



2020 | FORM 10K

2020 Highlights and Achievements

- > Advancing the continuum of great care
- > Expanding the product portfolio
- > Driving expansion to emerging markets
- > Driving operational efficiency and financial performance

Supporting the company's strategies and financial performance were several achievements aimed at advancing patient care, expanding the product portfolio, and delivering value to stockholders. 2020 highlights included:

1 Advancing Masimo's goal to help hospitals improve the continuum of great care through hospital automation, connectivity, and innovative noninvasive monitoring technologies, Masimo acquired the Connected Care product portfolio including DCX™ device connectivity (formerly known as DeviceConX™), VCX™ patient vitals software (formerly known as VitalsConX™), HBox® connectivity hub, and Shuttle interface cable from Nanthealth, Inc.

2 Expanding the respiratory health portfolio with the acquisition of TNI medical AG, an innovative ventilation company. This technology will provide clinicians with important additional tools to address the growing number of people affected by pulmonary diseases and respiratory-related illnesses, including those suffering from COVID-19.

3

Expanding into new and emerging markets, Masimo reached an agreement to acquire the share capital of LiDCO Group PLC, a UK public company, specializing in the development, manufacturing and sales of advanced hemodynamic monitoring devices for critical care and high risk surgical patients. This acquisition allows for measurement of crucial physiological parameters such as cardiac output, stroke volume and systematic vascular resistance, monitoring the amount of blood flowing throughout the body, the requirement for intravenous fluids, and vasoactive support to help ensure that the body's tissues and organs are adequately oxygenated.



4

With the latest automation and connectivity solution, Masimo **UniView: 60™**. UniView: 60™ uses the Masimo Hospital Automation™ platform to aggregate and display pertinent patient information on a digital display just outside each patient's room, allowing clinicians to familiarize themselves with the most relevant details of each patient's case at the door in 60 seconds or less before they see the patient.



5

With the full market release of **Masimo SafetyNet™**, an innovative, economically scalable cloud-based patient management solution designed to help clinicians care for patients remotely in hospital settings and in non-traditional settings and circumstances. Masimo SafetyNet™ is now available worldwide to help clinicians and public health officials combat the global COVID-19 pandemic.



6

Developed for the consumer market and released in conjunction with Masimo SafetyNet™, Masimo **Radius T™** represents a paradigm shift in thermometry by making it continuous, wearable, and hassle-free. Radius T™ measures body temperature continuously, transmitting data and customizable temperature notifications to the user's smartphone.

Highlights and Achievements

Fiscal 2020 Financial Highlights

In fiscal 2020, our performance exceeded expectations despite significant global challenges. We delivered product revenue growth of 22%, GAAP EPS growth of 20% and finished the year with a strong balance sheet with over \$641 million in cash. During the year, we acquired three companies through all cash transactions, and we returned more than \$111 million to stockholders through share repurchases.

For fiscal 2020, we shipped approximately 472,300 noninvasive technology boards and monitors, an increase of approximately 226,100 units, or 92% over the prior year period. As a result, we have now shipped approximately 2.2 million technology boards and instruments over the last 10 years, representing a 17% increase over the same metric as last year.

We continued to make progress on our cost savings initiatives, particularly within our global manufacturing and supply chain, through our efforts were slight-

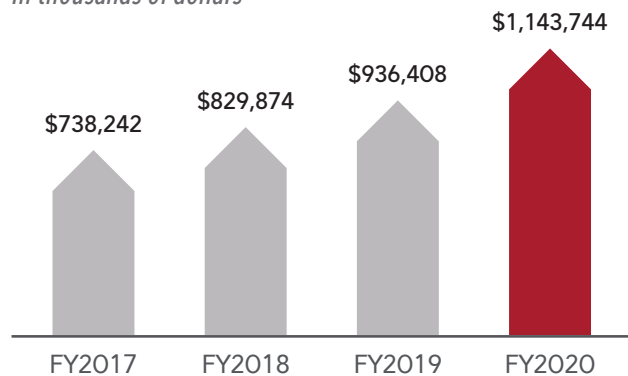
ly hampered by increased freight costs, import duties and additional costs related to the implementation of COVID-19 safety protocols. In addition, we continued to make investments in R&D initiatives that will enhance our future product portfolio.

In fiscal 2020, we demonstrated our ability to execute through unprecedented challenges by winning new customers, entering new markets and expanding our installed base. We remain steadfast in our commitment to delivering on our long-range goals for revenue growth and profitability.

We have now shipped approximately 2.2 million technology boards and instruments over the last 10 years.

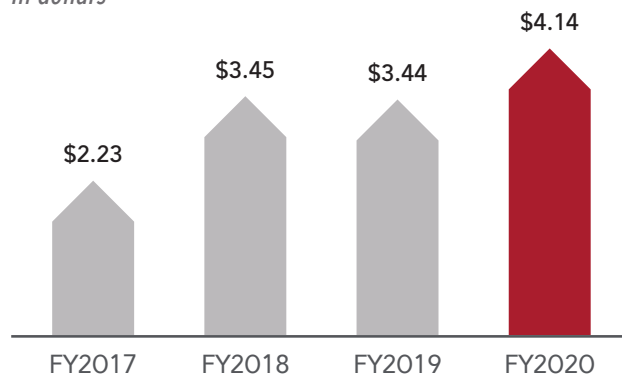
TOTAL REVENUES BY YEAR

In thousands of dollars



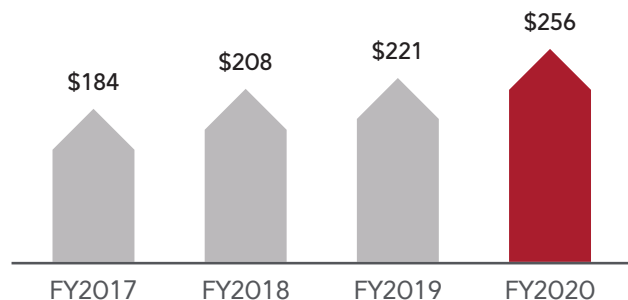
EPS

In dollars

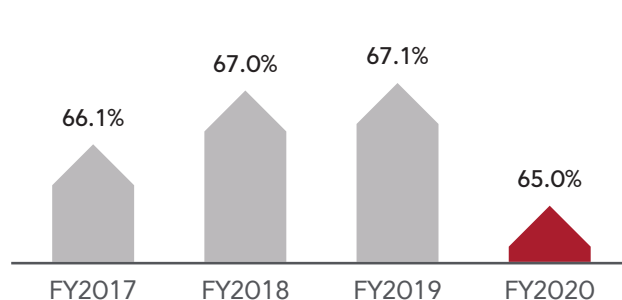


OPERATING PROFIT

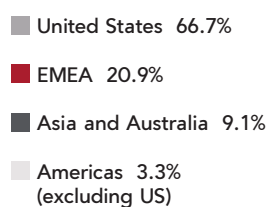
In thousands of dollars



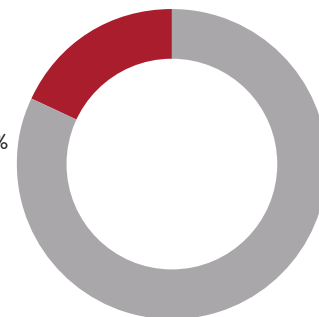
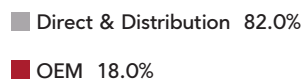
GROSS PROFIT %



SALES BY GEOGRAPHY



SALES BY CHANNEL



MASI - STOCK PRICE



Guiding Principles

- > Remain faithful to your promises and responsibilities.
- > Thrive on fascination and accomplishment and not on greed and power.
- > Strive to make each year better than the year before both personally and for the team.
- > Make each day as fun as possible.
- > Do what is best for patient care.



The coronavirus (COVID-19) continues to be a growing health emergency. First responders and care teams are on the front lines of the crisis, working directly with patients and health authorities to contain the spread and treat vulnerable patients—while protecting their own wellbeing and that of their families.



Our Response to COVID-19 PANDEMIC

At Masimo, we are committed to supporting the needs of the medical community—for the benefit of care teams and patients alike. At this time there is still much to learn about COVID-19, but what we do know indicates it is highly contagious and spreads easily between people in close contact with one another.

While the full scope and true impact of the crisis cannot be predicted, what is clear is the urgent need for the medical community to prepare for a prolonged outbreak. Our clinical solutions, including noninvasive monitoring technologies and ancillary single-use products, can help care teams with:

- > Surge capacity management efforts
- > Home monitoring and telemedicine
- > Infection control and prevention

Furthermore, the COVID-19 health emergency has created increased demand for medical supplies—including noninvasive monitoring devices, thermometry, single-use sensors, and home monitoring solutions that enable care teams to check in on patients while they remain safely quarantined at home.

We have scaled up production to meet the increased demand for our products. We are committed, as your partner in health, to providing solutions care providers and patients have come to rely on.

From everyone at Masimo, we'd like to thank the medical community for their selfless dedication to the health and well being of patients around the world. It's an honor and a privilege to be trusted to serve alongside you.

COVID - 19 Solutions

Seamlessly Extended Care from Hospital to Home

Surge Capacity Management

Rapidly respond to an increase in patient volume:

- > Quickly adapt non-clinical spaces into advanced care environments with a range of out-of-the box Pulse CO-Oximeters® and vital signs monitors
- > Remotely monitor all patients at a glance at a centralized view station with Patient SafetyNet™
 - With Replica™, view and respond to alarms and alerts from a smartphone, regardless of location
- > Use Early Warning Scores (EWS), configured per hospital protocol, to quickly assess patient status
- > Support patients suffering from pulmonary conditions and respiratory distress with softFlow™, nasal high-flow therapy that administers warmed and humidified respiratory gases through a comfortable nasal cannula

Home Monitoring and Telemedicine

Masimo supplies a range of advanced remote monitoring solutions that help ensure you can monitor with confidence from a distance, including:

- > Secure cloud-based patient management with Masimo SafetyNet™, which combines tetherless pulse oximetry with a remote data capture and surveillance platform
- > Compact, hospital-grade portable monitors with supplemental remote monitoring
- > Automated remote care that facilitates the collection of physiological data and patient responses, while providing notification and guidance



The COVID-19 pandemic has created increased demand across the globe surge capacity management support, home monitoring, telemedicine solutions, infection control, prevention solutions, support for screening and clinical management protocols. Masimo supports surge capacity efforts with a range of noninvasive monitoring and ancillary single-use solutions that can help care teams prepare for and manage an influx of patients quickly and efficiently.

