. Kiani’s role in the Patient Safety Movement Foundation, which could adversely affect our business, financial condition and results of operations. Mr. Kiani’s role in the Patient Safety Movement Foundation and our support of it may also result in the actions of the Patient Safety Movement Foundation being deemed actions of ours. This could result in Masimo being held liable for any acts of the Patient Safety Movement Foundation that would not be in compliance with applicable law if performed by Masimo, which could subject us to fines and other penalties.

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 and could continue to be significant volatility in the market price and trading volume of equity securities. For example, our closing stock price ranged from $82.06 to $125.32 per share from January 2, 2018 to December 29, 2018. Factors contributing to our stock price volatility may include our financial performance, as well as broader economic, political and market factors. In addition to the other risk factors previously discussed in this Annual Report on Form 10-K, there are many other factors that we may not be able to control that could have a significant effect on our stock price. These include, but are not limited to:

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

- strategic actions by us or our competitors, such as acquisitions or restructurings;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;

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- changes in accounting standards, policies, guidance, interpretations or principles;
- changes in our growth rates or our competitors' growth rates;
- developments regarding our patents or proprietary rights or those of our competitors;
- ongoing legal proceedings;
- our inability to raise additional capital as needed;
- concerns or allegations as to the safety or efficacy of our products;
- changes in financial markets or general economic conditions, including the effects of recession or slow economic growth in the U.S. and abroad;
- sales of stock by us or members of our management team, our Board of Directors (Board) or certain institutional stockholders; and
- changes in stock market analyst recommendations or earnings estimates regarding our stock, other comparable companies or our industry generally.

Therefore, you may not be able to resell your shares at or above the price you paid for them.

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

As of December 29, 2018, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 11.3% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, these stockholders may be able to exercise significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have some control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of us, or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our stock.

In addition, these stockholders could use their voting influence to maintain our existing management and directors in office or support or reject other management and Board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

Our investors could experience substantial dilution of their investments as a result of subsequent exercises of our outstanding options, vesting of outstanding restricted stock units (RSUs) and performance stock units (PSUs), or the grant of future equity awards by us.

As of December 29, 2018, approximately 11.9 million shares of our common stock were reserved for issuance under our equity incentive plans, of which approximately 5.7 million shares were subject to options outstanding at such date at a weighted-average exercise price of $43.61 per share, approximately 2.7 million shares were subject to outstanding RSUs, approximately 0.3 million shares were subject to outstanding PSUs and approximately 3.2 million shares were available for future awards under our 2017 Equity Incentive Plan. Over the past 24 months, we have experienced higher rates of stock option exercises compared to many earlier periods, and this trend may continue. To the extent outstanding options are exercised or outstanding RSUs or PSUs vest, our existing stockholders may incur dilution. We rely on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

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

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

reduce the market price of our stock.

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We have registered and expect to continue to register shares reserved under our equity plans pursuant to Registration Statements 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 to issue up to 5.0 million shares of "blank check" preferred stock. As a result, without further stockholder approval, our Board has the authority to attach special rights, including voting and dividend rights, to this preferred stock, including pursuant to a stockholder rights plan. With these rights, preferred stockholders could make it more difficult for a third-party to acquire us. In addition, our amended and restated certificate of incorporation provides for a staggered board of directors, whereby directors serve for three year terms, with one-third of the directors coming up for reelection each year. A staggered Board will make it more difficult for a third-party to obtain control of our Board through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our Board.

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

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

Our Board may from time to time declare, and we may pay, dividends on our outstanding shares in the manner and upon the terms and conditions provided by law. However, we may elect to retain all future earnings for the operation and expansion of our business, rather than paying cash dividends on our stock.

Any payment of cash dividends on our stock will be at the discretion of our Board and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our Board. In the event our Board declares any dividends, there is no assurance with respect to the amount, timing or frequency of any such dividends.

In July 2018, our Board approved a stock repurchase program, authorizing us to purchase up to 5.0 million additional shares of our common stock over a period of up to three years (2018 Repurchase Program). Any repurchase of our common stock under the 2018 Repurchase Program will be at the discretion of a committee comprised of our CEO and Chief Financial Officer, and will depend on several factors, including, but not limited to, results of operations, capital requirements, financial conditions, available capital from operations or other sources and the market price of our common stock. Therefore, there is no assurance with respect to the amount, price or timing of any such repurchases. We may elect to retain all future earnings for the operation and expansion of our business, rather than repurchasing additional outstanding shares. For additional information related to our 2018 Repurchase Program, please see Note 15, to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

In the event we pay dividends, or make any stock repurchases in the future, our ability to finance any material expansion of our business, including through acquisitions, investments or increased capital spending, or to fund our operations, may be limited. In addition, any repurchases we may make in the future may not prove to be at optimal

prices. Our Board may modify or amend the 2018 Repurchase Program, or adopt a new stock repurchase program, at any time at its discretion without stockholder approval.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

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ITEM 2. PROPERTIES

We own approximately 213,400 square feet of property in Irvine, California that houses our corporate headquarters, manufacturing and U.S. research and development activities. We also own approximately 86,500 square feet of property in Hudson, New Hampshire, which is used to manufacture advanced light emitting diodes and other advanced component-level technologies, as well as warehousing and administrative operations.

We continue to lease and occupy various buildings in Irvine, California approximating a total of 176,000 square feet for product manufacturing, warehousing, distribution and sales support operations. These leases expire from November 2019 through November 2026. We also operate two separate facilities in Mexicali and San Luis Rio Colorado, Mexico with combined square footage of approximately 216,900 square feet, which are used to manufacture our products under a shelter labor agreement with Industrial Vallera de Mexicali, S.A. de C.V. (IVEMSA). IVEMSA leases these manufacturing facilities directly from the owners of the properties under separate agreements. These leases expire in June 2021.

Our international headquarters are located in approximately 13,500 square feet of leased office space in Neuchâtel, Switzerland. This office space is focused on operations that include sales, marketing, customer service and other administrative functions. In addition, we currently lease approximately 19,800 square feet of space in Canada, which we use primarily for research, development, sales and marketing activities. We also lease approximately 16,400 square feet in Danderyd, Sweden, primarily for manufacturing, research, development and administrative functions related to our capnography and gas monitoring products. Our operations in various cities within Japan are located in approximately 14,600 square feet of leased space that we use for sales, marketing, customer service, administrative and warehousing operations. We also maintain a number of small sales offices throughout Europe, Asia, India, the Middle East, Australia and Latin America. We believe that our existing facilities are adequate to meet our needs and that existing needs and future growth can be accommodated by leasing alternative or additional space.

ITEM 3. LEGAL PROCEEDINGS

The information set forth in Note 19 to our accompanying consolidated financial statements under the caption “Litigation” included in Part IV, Item 15(a) of this Annual Report on Form 10-K is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Market Information

Our stock is traded on the Nasdaq Global Select Market under the symbol "MASI". As of February 12, 2019, the closing price of our stock was $129.74 per share, and the number of stockholders of record was 20. 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 December 29, 2012 through December 29, 2018 against the Nasdaq Market Composite Index and Nasdaq Medical Equipment Index, assuming a $100 investment made on December 28, 2013. Each of the two comparative measures of cumulative total return assumes reinvestment of dividends. The stock performance shown on the graph below is not necessarily indicative of future price performance.

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COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Masimo Corporation, the Nasdaq Market Composite Index, and
the Nasdaq Medical Equipment Index
*$100 invested on 12/28/13 in stock or 01/01/11 in index, including reinvestment of dividends. Indexes calculated on month-end basis.

Repurchases and Withholdings of Issuer Securities

In September 2015, our Board of Directors (Board) authorized a stock repurchase program, whereby we could purchase up to 5.0 million shares of our common stock over a period of up to three years (2015 Repurchase Program). A total of 3.1 million shares were purchased by us pursuant to the 2015 Repurchase Program prior to its expiration in September 2018.

In July 2018, the Board approved a new stock repurchase program, authorizing us to purchase up to 5.0 million additional shares of its common stock over a period of up to three years (2018 Repurchase Program). The 2018 Repurchase Program became effective in September 2018 upon the expiration of the 2015 Repurchase Program. We expect to fund the 2018 Repurchase Program through its available cash, cash expected to be generated from future operations and other potential sources of capital. The 2018 Repurchase Program can be carried out at the discretion of a committee comprised of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO) through open market purchases, one or more Rule 10b5-1 trading plans, block trades and privately negotiated transactions. Any repurchases under the 2018 Repurchase Plan are subject to the availability of stock, general market conditions, the trading price of the stock, available capital, alternative uses for capital and our financial performance. There were no repurchases of stock under the 2018 Repurchase Program during the three months ended December 29, 2018.

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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 operations data for the years ended December 29, 2018, December 30, 2017 and December 31, 2016 and the consolidated balance sheet data as of December 29, 2018 and December 30, 2017 were derived from our audited consolidated financial statements included in this Annual Report on Form 10-K. The consolidated statement of operations data for the years ended January 2, 2016 and January 3, 2015, and the consolidated balance sheet data as of December 31, 2016, January 2, 2016 and January 3, 2015 were derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of future results.

Certain information presented as of and for the periods ended December 30, 2017 and December 31, 2016 have been restated to reflect the full retrospective application of the new revenue accounting standard, Accounting Standards Update (ASU) No. 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09). Information presented as of and for the periods ended January 2, 2016 and January 3, 2015 have not been restated and continue to reflect the prior revenue recognition guidance pursuant to ASC Topic 605, Revenue Recognition. See Note 2 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to our adoption of this new accounting standard.

The selected financial data set forth below should be read in conjunction with our consolidated financial statements, the related notes and Item 7 - “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this Annual Report on Form 10-K.

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	Year ended December 29, 2018	Year ended December 30, 2017 As Adjusted	Year ended December 31, 2016 As Adjusted	Year ended January 2, 2016	Year ended January 3, 2015
	(in thousands, except per share amounts)				
Statement of Operations[1]:					
Revenue:					
Product	$829,874	$738,242	$673,962	$599,334	$556,764
Royalty and other revenue	28,415	52,006	38,936	30,777	29,879
Total revenue	858,289	790,248	712,898	630,111	586,643
Cost of goods sold	283,397	268,216	234,560	220,128	195,864
Gross profit	574,892	522,032	478,338	409,983	390,779
Operating expenses:					
Selling, general and administrative	289,456	276,292	254,707	252,725	241,016
Research and development	76,967	61,953	57,686	56,617	56,581
Litigation settlement, award and/or defense costs	425	—	(270,000)	(19,609)	(10,331)
Total operating expenses	366,848	338,245	42,393	289,733	287,266
Operating income	208,044	183,787	435,945	120,250	103,513
Non-operating (income) expense	(5,732)	(2,013)	2,429	3,905	1,472
Income before provision for income taxes	213,776	185,800	433,516	116,345	102,041
Provision for income taxes	20,233	61,011	122,419	34,845	27,678
Net income including noncontrolling interests	193,543	124,789	311,097	81,500	74,363
Net income (loss) attributable to noncontrolling interests	—	—	—	(1,800)	1,845
Net income attributable to Masimo Corporation stockholders	$193,543	$124,789	$311,097	$83,300	$72,518
Net income per common share attributable to Masimo Corporation stockholders[2]:					
Basic	$3.70	$2.42	$6.28	$1.62	$1.33
Diluted	$3.45	$2.23	$5.85	$1.55	$1.30
Weighted-average number of common shares:					
Basic	52,296	51,516	49,530	51,311	54,708
Diluted	56,039	55,874	53,195	53,707	55,571

(1) Cercacor was consolidated as a variable interest entity within our financial statements for all periods prior to January 3, 2016. Accordingly, all intercompany royalties, option and licensing fees, and other charges between us and Cercacor for such periods have been eliminated in the consolidation. For additional discussion of Cercacor, see Note 3 to our accompanying consolidated financial statements in Part IV, Item 15(a) of this Annual Report on Form 10-K.

(2) See Note 2 to our accompanying consolidated financial statements in Part IV, Item 15(a) of this Annual Report on Form 10-K for a description of the method used to compute basic and diluted net income per common share.

December 29, 2018	December 30, 2017 As Adjusted	December 31, 2016 As Adjusted	January 2, 2016	January 3, 2015
(in thousands)				

Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$552,490	$ 315,302	$ 305,970	$132,317	$134,453
Working capital	637,490	430,041	289,830	166,509	173,182
Total assets	1,154,818	905,436	814,352	601,735	565,006
Total debt	—	—	71	185,145	125,224
Total equity	969,065	724,025	584,177	275,712	307,741

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

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

Executive Overview

We are a global medical technology company that develops, manufactures and markets a variety of noninvasive monitoring technologies. Our mission is to improve patient outcomes and reduce the cost of care. We invented Masimo SET®, which provides the capabilities of Measure-through Motion and Low Perfusion® pulse oximetry to address the primary limitations of conventional pulse oximetry. Pulse oximetry is the noninvasive measurement of the oxygen saturation level of arterial blood, or the blood that delivers oxygen to the body's tissues, and pulse rate. Pulse oximetry is one of the most common measurements made in and out of hospitals around the world. Masimo SET® has been validated in over 100 independent clinical studies and is the only pulse oximetry technology we are aware of that has been proven to help clinicians detect critical congenital heart disease in newborns, reduce retinopathy of prematurity in neonates, and decrease intensive care unit transfers and rapid response activations on the general floor. After introducing Masimo SET®, we have continued to innovate by introducing noninvasive measurements beyond arterial blood oxygen saturation level (SpO_2) and pulse rate (PR), creating new market opportunities in both the hospital and non-hospital care settings. We believe our Masimo rainbow SET™ platform, which utilizes Masimo SET® and both licensed and proprietary rainbow® technologies, includes the first devices cleared by the U.S. Food and Drug Administration (FDA) to noninvasively and continuously monitor multiple measurements that previously required invasive or complicated procedures. Following the introduction of our rainbow SET™ platform, we introduced additional noninvasive measurements and technologies including SedLine® brain function monitoring, NomoLine® capnography and gas monitoring, and O3® regional oximetry. Our current technology offerings also include Patient SafetyNet, Patient SafetyNet Surveillance, MyView®, Replica™ and Trace.™ Please see Part I, Item 1 of this Annual Report on Form 10-K for additional information related to our business, products and technologies.

Adoption of New Revenue Accounting Standard

Effective December 31, 2017, we adopted Financial Accounting Standards Board Accounting Standards Update (ASU) No. 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09). Our adoption of ASU 2014-09 generally resulted in (a) the acceleration of when we recognize certain revenue, and (b) the deferral of certain incremental costs associated with obtaining a customer contract. As indicated by the notation "as adjusted", prior period amounts and disclosures set forth in this Annual Report on Form 10-K have been updated to comply with the full retrospective application of Accounting Standards Codification (ASC) Topic 606 (ASC 606). See Note 2 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to our adoption of this new accounting standard.

Tax Cuts and Jobs Act of 2017 (2017 Tax Act)

On December 22, 2017, the 2017 Tax Act was signed into law, and became effective January 1, 2018. The 2017 Tax Act included a number of changes to existing U.S. federal tax law impacting businesses including, among other things, a permanent reduction in the corporate income tax rate from 35% to 21%, a one-time transition tax on the "deemed repatriation" of cumulative undistributed foreign earnings as of December 31, 2017 and changes in the prospective taxation of the foreign operations of U.S. multinational companies. Given the complexity of the 2017 Tax Act, we made certain estimates and assumptions in connection with the calculation of our provision for income taxes for the year ended December 30, 2017 and recorded a discrete tax charge of approximately $37.0 million. In addition, as a result of this change in U.S. tax policy, we recorded a related discrete tax charge of $6.5 million as a result of our decision to repatriate up to $180.0 million of accumulated undistributed earnings from our foreign subsidiaries. During the year ended December 29, 2018, we recorded an adjustment of approximately $0.9 million in our tax provision to reduce our previous estimated accrual as the result of additional information and guidance that became

available with respect to the application of certain provisions of the 2017 Tax Act. See Note 18 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to the impact of the 2017 Tax Act on our tax provision and tax rate.

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Settlement Agreement with Koninklijke Philips N.V. (Philips N.V.)

In November 2016, we entered into a settlement agreement with Philips N.V. (the Philips Settlement Agreement), pursuant to which Philips N.V. agreed to pay us $300 million, and Philips N.V. and its affiliates (collectively, the Philips Group) and us (collectively, the Parties) agreed to dismiss, with prejudice, all pending legal and contractual disputes between the Parties and agreed not to sue each other for patent infringement for certain of each other's products. In addition, the Parties agreed to work together to integrate our technologies into additional Philips Group products, and to jointly develop certain other products. Each of the Parties has additional obligations to the other in the event that such party does not meet certain objectives under the settlement agreement. The Philips Settlement Agreement also contains rainbow® parameter pricing and related terms. The Parties further agreed to undertake a joint marketing program to promote rainbow® adoption with Philips Group products.

Stock Repurchase Programs

In July 2018, our Board approved a stock repurchase program authorizing us to purchase up to 5.0 million shares of our common stock over a period of up to three years (2018 Repurchase Program). The 2018 Repurchase Program may be carried out at the discretion of a committee comprised of our CEO and CFO through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. For additional information regarding our current and prior stock repurchase programs, see Part II, Item 5 and Note 15 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

Cercacor

Cercacor is an independent entity spun off from Masimo to our stockholders in 1998. We are a party to a cross-licensing agreement with Cercacor, which was amended and restated effective January 1, 2007 (the Cross-Licensing Agreement), that governs each party's rights to certain intellectual property held by the two companies. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Cercacor. We have also entered into various other agreements with Cercacor, including an Administrative Services Agreement, a Consulting Services Agreement and a Sublease Agreement. For periods prior to January 3, 2016, Cercacor was consolidated as a variable interest entity within our financial statements. See Note 3 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to Cercacor.