Infection Control and Prevention

Innovative solutions help care teams minimize transmission risks and increase clinician and patient safety:

- > Immediately convert existing monitoring platforms to single-patient or non-contact solutions to minimize cross contamination and help manage infection control
- > Tetherless Radius PPG™ sensors enable the placement of point-of-care monitors outside of a patient's room—ensuring continuous monitoring from a distance
- > Expand visibility of point-of-care monitoring data with wireless supplemental display solutions such as Kite® that can be quickly deployed without any additional IT infrastructure

Remote Home Monitoring Kit

Patients receive a multi-day supply of sensors, along with access to the Masimo SafetyNet mobile application. Powered by Masimo SET® measure-through-motion technology, the tetherless single-patient-use sensor provides continuous respiration rate and oxygen saturation monitoring, with a second tetherless sensor, Radius T®, for continuous temperature measurements. Patient data is sent securely via Bluetooth® to the Masimo SafetyNet™ mobile application.



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended January 2, 2021
OR

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

For the transition period from _____ to _____
Commission File Number 001-33642



MASIMO CORPORATION

(Exact name of registrant as specified in its charter)

DE

(State or Other Jurisdiction of
Incorporation or Organization)

52 Discovery Irvine, CA

(Address of principal executive offices)

33-0368882

(I.R.S. Employer
Identification Number)

92618

(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:

Common Stock, par value \$0.001

Trading symbol:

MASI

Name of each exchange on which registered:

The Nasdaq Stock Market, LLC

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

None

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

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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

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 27, 2020, the last business day of the registrant's most recently completed second fiscal quarter, as reported on the Nasdaq Global Select Market, was approximately \$9.2 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 30, 2021, the registrant had 55,266,559 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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report on Form 10-K.

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MASIMO CORPORATION
FISCAL YEAR 2020 FORM 10-K ANNUAL REPORT
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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 of 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 “would,” and similar expressions and variations or negatives of these words. These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which is subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause our actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed under Item 1A—“Risk Factors” in this 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 and hospital automation solutions. Our mission is to improve patient outcomes and reduce the cost of patient care. Our patient monitoring solutions generally incorporate a monitor or circuit board, proprietary single-patient use or reusable sensors, software and/or cables. We provide our products to hospitals, emergency medical service (EMS) providers, home care providers, long-term care facilities, physician offices, veterinarians and consumers through our direct sales force, distributors and original equipment manufacturers (OEM) partners. 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, 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 regional oximetry monitoring, electrical brain function monitoring, acoustic respiration monitoring, exhaled gas monitoring, nasal high flow ventilation, minimally invasive neuromodulation technology for pain and addiction reduction, hospital automation and connectivity solutions and home wellness and monitoring.

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.

Core Business

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.

Masimo Difference

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 200 million patients each year and has been chosen as the primary pulse oximeter technology used by nine of the top ten hospitals according to the 2020-2021 *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 rainbowSET® Platform

Since introducing Masimo SET®, we have continued to innovate by introducing noninvasive measurements that go beyond arterial blood oxygen saturation and pulse rate. Our Masimo rainbow SET® platform leverages our Masimo SET® technology and incorporates 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 SpO₂, 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 (SpfO₂™).

Additionally, the rainbow SET® platform also allows for the calculation of Oxygen Content (SpOC™) and Oxygen Reserve Index™ (ORi™). SpfO₂™ and ORi™ have received CE Marking, but are not currently available for sale in the U.S.

We believe that Masimo rainbow® Pulse CO-Oximetry products will become widely adopted for the noninvasive monitoring of these measurements in the future. 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 such customers to incrementally expand their patient monitoring systems with a cost-effective solution. To date, over thirty-eight 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.

While SpCO® is not intended to replace invasive carboxyhemoglobin tests, when used with other clinical variables, SpCO® may help clinicians identify elevated CO levels and help determine additional test and treatment options. Multiple leading emergency first responder associations, including the National Association of Emergency Medical Technicians, the National Association of EMS Educators, the International Association of Fire Fighters and the International Association of Fire Chiefs, 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.

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 Perfusion Index (Pi) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. PVi® is displayed as a percentage. The lower the number, the less variability there is in 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. In August 2020, PVi® received FDA 510(k) clearance as a continuous, noninvasive, dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients.

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 (EtCO₂) 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.

In March 2020, RRp® received FDA 510(k) clearance for continuous RRp® monitoring of adult and pediatric patients with Rad-97®, Radical-7® and Radius-7® Pulse Co-Oximeters®. With this clearance, both continuous and spot-check RRp® are now available in the U.S. and supported in a variety of pulse oximetry sensors and configurations, including a non-cabled, tetherless, wearable Radius PPG™.

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 EtCO₂ 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 EtCO₂ 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.

SpfO₂[™]

Prior to our debut of SpfO₂[™], pulse oximeters could only measure and display functional SpO₂ oxygen saturation. Therefore, when patients had elevated carboxyhemoglobin and/or elevated methemoglobin, the displayed *functional* SpO₂ oxygen saturation overestimated the actual oxygen saturation value. SpfO₂[™], 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. SpfO₂[™] has received the 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 SpO₂ 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 unitless 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 (PaO₂). 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

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.

Our NomoLine[®] capnography 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, facilitating easy to use sidestream capnography and gas monitoring. These products have the ability to measure multiple expired gases, such as carbon dioxide (CO₂), nitrous oxide (N₂O), oxygen (O₂) and other anesthetic agents. In addition, respiration rate is calculated from the CO₂ 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. NomoLine® capnography sampling lines have received FDA 510(k) clearance.

O3® Organ Oximetry

O3® organ or Regional Oximetry, also known as tissue or cerebral oximetry, uses near-infrared spectroscopy (NIRS) to provide continuous measurement of tissue oxygen saturation (rSO₂) 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 the CE Mark and FDA 510(k) clearance for use in adult and pediatric patients. In June 2019, we announced FDA 510(k) clearance for use of O3® in infant and neonatal patients. In August 2020, O3® Regional Oximetry received 510(k) clearance for expanded use in monitoring somatic tissue oxygenation saturation in all patient populations and monitoring relative changes in hemoglobin, oxyhemoglobin and deoxyhemoglobin in adult brains. With this FDA 510(k) clearance, O3® Regional Oximetry is now indicated for use in both cerebral and somatic applications, both in the U.S. and in CE Mark countries, for all patient populations.

Advanced Hemodynamic Monitoring Solutions

In December 2020, we acquired a majority ownership stake of LiDCO Group, PLC, which specializes in hemodynamic monitoring solutions. With this acquisition, we will be able to provide clinicians with access to patients' cardiac output, stroke volume and systemic vascular resistance, which are used to assess preload and afterload, to help determine the current state of a patient's hemodynamic stability and whether any interventions are needed to optimize the delivery of oxygen to the tissues. Hemodynamic monitoring solutions is also used to monitor the response to therapies such as vasopressors, inotropes and fluids.

The Masimo Hospital Automation™ Platform

Patient SafetyNet™⁽¹⁾

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 Hospital Automation™ Connectivity, Iris® Gateway, Kite®, UniView™, UniView : 60™ 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® ports 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.

⁽¹⁾ The use of the trademark Patient SafetyNet™ is under license from the University HealthSystem Consortium.

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 a series of studies published between 2010 and 2020 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. Per these studies, over ten years, there were zero preventable deaths or brain damage due to opioid-induced respiratory depression in monitored patients. In addition, we believe these studies demonstrated that the use of Masimo SET® and Patient SafetyNet™ can result in significant cost savings.

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.

Kite®

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™

UniView™, an integrated display of real-time data and alarms from multiple Masimo and third-party devices, designed to reduce clinician cognitive overload and improve patient safety. *UniView™* promotes data sharing and team coordination among multiple clinicians. *UniView™* brings together data from a variety of sources – such as patient monitors, ventilators, anesthesia gas machines, and IV pumps – and provides a supplementary display for them, clearly organized, on one or more large, central monitors, so that all clinicians can simultaneously view and act upon the same, comprehensive real-time patient status and historical trends.

UniView : 60™

UniView : 60™ uses the Masimo Hospital Automation™ platform to aggregate and display pertinent patient information on a digital display just outside each patient's room, allowing clinicians to familiarize themselves with the most relevant details of each patient's case at the door in 60 seconds or less before they see the patient.

Replica™

Replica™, working in conjunction with Patient SafetyNet™, is a mobile application for smart phones and tablets that provides for supplemental remote monitoring and clinician notification. *Replica™* was developed to allow 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.

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.

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, while avoiding installation of separate costly systems and potentially reducing costs by leveraging existing network infrastructure.

Nasal High Flow Ventilation

With the acquisition of TNI medical AG (TNI®) in March 2020, we added TNI softFlow® technology to our product portfolio. The TNI softFlow® technology provides respiratory support by generating a precisely regulated, stable high flow of room air or a mix of room air and oxygen through the nose of the patient by means of thin nasal prongs. Controlled oxygen supply ensures oxygenation while, at the same time, the respiratory airways are humidified. A stable air flow is essential for treating hypoxemic and hypercapnic respiratory failure. Together with the TNI applicator, the TNI Flow generator provides a constant air flow and in doing so, it is completely independent of external pneumatic systems. Due to this, the TNI softFlow® technology is able to treat respiratory insufficiency and allows therapy at home in a manner that is as reliable and efficient as in the hospital.

Neuromodulation Solution

Bridge™ is the first FDA-cleared, drug-free, non-surgical device to use neuromodulation to aid in the reduction of symptoms associated with opioid withdrawal. Bridge™ can be used for patients experiencing opioid withdrawal symptoms, while undergoing treatment for opioid use disorder when initiating treatment, transitioning to naltrexone or tapering off medication-assisted treatment. In addition, we believe Bridge™ may reduce pain and addiction-related side-effects. Bridge™ is a small electrical nerve stimulator device that contains a battery-powered chip and wires that are applied percutaneously around a patient's ear. It requires a prescription and is offered to qualified healthcare professionals with training. Bridge™ has been granted a FDA 510(k) de novo classification.

Coronavirus-2019 (COVID-19) Response and Telehealth Solutions

Masimo SafetyNet™

In an effort to help clinicians and public health officials combat the COVID-19 pandemic, we developed the Masimo SafetyNet™ solution. The Masimo SafetyNet™ solution provides continuous tetherless pulse oximetry and respiration rate monitoring coupled with a patient surveillance platform. We announced the full market release of the Masimo SafetyNet™ solution in April 2020, and it is available worldwide.

In addition, we announced a partnership with Samsung Electronics America (Samsung) to make the Masimo SafetyNet™ Patient App available on select Samsung smartphones, pre-installed and pre-configured.

Masimo SafetyNet-OPEN™

As the COVID-19 pandemic continues, companies and organizations worldwide struggle to find the appropriate balance between reopening and keeping people safe by reducing the risk of infection. Masimo SafetyNet-OPEN™ was designed to help businesses, governments and schools more responsibly manage employee and student health and safety during the COVID-19 pandemic. Masimo SafetyNet-OPEN™ helps address certain challenges of reopening responsibly and safely with a comprehensive, flexible, and easy-to-deploy continuous monitoring solution that, in conjunction with clinical guidance from partner hospitals, helps manage prevention, early identification, and recovery monitoring. As a global leader in noninvasive patient monitoring technologies and advanced connectivity and automation solutions, we believe we are uniquely positioned to provide organizations with tools to assist them in reopening safely.

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 \$1,143.7 million in 2020 from \$738.2 million in 2017, representing a three-year compound annual growth rate of 15.7%. 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 \$958.8 million, or 83.8% of product revenue in 2020, from \$644.7 million, or 87.3% of product revenue, in 2017. 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' SpO₂, PR, RRp® and with rainbow SET®, noninvasive monitoring of hemoglobin and other advanced measurements. 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 measurements of rainbow® Pulse CO-Oximetry (SpHb®, SpCO®, SpMet®, PVi®, SpfO₂™, SpOC™ and ORi™), RAM® and Halo Ion®, as well as future measurements, provide an excellent opportunity to help our customers improve patient care while reducing their overall cost of care.
- *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 physician offices, 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 Hospital Automation™ 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. Hospital Automation™, in conjunction with the Iris® ports found on Root®, 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.
- *Expand Hospital Automation and Connectivity in Hospital Settings.* We believe we can improve and automate the continuum of care through our connectivity platform by reducing complexity by integrating data from multiple disparate monitors and therapeutic devices through Root® and Iris® Gateway; by deploying decision support algorithms like Halo ION®; by saving time through semi-automated and automated bedside vital signs measurement and documentation with

Patient SafetyNet™; by keeping patients connected with their care providers through Masimo SafetyNet™ and Rad 97® when they are discharged from hospitals; by improving data interpretation through adaptable and intuitive displays like UniView™, UniView : 60™ and MyView®; and through remote monitoring via Patient SafetyNet™ and Replica™.

- *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 RAM® 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.
- *Expand Masimo technology into the personal health consumer market.* Our first general wellness and personal health consumer market application was the MightySat®, a fingertip pulse oximeter with five important health and breathing measurements that was targeted at sports, fitness and relaxation. These values include: O₂, PR, RRp®, PI and PVi®. In 2020, we launched four additional products for the consumer market.

We released the Radius T™, a means to monitor a loved one's fever in a hassle-free continuous manner; Masimo Sleep™, a means to help you understand what is going on in your body that may be impacting your sleep; Bridge™, the first FDA-cleared, drug-free, non-surgical device to use neuromodulation to aid in the reduction of symptoms associated with opioid withdrawal; and finally, SafetyNet-OPEN™, a remote patient management solution for tracking key vital signs at the organizational level.

- *Expand the Masimo product portfolio through strategic investments and acquisitions.* In 2020, we successfully completed three strategic acquisitions and an exclusive license agreement, all of which are currently being integrated into our product portfolio. We continually evaluate new and exciting opportunities to expand our product portfolio. After we have applied both our strategic and financial filters, we pursue the opportunities that we believe will add stockholder value, can be successfully integrated within our business and show positive potential to achieve our short and long-term financial forecasts.

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.

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

Patient Monitoring Solutions:

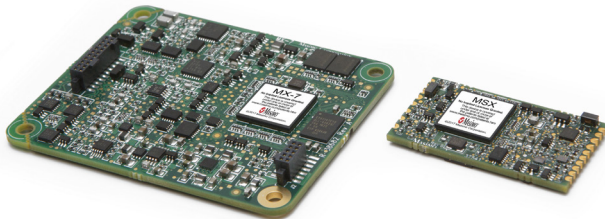
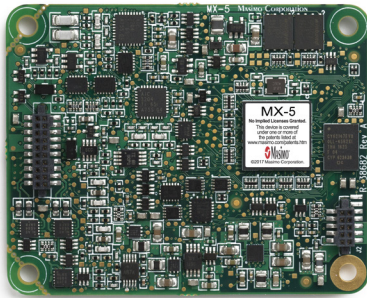
Description:

Use:

Distribution Channel:

Circuit Boards and Modules

(e.g., MX-5, MSX (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

Description:

Use:

Distribution Channel:

Monitors and Devices

(e.g., Radical-7®, Rad-97® (both shown below), Rad-67®, Rad-57®, Root®, Rad-8®, Rad-5®, Radius-7®, Rad-G™, TIR-1™)



- 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

Description:

*Patient Monitoring and Connectivity Platform
(e.g., Root®, Radius-7® and Root® with NIBP (shown below))*



Use:

- 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®)

Distribution Channel:

- Sold directly to end-users and through distributors



- 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

Description:

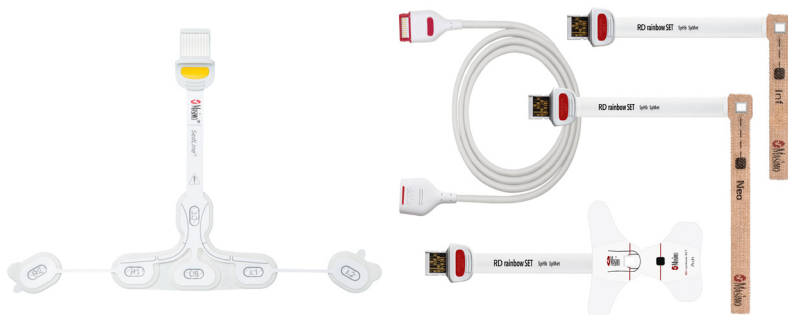
*Sensors
(e.g., SET®, rainbow® Pulse CO-Oximetry, rainbow Acoustic Monitoring® Sensors, RD SedLine™, TFA-1®, RD SET®, RD rainbow SET®, O3® Pediatric, RD rainbow Lite SET®, rainbow® DCI®-Mini, Centroid™, Radius PPG™ (last six shown below))*

Use:

- 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

Distribution Channel:

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

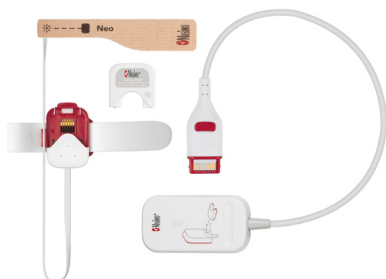


Description:

Use:

Distribution Channel:

Sensors - (Continued)



Description:

Use:

Distribution Channel:

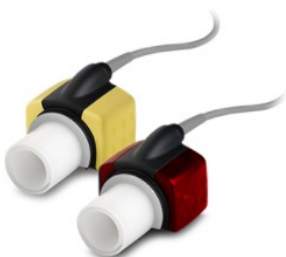
Line Filters and Mainstream Adapters for Capnography and Gas Monitoring

(e.g., NomoLine® Cannula with Radius PCG™ Capnograph with disposable adapter, IRMA CO2, IRMA AX+, and EMMA® (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



Description:

Proprietary Measurements

(e.g., SpHb®, SpCO®, SpMet®, PVi®, RRa®, RRp®, ORi™, 3D Alarms® and Adaptive Threshold Alarm)



Use:

Distribution Channel:

- rainbow® measurements and other proprietary features

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



Description:

Hospital Automation™ and Connectivity Suite

(e.g., Iris® Connectivity, Iris® Gateway, Patient SafetyNet™, UniView™, and UniView : 60™, Replica™, Iris® Analytics, and Halo ION® (shown below))

Use:

Distribution Channel:



- Software and hardware enabling third-party devices to connect through Patient SafetyNet™ and to document data in the EMR