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Results of Operations[1]

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

	Year ended December 29, 2018		Year ended December 30, 2017 As Adjusted		Year ended December 31, 2016 As Adjusted	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(dollars in thousands)					
Revenue:						
Product	$829,874	96.7 %	$738,242	93.4 %	$673,962	94.5 %
Royalty and other revenue	28,415	3.3	52,006	6.6	38,936	5.5
Total revenue	858,289	100.0	790,248	100.0	712,898	100.0
Cost of goods sold	283,397	33.0	268,216	33.9	234,560	32.9
Gross profit	574,892	67.0	522,032	66.1	478,338	67.1
Operating expenses:						
Selling, general and administrative	289,456	33.7	276,292	35.0	254,707	35.7
Research and development	76,967	9.0	61,953	7.8	57,686	8.1
Litigation settlement, award and/or defense costs	425	—	—	—	(270,000)	(37.9)
Total operating expenses	366,848	42.7	338,245	42.8	42,393	5.9
Operating income	208,044	24.2	183,787	23.3	435,945	61.2
Non-operating (income) expense	(5,732)	(0.7)	(2,013)	(0.3)	2,429	0.3
Income before provision for income taxes	213,776	24.9	185,800	23.5	433,516	60.8
Provision for income taxes	20,233	2.4	61,011	7.7	122,419	17.2
Net income	$193,543	22.5 %	$124,789	15.8 %	$311,097	43.6 %

Comparison of the Year ended December 29, 2018 to the Year ended December 30, 2017[1]

Revenue. Total revenue increased $68.0 million, or 8.6%, to $858.3 million for the year ended December 29, 2018, from $790.2 million for the year ended December 30, 2017. The following table details our total product revenues by the geographic area to which the products were shipped for fiscal years 2018 and 2017 (dollars in thousands):

	Year ended December 29, 2018		Year ended December 30, 2017 As Adjusted		Increase/ (Decrease)	Percentage Change
United States	$566,816	68.3 %	$502,983	68.1 %	$ 63,833	12.7 %
Europe, Middle East and Africa	160,910	19.4	138,689	18.8	22,221	16.0
Asia and Australia	75,534	9.1	72,434	9.8	3,100	4.3
North and South America (excluding United States)	26,614	3.2	24,136	3.3	2,478	10.3
Total product revenue	$829,874	100.0%	$738,242	100.0%	$ 91,632	12.4 %
Royalty and other revenue	28,415		52,006		(23,591)	(45.4)%
Total revenue	$858,289		$790,248		$ 68,041	

(1) Certain information presented for the periods ended December 30, 2017 and December 31, 2016 has been restated to reflect the full retrospective application of ASU 2014-09. See Note 2 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to our adoption of this new accounting standard.

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Product revenues increased $91.6 million, or 12.4%, to $829.9 million for the year ended December 29, 2018 from $738.2 million for the year ended December 30, 2017. This increase was primarily due to higher sales of our sensor products resulting from an increase in our installed base of circuit boards and monitors, an increase in sales of parameter licenses as well as higher sales of circuit boards, monitoring equipment and parameter licenses. Included in our product revenue growth was approximately $4.0 million of favorable foreign exchange rate movements from the prior year period that increased the U.S. Dollar translation of foreign sales that were denominated in various foreign currencies. During the year ended December 29, 2018, we shipped approximately 231,700 noninvasive technology boards and monitors, an increase of approximately 28,700 units, or 14.1%, from approximately 203,000 units shipped during the year ended December 30, 2017.

Product revenue generated through our direct and distribution sales channels increased $73.9 million, or 11.5%, to $718.6 million for the year ended December 29, 2018, compared to $644.7 million for the year ended December 30, 2017. Revenues from our OEM channel increased $17.7 million, or 18.9%, to $111.3 million for the year ended December 29, 2018 as compared to $93.6 million for the year ended December 30, 2017.

Royalty and other revenue consists primarily of royalties received from Medtronic plc (Medtronic, formerly Covidien Ltd.) related to its U.S. sales pursuant to the terms of settlement agreement, and revenue from non-recurring engineering (NRE) services for a certain OEM customer. For the year ended December 29, 2018, royalty and other revenue decreased $23.6 million, or 45.4%, to $28.4 million from $52.0 million for the year ended December 30, 2017, primarily due to the completion of the majority of our contracted NRE services in the prior year. In addition, Medtronic was no longer required to pay royalties to us after October 6, 2018. We currently do not expect to replace this royalty and NRE services revenue with similar revenue from other sources.

Gross Profit. Gross profit consists of total revenue less cost of goods sold. Our gross profit for fiscal years 2018 and 2017 was as follows (dollars in thousands):

	Gross Profit					
	Year ended December 29, 2018	Percentage of Net Revenues	Year ended December 30, 2017 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
Product gross profit	$547,188	65.9 %	$473,647	64.2 %	$ 73,541	15.5 %
Royalty and other revenue gross profit	27,704	97.5	48,385	93.0	(20,681)	(42.7)
Total gross profit	$574,892	67.0 %	$522,032	66.1 %	$ 52,860	10.1 %

Cost of goods sold includes labor, material, overhead and other similar costs related to the production, supply, distribution and support of our products and the rendering of NRE services. Cost of goods sold increased $15.2 million to $283.4 million for the year ended December 29, 2018, from $268.2 million for the year ended December 30, 2017, primarily due to increased product revenue that was partially offset by improved manufacturing efficiencies and product cost reductions. Product gross margins increased to 65.9% for the year ended December 29, 2018 from 64.2% for the year ended December 30, 2017. This increase in product gross margin was primarily due to improved manufacturing efficiencies and product cost reductions. Royalty and other revenue gross profit decreased by $20.7 million for the year ended December 29, 2018 compared to the year ended December 30, 2017, primarily due to lower NRE service revenue in the current year.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of salaries and related expenses for sales, marketing and administrative personnel, sales commissions, advertising and promotion costs, professional fees related to legal, accounting and other outside services, public company costs and other corporate expenses. Selling, general and administrative expenses for fiscal years 2018 and 2017 were as follows (dollars in thousands):

Selling, General and Administrative

Year ended December 29, 2018	Percentage of Net Revenues	Year ended December 30, 2017 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$289,456	33.7%	$276,292	35.0%	$13,164	4.8%

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Selling, general and administrative expenses increased $13.2 million, or 4.8%, to $289.5 million for the year ended December 29, 2018 from $276.3 million for the year ended December 30, 2017. This net increase was primarily attributable to higher payroll-related costs of approximately $24.8 million, higher GPO fees and third-party commission expenses of approximately $2.8 million and higher charitable donations of approximately $2.6 million. These increased expenses were partially offset by lower legal expenses of approximately $2.7 million and the non-recurrence of a net charge of approximately $10.5 million recorded during the year ended December 30, 2017 related to an arbitration proceeding that we initiated against a former appointed foreign agent, as well as a $2.0 million partial recovery against such charge during the year ended December 29, 2018. See Note 19 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on the status of this arbitration proceeding.

Approximately $21.4 million and $13.3 million of stock-based compensation expense was included in selling, general and administrative expenses for the years ended December 29, 2018 and December 30, 2017, respectively. The increase in stock-based compensation expense during the year ended December 29, 2018 was due to both the composition of the equity awards granted and a significant increase in the fair market value of our stock from the prior year that increased the value of the equity awards granted during the year. See Note 16 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on our stock-based compensation programs.

Research and Development. Research and development expenses consist primarily of salaries and related expenses for engineers and other personnel engaged in the design and development of our products. These expenses also include third-party fees paid to consultants, prototype and engineering supply expenses and the costs of clinical trials.

Research and development expenses for fiscal years 2018 and 2017 were as follows (dollars in thousands):

Research and Development

Year ended December 29, 2018	Percentage of Net Revenues	Year ended December 30, 2017	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$76,967	9.0%	$61,953	7.8%	$15,014	24.2%

Research and development expenses increased $15.0 million, or 24.2%, to $77.0 million for the year ended December 29, 2018 from $62.0 million for the year ended December 30, 2017. This net increase was due primarily to increases in payroll-related costs of approximately $9.5 million, engineering project costs of approximately $0.8 million and occupancy-related costs of approximately $0.8 million, as well as $2.9 million less in allocations to cost of goods sold due to lower NRE service revenue.

Included in research and development expenses was approximately $5.7 million and $3.6 million of stock-based compensation expense for the years ended December 29, 2018 and December 30, 2017, respectively. The increase in stock-based compensation expense during the year ended December 29, 2018 was primarily due to the increase in the fair market value of our stock from the prior year that increased the value of the equity awards granted during the year. See Note 16 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on our stock-based compensation programs.

Non-operating (Income) Expense. Non-operating (income) expense consists primarily of interest income, interest expense and foreign exchange losses. Non-operating income for fiscal years 2018 and 2017 was as follows (dollars in thousands):

Non-operating (income)

Year ended December 29, 2018	Percentage of Net Revenues	Year ended December 30, 2017	Percentage of Net Revenues	(Increase)/ Decrease	Percentage Change
$(5,732)	(0.7)%	$(2,013)	(0.3)%	$(3,719)	184.7%

Non-operating income was $5.7 million for the year ended December 29, 2018, as compared to $2.0 million of non-operating income for the year ended December 30, 2017. This net increase of approximately $3.7 million was primarily due to approximately $5.2 million in higher interest income. In addition, we recognized approximately $2.0

million of net realized and unrealized losses on foreign currency denominated transactions during the year ended December 29, 2018, as compared to $0.3 million of net realized and unrealized losses on foreign currency denominated transactions during the year ended December 30, 2017.

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Provision for Income Taxes. Our provision for income taxes for fiscal years 2018 and 2017 was as follows (dollars in thousands):

Provision for Income Taxes

Year ended December 29, 2018	Percentage of Net Revenues	Year ended December 30, 2017 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$20,233	2.4%	$61,011	7.7%	$(40,778)	(66.8)%

Our provision for income taxes was $20.2 million for the year ended December 29, 2018 compared to $61.0 million for the year ended December 30, 2017. Our effective tax rate was 9.5% for the year ended December 29, 2018 compared to 32.8% for the year ended December 30, 2017. This decrease in our effective tax rate was primarily due to discrete charges of $43.5 million during the year ended December 30, 2017 for the estimated impact of the 2017 Tax Act and our related decision to repatriate up to $180.0 million of accumulated undistributed foreign earnings. During the year ended December 29, 2018, we recorded a tax benefit of approximately $5.0 million related to the derecognition of uncertain tax positions due to the expiration of the statutes of limitations. Partially offsetting these decreases to our effective tax rate were lower tax benefits for stock-based compensation of approximately $22.0 million for the year ended December 29, 2018 as compared to $39.2 million for the year ended December 30, 2017. See Note 18 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to the impact of the 2017 Tax Act on our tax provision and tax rate for the years ended December 29, 2018 and December 30, 2017.

We have made no provision for U.S. income taxes or foreign withholding taxes on approximately $44.8 million in accumulated earnings from our foreign subsidiaries as we expect that such amounts will continue to be indefinitely reinvested in operations outside the U.S. Our effective tax rate was lower than the U.S. federal statutory rate primarily due to a portion of our earnings being generated from countries other than the U.S., where such earnings are generally subject to lower tax rates than the U.S., excess tax benefits from U.S. stock-based compensation and research and development tax credits. While we expect our worldwide consolidated effective tax rate will continue to be lower than the U.S. federal statutory rate, our actual future effective income tax rate will depend on various factors, including the geographic composition of our pre-tax income, the amount of excess tax benefits realized from U.S. stock-based compensation, the amount of our research and development tax credits, the deductibility of executive compensation, changes in tax laws, changes in deferred tax asset valuation allowances and the recognition and derecognition of tax benefits associated with uncertain tax positions.

Comparison of the Year ended December 30, 2017 to the Year ended December 31, 2016[(2)]

Revenue. Total revenue increased $77.4 million, or 10.9%, to $790.2 million for the year ended December 30, 2017, from $712.9 million for the year ended December 31, 2016.

The following table details our total product revenues by the geographic area to which the products were shipped for fiscal years 2017 and 2016 (dollars in thousands):

	Year ended December 30, 2017 As Adjusted		Year ended December 31, 2016 As Adjusted		Increase/ (Decrease)	Percentage Change
United States	$502,983	68.1 %	$475,068	70.5 %	$ 27,915	5.9 %
Europe, Middle East and Africa	138,689	18.8	113,015	16.8	25,674	22.7
Asia and Australia	72,434	9.8	66,136	9.8	6,298	9.5
North and South America (excluding United States)	24,136	3.3	19,743	2.9	4,393	22.3
Total product revenue	$738,242	100.0%	$673,962	100.0%	$ 64,280	9.5 %
Royalty and other revenue	52,006		38,936		13,070	
Total revenue	$790,248		$712,898		$ 77,350	

(2) Certain information presented for the periods ended December 30, 2017 and December 31, 2016 has been restated to reflect the full retrospective application of ASU 2014-09. See Note 2 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to our adoption of this new accounting standard.

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Product revenues increased $64.3 million, or 9.5%, to $738.2 million for the year ended December 30, 2017 from $674.0 million for the year ended December 31, 2016. This increase was primarily due to higher sales of our sensor products resulting from an increase in our installed base of circuit boards and pulse oximeters, as well as higher sales of monitoring equipment. During the year ended December 30, 2017, the movement in foreign exchange rates from the prior year period on the U.S. Dollar translation of foreign sales that were denominated in various foreign currencies did not have a significant impact on product revenue. During the year ended December 30, 2017, we shipped approximately 203,000 noninvasive technology boards and monitors, an increase of approximately 17,100 units, or 9.2%, from approximately 185,900 units shipped during the year ended December 31, 2016.

Product revenue generated through our direct and distribution sales channels increased $62.5 million, or 10.7%, to $644.7 million for the year ended December 30, 2017, compared to $582.1 million for the year ended December 31, 2016. Revenues from our OEM channel increased $1.7 million, or 1.9%, to $93.6 million for the year ended December 30, 2017 as compared to $91.8 million for the year ended December 31, 2016.

Royalty and other revenue consists primarily of royalties received from Medtronic plc (Medtronic, formerly Covidien Ltd.) related to its U.S. sales pursuant to the terms of settlement agreement, and revenue from non-recurring engineering (NRE) services for a certain OEM customer. For the year ended December 30, 2017, royalty and other revenue increased 33.6%, or $13.1 million to $52.0 million from $38.9 million for the year ended December 31, 2016, primarily due to higher revenue from NRE services.

Gross Profit. Gross profit consists of total revenue less cost of goods sold. Our gross profit for fiscal years 2017 and 2016 was as follows (dollars in thousands):

	Gross Profit							
	Year ended December 30, 2017 As Adjusted	Percentage of Net Revenues		Year ended December 31, 2016 As Adjusted	Percentage of Net Revenues		Increase/ (Decrease)	Percentage Change
Product gross profit	$473,647	64.2	%	$441,078	65.4	%	$ 32,569	7.4 %
Royalty and other revenue gross profit	48,385	93.0		37,260	95.7		11,125	29.9
Total gross profit	$522,032	66.1	%	$478,338	67.1	%	$ 43,694	9.1 %

Cost of goods sold includes labor, material, overhead and other similar costs related to the production, supply, distribution and support of our products and the rendering of NRE services. Cost of goods sold increased $33.7 million to $268.2 million for the year ended December 30, 2017, from $234.6 million for the year ended December 31, 2016, primarily due to increased product revenue, higher production costs associated with the expansion of our manufacturing capacity and increased inventory valuation reserves associated with certain product transitions. Product gross margins decreased to 64.2% for the year ended December 30, 2017 from 65.4% for the year ended December 31, 2016. This decrease in product gross margin was primarily due to differences in customer and product mix, unfavorable production variances associated with the expansion of our manufacturing capacity and increased inventory valuation reserves associated with certain product transitions. Royalty and other revenue gross profit increased by $13.1 million for the year ended December 30, 2017 compared to the year ended December 31, 2016, primarily due to higher NRE service revenue.

Selling, General and Administrative. Selling, general and administrative expenses for fiscal years 2017 and 2016 were as follows (dollars in thousands):

Selling, General and Administrative					
Year ended December 30, 2017 As Adjusted	Percentage of Net Revenues	Year ended December 31, 2016 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change

$276,292	35.0%	$254,707	35.7%	$21,585	8.5%

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Selling, general and administrative expenses increased $21.6 million, or 8.5%, to $276.3 million for the year ended December 30, 2017 from $254.7 million for the year ended December 31, 2016. This net increase was primarily attributable to higher payroll-related expenses of approximately $11.9 million, higher sales and marketing related expenses of approximately $5.3 million and higher occupancy costs of approximately $3.1 million. In addition, we also recorded a net charge of approximately $10.5 million related to arbitration proceedings that we initiated during the year ended December 30, 2017 against a former appointed foreign agent seeking to collect amounts that were paid by a foreign government customer to such agent in connection with a foreign government tender. See Note 19 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on this arbitration proceeding. These increases were partially offset by a decrease in donations of approximately $5.3 million and lower legal and professional fees of approximately $4.7 million. Approximately $13.3 million and $9.4 million of stock-based compensation expense was included in selling, general and administrative expenses for the years ended December 29, 2018 and December 30, 2017, respectively. The increase in stock-based compensation expense during the year ended December 29, 2018 was due to both the composition of the equity awards granted and a significant increase in the fair market value of our stock from the prior year that increased the value of the equity awards granted during the year. See Note 16 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information on our stock-based compensation programs.