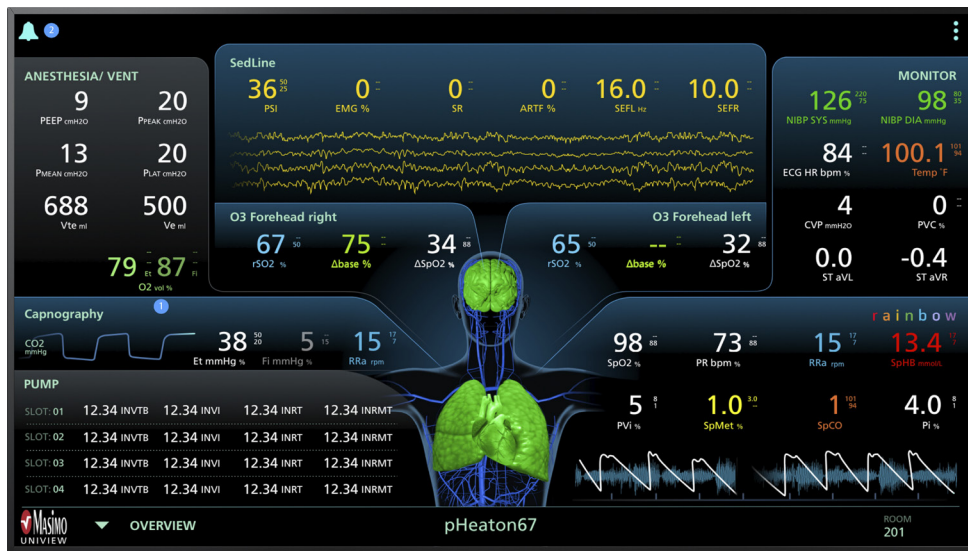
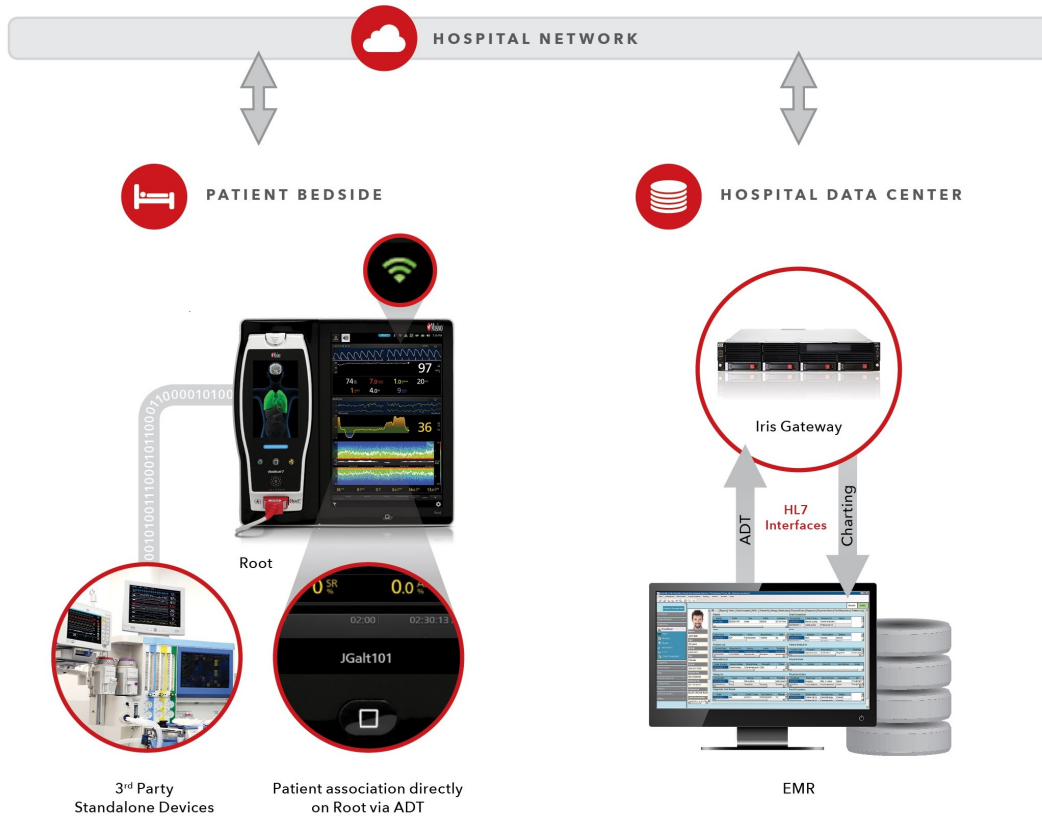
- Sold directly to end-users

Description:

Use:

Distribution Channel:

Hospital Automation and Connectivity Suite - (Continued)



Description:

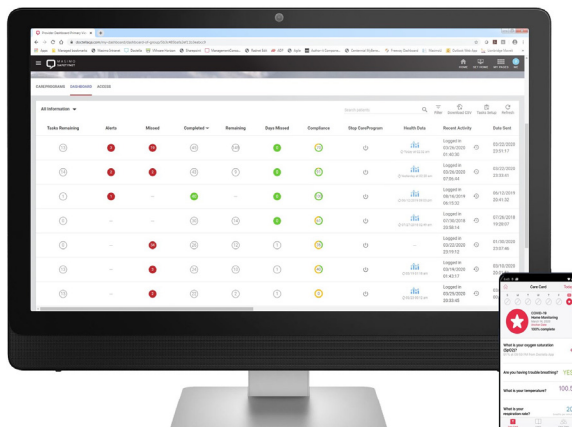
Use:

Distribution Channel:

Hospital Automation and Connectivity Suite - (Continued)



- Network-linked, wired or wireless, multiple patient floor monitoring solutions
- Sold directly to end-users
- Standalone wireless alarm notification solutions



- Home-based patient engagement and remote data capture platform
- Sold directly to end-users and through distributors

Description:

Use:

Distribution Channel:

Nasal High Flow Ventilation (e.g. TNI softFlow® 50 and TNI softFlow® junior (shown below))



- Intensive care and inpatient care in clinics as well as home care
- Sold directly to end-users and through distributors

Description:

Use:

Distribution Channel:

*Home Wellness and Monitoring
(e.g. Radius T[™], Masimo Sleep[™], MightySat[®] with PVi[®] and RRp[®], and iSpO₂[®])*



- Disposable thermometers, disposable fingertip sensors for sleep monitoring, 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 through the Masimo Personal Health website 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 SpO₂, PR and Pi. Our latest MSX family of circuit boards provide Masimo SET[®] SpO₂, PR, and Pi in a variety of small form factors with a typical power consumption of only 45 milliwatts.

uSpO₂[®] 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 uSpO₂[®] 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 uSpO₂[®] 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.

Masimo rainbow SET[®] MX Circuit Boards. Our 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 the full 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 SpO₂, PR and Pi measurement capabilities of Masimo SET[®] pulse oximetry. Customers can choose to purchase additional measurements beyond SpO₂, 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.

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 the CE Mark and FDA 510(k) clearance.

Early Warning Signs (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.

Pathway™, a newborn oxygenation visualization mode for Root®, provides clinicians with a way to visualize a hospital's recommended resuscitation protocol for a newborn's oxygen saturation while continuously monitoring SpO₂ and PR during the first ten minutes after birth. Use of Pathway™ is intended to help streamline clinician workflow and improve protocol adherence during this critical period.

Radical-7®. The Radical-7® Pulse CO-Oximeter® is a wireless touchscreen device that incorporates our MX circuit board to allow upgradeable 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 SpO₂ 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.

Radius PPG™. Radius PPG™ is a tetherless sensor solution powered by Masimo SET® that represents a significant breakthrough in patient monitoring. Radius PPG™ eliminates the need for a cabled connection to a pulse oximetry monitor, allowing patients to move freely and comfortably while still being continuously monitored reliably and accurately. Via wireless connection, measurements are displayed on Masimo host devices or third-party multi-parameter monitors with integrated Masimo technology. Coupled with the proven benefits of Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry, Radius PPG™ is ideally suited for use anywhere patients can benefit from mobility. Radius PPG™ is also available as part of the Masimo SafetyNet™ remote patient management solution designed for at home use.

Radius VSM™. Radius VSM™ is a wearable, tetherless vital signs monitor that provides the ability to monitor a wide variety of physiological measurements, including continuous SET® Pulse Oximetry, noninvasive blood pressure, body temperature, respiration rate and ECG. Designed on a wearable, modular platform, Radius VSM™ features can be scaled to accommodate surges in patient volume and for use across the continuum of patient care, based upon each patient's needs and level of acuity. For additional versatility, Radius VSM™ can operate as a self-contained device or be used wirelessly with Masimo bedside monitors and patient surveillance systems, automating the integration of expanded monitoring and the transfer of continuous monitoring data to EMRs. Radius VSM™ has received the CE Mark, and has been released in limited European markets.

Radius PCG™. Radius PCG™ is a portable-real-time capnograph with wireless Bluetooth® connectivity. Radius PCG™ connects with Root® to provide seamless, tetherless mainstream capnography for patients of all ages. Radius PCG™ has received the CE Mark.

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 Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry technology that can be used to measure SpO₂, 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. 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® has received the CE Mark and FDA 510(k) clearance, 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.

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).

Rad-67®. Rad-67®, our handheld Pulse CO-Oximeter®, is a compact, portable spot-check device that offers Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry technology with SpO₂, PR and Pi measurements and upgradeable rainbow® noninvasive monitoring technology for SpHb®. With the universal reusable rainbow® DCI®-mini sensor, Rad-67® features Next Generation SpHb® technology. The Rad-67® with next generation SpHb® technology has received the CE Mark and FDA 510(k) clearance.

Rad-57®. Rad-57® is a fully featured handheld Pulse CO-Oximeter® that provides continuous, noninvasive measurement of SpO₂, 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® Measure-through Motion and Low Perfusion™ pulse oximetry technology with SpO₂, PR and Pi measurement, but without the ability to update to rainbow® technology. Rad-8® is an affordable, low-cost design 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® Measure-through Motion and Low Perfusion™ technology with SpO₂, PR and Pi measurements, but 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 Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry technology to measure SpO₂, PR, Pi, PVi® and RRp®. Rad-G™ was designed primarily for use in pneumonia screening, spot-checking, and continuous measurement of SpO₂ and RRp® in low-resource settings. Rad-G™ has received FDA 510(k) clearance.

Pronto®. Pronto® is a handheld noninvasive multiparameter testing device that uses Masimo rainbow SET® technology to provide spot-check measurement of SpO₂, 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 SET® Measure-through Motion and Low Perfusion™ pulse oximetry technology, which measures and displays SpO₂, PR and Pi with the option to add PVi® and RRp®. The MightySat® Rx has received the CE Mark and FDA 510(k) clearance. The RRp® measurement on the MightySat® Rx fingertip pulse oximeter has received the CE Mark. MightySat® Rx also received FDA 510(k) clearance of spot-check RRp® measurement.

iSpO₂® Rx. The iSpO₂® 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. iSpO₂® Rx uses Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry technology to measure SpO₂, PR and Pi. The Masimo Professional Health app, available for both iOS® and Android® devices, allows clinicians to track, trend and download patient data. iSpO₂® 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.

O3® MOC-9® Module. Our O3® MOC-9® module for Root® uses NIRS to detect regional hypoxemia by continuously measuring tissue oxygen saturation (rSO₂), 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 CO₂, N₂O, O₂ and anesthetic agent monitoring in many hospital environments.