Research and Development. Research and development expenses for fiscal years 2017 and 2016 were as follows (dollars in thousands):

Research and Development

Year ended December 30, 2017	Percentage of Net Revenues	Year ended December 31, 2016 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$61,953	7.8%	$57,686	8.1%	$4,267	7.4%

Research and development expenses increased $4.3 million, or 7.4%, to $62.0 million for the year ended December 30, 2017 from $57.7 million for the year ended December 31, 2016. This net increase was due primarily to increases in payroll-related costs of approximately $4.9 million, which were offset by approximately $1.9 million of higher allocations of costs related to NRE services that were reclassified to cost of goods sold.

Included in research and development expenses was approximately $3.6 million and $2.7 million of stock-based compensation expense for the years ended December 30, 2017 and December 31, 2016, respectively.

Litigation Settlement, Award and/or Defense Costs. Litigation settlement, award and/or defense costs for fiscal years 2017 and 2016 were as follows (dollars in thousands):

Litigation Settlement, Award and/or Defense Costs

Year ended December 30, 2017	Percentage of Net Revenues	Year ended December 31, 2016	Percentage of Net Revenues	(Increase)/ Decrease	Percentage Change
$—	—%	$(270,000)	(37.9)%	$270,000	(100.0)%

On November 5, 2016, we entered into a settlement agreement (the Philips Settlement Agreement) with Philips N.V., which among other things, settled all of the claims, legal proceedings and contractual disputes between us, Philips and its affiliates. Pursuant to the Philips Settlement Agreement, Philips N.V. paid us $300 million, $30 million of which related to certain future performance obligations by us and, therefore, was deferred to future periods. See “Settlement Agreement with Koninklijke Philips N.V. (Philips N.V.)” previously discussed within Part II, Item 7 of this Annual Report on Form 10-K for additional information on the Philips Settlement Agreement.

Non-operating (Income) Expense. Non-operating (income) expense consists primarily of interest income, interest expense and foreign exchange losses. Non-operating (income) expense for fiscal years 2017 and 2016 was as follows (dollars in thousands):

Non-operating (income) expense

Year ended December 30, 2017	Percentage of Net Revenues	Year ended December 31, 2016	Percentage of Net Revenues	(Increase)/ Decrease	Percentage Change
$(2,013)	(0.3)%	$2,429	0.3%	$(4,442)	(182.9)%

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Non-operating income was $2.0 million for the year ended December 30, 2017, as compared to $2.4 million of non-operating expense for the year ended December 31, 2016. This net increase of approximately $4.4 million was primarily due to increased interest income of $2.5 million and lower interest expense of approximately $2.6 million, both of which resulted primarily from the cash received pursuant to the Philips Settlement Agreement in the fourth quarter of 2016. In addition, we recognized approximately $0.3 million of net realized and unrealized losses on foreign currency denominated transactions during the year ended December 30, 2017, as compared to $0.1 million of net realized and unrealized gains on foreign currency denominated transactions during the year ended December 31, 2016.

Provision for Income Taxes. Our provision for income taxes for fiscal years 2017 and 2016 was as follows (dollars in thousands):

Provision for Income Taxes					
Year ended December 30, 2017 As Adjusted	Percentage of Net Revenues	Year ended December 31, 2016 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$61,011	7.7%	$122,419	17.2%	$(61,408)	(50.2)%

Our provision for income taxes was $61.0 million for the year ended December 30, 2017 compared to $122.4 million for the year ended December 31, 2016. Our effective tax rate was 32.8% for the year ended December 30, 2017 compared to 28.2% for the year ended December 31, 2016. This increase in our effective tax rate was primarily due to discrete charges during the year ended December 30, 2017of approximately $43.5 million, including $37.0 million related to the direct impact of the 2017 Tax Act and $6.5 million resulting from our decision to repatriate up to $180.0 million of accumulated undistributed earnings from our foreign subsidiaries as a result of the changes in U.S. tax policy under the 2017 Tax Act. An unfavorable mix in the geographic composition of our pre-tax earnings between higher tax and lower tax jurisdictions also contributed to the increase in our effective tax rate. These increases to our effective tax rate were partially offset by incremental excess tax benefits realized for stock-based compensation of approximately $39.2 million for the year ended December 30, 2017 as compared to $13.0 million for the year ended December 31, 2016. See Note 18 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to the impact of the 2017 Tax Act on our tax provision and tax rate for the year ended December 30, 2017.

Liquidity

Our principal sources of liquidity consist of our existing cash and cash equivalent balances and funds expected to be generated from operations. As of December 29, 2018, we had approximately $637.5 million in working capital and approximately $552.5 million in cash and cash equivalents as compared to approximately $430.0 million in working capital and approximately $315.3 million in cash and cash equivalents at December 30, 2017. We carry cash equivalents at cost that approximates fair value. We currently do not maintain a significant investment portfolio but have the ability to invest in various security holdings, types and maturities that meet credit quality standards in accordance with our investment guidelines.

In managing our day-to-day liquidity and capital structure, we generally do not rely on foreign earnings as a source of funds. As of December 29, 2018, we had cash totaling $78.7 million held outside of the U.S., all of which was accessible without additional tax cost. We currently have sufficient domestic funds on-hand and cash held outside the U.S. that is available without additional tax cost to fund our domestic operations. In the event funds that are treated as permanently reinvested are repatriated, we may be required to accrue and pay additional U.S. taxes to repatriate these funds.

During fiscal years 2018, 2017 and 2016, we received $33.3 million, $32.9 million, and $30.5 million, respectively, in cash from Medtronic for royalties related to their U.S. sales pursuant to the terms of our amended settlement agreement. Pursuant to the terms of the Third Amendment to Settlement Agreement and Release of Claims, Medtronic is no longer required to pay royalties to us on their sales after October 6, 2018. We currently do not expect to replace this royalty income stream.

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Cash Flows[3]

The following table summarizes our cash flows (in thousands):

	Year Ended	
	December 29, 2018	December 30, 2017 As Adjusted
Net cash provided by (used in):		
Operating activities	$239,527	$ 56,062
Investing activities	(26,152)	(47,908)
Financing activities	25,780	(4,138)
Effect of foreign currency exchange rates on cash	(1,997)	3,269
Increase in cash and cash equivalents, and restricted cash	$237,158	$ 7,285

Operating Activities. Cash provided by operating activities for the year ended December 29, 2018 was $239.5 million and was driven primarily by net income of $193.5 million. Non-cash activity included stock based compensation of $27.4 million, depreciation and amortization of $21.1 million and a deferred income tax benefit of $8.3 million. Additional sources of cash related to changes in operating assets and liabilities included a decrease in accounts receivable of $10.8 million, primarily due to the timing of collections, and increases in accrued compensation, accounts payable and other current liabilities of $10.2 million, $5.2 million and $3.9 million, respectively, primarily due to the timing of payments. These sources of cash were partially offset by other changes in operating assets and liabilities related to an increase in deferred cost of goods of $17.9 million, primarily due to the growth in our business, and a decrease in other liabilities of $7.6 million, primarily due to the derecognition of uncertain tax positions as a result of the expiration of certain statutes of limitations.

Cash provided by operating activities for the year ended December 30, 2017 was $56.1 million and was driven primarily by net income of $124.8 million and non-cash adjustments for depreciation and amortization, deferred income taxes, stock-based compensation and a provision related to a former appointed foreign agent of $20.1 million, $17.3 million, $17.2 million and $10.5 million, respectively. In addition, during the year ended December 30, 2017, other liabilities increased by $28.0 million, primarily due to income taxes payable after 2018 under the 2017 Tax Act. These sources of cash were partially offset by other changes in operating assets and liabilities related to increases in inventories, deferred cost of goods sold and other assets of $24.0 million, $14.1 million and $10.8 million, respectively, primarily due to the growth in our business; an increase in accounts receivable of $19.8 million, primarily due to the timing of collections; and decreases in income taxes payable and deferred revenue of $72.1 million and $13.3 million, respectively, primarily due to the timing of payments.

Investing Activities. Cash used in investing activities for the fiscal year ended December 29, 2018 was $26.2 million, consisting primarily of $17.1 million for purchases of property and equipment, $5.6 million for intangible assets related to capitalized patent and trademark costs and $3.9 million related to the acquisition of a private patient monitoring software company.

Cash used in investing activities for the fiscal year ended December 30, 2017 was $47.9 million, consisting primarily of $43.7 million for purchases of property and equipment and $3.1 million for intangible assets related to capitalized patent and trademark costs.

Financing Activities. Cash provided by financing activities for the fiscal year ended December 29, 2018 was $25.8 million, resulting primarily proceeds from the issuance of common stock (upon exercise of options) of $44.7 million, which were partially offset by cash paid for common stock repurchase transactions that settled during the year of $18.5 million.

Cash used in financing activities for the fiscal year ended December 30, 2017 was $4.1 million, resulting primarily from common stock repurchase transactions that settled during the year totaling $66.3 million, which were offset by proceeds from the issuance of common stock (upon exercise of options) totaling $62.2 million.

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(3) Certain information presented for periods ending prior to December 31, 2017 has been restated to reflect the full retrospective application of the new revenue accounting standard, ASU 2014-09. See Note 2 to the condensed consolidated financial statements included in Part IV, Item 16 of this Annual Report on Form 10-K

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Capital Resources and Prospective Capital Requirements

On December 17, 2018, we entered into a Credit Agreement (Credit Facility) with JPMorgan Chase Bank, N.A., as Administrative Agent and a Lender, and Bank of the West, as a Lender (collectively, the Initial Lenders). The Credit Facility provides for up to $150.0 million of unsecured borrowings, with an option, subject to certain conditions, for us to increase the aggregate borrowing capacity to up to $550.0 million in the future with the Initial Lenders and additional Lenders, as required. The Credit Facility also provides for a sublimit of up to $25.0 million for the issuance of letters of credit and a sublimit of $75.0 million for borrowings in specified foreign currencies. All unpaid principal under the Credit Facility will become due and payable on December 17, 2023. Proceeds from the Credit Facility are expected to be used for general corporate, capital investment and working capital needs. For additional information regarding the Credit Facility, see Note 13 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

In July 2018, our Board approved the 2018 Repurchase Program, authorizing us to purchase up to 5.0 million additional shares of its common stock over a period of up to three years. The 2018 Repurchase Program became effective in September 2018 upon the expiration of our previous repurchase program. For additional information regarding our stock repurchase programs, see Note 15 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

We expect to fund our future operating, investing and financing activities through our available cash, future cash from operations, our Credit Facility and other potential sources of capital. In addition to funding our working capital requirements, we anticipate additional capital expenditures during fiscal year 2019 of approximately $80.0 million, primarily related to investments in infrastructure growth. Possible additional uses of cash may include the acquisition of technologies or technology companies, as well as repurchases of stock under our authorized stock repurchase program. However, any repurchases of stock will be subject to numerous factors, including the availability of our stock, general market conditions, the trading price of our stock, available capital, alternative uses for capital and our financial performance. In addition, the amount and timing of our actual investing activities will vary significantly depending on numerous factors, including the timing and amount of capital expenditures, costs of product development efforts, our timetable for international sales operations and manufacturing expansion, stock repurchase activity and costs related to our domestic and international regulatory requirements. Despite these investment requirements, we anticipate that our existing cash and cash equivalents and amounts available under our new Credit Facility will be sufficient to meet our working capital requirements, capital expenditures and other operational funding needs for at least the next 12 months.

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 for 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.

Contractual Obligations and Commercial Commitments

The following table summarizes our outstanding contractual obligations and commercial commitments as of December 29, 2018 and the effect those obligations are expected to have on our cash liquidity and cash flow in future periods (in thousands). The estimated payments reflected in this table are based on management’s estimates and assumptions about these obligations. As a result, the actual cash outflows in future periods will vary, possibly materially, from those reflected in this table.

	Payments Due By Period				
	Less than 1 year	Between 1-3 years	Between 3-5 years	More than 5 years	Total
Operating leases[1]	$6,926	$ 6,806	$ 3,269	$ 9,921 [3]	$26,922

Purchase commitments[2]	90,400	—	—	—	90,400
Total contractual obligations	$97,326	$ 6,806	$ 3,269	$ 9,921	$117,322

(1) Facility, equipment and automobile leases.
(2) Certain inventory items under non-cancellable purchase orders.
(3) Includes optional renewal periods for certain leases.

Other obligations: As of December 29, 2018, our estimated liabilities related to uncertain tax positions, including interest, were $11.7 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 had the following annual minimum royalty commitments to Cercacor, as of December 29, 2018 (in thousands):

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

(1) Subsequent to 2022, the royalty arrangement requires a $5.0 million minimum annual royalty payment unless the agreement is amended, restated or terminated.

See Note 3 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K for additional information related to Cercacor.

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. 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. Although we regularly evaluate these estimates and assumptions, changes in judgments and uncertainties relating to these estimates could potentially result in materially different results under different assumptions and conditions. If these estimates differ significantly from actual results, the impact to the consolidated financial statements may be material.

We believe that the critical accounting policies that are the most significant for purposes of fully understanding and evaluating our reported financial results include the following:

Revenue Recognition, Deferred Revenue and Other Contract Liabilities

Effective December 31, 2017, we adopted ASC 606. ASC 606 provides a single, principles-based five-step model to be applied to all contracts with customers and generally provides for the recognition of revenue in an amount that reflects the consideration to which we expect to be entitled when control over the promised goods or services are transferred to the customer, net of allowances for estimated returns, discounts or sales incentives, as well as taxes collected from customers that are remitted to government authorities.

We derive the majority of our product revenue from four primary sources: (i) direct sales under deferred equipment agreements with end-user hospitals where we provide up-front monitoring equipment at no up-front charge in exchange for a multi-year sensor purchase commitment, (ii) other direct sales of noninvasive monitoring solutions to end-user hospitals, emergency medical response organizations and other direct customers; (iii) sales of noninvasive monitoring solutions to distributors who then typically resell to end-user hospitals, emergency medical response organizations and other customers; and (iv) sales of integrated circuit boards to OEM customers who incorporate our embedded software technology into their multiparameter monitoring devices. Subject to customer credit considerations, the majority of such sales are made on open account using industry standard payment terms based on the geography within which the specific customer is located.

We enter into agreements to sell our monitoring solutions and services, sometimes as part of arrangements with multiple performance obligations that include various combinations of products and services. In the case of contracts with multiple performance obligations, the authoritative guidance provides that the total consideration be allocated to each performance obligation on the basis of relative standalone selling prices. When a standalone selling price is not readily observable, we estimate the standalone selling price by considering multiple factors including, but not limited to, features and functionality of the product, geographies, type of customer, contractual prices pursuant to Group Purchasing Organization (GPO) contracts, our pricing and discount practices, and other market conditions.

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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 and analysis is required to determine the appropriate accounting, including: (i) the amount of the total consideration, including variable consideration, (ii) how the arrangement consideration should be allocated to each performance obligation when multiple performance obligations exist, including the determination of standalone selling price, (iii) when to recognize revenue on the performance obligations, and (iv) whether uncompleted performance obligations are essential to the functionality of the completed performance obligations. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

Sales under deferred equipment agreements are generally structured such that we agree to provide at no up-front charge certain monitoring-related equipment, software, installation, training and/or warranty support in exchange for the hospital's agreement to purchase sensors over the term of the agreement, which generally ranges from three to six years. We generally recognize revenue for performance obligations related to licensed software parameters and monitoring equipment that is sold under deferred equipment agreements with fixed annual commitments at the time such software or monitoring equipment is provided to the customer. Revenue allocable to performance obligations related to sensor sales and monitoring-related equipment leased under deferred equipment agreements is generally recognized as the sensors are provided to the customer over the life of the contract.

Revenue from direct sales of our products to end-user hospitals, emergency medical response organizations and other direct customers, as well as to distributors, is generally recognized either at the time of delivery or at shipment, based upon the terms of the contract or underlying purchase order.

Sales of integrated circuit boards and other products to our OEMs are generally recognized as revenue at the time of shipment. Revenue related to OEM rainbow® parameter software licenses is generally recognized upon shipment of the OEM's product to its customers, as reported to us by the OEM.

We provide certain customers with various sales incentives that may take the form of discounts or rebates. We estimate and provide allowances for these programs as a reduction to revenue at the time of sale. In general, customers do not have a right of return for credit or refund. However, we allow returns under certain circumstances. At the end of each period, we estimate and accrue for these returns as a reduction to revenue. We estimate the revenue constraints related to these forms of variable consideration based on various factors, including expected purchasing volumes, prior sales and returns history, and specific contractual terms and limitations.

The majority of our royalty revenue arises from one agreement and is due and payable quarterly in arrears. An estimate of these royalty revenues is recorded quarterly in the period earned based on historical results, adjusted for any new information or trends known to management at the time of estimation. This estimated revenue is adjusted prospectively when we receive the royalty report, approximately sixty days after the end of the previous quarter. We also recognize revenue from time-to-time related to NRE services provided to a certain OEM customer. NRE revenue is generally recognized on a proportionate basis as the costs of performing such services are incurred by us.