TIR-I™. Our non-contact clinical-grade infrared thermometer with Bluetooth® connectivity provides forehead temperature measurement across all patient populations. The non-contact module reduces the risk for patient cross-contamination while also reducing costs and waste by eliminating the need for probe covers and other disposables. The Bluetooth® technology automates data transfer to a connected Masimo device, such as Root®, enabling streamlined integration into the bedside device and EMR.

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 150 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.

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 SpO₂ 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 the 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 SpO₂ on the same noninvasive reusable sensor. The rainbow® Super DCI®-mini has received the CE Mark in Europe and Ministry of Health, Labour and Welfare (MHLW) approval in Japan, but is not currently available for sale in the U.S.

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. RAS-45 has received FDA 510(k) clearance and the 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. RD SedLine™ sensors 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 rSO₂. Our pediatric application of O3® regional oximetry with the O3® pediatric sensor for both adult patients and pediatric patients weighing more than 5 kg (11 lbs) and less than 40 kg (88 lbs) has received FDA 510(k) clearance. O3® sensors for use with infants and neonatal patients has also received FDA 510(k) clearance.

Centroid™. Centroid™ is a wearable wireless patient orientation, activity and respiration rate sensor. Centroid™ helps clinicians monitor a patient's position to avoid preventable pressure ulcers and can alert clinicians to sudden movements such as fall-like events. In addition, Centroid™ detects chest movements to continuously provide respiration rate, providing clinicians with additional data that may inform care decisions. Centroid™ pairs with the Root® platform using Bluetooth® to track a patient's posture, orientation and activity. The data transmitted by Centroid™ can be displayed in various formats on Root®, giving clinicians multiple ways to assess adherence to protocols regarding tissue stress and to tailor care to the specific needs of each patient.

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®, SpfO₂™ and RRa®.

Eve™. *Eve™* is 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 Marking, but is currently not available for sale in the U.S.

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 counterfeit 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.

The Masimo Hospital Automation Platform and Iris® Connectivity

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.

Iris®. *Iris®* connectivity ports 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. *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.

Iris® Device Management System (Iris® DMS). *Iris® DMS* is an automation and connectivity solution designed to streamline management of Masimo devices used throughout a hospital system. *Iris® DMS* is designed to address the challenges of maintaining many patient monitors in a complex hospital environment. *Iris® DMS* securely connects over a hospital's existing network to all connected Masimo devices to provide an easy-to-use dashboard that allows biomedical engineers and IT professionals to view detailed diagnostic information about connected Masimo devices at a glance, without the need to physically interact with each device. *Iris® DMS* supports remote software upgrades to ensure all devices stay up to date, easily and efficiently.

Analytics and 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.

Iris® Analytics is a supplemental tool that works in conjunction with the Masimo Hospital Automation™ platform to generate customizable alarm analytics, individual patient reports, and even hospital-wide reports across the continuum of care.

Halo ION®. Halo ION® is a comprehensive, scalable and customizable continuous early warning score. Halo ION® allows clinicians to aggregate trend data from as few as three physiological parameters (for example, SpO₂, PR and PI), and as many as are available, including data from EMRs, into a single continuous early warning score. Each patient's Halo ION® score is displayed on the Masimo Patient SafetyNet™ Supplemental Remote Monitoring and Clinician Notification System as a number ranging from zero to 100, helping to streamline clinicians' patient assessment workflow.

Hospital-to-Home and Wellness

Masimo SafetyNet™ is a home-based patient engagement and remote care automation platform. Originally named Doctella™, Masimo SafetyNet™ provides a complete end-to-end home care solution, allowing clinicians to create and manage treatment plans, patient schedules and patient data flow using automated, customizable CarePrograms™, home device data aggregation, and a web-based provider dashboard. CarePrograms™ are delivered to patients' smartphones via an app (available for both iOS® and Android® devices) and dynamically update based on patient input, including both self-reported data and physiological data collected by connected monitoring devices. Masimo SafetyNet™ was developed in the wake of the COVID-19 pandemic to assist with hospital surge capacity and provide clinicians a secure cloud-based platform to remotely manage a patient's health. Powered by Masimo SET® Measure-through Motion and Low Perfusion™ technology, the tetherless single-patient-use sensor (Radius PPG™) provides continuous respiration rate and oxygen saturation monitoring, with a second tetherless sensor, Radius T^{o™}, for continuous temperature measurements. Patient data is sent securely via Bluetooth to the Masimo SafetyNet™ mobile application.

Radius T^{o™} Continuous Thermometer is a wearable wireless thermometer that continuously and seamlessly measures temperatures using a small, inconspicuous, wearable sensor that can be easily applied to anyone from children to elderly adults with no action needed after initial application to the skin. Radius T^{o™} eliminates manual measurements while providing continuous insight into changes in the user's temperature and helps users understand which way their temperature is trending. In addition, Radius T^{o™} uses proprietary algorithms to provide body temperature measurements, for users five years or older, that approximate oral temperature, not just external skin temperature, with laboratory accuracy within ±0.1°C, whereas other thermometry solutions typically have laboratory accuracy within ±0.2°C.

Masimo Sleep™ was designed to help consumers better understand the quality of their sleep. Masimo Sleep™ is fueled by the same expertise in signal processing and sensor development that drives our hospital products used by leading institutions to monitor millions of patients a year.

MightySat®, our fingertip pulse oximeter for personal use provides SpO₂, 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.

iSpO₂® 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. iSpO₂® uses Measure-through Motion and Low Perfusion™ SET® technology to measure SpO₂, 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. iSpO₂® is available through consumer retailers and directly from Masimo and is intended for general health and wellness use only. iSpO₂® 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, SpO₂, 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, CO₂, 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.

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. Pursuant to the terms of the license, 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.

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.

Product Clearance and Approval Requirements

Many of our products are regulated by numerous government agencies, the most significant of which are the U.S. FDA, the national authorities in the European Union (EU) and the United Kingdom (UK), and MHLW in Japan. In addition, there are government agencies that regulate our products in other countries, whose requirements vary substantially from country to country. These agencies require us to comply with laws that regulate the design, development, clinical trials, testing, manufacture, packaging, labeling, storage, distribution, import, export and promotion of many of our products.

In the U.S., unless an exemption applies, each medical device that we wish to market in the U.S. must, generally, first receive from the FDA either clearance of a 510(k) premarket notification or approval of a premarket application (PMA). In some cases, the device may be authorized by FDA through the *de novo* classification process. The FDA’s 510(k) clearance process requires us to show that our new medical device is substantially equivalent to a legally marketed “predicate” medical device and usually takes from four to nine months, but it may take longer. The PMA process requires us to demonstrate through valid scientific evidence that there is reasonable assurance of safety and effectiveness of the device for its intended use.

The PMA process is much more costly, lengthy and uncertain than the process of obtaining 510(k) clearance. Both 510(k) and PMA submissions are subject to user fees. The FDA determines the appropriate process based on the risk classification of the medical device. There are three classifications, from Class I to Class III. The majority of our current regulated products have been deemed Class II devices, requiring 510(k) clearance, while some have been deemed Class I devices.

Most of our OEM partners are required to obtain clearance or approval of their devices that incorporate Masimo's technologies, like Masimo SET® technology, Masimo rainbow SET® technology, Masimo Board-in-Cable technology, or are used with Masimo's sensors. We generally 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.

In the EU, medical devices are currently subject to the Medical Devices Directive 93/42/EEC (MDD). Under the MDD, a medical device may only be placed on the market within the EU if it conforms to certain "essential requirements". Key requirements include that a medical device achieves its intended performance and does not compromise the clinical condition or safety of patients or the safety and health of users and others, and bears the CE Mark. A medical device that conforms to such essential requirements can bear a CE Mark, which allows the device to be placed on the market throughout the EU. Each medical device that we wish to market in the EU must conform to these requirements.

Conformity is determined through an assessment procedure, which depends upon the risk classification of the device. For our EU medical devices, conformity assessment generally involves a notified body. Notified bodies are often private entities that are authorized or licensed by government authorities to perform, or otherwise have oversight over, such assessments. Notified bodies may also review a manufacturer's quality systems. If the conformity assessment is successfully completed, the manufacturer may apply a CE Mark to the product. This allows the general commercializing of a product in the EU. However, the product can also be subject to local registration requirements depending on the country.

On May 26, 2021, the existing MDD will be repealed and replaced by the Medical Devices Regulation (EU) 2017/745 (MDR). The MDR is similar to the MDD, though it includes significantly more stringent requirements, notably stronger conformity assessment procedures, greater control over notified bodies and their standards, increased transparency, and more robust device vigilance requirements. The MDR will apply to the medical devices we commercialize in the EU after May 26, 2021.

However, the MDR is subject to certain transitional periods that enable certain notified body certificates to remain valid beyond 2021. For some of our devices, this could be as late as May 2024.

The UK exited the EU on December 31, 2020 (Brexit). The UK does not intend to implement the MDR into the laws of Great Britain (England, Scotland and Wales). Northern Ireland is an exception where the MDR will continue to apply. Great Britain instead introduced a new, standalone medical devices framework. Currently, this aligns closely to the MDD. Instead of a CE mark, medical devices marketed in Great Britain must bear a UKCA mark. However, EU CE marks will continue to be recognized in Great Britain until June 30, 2023, as will certificates issued by EU-recognized notified bodies. This arrangement is not reciprocated in the EU. Each medical device that we wish to market in the UK must comply with the national laws in the UK, which going forward may differ from the laws in the EU.

Continuing FDA Regulation

Clinical trials involving medical devices are subject to FDA regulation. Among other requirements, clinical trial sponsors must comply with requirements related to informed consent, Institutional Review Board (IRB) approval, monitoring, reporting, record-keeping, labeling and promotion. If the study involves a significant risk device, the sponsor must obtain FDA approval of an investigational device exemption in addition to IRB approval prior to beginning the study. Information regarding certain device clinical trials must also be submitted to a public database maintained by the National Institutes of Health.