Inventory/Reserves for Excess or Obsolete Inventory

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

We develop our inventory reserve based on an evaluation of the expected future use of our inventory on an item by item basis. We apply historical obsolescence rates to estimate the loss on inventory expected to have a recovery value below cost. Our historical obsolescence rates are developed from our company specific experience for major categories of inventory, which are then applied to excess inventory on an item by item basis. We also develop other

specific inventory reserves when we become aware of other unique events that result in a known recovery value below cost. For inventory items that have been written down, either due to the inventory reserve analysis or due to a specific event, the reduced value becomes the new cost basis. If our estimates for potential inventory losses prove to be too low, our future earnings will be affected when any related additional inventory losses are recorded.

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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. Therefore, 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.

Stock-Based Compensation

Our stock-based compensation awards are currently comprised of stock options, restricted stock units (RSUs) and performance share units (PSUs), all of which are equity-classified awards. For equity-classified awards granted on or after January 1, 2006, we estimate the fair value of the award on the date of grant and expense stock-based compensation over the requisite service period. In the case of PSUs, the amount of expense recognized is also dependent upon the expected achievement level for the specified performance criteria. The fair value of RSU and PSU awards is the closing price of our common stock on the grant date. To calculate the fair value of stock option awards, we use the Black-Scholes option pricing model, which, in addition to the closing price of our stock on the grant date and the option strike price, requires the input of subjective assumptions. These assumptions include the estimated length of time employees will retain their stock options before exercising them (the expected term), the estimated volatility of our stock price over the expected term and the dividend yield on our common stock. We estimate expected term based on both our specific historical option exercise experience, as well as expected term information available from a peer group of companies with similar vesting schedules. The estimated volatility is based on both the historical and implied volatilities of our share price.

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

Changes in the types and quantity of equity awards, as well as the fair market value of our stock may impact the cost of future stock option grants. In general, 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 stock-based compensation see Note 16 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

Intangible and Other Long-Lived Assets

Intangible assets from acquisitions or licensing agreements, as well as intangible assets related to the costs of registering and maintaining our patents and trademarks, are carried at cost less accumulated amortization and impairment charges, if any. For assets with determinable useful lives, amortization is computed using the straight-line method over the estimated economic lives of the respective intangible assets, ranging from one to seventeen years. Acquired in-process research and development (IPR&D) is recorded at fair value as an indefinite-lived intangible asset at the acquisition date until the completion or abandonment of the associated research and development efforts or impairment. IPR&D projects relate to in-process projects that have not reached technological feasibility as of the acquisition date and have no alternative future use. Upon completion of development, acquired in-process research and development assets are transferred to finite-lived intangible assets and amortized over their useful lives.

We assess whether our intangible assets and other long-lived assets should be tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. The amount of impairment, if any,

is measured based on fair value, which is determined using projected discounted future operating cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

Goodwill

Goodwill is recorded as the difference, if any, between the aggregate consideration paid for an acquisition and the fair value of the acquired net tangible and intangible assets. Goodwill is not amortized but instead is tested at least annually for impairment, or more frequently when events or changes in circumstances indicate that goodwill might be impaired. Our annual impairment test is performed during the fourth fiscal quarter.

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In assessing goodwill impairment, we have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that the fair value of such reporting unit is less than its carrying amount. Our qualitative assessment of the recoverability of goodwill considers various macro-economic, industry-specific and company-specific factors. These factors include: (i) severe adverse industry or economic trends; (ii) significant company-specific actions, including exiting an activity in conjunction with restructuring of operations; (iii) current, historical or projected deterioration of our financial performance; or (iv) a sustained decrease in our market capitalization below its net book value. If, after assessing the totality of events or circumstances, we determine it is unlikely that the fair value of such reporting unit is less than its carrying amount, then a quantitative analysis is unnecessary. However, if we conclude otherwise, or if we elect to bypass the qualitative analysis, then we are required to perform a quantitative analysis that compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is not considered impaired; otherwise, a goodwill impairment loss is recognized for the lesser of: (a) the amount that the carrying amount of a reporting unit exceeds its fair value; or (b) the amount of the goodwill allocated to that reporting unit.

Accounting for Income Taxes

We account for income taxes using the asset and liability method, under which we recognize deferred tax assets and liabilities for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and for net operating loss and tax credit carryforwards. A tax position that meets a more-likely-than-not recognition threshold is recognized in the first reporting period that it becomes more-likely-than-not such tax position will be sustained upon examination. A tax position that meets this more-likely-than-not recognition threshold is recorded at the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. Previously recognized income tax positions that fail to meet the recognition threshold in a subsequent period are derecognized in that period. Differences between actual results and our assumptions, or changes in our assumptions in future periods, are recorded in the period they become known. We record potential accrued interest and penalties related to unrecognized tax benefits in income tax expense.

As a multinational corporation, we are subject to complex tax laws and regulations in various jurisdictions. The application of tax laws and regulations is subject to legal and factual interpretation, judgment and uncertainty. Tax laws themselves are subject to change as a result of changes in fiscal policy, changes in legislation, evolution of regulations and court rulings. We have concluded all U.S. federal income tax matters for years through 2014 and all material state, local and foreign income tax matters for years through 2011. Given the foregoing, our actual liability for U.S. or foreign taxes may be materially different from our estimates, which could result in the need to record additional liabilities or potentially to reverse previously recorded tax liabilities.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. A valuation allowance is recorded against any deferred tax assets when, in the judgment of management, it is more likely than not that all or part of a deferred tax asset will not be realized. In assessing the need for a valuation allowance, we consider all positive and negative evidence, including recent financial performance, scheduled reversals of temporary differences, projected future taxable income, availability of taxable income in carryback periods and tax planning strategies.

Litigation Costs and Contingencies

We record a charge equal to at least the minimum estimated liability for a loss contingency or litigation settlement when both of the following conditions are met: (i) information available prior to issuance of the financial statements indicates that it is probable that a liability had been incurred at the date of the financial statements and (ii) the range of loss can be reasonably estimated. The determination of whether a loss contingency or litigation settlement is probable or reasonably possible involves a significant amount of management judgment, as does the estimation of the range of loss given the nature of contingencies. Liabilities related to litigation settlements with multiple elements are recorded based on the fair value of each element. Legal and other litigation related expenses are recognized as the services are

provided. We record insurance and other indemnity recoveries for litigation expenses when both of the following conditions are met: (i) the recovery is probable and (ii) collectability is reasonably assured. The insurance recoveries recorded are only to the extent the litigation costs have been incurred and recognized in the financial statements; however, it is reasonably possible that the actual recovery may be significantly different from our estimates. There are many uncertainties associated with any litigation, and we cannot provide assurance that any actions or other third party claims against us will be resolved without costly litigation or substantial settlement charges. If any of those events were to occur, our business, financial condition and results of operations could be materially and adversely affected.

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Recent Accounting Pronouncements

For details regarding any recently adopted and recently issued accounting standards, see Note 2 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

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 cash and cash equivalents and on the increase or decrease in the amount of interest expense we must pay with respect to our various outstanding debt instruments. We do not believe our cash equivalents are subject to significant interest rate risk due to their short terms to maturity. As of December 29, 2018, the carrying value of our cash equivalents approximated fair value. We currently do not have any significant risks associated with interest rates fluctuations related to interest expense. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. Therefore, declines in interest rates over time will reduce our interest income while increases in interest rates will increase our interest income. A hypothetical 100 basis point change in interest rates along the entire interest rate yield curve would increase or decrease our interest rate yields on our investments and interest income approximately $0.1 million for each $10.0 million in interest-bearing investments.

Foreign Currency Exchange Rate Risk

A majority of our assets and liabilities are maintained in the United States in U.S. Dollars and a majority of our sales and expenditures are transacted in U.S. Dollars. However, we transact with foreign customers in currencies other than the U.S. Dollar. These foreign currency revenues, when converted into U.S. Dollars, can vary depending on average exchange rates during a respective period. In addition, 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 also vary depending on average monthly exchange rates during a respective period.

We are exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables and payables, as well as our foreign currency denominated cash balances and certain intercompany transactions. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of operations as incurred. Furthermore, other transactions between us or our 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 on these transactions are also included in our statements of operations 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 operations 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).

Our primary foreign currency exchange rate exposures are with the Canadian dollar, Euro, Japanese Yen, Swedish Krona, the British Pound, Mexico Peso and Australian Dollar. Foreign currency exchange rates may experience significant volatility from one period to the next. Specifically, during the fiscal year ended December 29, 2018, we estimate that fluctuations in the exchange rates between the U.S. Dollar and other foreign currencies, including the Japanese Yen, the Swedish Krona, and the Australian Dollar, adversely impacted our revenues by $4.0 million. 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 additional changes 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). We estimate that the potential impact of a hypothetical 10% adverse change in all applicable foreign currency exchange rates from the rates in effect as of December 29, 2018 would have resulted in an estimated reduction of $21.6 million in reported pre-tax income for the year ended December 29, 2018. As our foreign operations continue to grow, our exposure to foreign currency exchange rate risk may become more significant.

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Inflation Risk

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Part IV, Item 15(a)(1) and 15(a)(2), respectively, of this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. We recognize that any controls and procedures, no matter how well designed 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 and may not prevent or detect all misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

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 criteria established in the 2013 Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 29, 2018.

Grant Thornton LLP, an independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of December 29, 2018. Their attestation report, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 29, 2018, is included in Part IV, Item 15(a)(1) of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes to our internal controls over financial reporting during the quarter ended December 29, 2018 that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting. We expect that our existing internal controls will continue to be modified and augmented, as necessary, to consider the new lease accounting standard and related disclosure requirements related to our adoption of ASC Topic 842, Leases, effective as of December 30, 2018, but we do not expect that such changes will materially affect our existing internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the information contained in our Definitive Proxy Statement to be filed with the SEC in connection with the Annual Meeting of Stockholders to be held in 2019 (2019 Proxy Statement) under the headings “Executive Officers”, “Board of Directors”, “Corporate Governance and Board Matters” and “Section 16(a) Beneficial Ownership Reporting Compliance”.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2019 Proxy Statement under the heading “Executive Compensation”.

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 contained in the 2019 Proxy Statement under the heading “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 contained in the 2019 Proxy Statement under the headings “Corporate Governance and Board Matters” and “Transactions with Related Persons, Promoters and Certain Control Persons”.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2019 Proxy Statement under the heading “Audit Related Matters-Principal Accountant Fees and Services”.

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PART IV

ITEM 15. EXHIBITS, 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 Annual Report on Form 10-K beginning on page F-1.

(a)(2) Financial Statement Schedules

The financial statement schedule is included in a separate section of this Annual Report on Form 10-K beginning on page F-1.

(a)(3) Exhibits

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation (Exhibit 3.2)
3.2(2)	Amended and Restated Bylaws (Exhibit 3.2)
4.1(1)	Form of Common Stock Certificate (Exhibit 4.1)
4.2(1)	Fifth Amended and Restated Registration Rights Agreement made and entered into as of September 14, 1999 between the Registrant and certain of its stockholders (Exhibit 4.2)
4.3(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(5)#	Amended and Restated Employment Agreement, dated November 4, 2015, between Joe Kiani and the Registrant (Exhibit 10.1)
10.3(17)	First Amendment to November 4, 2015 Amended and Restated Employment Agreement, dated July 27, 2017, by and between Masimo Corporation and Joe Kiani (Exhibit 10.1)
10.4(1)#	Offer Letter, dated February 15, 1996, between Yongsam Lee and the Registrant (Exhibit 10.7)
10.5(1)#	Offer Letter, dated March 30, 2007, between Anand Sampath and the Registrant (Exhibit 10.8)
10.6(6)#	Offer Letter, dated July 23, 2008, between Jon Coleman and the Registrant (Exhibit 10.9)
10.7#*	Offer Letter, dated March 31, 2011 between Tom McClenahan and the Registrant
10.8(18)#	Offer Letter, dated September 22, 2017, between the Company and Micah Young (Exhibit 10.1)
10.9(5)#	Restricted Share Unit Award Agreement, dated November 4, 2015, by and between Joe Kiani and the Registrant (Exhibit 10.2)
10.10(5)#	Equity-Holder Non-Competition and Confidentiality Agreement, dated November 4, 2015, by and between Joe Kiani and the Registrant (Exhibit 10.3)

10.11(7)#	Amended and Restated 2007 Severance Protection Plan and Summary Plan Description, effective December 31, 2008 (Exhibit 10.11)
10.12(12)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Yongsam Lee (Exhibit 10.3)
10.13#*	Amended and Restated 2007 Severance Protection Plan Agreement, dated November 12, 2013, by and between the Registrant and Jon Coleman (Exhibit 10.17)
10.14#*	Amended and Restated 2007 Severance Protection Plan Agreement, dated December 9, 2013, by and between the Registrant and Anand Sampath
10.15(3)#	Amended and Restated 2007 Severance Protection Plan Agreement, dated November 3, 2014, by and between the Registrant and Tom McClenahan (Exhibit 10.21)
10.16(21)#*	Amended and Restated 2007 Severance Protection Plan, Limited Participation Agreement, dated December 12, 2017, by and between the Registrant and Micah Young (Exhibit 10.16)

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Exhibit Number	Description of Document
10.17(1)#	2007 Stock Incentive Plan of the Registrant, and forms of agreements related thereto (Exhibit 10.33)
10.18(19)#	Masimo Corporation 2017 Equity Incentive Plan
10.19(20)#	Masimo Corporation Executive Bonus Incentive Plan
10.20(6)+	Manufacturing and Purchase Agreement, dated October 2, 2008, by and between Analog Devices, Inc.and the Registrant (Exhibit 10.21)
10.21(1)+	Purchase Agreement, dated July 26, 2001, between Jabil Circuit, Inc. and the Registrant (Exhibit 10.15)
10.22(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)
10.23(8)+	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)
10.24(10)+	First Amendment, Lease Agreement effective as of December 17, 2013, 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 10.26)
10.25(1)	Settlement Agreement and Release of Claims, dated January 17, 2006, between Cercacor Laboratories, Inc., Nellcor Puritan Bennett, Inc., Mallinckrodt, Inc., Tyco Healthcare Group LP, Tyco International Ltd., Tyco International (US) Inc. and the Registrant (Exhibit 10.30)
10.26(9)	Second Amendment to the January 17, 2006 Settlement Agreement and Release of Claims, as amended pursuant to the January 24, 2006 Amendment to Settlement Agreement and Release of Claims, dated January 28, 2011, by and among Masimo Corporation, Masimo Laboratories, Inc., Nellcor Puritan Bennett LLC, Mallinckrodt Inc., Tyco Healthcare Group LP and Covidien Inc. (Exhibit 10.1)
10.27(1)	Amended and Restated Cross-Licensing Agreement, effective January 1, 2007, between Cercacor Laboratories, Inc. and the Registrant (Exhibit 10.34)
10.28(1)	Services Agreement, effective January 1, 2007, between Cercacor Laboratories, Inc. and the Registrant (Exhibit 10.35)
10.29(11)	Agreement of Purchase and Sale and Escrow Instructions, dated as of November 1, 2013, by and between the Company and Nikken, Inc. (Exhibit 10.1)
10.30(11)	First Amendment to Purchase and Sale Agreement, made and entered into effective as of January 8, 2014, by and between the Company and Nikken, Inc. (Exhibit 10.2)
10.31(11)	Second Amendment to Purchase and Sale Agreement, made and entered into effective as of January 10, 2014, by and between the Company and Nikken, Inc. (Exhibit 10.3)

10.32(11)	Third Amendment to Purchase and Sale Agreement, made and entered into effective as of March 10, 2014, by and between the Company and Nikken, Inc. (Exhibit 10.4)
10.33(11)	Fourth Amendment to Purchase and Sale Agreement, made and entered into effective as of March 12, 2014, by and between the Company and Nikken, Inc. (Exhibit 10.5)
10.34(13)+	Settlement and Covenant Not to Sue Agreement, entered into as of the Effective Date of November 16, 2015, between Masimo Corporation, Masimo Technologies SARL, and Masimo International SARL and Mindray Medical International, Limited, Shenzhen Mindray Biomedical Electronics Co., Ltd and Mindray DS USA, Inc. (Exhibit 10.44)
10.35(13)	Lease Agreement, dated July 15, 2012, related to the premises at 9600 Jeronimo, between the Registrant and The Irvine Company, LLC (Exhibit 10.45)
10.36(13)	First Amendment to June 22, 2012 Lease Agreement, relating to the premises at 9600 Jeronimo, between the Registrant and Irvine Company, LLC (Exhibit 10.46)
10.37(3)	Second Amendment to June 22, 2012 Lease Agreement, relating to the premises at 9600 Jeronimo, between the Registrant and Irvine Company, LLC (Exhibit 10.34)

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Exhibit Number	Description of Document
10.38(13)	Third Amendment to June 22, 2012 Lease Agreement, relating to the premises at 9600 Jeronimo, between the Registrant and Irvine Company, LLC (Exhibit 10.48)
10.39(14)	Single-Tenant Lease, relating to the premises at 9600 Jeronimo, dated as of July 13, 2016, by and between Masimo Corporation and The Irvine Company LLC (Exhibit 10.1)
10.40(15)	Third Amendment to Settlement Agreement and Release of Claims, dated as of September 1, 2016, by and among Masimo Corporation and Cercacor Laboratories, Inc., and Medtronic Plc., Covidien LP, Nellcor Puritan Bennett LLC and Covidien Holdings Inc. (Exhibit 10.1)
10.41(16)+	Settlement Agreement, dated November 5, 2016, by and between Masimo Corporation, Masimo International Technologies SARL and Masimo International SARL and Koninklijke Philips N.V. (Exhibit 10.1)
10.42*	Credit Agreement dated as of December 17, 2018, among Masimo Corporation, the Lenders party thereto and JPMorgan Chase Bank, N.A. as Administrative Agent
10.43(22)#	Offer Letter, dated April 17, 2002, between the Company and Bilal Muhsin (Exhibit 10.1)
10.44(22)#	Offer Letter, dated December 15, 2017, between the Company and Tao Levy (Exhibit 10.2)
10.45(22)#	2007 Severance Protection Plan Participation Agreement, dated March 26, 2018, by and between the Company and Bilal Muhsin (Exhibit 10.3)
10.46(22)#	2007 Severance Protection Plan Participation Agreement, dated March 16, 2018, by and between the Company and Tao Levy (Exhibit 10.4)
21.1*	List of Registrant's Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Joe Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Micah Young, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Joe Kiani, Chief Executive Officer, and Micah Young, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* XBRL Taxonomy Extension Label Linkbase Document

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

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Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 29, 2018 and December 30, 2017, (ii) Consolidated Statements of Operations for the years ended December 29, 2018, December 30, 2017 and December 31, 2016, (iii) Consolidated Statements of Comprehensive Income for the years ended December 29, 2018, December 30, 2017 and December 31, 2016, (iv) Consolidated Statements of Equity for the years ended December 29, 2018, December 30, 2017 and December 31, 2016, (v) Consolidated Statements of Cash Flows for the years ended December 29, 2018, December 30, 2017 and December 31, 2016, and (vi) Notes to Consolidated Financial Statements.

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(1) Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (No. 333-142171), originally filed on April 17, 2007. The number given in parentheses indicates the corresponding exhibit number in such Form S-1, as amended.

(2) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K, filed on October 26, 2011. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

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(3) Incorporated by reference to the exhibit to the Registrant's Annual Report on Form 10-K, filed on February 17, 2015. The number given in parentheses indicates the corresponding exhibit number in such Form 10-K.

(4) Incorporated by reference to the exhibit to the Registrant's Registration Statement on Form S-8, filed on February 11, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form S-8.

(5) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K, filed on November 5, 2015 at 4:45 p.m. Eastern Time. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(6) Incorporated by reference to the exhibit to the Registrant's Annual Report on Form 10-K, filed on March 4, 2009. The number given in parentheses indicates the corresponding exhibit number in such Form 10-K.

(7) Incorporated by reference to the exhibit to the Registrant's Annual Report on Form 10-K, filed on February 15, 2013. The number given in parentheses indicates the corresponding exhibit number in such Form 10-K.

(8) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K, filed on June 5, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(9) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K, filed on January 31, 2011. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(10) Incorporated by reference to the exhibit to the Registrant's Annual Report on Form 10-K filed February 14, 2014. The number given in parentheses indicates the corresponding exhibit number in such Form 10-K.

(11) Incorporated by reference to the exhibit to the Registrant's Quarterly Report on Form 10-Q, filed on May 1, 2014. The number given in parentheses indicates the corresponding exhibit number in such Form 10-Q.

(12) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K, filed on January 17, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(13) Incorporated by reference to the exhibit to the Registrant's Annual Report on Form 10-K, filed on February 24, 2016. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(14) Incorporated by reference to the exhibit to the Registrant's Quarterly Report on Form 10-Q, filed on August 3, 2016. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(15) Incorporated by reference to the exhibit to the Registrant's Quarterly Report on Form 8-K, filed on September 2, 2016. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(16) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K, filed on November 7, 2016. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(17) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K filed on August 2, 2017. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(18) Incorporated by reference to the exhibit to the Registrant's Current Report on Form 8-K filed on September 25, 2017. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(19) Incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement on Schedule 14A (File No. 001-33642) filed on April 12, 2017.

(20) Incorporated by reference to Appendix C to the Registrant's Definitive Proxy Statement on Schedule 14A (File No. 001-33642) filed on April 12, 2017.

(21) Incorporated by reference to the exhibit to the Registrant's Annual Report on Form 10-K filed February 28, 2018. The number given in parentheses indicates the corresponding exhibit number in such Form 10-K.

(22) Incorporated by reference to the exhibit to the Registrant's Quarterly Report on Form 10-Q filed May 7, 2018. The number given in parentheses indicates the corresponding exhibit number in such Form 10-Q.

* Filed herewith.

# Indicates management contract or compensatory plan.

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

(b) Exhibits

See Item 15(a)(3) above.

(c) Financial Statement Schedules
See Item 15(a)(2) above.

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ITEM 16. FORM 10-K SUMMARY

None.

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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 26, 2019 By: /s/ JOE KIANI
Joe Kiani
Chairman of the Board & Chief Executive Officer

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

SIGNATURE	TITLE(S)	DATE
/s/ JOE KIANI Joe Kiani	Chairman of the Board & Chief Executive Officer (Principal Executive Officer)	February 26, 2019
/s/ MICAH YOUNG Micah Young	Executive Vice President, Finance & Chief Financial Officer (Principal Financial Officer)	February 26, 2019
/s/ DAVID J. VAN RAMSHORST David J. Van Ramshorst	Senior Vice President, Chief Accounting Officer (Principal Accounting Officer)	February 26, 2019
/s/ STEVEN J. BARKER, M.D. PH.D. Steven J. Barker, M.D., Ph.D.	Director	February 26, 2019
/s/ H MICHAEL COHEN H Michael Cohen	Director	February 26, 2019
/s/ SANFORD FITCH Sanford Fitch	Director	February 26, 2019
/s/ THOMAS HARKIN Thomas Harkin	Director	February 26, 2019
/s/ ADAM MIKKELSON Adam Mikkelson	Director	February 26, 2019
/s/ CRAIG REYNOLDS Craig Reynolds	Director	February 26, 2019

/s/ JULIE A. SHIMER, PH.D Julie A. Shimer, Ph.D.	Director	February 26, 2019

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MASIMO CORPORATION

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Masimo Corporation
Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of Masimo Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 29, 2018 and December 30, 2017, the related consolidated statements of operations, comprehensive income, equity, and cash flows for each of the three years in the period ended December 29, 2018, and the related notes and financial statement schedule included under Item 15(a)(2) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 29, 2018 and December 30, 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 29, 2018, 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) ("PCAOB"), the Company's internal control over financial reporting as of December 29, 2018, based on criteria established in the 2013 Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 26, 2019 expressed an unqualified opinion.
Change of accounting principle
As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for revenue from contracts with customers in fiscal year 2018 due to the adoption of the new revenue standard. The Company adopted the new revenue standard using the full retrospective approach.
Basis for opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP
We have served as the Company's auditor since 2006.
Newport Beach, California
February 26, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Masimo Corporation

Opinion on internal controls over financial reporting
We have audited the internal control over financial reporting of Masimo Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 29, 2018, based on criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 29, 2018, based on criteria established in the 2013 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) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 29, 2018, and our report dated February 26, 2019 expressed an unqualified opinion on those financial statements.
Basis for opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audit in accordance with the standards of the PCAOB. 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.
Definition and limitations of internal control over financial reporting
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.

/s/ GRANT THORNTON LLP
Newport Beach, California

February 26, 2019

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MASIMO CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value)

	December 29, 2018	December 30, 2017 As Adjusted
ASSETS		
Current assets		
Cash and cash equivalents	$ 552,490	$ 315,302
Trade accounts receivable, net of allowance for doubtful accounts of $1,535 and $2,116 at December 29, 2018 and December 30, 2017, respectively	109,629	118,532
Inventories	93,751	92,259
Other current assets	29,227	33,602
Total current assets	785,097	559,695
Deferred costs and other contract assets	127,086	109,256
Property and equipment, net	165,972	164,096
Intangible assets, net	27,924	27,123
Goodwill	23,297	20,617
Deferred tax assets	21,210	19,981
Other assets	4,232	4,668
Total assets	$ 1,154,818	$ 905,436
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 40,388	$ 33,780
Accrued compensation	49,486	39,515
Deferred revenue and other contract liabilities, current	33,106	32,105
Other current liabilities	24,627	24,254
Total current liabilities	147,607	129,654
Other liabilities	38,146	51,757
Total liabilities	185,753	181,411
Commitments and contingencies (Note 19)		
Stockholders' Equity		
Preferred stock, $0.001 par value; 5,000 shares authorized at December 29, 2018 and December 30, 2017; 0 shares issued and outstanding at December 29, 2018 and December 30, 2017	—	—
Common stock, $0.001 par value, 100,000 shares authorized at December 29, 2018 and December 30, 2017; 53,085 and 51,636 shares issued and outstanding at December 29, 2018 and December 30, 2017, respectively	53	52
Treasury stock, 15,255 and 15,059 shares at December 29, 2018 and December 30, 2017, respectively	(489,026)	(472,536)
Additional paid-in capital	533,164	461,494
Accumulated other comprehensive loss	(6,199)	(2,941)
Retained earnings	931,073	737,956
Total stockholders' equity	969,065	724,025
Total liabilities and stockholders' equity	$ 1,154,818	$ 905,436

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

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MASIMO CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share information)

	Year ended December 29, 2018	Year ended December 30, 2017 As Adjusted	Year ended December 31, 2016 As Adjusted
Revenue:			
Product	$829,874	$738,242	$673,962
Royalty and other revenue	28,415	52,006	38,936
Total revenue	858,289	790,248	712,898
Cost of goods sold	283,397	268,216	234,560
Gross profit	574,892	522,032	478,338
Operating expenses:			
Selling, general and administrative	289,456	276,292	254,707
Research and development	76,967	61,953	57,686
Litigation settlement, award and/or defense costs	425	—	(270,000)
Total operating expenses	366,848	338,245	42,393
Operating income	208,044	183,787	435,945
Non-operating (income) expense	(5,732)	(2,013)	2,429
Income before provision for income taxes	213,776	185,800	433,516
Provision for income taxes	20,233	61,011	122,419
Net income	$193,543	$124,789	$311,097
Net income per share:			
Basic	$3.70	$2.42	$6.28
Diluted	$3.45	$2.23	$5.85
Weighted-average shares used in per share calculations:			
Basic	52,296	51,516	49,530
Diluted	56,039	55,874	53,195

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

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MASIMO CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year ended December 29, 2018	Year ended December 30, 2017 As Adjusted	Year ended December 31, 2016 As Adjusted
Net income	$193,543	$124,789	$311,097
Other comprehensive gain (loss), net of tax:			
Foreign currency translation gains (losses)	(3,258)	4,201	(2,288)
Unrealized loss on marketable securities	—	(115)	—
Total comprehensive income	$190,285	$128,875	$308,809

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

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MASIMO CORPORATION
CONSOLIDATED STATEMENTS OF EQUITY
(in thousands)

	Masimo Corporation Stockholders								
	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Noncontrolling Interest	Total Equity
	Shares	Amount	Shares	Amount					
Balance at January 2, 2016	49,881	$ 50	12,759	$(340,873)	$332,417	$ (4,739)	$288,560	$ 297	$275,712
Adoption of ASU 2014-09	—	—	—	—	—	—	13,510	—	13,510
Balance at January 2, 2016, as adjusted	49,881	50	12,759	(340,873)	332,417	(4,739)	302,070	297	289,222
Stock options exercised	1,799	—	—	—	37,342	—	—	—	37,342
Restricted/Performance stock units vested	4	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	12,503	—	—	—	12,503
Repurchases of common stock	(1,496)	—	1,496	(63,403)	1	—	—	—	(63,402)
Gain on deconsolidation of variable interest entity	—	—	—	—	—	—	—	(297)	(297)
Net income, as adjusted	—	—	—	—	—	—	311,097	—	311,097
Foreign currency translation adjustment	—	—	—	—	—	(2,288)	—	—	(2,288)
Balance at December 31, 2016, as adjusted	50,188	50	14,255	(404,276)	382,263	(7,027)	613,167	—	584,177
Stock options exercised	2,246	2	—	—	62,044	—	—	—	62,046
Restricted/Performance stock units vested	6	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	17,187	—	—	—	17,187
Repurchases of common stock	(804)	—	804	(68,260)	—	—	—	—	(68,260)
Net income, as adjusted	—	—	—	—	—	—	124,789	—	124,789
Foreign currency translation adjustment	—	—	—	—	—	4,201	—	—	4,201
Unrealized loss on marketable securities	—	—	—	—	—	(115)	—	—	(115)
Balance at December 30, 2017, as adjusted	51,636	52	15,059	(472,536)	461,494	(2,941)	737,956	—	724,025
Stock options exercised	1,608	1	—	—	44,421	—	—	—	44,422
Restricted/Performance stock units vested	39	—	—	—	—	—	—	—	—
Shares paid for tax withholding	(2)	—	—	—	(168)	—	—	—	(168)
	—	—	—	—	27,417	—	—	—	27,417

Stock-based compensation									
Repurchases of common stock	(196)	—	196	(16,490)	—	—	—	—	(16,490)
Net income	—	—	—	—	—	—	193,543	—	193,543
Adoption of ASU 2016-16	—	—	—	—	—	—	(426)	—	(426)
Foreign currency translation adjustment	—	—	—	—	—	(3,258)	—	—	(3,258)
Balance at December 29, 2018	53,085	$ 53	15,255	$(489,026)	$533,164	$ (6,199)	$931,073	$ —	$969,065

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 December 29, 2018	Year ended December 30, 2017 As Adjusted	Year ended December 31, 2016 As Adjusted
Cash flows from operating activities:			
Net income	$193,543	$124,789	$311,097
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	21,127	20,061	16,817
Stock-based compensation	27,417	17,187	12,503
Loss on disposal of equipment, intangibles and other assets	949	522	658
Provision for doubtful accounts	(439)	251	259
Provision for amount due from former foreign agent	(2,016)	10,477	—
Gain on deconsolidation of variable interest entity	—	—	(273)
(Benefit) provision from deferred income taxes	(8,274)	17,276	10,149
Changes in operating assets and liabilities:			
Decrease (increase) in trade accounts receivable	10,826	(19,772)	(21,244)
Increase in inventories	(1,885)	(24,014)	(8,955)
Decrease (increase) in other current assets	3,843	(2,908)	(4,816)
Increase in deferred cost of goods sold	(17,935)	(14,102)	(7,661)
(Increase) decrease in prepaid income taxes	—	(2,498)	1,355
Decrease (increase) in other assets	407	(10,771)	455
Increase (decrease) in accounts payable	5,211	(4,057)	11,048
Increase (decrease) in accrued compensation	10,195	(4,292)	5,675
Increase (decrease) in deferred revenue and other contract liabilities	1,420	(13,295)	27,945
(Decrease) increase in income taxes payable	(1,208)	(72,087)	73,755
Increase (decrease) in other current liabilities	3,923	5,282	(16,207)
(Decrease) increase in other liabilities	(7,577)	28,013	6,565
Net cash provided by operating activities	239,527	56,062	419,125
Cash flows from investing activities:			
Purchases of property and equipment	(17,126)	(43,684)	(19,707)
Increase in intangible assets	(5,557)	(3,079)	(4,644)
Business combination, net of cash acquired	(3,922)	—	—
Acquisitions of equity investments	—	(1,145)	(200)
Other	453	—	(763)
Net cash used in investing activities	(26,152)	(47,908)	(25,314)
Cash flows from financing activities:			
Borrowings under revolving line of credit	—	—	45,000
Repayments under revolving line of credit	—	—	(230,000)
Proceeds from issuance of common stock	44,748	62,205	37,290
Repurchases of common stock	(18,478)	(66,272)	(68,218)
Other	(490)	(71)	(696)
Net cash provided by (used in) financing activities	25,780	(4,138)	(216,624)

Effect of foreign currency exchange rates on cash	(1,997)	3,269	(1,451)
Net increase in cash, cash equivalents and restricted cash	237,158	7,285	175,736
Cash, cash equivalents and restricted cash at beginning of period	315,483	308,198	132,462
Cash, cash equivalents and restricted cash at end of period	$552,641	$315,483	$308,198

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 (the Company), is a global medical technology company that develops, manufactures and markets a variety of noninvasive patient monitoring technologies. The Company's mission is to improve patient outcomes and reduce the cost of care. The Company's patient monitoring solutions generally incorporate a monitor or circuit board, proprietary single-patient use or reusable sensors, software and/or cables. The Company primarily sells its products to hospitals, emergency medical service providers, home care providers, physician offices, veterinarians, long term care facilities and consumers through its direct sales force, distributors and original equipment manufacturer (OEM) partners.

The Company invented Masimo Signal Extraction Technology® (SET®), which provides the capabilities of Measure-through Motion and Low Perfusion® pulse oximetry to address the primary limitations of conventional pulse oximetry. Over the years, the Company's product offerings have expanded significantly to also include rainbow® Pulse CO-Oximetry, with its ability to measure and monitor carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), total hemoglobin concentration (SpHb®), fractional arterial oxygen saturation ($SpfO_2$)™, Oxygen Content (SpOC)™, Pleth Variability Index (PVi®), rainbow® Pleth Variability Index (RPVi)™, respiration rate from the pleth (RRp® and Oxygen Reserve Index (ORi)™, as well as acoustic respiration monitoring (RRa®), SedLine® brain function monitoring, NomoLine® capnography and gas monitoring and O3® regional oximetry. The Company's current technology offerings also include Masimo Patient SafetyNet[1], Masimo Patient SafetyNet Surveillance[1], MyView®, Replica™ and Trace™. These solutions and related products are based upon Masimo SET®, rainbow® and other proprietary algorithms. These software-based technologies are incorporated into a variety of product platforms depending on customers' specifications. This technology is supported by a substantial intellectual property portfolio that the Company has built through internal development and, to a lesser extent, acquisitions and license agreements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP), and include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

As further discussed below in this Note 2 to these consolidated financial statements, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) No. 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09) and ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other than Inventory (ASU 2016-16) effective December 31, 2017. All prior period amounts and disclosures set forth in this Annual Report on Form 10-K have been updated to comply with the applicable method of adoption, as indicated by the "as adjusted" notation.