After a device is approved and placed on the market, numerous regulatory requirements continue to apply. These regulatory requirements include, but are not limited to, the following: product listing and establishment registration; adherence to the Quality System Regulation (QSR) which requires stringent testing, control, documentation and other quality assurance procedures for the design, manufacture, storage and handling of devices; labeling requirements and FDA prohibitions against the promotion of off-label uses or indications; adverse event and device malfunction reporting; post-approval restrictions or conditions, including post-approval clinical trials or other required testing; post-market surveillance requirements; the FDA's recall authority, whereby it can ask for, or require, the recall of products from the market; and requirements relating to voluntary corrections or removals. Device manufacturers are subject to announced and unannounced inspections by the FDA to evaluate compliance with these requirements.

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 Federal Food, Drug and Cosmetics Act (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 Certificate of Foreign Government (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.

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). From January 1, 2021, similar rules are in force in the EU. Certain of these conflict minerals are used in the manufacture of our products. Although the U.S. 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.

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. Beginning in 2022, the reporting requirement will also apply to advance practice nurses and physician assistants.

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

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

Data Privacy and Protection of Health and Other Personal Information

Data protection legislation is becoming increasingly common in the United States at both the federal and state level. For example, the California Consumer Privacy Act of 2018 (CCPA), which became effective on January 1, 2020, requires us to make disclosures to consumers about our data collection, use and sharing practices, allows consumers to opt out of certain data sharing with third parties, and provides a cause of action for data breaches. The CCPA, together with the newly passed Consumer Privacy Rights Act, which is effective beginning January 1, 2023, is the most comprehensive data privacy law in the United States, and could be the precursor to other similar legislation in other states or at the federal level. Internationally, the General Data Protection Regulation (GDPR) took effect in May 2018 within the European Economic Area (EEA) and many EEA jurisdictions. Other jurisdictions outside of the EEA have also adopted their own data privacy and protection laws. We have implemented, and continue to implement, procedures and processes to comply with these regulations and, as international data privacy and protection laws continue to evolve, and as new regulations, interpretive guidance and enforcement information become 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.

In addition, numerous federal, state and international laws and regulations, including HIPAA and 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 by our customers 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. 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 included within a statutory benefit category and 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.

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 in 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 physician offices 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.

Markets

Competitive Conditions

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.

In addition, large technology companies that have not historically operated in the healthcare or medical device space, such as Alphabet, Apple, Samsung and others, have developed or may develop products and technologies that may compete with our current or future products and technologies in the consumer and clinical marketplaces.

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. In addition, some of our patents have expired and others 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;
- 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.

Market Demand

We currently sell all of our medical products both directly to hospitals and the alternate care market via our sales force and various distributors in the U.S. and around the world, including Europe, the Middle East, Asia, Latin America, Canada and Australia. We sell our non-medical/consumer products through e-commerce Internet sites such as www.masimopersonalhealth.com and www.amazon.com.

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 technologies. Our sales representatives' primary focus 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.

For the year ended January 2, 2021, two just-in-time distributors, Medline Industries and Cardinal Health, represented approximately 11.5% and 10.1%, respectively, of our total revenue. These were the only two customers that represented 10% or more of our revenue for the year ended December 28, 2019. Importantly, these two distributors take and fulfill orders from our direct customers, many of which have signed long-term sensor purchase agreements with us. If 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 incorporate our technologies into their monitors and sometimes resell our sensors to their installed base. Our OEM agreements allow us to expand the availability of our technologies through the sales and distribution channels of each OEM partner. To facilitate clinician awareness of Masimo technologies, our OEM partners have generally agreed to place the applicable Masimo trademark 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 2020 and 2019, revenue from the sale of our pulse oximetry products to hospitals that are associated with GPOs amounted to \$564.0 million and \$517.6 million, respectively.

Resources

Intellectual Property

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

We have developed a patent portfolio internally, and, to a lesser extent, through acquisitions and licensing, that covers many aspects of our product offerings. As of January 2, 2021, we had approximately 800 issued patents and approximately 500 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 January 2, 2021, we owned approximately 90 U.S. registered trademarks and approximately 300 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 333,400 square feet. All three of these facilities 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.

We will continue to utilize third-party contract manufacturers for products and subassemblies that can be more efficiently manufactured by these parties, such as our circuit boards. We monitor our third-party manufacturers and perform inspections and product tests at various steps in the manufacturing cycle to ensure compliance with our specifications. We also do full functional testing of our circuit boards.

For raw materials, we and our contract manufacturers rely on sole source suppliers for some components, including digital signal processor chips and analog-to-digital converter chips. We and our contract manufacturers have taken steps to minimize the impact of a shortage or stoppage of shipments of digital signal processor chips or analog to digital converter chips, including maintaining a safety stock of inventory and designing software that may be easily ported to another digital signal processor chip.

We believe that our sources of supply for components and raw materials are adequate. In the event of a delay or disruption in the supply of sole source components, we believe that we and our contract manufacturers will be able to locate additional sources of these sole source components on commercially reasonable terms and without experiencing material disruption in our business or operations. We have agreements with certain major suppliers and each agreement provides for varying terms with respect to contract expiration, termination and pricing. Most of these agreements allow for termination upon specified notice, ranging from four to 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.

Human Capital Resources

Core to our long-term strategy for human capital is attracting, developing and retaining the best talent globally with the right skills to drive our future success. We consider our employees to be our greatest assets and the greatest strength behind our innovation and success. We seek to attract and retain highly-talented, experienced and well-educated individuals to support our long-term growth and profitability goals.

Our success and future growth is largely dependent on our ability to recruit, retain and develop a diverse workforce at all levels of the organization. To succeed, we have developed key recruitment and retention strategies that we focus on as part of our overall management of our business. These include:

- **Compensation.** Our compensation programs are designed to align the compensation of our employees with their performance and to provide the proper incentives to attract and retain employees while motivating them to achieve superior results. The structure of our compensation programs balance incentive earnings for both short-term and long-term performance.
 - Our executive compensation is aligned with stockholder interests by aligning pay-for-performance metrics.
 - We utilize nationally-recognized compensation consultants to evaluate our executive compensation benefit programs and provide benchmarking against our peer groups.
 - We provide employee wages that are competitive and consistent with employee positions, experience, skills, knowledge and geography.
 - Our annual increases and cash incentives are based on market and awarded based on merit.
 - We offer a wide variety of benefits, including health insurance, paid time off, retirement plans, and voluntary benefits such as financial and personal wellness benefits, etc.
- **Health and Safety.** We are committed to the safety and well-being of our employees. In response to the COVID-19 pandemic, we implemented changes to our business in an effort to protect our employees and customers and in support of the health and safety protocols. A large majority of our workforce has been working remotely since March 2020, and we instituted safety protocols and procedures for our essential employees who continue to work on site.

We installed plexiglass partitions for our manufacturing/assemblies facilities and implemented extensive cleaning sanitation procedures for our both manufacturing/assembly facilities and our general administration and sales facilities.

- **Developing Leaders of Tomorrow/Succession Planning.** We are committed to identifying and developing the talents of our next generation of leaders. Our executive management team conducts an annual organization and leadership review of all business leaders, focusing on our high-performing and high potential talent, diversity, and the succession planning for critical roles.
- **Employee Feedback and Retention.** In November 2020, we were certified as a Great Place to Work®, earning a positive response of 84%, proving that we have created an amazing employee experience. To assess and improve employee retention and engagement, we survey employees with the assistance of third-party consultants, and take actions to address areas of employee concerns. The average tenure of our employee is approximately 5.5 years and more than 20% of our employees have been employed by us for more than ten years.
- **Diversity.** Our workforce grew at a faster pace than past years, increasing from approximately 1,600 full-time employees and approximately 3,700 dedicated contract personnel worldwide as of December 28, 2019 to 2,000 full-time employees and approximately 4,200 dedicated contract personnel worldwide as of January 2, 2021. Of our full-time employees, approximately 65% were male and approximately 35% were female, and women represented approximately 27% of our management/leadership roles. Minorities represented approximately 49% of our U.S. workforce, of which minorities accounted for approximately 39% of the employees in our management/leadership roles.

Available Information

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 our website, 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.

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.

Summary of Material Risk Factors

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this summary, and other risks that we face, can be found following this summary and should be carefully considered together with all of the other information appearing in this Annual Report on Form 10-K.

- 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.
- 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.
- 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.
- 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.
- 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.
- If we fail to maintain or develop relationships with GPOs, sales of our products would decline.
- 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 or prevent us from realizing revenues from future products.
- Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of existing market participants from certain markets, which could have an adverse effect on our business, results of operations or financial condition.
- 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.
- 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.
- Counterfeit Masimo sensors and third-party medical device reproducers that reprocess our single-patient-use sensors may harm our reputation. Also, these counterfeit 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.
- 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.
- 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.
- 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.

- Our failure to obtain and maintain FDA clearances or approvals on a timely basis, or at all, would prevent us from commercializing our current, upgraded, or new products in the U.S., which could severely harm our business.
- We may be subject to or otherwise affected by federal and state healthcare laws, including fraud and abuse laws, and could face substantial penalties if we are unable to fully comply with these laws.
- Legislative and regulatory changes in the healthcare 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 healthcare reform legislation in the U.S. or in our key international markets.
- 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.
- 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.
- Failure to obtain regulatory authorizations in foreign jurisdictions may prevent us from marketing our products abroad.
- 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.
- Regulatory reforms may impact our ability 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, and may need to initiate voluntary corrective actions such as the recall of our products.
- Promotion of our products using claims that are off-label, unsubstantiated, false or misleading could subject us to substantial penalties.
- The regulatory environment governing information, cybersecurity and privacy laws is increasingly demanding and continues to evolve.
- Our business, financial condition and results of operations may be adversely affected by the COVID-19 pandemic.
- If we are unable to obtain key materials and components from sole or limited source suppliers, we will not be able to deliver our products to customers.
- If our essential employees who are unable to telework become ill or otherwise incapacitated, our operations may be adversely impacted.
- Future strategic initiatives, including acquisitions of businesses and strategic investments, 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 achieve the desired results of our investment.
- Our credit agreement contains certain covenants and restrictions that may limit our flexibility in operating our business.
- We may experience conflicts of interest with Cercacor with respect to business opportunities and other matters.
- 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®.
- 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.
- We may not be able to commercialize our products incorporating licensed rainbow® technology cost-effectively or successfully.
- Rights provided to Cercacor in the Cross-Licensing Agreement may impede a change in control of our company.
- Concentration of ownership of our stock among our existing directors, executive officers and principal stockholders may prevent new investors from influencing significant corporate decisions.
- 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.
- Our bylaws provide that the state or federal courts located within the State of Delaware are the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

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® and Masimo rainbow SET® technologies that serve as the basis of our primary product offerings. Continued market acceptance of products incorporating these technologies 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. Healthcare providers that currently have significant investments in competitive pulse oximetry products may be reluctant to purchase our products. If hospitals and other healthcare providers do not believe our Masimo SET® and Masimo rainbow SET® platforms are 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. Our product portfolio continues to expand, and we are investing significant resources to enter into, and in some cases create, new markets for these products. 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 healthcare 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.