Fiscal Periods

The Company follows a conventional 52/53 week fiscal year. Under a conventional 52/53 week fiscal year, a 52 week fiscal year includes four quarters of 13 fiscal weeks while a 53 week fiscal year includes three 13 fiscal week quarters and one 14 fiscal week quarter. The Company's last 53 week fiscal year was fiscal year 2014. Fiscal year 2018 is a 52 week fiscal year. All references to years in these notes to consolidated financial statements are fiscal years unless otherwise noted.

Use of Estimates

The Company prepares its financial statements in conformity with GAAP, which requires the Company 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 the determination of accounts receivable allowances, inventory reserves, warranty reserves, rebate accruals, valuation of the Company's equity awards, goodwill valuation, deferred taxes and any associated valuation allowances, royalty revenues, deferred revenue, deferred costs, uncertain income tax positions, and litigation costs and related accruals. In addition, for the year ended December 30, 2017, certain

estimates were made in calculating the provision for income taxes related to the impact of the Tax Cuts and Jobs Act of 2017 (2017 Tax Act). Actual results could differ from such estimates.

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[1] The use of the trademark Patient SafetyNet is under license from the University HealthSystem Consortium.

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Reclassifications

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

Fair Value Measurements

Authoritative 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.

Pursuant to current authoritative guidance, entities are allowed an irrevocable option to elect the fair value for the initial and subsequent measurement for specified financial assets and liabilities on a contract-by-contract basis. The Company did not elect to apply the fair value option under this guidance to specific assets or liabilities on a contract-by contract basis. There were no transfers between Level 1, Level 2 and Level 3 inputs during the years ended December 29, 2018 or December 30, 2017. The Company carries cash and cash equivalents at cost which approximates fair value. As of December 29, 2018 and December 30, 2017, the Company had an insignificant amount of other financial assets that were required to be measured under the fair value hierarchy, the measurement of which were based on Level 1 and Level 2 inputs.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity from date of purchase of three months or less, or highly liquid investments that are readily convertible into known amounts of cash, to be cash equivalents.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of trade receivables recorded upon recognition of 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 an evaluation of the customer’s financial condition. Collateral is generally 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.

Inventories

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

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Property and Equipment

Property and equipment are stated at cost. Depreciation is calculated using the straight-line method over estimated useful lives as follows:

	Useful Lives
Aircraft and components	10 to 20 years
Buildings	39 years
Building improvements	7 to 15 years
Computer equipment	2 to 6 years
Demonstration units	3 years
Furniture and office equipment	2 to 6 years
Leasehold improvements	Lesser of useful life or term of lease
Machinery and equipment	5 to 10 years
Tooling	3 years
Vehicles	5 years

Land is not depreciated and construction in progress is not depreciated until placed in service. 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 December 29, 2018, December 30, 2017 and December 31, 2016, depreciation and amortization expense of property and equipment was $16.3 million, $15.2 million and $13.0 million, respectively.

Intangible Assets

Intangible assets consist primarily of patents, trademarks, software development costs, customer relationships and acquired technology. 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 are amortized over 17 years, and their associated amortization cost is included in selling, general and administrative expense in the accompanying consolidated statements of operations. For intangibles purchased in an asset acquisition or business combination, which mainly include patents, trademarks, customer relationships and acquired technology, the useful life is determined in the same manner as noted above.

The Company’s policy is to renew its patents and trademarks. Costs to renew intangibles are capitalized and amortized over the remaining useful life of the intangible. The Company 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.

For the years ended December 29, 2018, December 30, 2017 and December 31, 2016, amortization of intangible assets was $4.8 million, $4.9 million and $3.8 million, respectively. As of December 29, 2018 and December 30, 2017, the total costs of patents not yet amortizing was $5.3 million and $4.3 million, respectively. As of December 29, 2018 and December 30, 2017, the total costs of trademarks not yet amortizing was $0.5 million and $0.6 million, respectively. For the years ended December 29, 2018 and December 30, 2017, total renewal costs capitalized for patents and trademarks was $0.5 million and $0.6 million, respectively. As of December 29, 2018, the weighted-average number of years until the next renewal was one year for patents and five years for trademarks.

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 December 29, 2018 and December 30, 2017, the Company capitalized $0.7 million and $0.2 million of software development costs, respectively. For the year ended December 31, 2016, the Company did not capitalize any software development costs.

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The capitalized costs are amortized over the estimated life of the products, which is generally seven years. For the years ended December 29, 2018, December 30, 2017 and December 31, 2016, the Company amortized $2.0 million, $1.9 million and $1.8 million of capitalized costs, respectively. The Company had unamortized software development costs of $1.4 million and $0.8 million at December 29, 2018 and December 30, 2017, respectively, which is included within intangible assets, net, on the consolidated balance sheets.

Impairment of Goodwill, Intangible Assets and Other Long-Lived Assets

Goodwill is recorded as the difference, if any, between the aggregate consideration paid for an acquisition and the fair value of the acquired net tangible and intangible assets. Goodwill is not amortized, but instead is tested annually for impairment, or more frequently when events or changes in circumstances indicate that goodwill might be impaired. In assessing goodwill impairment for each of its reporting units, the Company has the option to first assess the qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. The Company's qualitative assessment of the recoverability of goodwill considers various macroeconomic, industry-specific and Company-specific factors, including: (i) severe adverse industry or economic trends; (ii) significant Company-specific actions; (iii) current, historical or projected deterioration of the Company's financial performance; or (iv) a sustained decrease in the Company's market capitalization below its net book value. If, after assessing the totality of events or circumstances, the Company determines it is unlikely that the fair value of a reporting unit is less than its carrying amount, then a quantitative analysis is unnecessary. However, if the Company concludes otherwise, or if the Company elects to bypass the qualitative analysis, then the Company must perform a quantitative analysis that compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is not considered impaired; otherwise, a goodwill impairment loss is recognized for the lesser of: (a) the amount that the carrying amount of a reporting unit exceeds its fair value; or (b) the amount of the goodwill allocated to that reporting unit. The annual impairment test is performed during the fourth fiscal quarter.

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 flows 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.

Income Taxes

The Company accounts for income taxes using the asset and liability method, under which the Company recognizes deferred tax assets and liabilities for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and for net operating loss and tax credit carryforwards. Tax positions that meet a more-likely-than-not recognition threshold are recognized in the first reporting period that it becomes more-likely-than-not such tax position will be sustained upon examination. A tax position that meets this more-likely-than-not recognition threshold is recorded at the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. Previously recognized income tax positions that fail to meet the recognition threshold in a subsequent period are derecognized in that period. Differences between actual results and the Company's assumptions, or changes in the Company's assumptions in future periods, are recorded in the period they become known. The Company records potential accrued interest and penalties related to unrecognized tax benefits in income tax expense.

As a multinational corporation, the Company is subject to complex tax laws and regulations in various jurisdictions. The application of tax laws and regulations is subject to legal and factual interpretation, judgment and uncertainty. Tax laws themselves are subject to change as a result of changes in fiscal policy, changes in legislation, evolution of regulations and court rulings. Therefore, the actual liability for U.S. or foreign taxes may be materially different from the Company's estimates, which could result in the need to record additional liabilities or potentially to reverse previously recorded tax liabilities.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. A valuation allowance is recorded against any deferred tax assets when, in the judgment of management, it is more likely than not that all or part of a deferred tax asset will not be realized. In assessing the need for a valuation allowance, the Company considers all positive and negative evidence, including recent financial performance, scheduled reversals of temporary differences, projected future taxable income, availability of taxable income in carryback periods and tax planning strategies.

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The 2017 Tax Act introduced certain international provisions effective for the Company beginning in the year ended December 29, 2018. As part of these provisions, an accounting policy election is available to either (1) treat taxes due on certain inclusions in U.S. taxable income as a current-period expense when incurred ("period cost method") or (2) factor such amounts into the measurement of its deferred taxes ("deferred method"). The Company has elected to use the period cost method. See Note 18 - Income Taxes for additional information related to the impact of the 2017 Tax Act on the Company's tax provision, taxes payable and deferred taxes for the periods presented in these consolidated financial statements.

Revenue Recognition, Deferred Revenue and Other Contract Liabilities

Effective December 31, 2017, the Company adopted ASU No. 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09). Accounting Standards Codification (ASC) Topic 606 (ASC 606) provides a single, principles-based five-step model to be applied to all contracts with customers and generally provides for the recognition of revenue in an amount that reflects the consideration to which the Company expects to be entitled, net of allowances for estimated returns, discounts or sales incentives, as well as taxes collected from customers that are remitted to government authorities, when control over the promised goods or services are transferred to the customer. The Company derives the majority of its product revenue from four primary sources: (i) direct sales under deferred equipment agreements with end-user hospitals where the Company provides up-front monitoring equipment at no up-front charge in exchange for a multi-year sensor purchase commitment, (ii) other direct sales of noninvasive monitoring solutions to end-user hospitals, emergency medical response organizations and other direct customers; (iii) sales of noninvasive monitoring solutions to distributors who then typically resell to end-user hospitals, emergency medical response organizations and other customers; and (iv) sales of integrated circuit boards to OEM customers who incorporate the Company's embedded software technology into their multiparameter monitoring devices. Subject to customer credit considerations, the majority of such sales are made on open account using industry standard payment terms based on the geography within which the specific customer is located.

The Company enters into agreements to sell its monitoring solutions and services, sometimes as a part of arrangements with multiple performance obligations that include various combinations of product sales, equipment leases and services. In the case of contracts with multiple performance obligations, the authoritative guidance provides that the total consideration be allocated to each performance obligation on the basis of relative standalone selling prices. When a standalone selling price is not readily observable, the Company estimates the standalone selling price by considering multiple factors including, but not limited to, features and functionality of the product, geographies, type of customer, contractual prices pursuant to Group Purchasing Organization (GPO) contracts, the Company's pricing and discount practices, and other market conditions.

While the majority of the Company's revenue contracts and transactions contain standard business terms and conditions, there are some transactions that contain non-standard business terms and conditions. As a result, contract interpretation, judgment and analysis is required to determine the appropriate accounting, including: (i) the amount of the total consideration, including variable consideration, (ii) how the arrangement consideration should be allocated to each performance obligation when multiple performance obligations exist, including the determination of standalone selling price, (iii) when to recognize revenue on the performance obligations, and (iv) whether uncompleted performance obligations are essential to the functionality of the completed performance obligations. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

Sales under deferred equipment agreements are generally structured such that the Company agrees to provide at no up-front charge certain monitoring-related equipment, software, installation, training and/or warranty support in exchange for the hospital's agreement to purchase sensors over the term of the agreement, which generally ranges from three to six years. The Company generally recognizes revenue for performance obligations related to licensed software parameters and monitoring equipment that are sold under deferred equipment agreements with fixed annual commitments at the time such software or monitoring equipment is provided to the customer. Revenue allocable to performance obligations related to sensor sales and monitoring-related equipment leased under deferred equipment agreements is generally recognized as the sensors are provided to the customer over the life of the contract.

Revenue from direct sales of products to the Company's end-user hospitals, emergency medical response organizations and other direct customers, as well as to its distributors, is generally recognized upon shipment or delivery to the customer based on the terms of the contract or underlying purchase order.

The Company also earns revenue from the sale of integrated circuit boards and other products, as well as from software parameter licenses, to OEMs under various agreements. Revenue from the sale of products to the OEMs is generally recognized at the time of shipment. Revenue related to software licenses to OEMs is generally recognized upon shipment of the OEM's product to its customers, as represented to the Company by the OEM.

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The Company provides certain customers with various sales incentives that may take the form of discounts or rebates. The Company estimates and provides allowances for these programs as a reduction to revenue at the time of sale. 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. The Company estimates the revenue constraints related to these forms of variable consideration based on various factors, including expected purchasing volumes, prior sales and returns history, and specific contractual terms and limitations.

The majority of the Company's royalty revenue arises from one agreement and is due and payable quarterly in arrears. An estimate of these royalty revenues is recorded quarterly in the period earned based on historical results, adjusted for any new information or trends known to management at the time of estimation. This estimated revenue is adjusted prospectively when the Company receives the royalty report, approximately sixty days after the end of the previous quarter. The Company also recognizes revenue from time-to-time related to NRE services provided to a certain OEM customer. NRE service revenue is generally recognized on a proportionate basis as the costs of performing such services are incurred by the Company. See "Concentrations of Risk" under Note 19 - Commitments and Contingencies for additional information related to these agreements.

Taxes Collected From Customers and Remitted to Governmental Authorities

The Company's policy is to present revenue net of taxes collected from customers and remitted to governmental authorities.

Shipping and Handling Costs and Fees

All shipping and handling costs are expensed as incurred and are recorded as a component of cost of goods sold in the accompanying consolidated statements of operations. Charges for shipping and handling billed to customers are included as a component of product revenue.

Deferred Costs and Other Contract Assets

The costs of monitoring-related equipment leased to hospitals under deferred equipment agreements are generally deferred and amortized to cost of goods sold over the life of the underlying contracts. Some of the Company's deferred equipment agreements also contain provisions for certain payments to be made directly to the end-user hospital customer at the inception of the arrangement. These contractual incentive payments are generally deferred and amortized on a straight-line basis as contra-revenue over the life of the underlying agreement.

The Company records an unbilled contract receivable related to software licenses and monitoring equipment sold under deferred equipment agreements with fixed annual commitments until such amounts are billed to the customer, which generally occurs at the time the sensors are provided over the term of the agreement.

The incremental costs of obtaining a contract with a customer are capitalized and deferred if the Company expects such costs to be recoverable over the life of the contract and the contract term is greater than one year. Such deferred costs generally relate to certain incentive sales commissions earned by the Company's internal sales team in connection with the execution of deferred equipment agreements and are amortized to expense over the expected term of the underlying contract.

Product Warranty

The Company generally provides a warranty against defects in material and workmanship for a period that generally ranges from six to forty-eight months, depending on the product type. In traditional sales activities, including direct and OEM sales, the Company establishes an accrued liability for the estimated warranty costs at the time of revenue recognition, with a corresponding provision to cost of sales. Customers may also purchase extended warranty coverage separately or as part of a deferred equipment agreement. Revenue related to extended warranty coverage is recognized over the extended life of the contract, which is reasonably expected to be the period over which such services will be provided. The related extended warranty costs are expensed as incurred.

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

	Year Ended		
	December 29, 2018	December 30, 2017	December 31, 2016
Warranty accrual, beginning of period	$1,149	$ 910	$ 1,222
Accrual for warranties issued (including specific accrual)	1,549	1,061	871
Changes in pre-existing warranties (including changes in estimates)	551	332	110
Settlements made	(1,339)	(1,154)	(1,293)
Warranty accrual, end of period	$1,910	$ 1,149	$ 910

Advertising Costs

Advertising costs are expensed as incurred. These costs are included in selling, general and administrative expense in the accompanying consolidated statements of operations. Advertising costs for the years ended December 29, 2018, December 30, 2017 and December 31, 2016 were $17.9 million, $17.8 million and $14.3 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.

Litigation Costs and Contingencies

The Company records a charge equal to at least the minimum estimated liability for a loss contingency or litigation settlement when both of the following conditions are met: (i) information available prior to issuance of the financial statements indicates that it is probable that a liability had been incurred at the date of the financial statements, and (ii) the range of loss can be reasonably estimated. The determination of whether a loss contingency or litigation settlement is probable or reasonably possible involves a significant amount of management judgment, as does the estimation of the range of loss given the nature of contingencies. Liabilities related to litigation settlements with multiple elements are recorded based on the fair value of each element. Legal and other litigation related expenses are recognized as the services are provided. The Company records insurance and other indemnity recoveries for litigation expenses when both of the following conditions are met: (a) the recovery is probable, and (b) collectability is reasonably assured. Insurance recoveries are only recorded to the extent the litigation costs to which they relate have been incurred and recognized in the financial statements.

On November 5, 2016, the Company entered into a settlement agreement (Philips Settlement Agreement) with Koninklijke Philips N.V. (Philips N.V.), which, among other things, settled all of the claims, legal proceedings and contractual disputes between the Company, Philips N.V. and its affiliates. Pursuant to the Philips Settlement Agreement, Philips N.V. paid us $300 million, $30 million of which related to certain future performance obligations by the Company and, therefore, was deferred to future periods.

Foreign Currency Translation

The Company’s international headquarters is in Switzerland, and its functional currency is the U.S. Dollar. The Company has many other foreign subsidiaries, the largest of which are located in Japan and Europe. The functional currencies of these subsidiaries are the Japanese Yen and Euro, respectively.

The Company records certain revenues and expenses in foreign currencies. These revenues and expenses are translated into U.S. Dollars based on the average exchange rate for the reporting period. Assets and liabilities denominated in foreign currencies are translated into U.S. Dollars at the exchange rate in effect as of the balance sheet date. Translation gains and losses related to foreign currency assets and liabilities of a subsidiary that are denominated in the functional currency of such subsidiary are included as a component of accumulated other comprehensive income (loss) within the accompanying consolidated balance sheets. Realized and unrealized foreign currency gains and losses related to foreign currency assets and liabilities of the Company or a subsidiary that are not denominated in the underlying functional currency are included as a component of non-operating (income) expense within the accompanying consolidated statements of operations.

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Comprehensive Income

Comprehensive income includes foreign currency translation adjustments and any related tax benefits that have been excluded from net income and reflected in stockholders' equity.