On March 30, 2020, we acquired TNI medical AG (TNI®) and added TNI softFlow® technology to our product portfolio. The TNI softFlow® technology provides respiratory support by generating a precisely regulated, stable high flow of room air or a mix of room air and oxygen. The TNI softFlow® technology is our first therapeutic product. We may not be able to achieve market acceptance of the TNI softFlow® technology, and any potential revenue from the TNI softFlow® technology could be limited, which would adversely affect our business, financial condition and results of operations.

In December 2020, we acquired a majority ownership of LiDCO Group, PLC, and added hemodynamic monitoring solutions to our product portfolio. The hemodynamic monitoring solutions provide clinicians with access to patients' cardiac output, stroke volume and systemic vascular resistance. We may not be able to achieve market acceptance of the hemodynamic monitoring solutions, and any potential revenue from it could be limited, which would adversely affect our business, financial condition and result 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:

- 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
- 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, effectively pricing their competing products at a loss.

Continuing technological advances and new product introductions within the medical device industry place our products at risk of obsolescence. For example, in September 2020, Apple, Inc. announced that its Apple Watch Series 6 includes a pulse oximetry monitoring feature, which may compete with certain of our existing products and products in development, including the consumer versions of our iSpO₂® and MightySat® pulse oximeters. 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. In addition, we may not be able to develop and successfully commercialize new products and technologies that we acquire. For example, in March 2020, we acquired TNI® and added TNI softFlow® technology to our product portfolio. As this is our first therapeutic product, we may not be able to successfully commercialize the TNI softFlow® technology for respiratory support applications. Also, in December 2020, we acquired majority ownership of LiDCO Group, PLC, and added hemodynamic monitoring solutions to our product portfolio. As these are our first therapeutic and hemodynamic monitoring solutions, we may not be able to successfully commercialize or obtain market acceptance of these products.

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 those of our products that are cleared or approved for use, 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 regulatory clearance or approval of their competing products. Competition could result in pressure from our

customers to reduce the price of our products and could cause them to 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 Alphabet Inc., Apple Inc., Samsung Electronics Co., Ltd. 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.

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 the choices 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 represent approximately 75% of our U.S. product sales. 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 or prevent us from realizing revenues from future products.

Sales of our products depend in part on the reimbursement and coverage policies of governmental and private healthcare 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 or begin reimbursing 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 for the use of such products.

These trends could lead to pressure to reduce prices for our current and future products, hinder our ability to obtain market adoption, 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 healthcare 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 healthcare costs and control healthcare expenditures as those in the U.S. In addition, as economies of emerging markets develop, these countries may implement changes in their healthcare 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 existing market participants from certain 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 existing market participants 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.

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.

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. Any reductions in capital spending budgets by hospitals 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.

From time to time, states and other local regulatory authorities may issue guidelines regarding the appropriate scope and use of our products. 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 of our products.

Additionally, increases in demand resulting from global medical crises such as the COVID-19 pandemic may be short lived. If the increased demand results in a stockpiling of our products by, or excess inventory at, our customers, future orders may be delayed or canceled until such on-hand inventory is consumed.

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 10% or more of our product sales for the fiscal year ended January 2, 2021. We cannot provide any assurances 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) related to its U.S. sales, and more recently, revenue from non-recurring engineering (NRE) services for a certain OEM customer. However, Medtronic is no longer required to pay us royalties and we have completed the majority of our contracted NRE services. We have not replaced this royalty and NRE services revenue with similar revenues, and such loss of revenue had an adverse effect on our results of operations for the fiscal year ended January 2, 2021.

Counterfeit Masimo sensors and third-party medical device reproducers that reprocess our single-patient-use sensors may harm our reputation. Also, these counterfeit 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 entities are manufacturing and selling counterfeit Masimo sensors. In addition, certain medical device reproducers have been collecting our used single-patient-use sensors from hospitals and then reprocessing, repackaging and reselling those sensors to hospitals. These counterfeit and third-party reprocessed sensors are sold at lower prices than new Masimo sensors. Our experience with both these counterfeit 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 counterfeit manufacturers and third-party reproducers in an effort to reduce their sensor costs.

These counterfeit 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 counterfeit or reprocessed sensors are original Masimo sensors.

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

In response to these counterfeit sensors and third-party reproducers, 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.

Certain of our patents related to our technologies have begun to expire. Upon the expiration of our issued or licensed patents, we generally 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 narrow the scope of patent protection available and weaken 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.

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. We believe some of the new market entrants in the healthcare and monitoring space, including some of the world's largest technology companies, may be infringing our intellectual property, and we may be required to engage in additional litigation to protect our intellectual property in the future. In addition, we believe that certain individuals who previously held high level technical and clinical positions with us misappropriated our intellectual property for the benefit of themselves and other companies.

For example, on January 9, 2020, we initiated litigation against Apple Inc. for infringement of a number of patents, for trade secret misappropriation and for ownership and correction of inventorship of a number of Apple Inc. patents that list one of our former employees as an inventor. 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, upgraded or new products in the U.S., which could severely harm our business.

Unless an exemption applies, each medical device that we 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* classification review process or obtaining approval of a premarket approval (PMA) application. Even if regulatory clearance or approval of a product is granted, the U.S. Food and Drug Administration (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 new 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 four to nine 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, FDA 510(k) clearance can be delayed for our products in some cases.

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 study 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, if the study involves a significant risk device, we are 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. In addition, public health emergencies and other extraordinary circumstances may disrupt the conduct of our clinical trials. 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* classification 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 review 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 year from the time of submission of the PMA, but may be longer.

We sell consumer versions of our iSpO₂® and MightySat® pulse oximeters that are not intended for medical use. Some of our products or product features may not be subject to 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. In addition, we may market certain products pursuant to enforcement discretion policies the FDA has recently announced to address the need for these products as a result of the COVID-19 pandemic. Such policies only remain in effect during the public health emergency, such that we will need to seek clearance or approval of such products to continue marketing these products at the end of the COVID-19 pandemic. If the FDA changes its policies or concludes that our marketing of these products is not in accordance with its current policies 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* classification review 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 certain of 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 California 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;
- 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/or meet certain pre-marketing requirements) 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.

Furthermore, foreign regulatory requirements may change from time to time, which could adversely affect our ability to market new products, and/or continue to market existing products, internationally. Certain significant changes in the international regulatory landscape have recently taken place or will take place in the near future.

These include the new EU Medical Devices Regulation (EU) 2017/745 (MDR) coming into effect from May 26, 2021 and a new regulatory regime applying in the UK from January 1, 2021 as a result of the UK's exit from the EU on December 31, 2020 (Brexit).

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 modification to a device that is cleared by the FDA that could significantly affect its safety or effectiveness or that could constitute a major change in its intended use would require a new clearance or approval and certain modifications to devices cleared or approved by foreign regulatory authorities may also require a new clearance or approval.

We may not be able to obtain such clearances or approvals in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business, financial condition and results of operations.

For device modifications that we conclude do not require a new regulatory clearance or approval, we may be required to recall and to stop marketing the modified devices if the government agency disagrees with our conclusion and requires new clearances or approvals for the modifications. This could have an adverse effect on our business, financial condition and results of operations.

During the COVID-19 pandemic, the FDA has issued enforcement policies under which the agency has said it will not require clearance of a new 510(k) for certain modifications to 510(k)-cleared non-invasive vital-sign patient monitoring devices. However, these policies remain in effect only during the COVID-19 pandemic. Manufacturers that make modifications pursuant to these policies will need to stop marketing the modifications at the end of the COVID-19 pandemic unless the manufacturer receives 510(k) clearance for the modifications.

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

From time to time, legislation is drafted and introduced by governments 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 services, and created 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, regulations and guidance are often revised or reinterpreted by the government agency 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. Public health emergencies may also prompt temporary or permanent regulatory reforms that could change the processes governing the clearance or approval, manufacture and marketing of medical devices.

In the EU, for example, the new Medical Devices Regulation (EU) 2017/745 (MDR) will apply to our medical devices from May 26, 2021. The MDR will require medical devices and their manufacturers to comply with more stringent standards than before. The MDR also imposes new and enhanced obligations on importers and distributors of medical devices in the EU. Although the MDR is subject to certain transitional periods, both we and others involved in the distribution and commercialization of our medical devices in the EU will need to comply with more stringent EU rules.

Due to Brexit, from January 1, 2021, a new regulatory framework applies to medical devices commercialized in Great Britain (England, Scotland and Wales). This is now separate to the regime in the EU. Although certain transition periods apply until June 30, 2023, the medical devices we intend to commercialize in Great Britain will need to conform to different requirements than the requirements in the EU. These factors are likely to add more complexity to our regulatory compliance obligations in Europe and our ability to commercialize medical devices in European markets.

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, and may need to initiate voluntary corrective actions such as the recall of our products.

Regulatory agencies in many countries require us to report anytime 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. For example, 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 be likely to cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices on the market 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.

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 or other regulations 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. While certain U.S. courts have held that truthful, non-misleading, off-label information is protected under the First Amendment under certain circumstances, the FDA continues to take the position that off-label promotion is subject to enforcement action.

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 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, such as the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), 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. The California Consumer Privacy Act of 2018 (CCPA), which became effective on January 1, 2020, requires us to make new disclosures to consumers about our data collection, use and sharing practices.