Net Income Per Share

Basic net income per share is computed by dividing net income by the weighted-average number of shares outstanding during the period. Net income per diluted share is computed by dividing the net income by the weighted-average number of shares and potential shares outstanding during the period, if the effect of potential shares is dilutive. Potential shares include incremental shares of stock issuable upon the exercise of stock options and the vesting of both Restricted Stock Units (RSUs) and Performance Stock Units (PSUs). For the years ended December 29, 2018, December 30, 2017 and December 31, 2016, weighted options to purchase 1.1 million, 0.4 million and 0.2 million shares of common stock, respectively, were outstanding, but were not included in the computation of diluted net income per share because the effect of including such shares would have been antidilutive in the applicable period. For the year ended December 29, 2018, certain RSUs are considered contingently issuable shares as their vesting is contingent upon the occurrence of certain future events. Since such events had not occurred and were not considered probable of occurring as of December 29, 2018, 2.7 million of weighted average shares related to such RSUs have been excluded from the calculation of potential shares. For additional information with respect to these RSUs, please see "Employment and Severance Agreements" in Note 19 to these consolidated financial statements.

The computation of basic and diluted net income per share is as follows (in thousands, except per share data):

	Year ended		
	December 29, 2018	December 30, 2017 As Adjusted	December 31, 2016 As Adjusted
Net Income	$193,543	$ 124,789	$ 311,097
Basic net income per share:			
Weighted-average shares outstanding - basic	52,296	51,516	49,530
Net income per basic share	$3.70	$ 2.42	$ 6.28
Diluted net income per share:			
Weighted-average shares outstanding - basic	52,296	51,516	49,530
Diluted share equivalents: stock options and RSUs	3,743	4,358	3,665
Weighted-average shares outstanding - diluted	56,039	55,874	53,195
Net income per diluted share	$3.45	$ 2.23	$ 5.85

Supplemental Cash Flow Information

Supplemental cash flow information includes the following (in thousands):

	Year ended		
	December 29, 2018	December 30, 2017	December 31, 2016
Cash paid during the year for:			
Interest (net of amounts capitalized)	$193	$ 551	$ 4,052
Income taxes	36,589	91,061	31,230
Noncash investing and financing activities:			
Unpaid purchases of property, plant and equipment	$2,391	$ 1,559	$ 2,009
Unsettled common stock proceeds from option exercises	4	161	165
Unsettled common stock repurchases	—	1,988	—
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$552,490	$ 315,302	$ 305,970
Restricted cash	151	181	2,228
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$552,641	$ 315,483	$ 308,198

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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.

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Shares-Based Payment Accounting (ASU 2018-07). The new standard aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees. Under this guidance, the measurement of the equity-classified nonemployee awards will be fixed at the grant date and the term used for measurement can be the expected term or the contractual term. ASU 2018-07 is effective for annual and interim fiscal reporting periods beginning after December 15, 2018. The Company early adopted this standard during the year ended December 29, 2018 and such adoption did not have a material impact on its consolidated financial statements.

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (Topic 740) Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (ASU 2018-05). ASU 2018-05 amends certain material in ASC Topic 740 for the income tax accounting implications of the recently issued Tax Cuts and Jobs Act of 2017. The Company early adopted this standard when it was issued.

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other than Inventory (ASU 2016-16). The new standard eliminates the exception that allowed the income tax consequences of an intra-entity transfer of assets other than inventory to be deferred until the transferred asset was sold to a third party or otherwise recovered through use, and now requires recognition of such income tax consequences at the time the non-inventory asset is transferred. ASU 2016-16 is effective for annual and interim fiscal reporting periods beginning after December 15, 2017. The standard required companies to apply a modified retrospective approach with a cumulative catch-up adjustment to opening retained earnings in the period of adoption. Accordingly, the Company recorded a $0.4 million decrease to retained earnings and a corresponding increase to deferred tax assets of $0.1 million, and a decrease to prepaid taxes of $0.5 million as of December 31, 2017.

Effective December 31, 2017, the Company adopted ASU 2014-09, which introduced ASC 606. ASC 606 provides a single, principles-based five-step model to be applied to all contracts with customers, and generally provides for the recognition of revenue in an amount that reflects the considerations to which the Company expects to be entitled when control over the promised goods or services are transferred to the customer. ASC 606 also enhances disclosures about revenue, provides additional guidance for transactions that were not previously addressed comprehensively and improves guidance for multiple-element arrangements. In addition, ASC 606 includes Subtopic 340-40, Other Assets and Deferred Costs - Contracts with Customers, which requires the deferral of incremental costs of obtaining a contract with a customer.

The Company adopted ASC 606 utilizing the full retrospective method of transition, which requires the Company to restate certain previously reported results, including the impact on the provision for income taxes. Adoption of the new standard resulted in changes to the Company’s accounting policies for revenue recognition and related cost of goods sold, as well as the capitalization and deferral of certain commission expenses, and a cumulative increase to retained earnings of approximately $23.9 million and $17.1 million as of December 31, 2016 and December 30, 2017, respectively. The areas impacted by ASC 606 include: (i) the acceleration of certain revenue from product sales to distributors that was previously deferred under the “sell-through” method; (ii) the acceleration of revenue related to certain software/parameter sales; (iii) the aggregation of all contract modifications occurring prior to the beginning of the earliest period presented; (iv) the acceleration of costs related to equipment for which control transfers up-front under certain contracts, the future consideration for which will now be treated as an optional purchase; (v) the capitalization and amortization of certain contract-related costs that were previously expensed when incurred; and (vi) the corresponding income tax effects related to these adjustments.

The Company applied the new standard using certain practical expedients, including: (i) excluding disclosures of transaction prices allocated to remaining performance obligations when the Company expects to recognize such revenue for all periods prior to the date of initial application of ASC 606; (ii) not adjusting the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company's transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less; (iii) expensing costs as incurred for costs to obtain a contract when the amortization period would have been one year or less; (iv) not recasting revenue for contracts that begin and end in the same fiscal year; and (v) not assessing whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer.

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Pursuant to the full retrospective method of adoption under ASC 606, the Company has adjusted certain amounts previously reported in its consolidated financial statements.

The reconciliations below reflect the adoption of ASC 606, the adoption of ASU 2016-16 and certain other immaterial reclassifications (in thousands, except per share amounts):

Consolidated Balance Sheet:	December 30, 2017		
	As Previously Reported	Adjustments	As Adjusted
Trade accounts receivable	$121,309	$ (2,777)	$118,532
Inventories	95,944	(3,685)	92,259
Other current assets	31,564	2,038	33,602
Deferred costs and other contract assets	99,600	9,656	109,256
Deferred tax assets	23,898	(3,917)	19,981
Other assets	10,782	(6,114)	4,668
Accrued and other liabilities	42,344	(18,090)	24,254
Deferred revenue and other contract liabilities, current	35,929	(3,824)	32,105
Retained earnings	720,842	17,114	737,956

Consolidated Statement of Operations:	Year ended December 30, 2017		
	As Previously Reported	Adjustments	As Adjusted
Product revenue	$741,324	$ (3,082)	$738,242
Royalty and other revenue	56,784	(4,778)	52,006
Cost of goods sold	263,008	5,208	268,216
Selling, general and administrative	275,786	506	276,292
Provision for income taxes	67,758	(6,747)	61,011
Net income	131,616	(6,827)	124,789
Net income per share:			
Basic	$2.55	$ (0.13)	$2.42
Diluted	$2.36	$ (0.13)	$2.23

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Consolidated Statement of Operations:	Year ended December 31, 2016		
	As Previously Reported	Adjustments	As Adjusted
Product revenue	$663,846	$ 10,116	$673,962
Royalty and other revenue	30,779	8,157	38,936
Cost of goods sold	230,826	3,734	234,560
Selling, general and administrative	253,667	1,040	254,707
Research and development	59,362	(1,676)	57,686
Provision for income taxes	117,675	4,744	122,419
Net income	300,666	10,431	311,097
Net income per share:			
Basic	$6.07	$ 0.21	$6.28
Diluted	$5.65	$ 0.20	$5.85

Consolidated Statement of Cash Flows:	Year ended December 30, 2017		
	As Previously Reported	Adjustments	As Adjusted
Cash flows from operating activities:			
Net income	$131,616	$ (6,827)	$124,789
Provision for deferred income taxes	24,023	(6,747)	17,276
Adjustments to reconcile net income to net cash provided by operating activities:			
Increase in inventories	(22,923)	(1,091)	(24,014)
Increase in other current assets	(3,855)	947	(2,908)
Increase in deferred cost of goods sold	(19,438)	5,336	(14,102)
Increase in other assets	(10,952)	181	(10,771)
Increase in other current liabilities	11,156	(5,874)	5,282
Decrease in deferred revenue and other contract liabilities	(27,370)	14,075	(13,295)

Consolidated Statement of Cash Flows:	Year ended December 31, 2016		
	As Previously Reported	Adjustments	As Adjusted
Cash flows from operating activities:			
Net income	$300,666	$ 10,431	$311,097
Provision for deferred income taxes	5,405	4,744	10,149
Adjustments to reconcile net income to net cash provided by operating activities:			
Increase in inventories	(10,831)	1,876	(8,955)
Increase in other current assets	(3,422)	(1,394)	(4,816)
Increase in deferred cost of goods sold	(8,251)	590	(7,661)
(Increase) decrease in other assets	(1,609)	2,064	455
Decrease in other current liabilities	(11,929)	(4,278)	(16,207)
Increase in deferred revenue and other contract liabilities	41,977	(14,032)	27,945

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In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, (ASU 2016-01). The new standard requires that (i) all equity investments, other than equity-method investments, in unconsolidated entities generally be measured at fair value, and (ii) changes in fair value due to instrument-specific credit risk be recognized separately in other comprehensive income when the fair value option has been elected for financial liabilities. ASU 2016-01 is effective for annual and interim fiscal reporting periods beginning after December 15, 2017. The Company adopted this standard during the year ended December 29, 2018 and such adoption did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-15, Intangibles–Goodwill and Other–Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (ASU 2018-15). The new standard aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). ASU 2018-15 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the expected impact of this standard, but does not expect it to have a material impact on its consolidated financial statements upon adoption.

In July 2018, the FASB issued ASU No. 2018-09, Codification Improvements (ASU 2018-09). This new standard amends, clarifies, corrects errors in and makes minor improvements to the ASC. The transition and effective date guidance is based on the facts and circumstances of each amendment. Some of the amendments of ASU 2018-09 do not require transition guidance and will be effective upon issuance. However, many of the amendments of ASU 2018-09 that contain transition guidance are effective for the Company for annual periods beginning after December 15, 2018. The Company is currently evaluating the expected impact of this standard, but does not expect it to have a material impact on its consolidated financial statements upon adoption.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (ASU 2018-02). The new standard allows a reclassification from accumulated other comprehensive income to retained earnings for the tax effects resulting from "An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for Fiscal Year 2018" (the Reconciliation Act) that are stranded in accumulated other comprehensive income. The new standard also requires certain disclosures about stranded tax effects. The new standard, however, does not change the underlying guidance that requires that the effect of a change in tax laws or rates be included in income from continuing operations. ASU 2018-02 is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. ASU 2018-02 must be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the Reconciliation Act is recognized. The Company is currently evaluating the expected impact of this standard, but does not expect it to have a material impact on its consolidated financial statements upon adoption.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU 2016-13). The new standard requires entities to use a current expected credit loss model, which is a new impairment model based on expected losses rather than incurred losses. Under this model, an entity would recognize an impairment allowance equal to its current estimate of all contractual cash flows that the entity does not expect to collect. The entity's estimate would consider relevant information about past events, current conditions, and reasonable and supportable forecasts. ASU 2016-13 is effective for annual and interim fiscal reporting periods beginning after December 15, 2019, with early adoption permitted for annual reporting periods beginning after December 15, 2018. In November 2018, the FASB issued ASU No. 2018-19, Codification Improvements to Topic 326, Financial Instruments-Credit Losses, (ASU 2018-19). The new standard clarifies that receivables arising from operating leases are accounted for using lease guidance and not as financial instruments. This standard should be applied on either a prospective transition or modified-retrospective approach depending on the

subtopic. ASU 2018-19 is effective for annual periods beginning after December 15, 2019, and interim periods therein. Early adoption is permitted for annual periods beginning after December 15, 2018 and interim periods therein. The Company is currently evaluating the expected impact of this standard, but does not expect it to have a material impact on its consolidated financial statements upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (ASU 2016-02). ASU 2016-02 replaces the existing lease guidance under ASC 840 with ASC 842, which among other things, requires lessees to recognize most leases on their balance sheets but continue to recognize lease expenses in their statement of operations in a manner similar to current practice. ASU 2016-02 states that a lessee will recognize a lease liability for the obligation to make lease payments and a right-of-use asset for the right to use the underlying asset for the lease term.

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Expense related to leases determined to be operating leases will be recognized on a straight-line basis, while those determined to be financing leases will be recognized following a front-loaded expense profile in which interest and amortization are presented separately in the statement of operations. ASU 2016-02 is effective for annual and interim fiscal reporting periods beginning after December 15, 2018, and early application is permitted.

In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases (ASU 2018-10). ASU 2018-10 provides clarification on the rate implicit in the lease, impairment of the net investment in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase options, variable payments that depend on an index or rate and certain transition adjustments. ASU 2018-10 is effective when ASU 2016-02 is adopted. The FASB also issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements (ASU 2018-11) in July 2018. ASU 2018-11 provides a transition option and a practical expedient for lessors to aid in cost reductions and complexity of implementing the new standard. Entities that elect this transition option still adopt the new leases standard using the modified retrospective transition method required by the standard, but they recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption rather than in the earliest period presented. The optional practical expedient allows lessors to elect, by class of underlying asset, to not separate non-lease components from the associated lease components if the non-lease components otherwise would be accounted for in accordance with ASC 606 and both of the following criteria are met: (1) the lease component and the associated non-lease components have the same timing and pattern of transfer and(2) the lease component, if accounted for separately, would be classified as an operating lease. ASU 2018-11 is also effective is effective when ASU 2016-02 is adopted.

In December 2018, the FASB issued ASU 2018-20, Leases (Topic 842): Narrow- Scope Improvements for Lessors (ASU 2018-20). The new standard is an amendment to help lessors apply the lease standard ASU No. 2016-02, Leases (Topic 842) (ASU 2016-02). It allows lessors to make an accounting policy election to exclude the sales taxes and other similar taxes on a specific lease from the measurement of lease revenue and associated expenses. ASU 2018-20 is effective when ASU 2016-02 is adopted.

The Company is continuing to evaluate the expected impact of ASC 842 on its consolidated financial statements, but anticipates that, among other things, the required recognition by a lessee of a lease liability and related right-of-use asset for operating leases will increase both the assets and liabilities recognized and reported on its balance sheet as of the adoption date. In addition, ASC 842 will also change the classification of certain leases for which the Company is the lessor, resulting in the acceleration of revenue under certain contracts, as well as the immediate expensing of certain costs that are currently deferred and expensed over the life of the lease. The Company is also continuing to evaluate the available practical expedients and its adoption method for this new standard. The Company anticipates that its internal control framework will not materially change upon adoption of ASC 842, but certain existing internal controls will be modified and augmented, as necessary, effective as of December 30, 2018. As the Company implements this new standard, it will also continue to develop additional internal controls, as required, to ensure that it adequately evaluates its contracts under the new lease standard and accurately reports its current and any required prior-period operating results, as well as all required disclosures. When adopted, the Company expects to recognize a lease asset and incremental lease liability related to the lessee provisions under ASC 842 between $19.0 million to $24.0 million and a cumulative decrease to retained earnings related to the lessor provisions under ASC 842 of between $16.0 million to $26.0 million as of December 29, 2018.

3. Related Party Transactions

Cercacor Laboratories, Inc. (Cercacor) is an independent entity that was spun off from the Company to its stockholders in 1998. Joe Kiani, the Company’s Chairman and Chief Executive Officer (CEO), is also the Chairman and CEO of Cercacor. Effective as of January 3, 2016, in connection with changes in the capital structure of Cercacor, the Company determined that Cercacor was no longer required to be consolidated. Although the Company believes that Cercacor continues to be considered a variable interest entity, the Company has determined that it is no longer the primary beneficiary of Cercacor as it does not have the power to direct the activities of Cercacor that most significantly impact Cercacor’s economic performance and has no obligation to absorb Cercacor’s losses.

The Company is a party to the following agreements with Cercacor:

Cross-Licensing Agreement - The Company and Cercacor are parties to the Cross-Licensing Agreement, which governs each party's rights to certain intellectual property held by the two companies. The Company is subject to certain annual minimum aggregate royalty obligations for use of the rainbow® licensed technology. The current annual minimum royalty obligation is $5.0 million. Aggregate liabilities payable to Cercacor arising under the Cross-Licensing Agreement were $10.9 million, $8.0 million and $6.4 million for the years ended December 29, 2018, December 30, 2017 and

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December 31, 2016, respectively. The Company had less than $0.1 million in sales to Cercacor for each of the years ended December 29, 2018, December 30, 2017 and December 31, 2016.

- Administrative Services Agreement - The Company is a party to an administrative services agreement with Cercacor (G&A Services Agreement), which governs certain general and administrative services that the Company provides to Cercacor. Amounts charged by the Company pursuant to the G&A Services Agreement were $0.2 million for each of the years ended December 29, 2018, December 30, 2017 and December 31, 2016.
- Patent Transfer and Licensing Agreement. The Company entered into a patent transfer and licensing agreement with Cercacor (the Patent Agreement) effective July 2015, pursuant to which, among other things, it purchased certain patents from Cercacor (the Purchased Patents) for an aggregate purchase price of $2.4 million. Pursuant to the Patent Agreement, the Company granted Cercacor an irrevocable, non-exclusive, worldwide license with respect to the products and services covered by the Purchased Patents.
- Sublease Agreement - In March 2016, the Company entered into a sublease agreement with Cercacor for approximately 16,830 square feet of excess office and laboratory space located at 40 Parker, Irvine, California (Cercacor Sublease). The Cercacor Sublease began on May 1, 2016 and expires on November 30, 2019. The Company recognized $0.4 million, $0.4 million and $0.3 million of sublease income for the years ended December 29, 2018, December 30, 2017, and December 31, 2016, respectively.

Net amounts due to Cercacor were approximately $2.9 million and $1.5 million as of December 29, 2018 and December 30, 2017, respectively. The Company’s CEO is also the Chairman of the Masimo Foundation for Ethics, Innovation and Competition in Healthcare (Masimo Foundation), a non-profit organization that was founded in 2010 to provide a platform for encouraging ethics, innovation and competition in healthcare. In addition, the Company’s Executive Vice President (EVP), General Counsel is a Director and also serves as the Secretary of the Masimo Foundation and the Company’s EVP, Chief Financial Officer (CFO) serves as the Treasurer of the Masimo Foundation. For the fiscal year ended December 29, 2018, the Company contributed approximately $2.0 million, a portion of which was, in turn, contributed by the Masimo Foundation to the Patient Safety Movement Foundation. For the fiscal year ended December 30, 2017, the Company did not make any contributions to the Masimo Foundation. For the fiscal year ended December 31, 2016, the Company contributed approximately $5.0 million to the Masimo Foundation.

The Company’s CEO is also the Chairman of the Patient Safety Movement Foundation (PSMF), a non-profit organization which was founded in 2013 to work with hospitals, medical technology companies and patient advocates to unite the healthcare ecosystem and eliminate the more than 200,000 U.S. preventable hospital deaths that occur every year by 2020. The Company’s EVP and General Counsel and the Company’s EVP, Chief Financial Officer serve as the Secretary and the Treasurer, respectively, of PSMF. During the fiscal years ended December 29, 2018, December 30, 2017 and December 31, 2016, the Company contributed approximately $207,530, $1,300 and $200,271, respectively to PSMF.

The Company’s CEO is also the Chairman of the Patient Safety Movement Coalition (PSMC), a not-for-profit social welfare organization which was founded in 2013 to promote patient safety legislation. The Company’s EVP and General Counsel and the Company’s EVP, Chief Financial Officer serve as the Secretary and the Treasurer, respectively, of the PSMC. During the fiscal years ended December 29, 2018 and December 30, 2017, the Company did not make any contributions to PSMC. During the fiscal year ended December 31, 2016, the Company contributed approximately $20,000 to PSMC.

The Company maintains an aircraft time share agreement, pursuant to which the Company has agreed from time to time to make its aircraft available to the Company’s CEO for lease on a time-sharing basis. The Company charges the Company’s CEO for personal use based on agreed upon reimbursement rates. During the fiscal years ended December 29, 2018 and December 30, 2017, the Company charged the Company’s CEO $0.2 million and less than $0.1 million, respectively, related to such reimbursements.

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4. Inventories

Inventories consist of the following (in thousands):

	December 29, 2018	December 30, 2017 As Adjusted
Raw materials	$ 38,955	$ 31,200
Work-in-process	9,036	8,619
Finished goods	45,760	52,440
Total	$ 93,751	$ 92,259

5. Other Current Assets

Other current assets consist of the following (in thousands):

	December 29, 2018	December 30, 2017 As Adjusted
Prepaid expenses	$ 10,582	$ 10,517
Indirect taxes receivable	6,516	6,556
Customer notes receivable	3,780	2,777
Prepaid income taxes	3,071	3,494
Royalties receivable	500	7,400
Other	4,778	2,858
Total other current assets	$ 29,227	$ 33,602

6. Deferred Costs and Other Contract Assets

Deferred costs and other contract assets consist of the following (in thousands):

	December 29, 2018	December 30, 2017 As Adjusted
Deferred cost of goods sold	$ 109,398	$ 93,261
Prepaid contract incentives	7,036	6,115
Unbilled contract receivables	5,567	4,267
Deferred commissions	5,085	5,613
Deferred costs and other contract assets	$ 127,086	$ 109,256

For the years ended December 29, 2018 and December 30, 2017, $30.0 million and $27.5 million, respectively, of deferred cost of goods sold was amortized to cost of goods sold.

For the years ended December 29, 2018 and December 30, 2017, $1.7 million and $2.0 million, respectively, of prepaid contract incentives was amortized as a reduction to revenue.

For the years ended December 29, 2018 and December 30, 2017, $2.2 million and $2.5 million, respectively, of deferred commissions was amortized to selling, general and administrative expenses.

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7. Property and Equipment

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

	December 29, 2018	December 30, 2017
Building and building improvements	$ 88,449	$ 87,999
Machinery and equipment	54,525	47,556
Aircraft and vehicles	25,555	25,329
Land	23,762	23,762
Computer equipment	16,582	15,789
Leasehold improvements	16,428	15,326
Tooling	14,212	13,754
Furniture and office equipment	10,459	9,967
Demonstration units	470	486
Construction-in-progress (CIP)	13,320	6,365
Total property and equipment	263,762	246,333
Accumulated depreciation and amortization	(97,790)	(82,237)
Total property and equipment, net	$ 165,972	$ 164,096

The balance in CIP at December 29, 2018 relates primarily to capitalized costs related to the implementation of a new enterprise resource planning (ERP) software system, capital improvements to various facilities and manufacturing equipment, the underlying assets for which have not been completed or placed into service. The balance in CIP at December 30, 2017 related primarily to capitalized costs related to leasehold improvements, furniture and equipment for a new manufacturing facility in Irvine, California, as well as other manufacturing equipment, the majority of which was placed into service during the year ended December 29, 2018.

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8. Intangible Assets

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

	December 29, 2018	December 30, 2017
Cost		
Patents	$ 21,323	$ 20,623
Customer relationships	7,669	7,669
Licenses-related party	7,500	7,500
Acquired technology	5,580	5,580
Trademarks	4,190	4,036
Capitalized software development costs	3,430	2,699
Other	5,466	3,691
Total cost	55,158	51,798
Accumulated amortization		
Patents	(8,868)	(8,473)
Customer relationships	(4,921)	(4,154)
Licenses-related party	(5,252)	(4,831)
Acquired technology	(3,624)	(3,066)
Trademarks	(1,889)	(1,611)
Capitalized software development costs	(1,983)	(1,864)
Other	(697)	(676)
Total accumulated amortization	(27,234)	(24,675)
Net carrying amount	$ 27,924	$ 27,123

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

Fiscal year	Amount
2019	$4,218
2020	3,748
2021	3,647
2022	2,941
2023	1,737
Thereafter	11,633
Total	$27,924

9. Goodwill

Changes in goodwill were as follows (in thousands):

	December 29, 2018	December 30, 2017
Goodwill, beginning of period	$ 20,617	$ 19,780
Goodwill as a result of acquisitions	3,402	—
Foreign currency translation adjustment	(722)	837
Goodwill, end of period	$ 23,297	$ 20,617

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On September 21, 2018, the Company acquired all of the outstanding shares of a private patient monitoring software company for approximately $4.0 million. Based on the Company's preliminary purchase price allocation, approximately $3.4 million of the purchase price has been assigned to goodwill. All of the assets and liabilities of the acquired company and its operating results as of December 29, 2018 are included in these condensed consolidated financial statements.

10. Other Assets, Long-Term

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

	December 29, 2018	December 30, 2017 As Adjusted
Prepaid deposits	$ 2,881	$ 3,286
Long term investments	1,200	1,234
Restricted cash	151	148
Total other assets, long-term	$ 4,232	$ 4,668

11. Deferred Revenue and Other Contract Liabilities

Deferred revenue and other contract liabilities consist of the following (in thousands):

	December 29, 2018	December 30, 2017 As Adjusted
Accrued customer reimbursements	$ 16,194	$ 16,896
Deferred revenue	10,883	11,589
Accrued rebates and incentives	6,282	3,598
Other	432	259
Total deferred revenue and other contract liabilities	33,791	32,342
Less: Non-current portion of deferred revenue	(685)	(237)
Deferred revenue and other contract liabilities - current	$ 33,106	$ 32,105

Deferred revenue relates to contracted amounts that have been invoiced to customers for which remaining performance obligations must be completed before the Company can recognize the revenue. These amounts primarily relate to undelivered equipment, sensors and services under deferred equipment agreements, extended warranty agreements and NRE service agreements.

Changes in deferred revenue for the year ended December 29, 2018 were as follows:

	December 29, 2018
Deferred revenue, beginning of the period	$ 11,589
Revenue deferred during the period	11,356
Recognition of revenue deferred in prior periods	(12,062)
Deferred revenue, end of the period	$ 10,883

Expected revenue from remaining contractual performance obligations (Unrecognized Contract Revenue) includes deferred revenue, as well as other amounts that will be invoiced and recognized as revenue in future periods, when the Company completes its performance obligations. While Unrecognized Contract Revenue is similar in concept to backlog, Unrecognized Contract Revenue excludes revenue allocable to monitoring-related equipment that is effectively leased to hospitals under deferred equipment agreements and other contractual obligations for which neither party has performed.

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The following table summarizes the Company's estimated Unrecognized Contract Revenue as of December 29, 2018 and the future periods within which the Company expects to recognize such revenue.

	Expected Future Revenue By Period (in thousands)				
	Less than 1 year	Between 1-3 years	Between 3-5 years	More than 5 years	Total
Unrecognized Contract Revenue	$194,151	$271,477	$128,116	$ 36,688	$630,432

The estimated timing of this revenue is based, in part, on management's estimates and assumptions about when its performance obligations will be completed. As a result, the actual timing of this revenue in future periods may vary, possibly materially, from those reflected in this table.

12. Other Current Liabilities

Other current liabilities consist of the following (in thousands):

	December 29, 2018	December 30, 2017 As Adjusted
Accrued indirect taxes payable	$ 6,465	$ 6,711
Related party payables	4,000	1,528
Income tax payable	3,071	4,292
Accrued expenses	2,875	2,924
Accrued customer rebates, fees and reimbursements	2,163	2,351
Accrued warranty	1,910	1,149
Accrued legal fees	1,481	975
Accrued stock repurchases	—	1,988
Other	2,662	2,336
Total other current liabilities	$ 24,627	$ 24,254

13. Credit Facilities

On December 17, 2018, the Company entered into a new Credit Agreement ("2018 Credit Facility") with JPMorgan Chase Bank, N.A., as Administrative Agent and a Lender, and Bank of the West, a Lender (collectively, the "Lenders"). The 2018 Credit Facility provides for up to $150.0 million of unsecured borrowings in multiple currencies, with an option, subject to certain conditions, for the Company to increase the aggregate borrowing capacity up to $550.0 million in the future with the Initial Lenders and additional Lenders, as required. The 2018 Credit Facility also provides for a sublimit of up to $25.0 million for the issuance of letters of credit and a sublimit of $75.0 million for borrowings in specified foreign currencies. All unpaid principal under the 2018 Credit Facility will become due and payable on December 17, 2023. Proceeds from the 2018 Credit Facility are expected to be used for general corporate, capital investment and working capital needs.

Borrowings under the 2018 Credit Facility will be deemed, at the Company's election, either: (a) an Alternate Base Rate (ABR) Loan, which bears interest at the ABR, plus a spread of 0.125% to 1.000% based upon a Company leverage ratio, or (b) a Eurocurrency Loan, which bears interest at the Adjusted LIBO Rate (as defined below), plus a spread of 1.125% to 2.000% based upon a Company net leverage ratio. Subject to certain conditions, the Company may also request swingline loans from time to time that bear interest similar to an ABR Loan. Pursuant to the terms of the 2018 Credit Facility, the ABR is equal to the greatest of (i) the prime rate, (ii) the Federal Reserve Bank of New York effective rate plus 0.50%, and (iii) the one-month Adjusted LIBO Rate plus 1.0%. The Adjusted LIBO Rate is equal to the Eurocurrency Rate (as defined within the 2018 Credit Facility) for the applicable interest period multiplied by the statutory reserve rate for such period, rounded upward, if necessary, to the next 1/16 of 1%. The Company is also obligated under the 2018 Credit Facility to pay an unused fee ranging from 0.150% to 0.275% per annum, based upon a Company leverage ratio, with respect to any unutilized portion of the 2018 Credit Facility.

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Pursuant to the terms of the 2018 Credit Facility, the Company is subject to certain covenants, including financial covenants related to a net leverage ratio and an interest charge coverage ratio, and other customary negative covenants. The 2018 Credit Facility also includes customary events of default which, upon the occurrence of any such event of default, provide the Lenders with the right to take either or both of the following actions: (a) immediately terminate the commitments, and (b) declare the loans then outstanding immediately due and payable in full. As of December 29, 2018, the 2018 Credit Facility had no outstanding draws or letters of credit. The Company was in compliance with all covenants under the 2018 Credit Facility as of December 29, 2018.

In January 2016, the Company entered into an Amended and Restated Credit Agreement (Restated Credit Facility) with JPMorgan Chase Bank, N.A., as Administrative Agent and a Lender, Bank of America, as Syndication Agent and a Lender, Citibank, N.A., as Documentation Agent and a Lender, and various other Lenders (collectively, the Lenders). The Restated Credit Facility provided for borrowings up to $250.0 million in multiple currencies, with an option, subject to certain conditions, for the Company to increase the aggregate borrowing capacity to up to $350.0 million. The Company terminated the Restated Credit Facility on February 15, 2018.

The Company incurred total combined interest expense of $0.6 million, $0.7 million and $3.5 million for the years ended December 29, 2018, December 30, 2017 and December 31, 2016, respectively, under the 2018 Credit Facility and Restated Credit Facility.

14. Other Non-Current Liabilities

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

	December 29, 2018	December 30, 2017 As Adjusted
Income tax payable, long-term	$ 21,522	$ 25,734
Unrecognized tax benefits	11,717	14,348
Deferred tax liabilities	2,956	9,880
Deferred rent, long-term	1,236	1,266
Deferred revenue, long-term	685	237
Other	30	292
Total other non-current liabilities	$ 38,146	$ 51,757

Unrecognized tax benefit relates to the Company’s long-term portion of tax liability associated with uncertain tax positions. Authoritative 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 18 to these consolidated financial statements for further details.

15. Stock Repurchase Program

In September 2015, the Company’s Board of Directors (Board) authorized a stock repurchase program, whereby the Company could purchase up to 5.0 million shares of its common stock over a period of up to three years (2015 Repurchase Program). A total of 3.1 million shares were purchased by the Company pursuant to the 2015 Repurchase Program prior to its expiration in September 2018.

In July 2018, the Board approved a new stock repurchase program, authorizing the Company to purchase up to 5.0 million additional shares of its common stock over a period of up to three years (2018 Repurchase Program). The 2018 Repurchase Program became effective in September 2018 upon the expiration of the 2015 Repurchase Program. The Company expects to fund the 2018 Repurchase Program through its available cash, cash expected to be generated from future operations, the Credit Facility and other potential sources of capital. The 2018 Repurchase Program can be carried out at the discretion of a committee comprised of the Company’s CEO and CFO through open market purchases, one or more Rule 10b5-1 trading plans, block trades and privately negotiated transactions.

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The following table provides a summary of the Company's stock repurchase activities during the years ended December 29, 2018, December 30, 2017 and December 31, 2016 (in thousands, except per share amounts):

	Years Ended		
	December 29, 2018	December 30, 2017	December 31, 2016
Shares repurchased	196 [1]	804 [1]	1,496
Average cost per share	$84.12	$ 84.90	$ 42.39
Value of shares repurchased	$16,490	$ 68,260	$ 63,403

[1] Excludes shares withheld from the shares of its common stock actually issued in connection the vesting of PSU awards to satisfy certain U.S. federal and state tax withholding obligations.

16. Stock-Based Compensation

Total stock-based compensation expense for the years ended December 29, 2018, December 30, 2017 and December 31, 2016 was $27.4 million, $17.2 million and $12.5 million, respectively. As of December 29, 2018, an aggregate of 11.9 million shares of common stock were reserved for future issuance under the Company's equity plans, of which 3.2 million shares were available for future grant under the Masimo Corporation 2017 Equity Incentive Plan (2017 Equity Plan). Additional information related to the Company's current equity incentive plans, stock-based award activity and valuation of stock-based awards is included below.

Equity Incentive Plans

2017 Equity Incentive Plan

On June 1, 2017, the Company's stockholders ratified and approved the 2017 Equity Plan. The 2017 Equity Plan permits the grant of stock options, restricted stock, RSUs, stock appreciation rights, PSUs, performance shares, performance bonus awards and other stock or cash awards to employees, directors and consultants of the Company and employees and consultants of any parent or subsidiary of the Company. The aggregate number of shares that may be awarded under the 2017 Equity Plan is 5.0 million shares.

The 2017 Equity Plan provides that at least 95% of the equity awards issued under the 2017 Equity Plan must vest over a period of not less than one year following the date of grant and generally expire within ten years from date of grant. The exercise price per share of each option granted under the 2017 Equity Plan may not be less than the fair market value of a share of the Company's common stock on the date of grant, which is generally equal to the c