The CCPA also allows consumers to opt out of certain data sharing with third parties, and provides a new cause of action for data breaches with the possibility of significant statutory damage awards as well as injunctive or declaratory relief if there has been unauthorized access, theft or disclosure of personal information due to failure to implement reasonable security procedures. The impact of the CCPA on our business is yet to be determined, but it could result in increased operating expenses as well as additional exposure to the risk of litigation by or on behalf of consumers.

The CCPA is the most comprehensive data privacy regulation to date in the United States, and could be the precursor to similar legislation in other states or at the federal level. Internationally, the General Data Protection Regulation (GDPR) took effect in May 2018 within 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 Singapore, South Korea, China, Brazil, Mexico 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 become 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.

Violations of these laws, or allegations of such violations, could subject us to monetary and non-monetary penalties for noncompliance, disrupt our operations, involve significant management distraction, subject us to class action lawsuits 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 healthcare laws, including fraud and abuse laws, and could face substantial penalties if we are unable to fully comply with these laws.

Healthcare 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 healthcare 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;
- the Physician Payments 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.; and
- state laws analogous to each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by governmental programs and non-governmental third-party payers, including commercial insurers.

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 healthcare 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 healthcare 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 healthcare reform legislation in the U.S. or in our key international markets.

Changes in the healthcare 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 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, the Tax Cuts and Jobs Act of 2017 (TCJA), 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.

In December 2018, a federal district court judge in Texas found the ACA's individual mandate to be unconstitutional; and therefore, the entire law to be invalid. In December 2019, the Fifth Circuit affirmed the ruling regarding the individual mandate but remanded the case to the district court for additional analysis of the question of severability and whether portions of the law remain valid. In November 2020, the U.S. Supreme Court heard the case and is expected to issue an opinion by June 2021. Although we cannot predict the ultimate content or timing of any healthcare reform legislation or court challenges to the ACA, potential changes resulting from any amendment, repeal, replacement or invalidation of these programs, including any reduction in the future availability of healthcare insurance benefits, may 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 healthcare 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 healthcare providers, pursuant to which we are required by law to disclose payments and other transfers of value to healthcare providers licensed by certain states.

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

Our business, financial condition and results of operations may be adversely affected by the COVID-19 pandemic.

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China and has since spread to many other countries, including the United States, where we have our principal executive offices and principal operations, Switzerland, where we have our international headquarters, and Mexico, where we have significant manufacturing operations. Government-imposed travel restrictions have resulted, and may continue to result, in direct operational and administrative disruptions to our domestic and foreign facilities. In addition, quarantines, shelter-in-place and similar orders by local governments have impacted and could further impact the productivity of our manufacturing, engineering, sales and administrative staff and facilities in the United States and other countries. Our operations would be disrupted if any of our employees or employees of our business partners were suspected of having contracted COVID-19, which could require quarantine of some or all such employees or closure of our facilities for disinfection.

If the current pace of the COVID-19 pandemic cannot be slowed and the spread of the virus is not contained, our business operations could be further delayed or interrupted. We expect that government and health authorities may announce new or extend existing restrictions, which could require us to make further adjustments to our operations in order to comply with any such restrictions. We may also experience limitations in employee resources. In addition, global supply chains and the timely availability of raw materials and products may be materially disrupted by quarantines, factory slowdowns or shutdowns, border closings and travel restrictions resulting from the COVID-19 pandemic.

The adverse effects of the COVID-19 pandemic on our business could be material in future periods, particularly if there are significant and prolonged economic slowdowns in regions where we derive a significant amount of our revenue or profit, or where our suppliers are located, or if we are forced to close facilities and limit or cease manufacturing operations for extended periods of time. Although we are currently experiencing an increase in the demand for our products, we could experience delays in receipt of customer payments. In addition, our ability to fulfill orders placed with us within the order's specified time line and for the cost we estimated when we accepted the order may be negatively affected.

Furthermore, we are unable to determine if the increase we are experiencing in the demand for our products is being driven by increased usage of our products or the stockpiling of our products by our customers, the latter of which could result in the delay or cancellation of future orders until such on-hand inventory is consumed. These factors could lead to a reduction in revenues, unfavorable gross margin impact due to product mix, and/or a delay in cash flows in future periods and have a material adverse effect on our business, financial condition and results of operations.

The COVID-19 pandemic has also led to extreme volatility in capital markets and a decline in interest rates, and has adversely affected, and may continue to adversely affect, the market price of our common stock. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, a continued or widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. The extent to which COVID-19 impacts our business and financial results continues to depend on numerous evolving factors that we are not able to accurately predict.

If our essential employees who are unable to telework become ill or otherwise incapacitated, our operations may be adversely impacted.

As a medical device manufacturer, we believe we fall within a "critical essential infrastructure" sector, specifically the "Healthcare/Public Health" sector, and we are considered exempt under various stay at home/shelter in place orders (Stay at Home Orders), including the Blueprint for a Safer Economy first implemented in August 2020 and the Stay Home Order in effect since March 2020, each of which places certain restrictions on persons and businesses in California. Accordingly, our employees in California and other locations may continue to work because of the importance of our operations to the health and well-being of citizens in the states in which we operate. Consistent with these Stay at Home Orders, we have implemented telework policies wherever possible for appropriate categories of "nonessential" employees. "Essential" employees that are unable to telework continue to work at our facilities. We have implemented a number of safety measures for our facilities, including social distancing, face covering, temperature checking and increased sanitation standards. We are following guidance from the Center for Disease Control and the Occupational Safety and Health Administration regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. While we have developed and implemented, and continue to develop and implement, health and safety guidelines in an effort to try to mitigate the negative impact of COVID-19, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that our employees will not otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

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.

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.

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

We depend on certain sole or limited source suppliers for certain key materials and components, including digital signal processor chips and analog-to-digital converter chips, for our noninvasive patient monitoring solutions.

These suppliers are located around the world, and the production and shipment of such materials and components may be constrained globally due to the COVID-19 pandemic. We may experience manufacturing problems related to these suppliers and other outside sources if such suppliers fail to develop, manufacture or 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.

Future strategic initiatives, including acquisitions of businesses and strategic investments, 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 achieve the desired results of our investment.

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 and/or external strategic investments depends on our ability to successfully conduct due diligence, negotiate acceptable terms, evaluate prospective opportunities and bring acquired technologies and/or products to market at acceptable margins and operating expense levels. For example, in March 2020, we acquired TNI® and added TNI softFlow® technology to our product portfolio. In addition, in December 2020, we acquired a majority of ownership of LiDCO Group, PLC, which specializes in hemodynamic monitoring solutions.

As these are our first therapeutic and hemodynamic monitoring solutions, the integration of these technologies may require substantial management time and attention and may divert attention and resources from other important areas, including our existing business and product lines, and we may not be able to sell the TNI softFlow® technology and hemodynamic monitoring solutions 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, product liabilities or other undisclosed liabilities that we did not uncover prior to our acquisition or investment, which could result in us becoming subject to penalties, other liabilities or asset impairments. In addition, if we do not achieve the anticipated benefits of an acquisition or other external investment as rapidly as expected, or at all, investors or analysts may downgrade our stock.

We also expect to continue to carry out internal strategic initiatives 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 our investments in these initiatives continue to be in the long-term best interests of Masimo and our stockholders, there are no assurances that such initiatives will yield favorable results for us. Accordingly, if these initiatives are not successful, our business, financial condition and results of operations could be adversely affected.

If these risks materialize, our stock price could be materially adversely affected. Any difficulties in the integration of acquired businesses or unexpected penalties, liabilities or asset impairments in connection with such acquisitions or investments could have a material adverse effect on our business, financial condition and results of operations.

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. See Note 15 to our accompanying condensed consolidated financial statements included in Part I, Item 1 of this Annual Report on Form 10-K for additional information on our Credit Facility.

Risks Related to Our Stock

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

As of January 2, 2021, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 9.4% 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 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 certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our 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 certificate of incorporation provides for a staggered Board, 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.

Our bylaws provide that the state or federal courts located within the State of Delaware are the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that the state or federal courts located within the State of Delaware are the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees or stockholders to our stockholders, (iii) any action asserting a claim against us arising pursuant to the General Corporation Law of the State of Delaware, our certificate of incorporation or our bylaws or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine. However, this choice of forum provision does not apply to (a) actions in which the Court of Chancery in the State of Delaware concludes that an indispensable party is not subject to the jurisdiction of Delaware courts, or (b) actions in which a federal court has assumed exclusive jurisdiction to a proceeding. This choice of forum provision is not intended to apply to any actions brought under the Securities Act of 1933, as amended (the Securities Act), or the Securities Exchange Act of 1934, as amended (the Exchange Act). Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees or stockholders, which may discourage such lawsuits against us and our directors, officers and other employees or stockholders.

Furthermore, the enforceability of similar choice of forum provisions in other companies’ certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

If a court were to find the choice of forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition and results of operations.

General Risk Factors

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.

We may experience significant fluctuations in our periodic financial 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 may raise the probability of inflationary pressures and contribute to future interest rate volatility.

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.

We are also unable to predict how changing global economic conditions or potential global health concerns such as the COVID-19 pandemic will affect our critical customers, suppliers and distributors. Any negative impact of such matters 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.

In addition, the methods, estimates and judgments that we use in applying our accounting policies are, by their nature, are 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 I, Item 2 of this Annual Report on Form 10-K.

Recent accounting changes related to our embedded leases within certain deferred equipment agreements have also resulted in the acceleration of the timing related to our recognition of revenue and expenses associated with certain equipment provided to customers at no up-front charge. Since we cannot control the timing of when our customers will request us to deliver such equipment, our revenue and costs with respect to leased equipment could vary substantially in any given quarter or year, which could further increase quarterly or annual fluctuations within our financial results.

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 issued new accounting standards that impact our reporting of revenue and expenses, including Accounting Standards Codification (ASC) Topic 606, *Revenue from Contracts with Customers* and ASC Topic 842, *Leases*. Changes made by these new accounting standards not only apply prospectively, but depending on the method of adoption, may also recast previously reported results.

For additional information related to the impact of new accounting pronouncements, please see Note 2 to our accompanying condensed consolidated financial statements included in Part I, Item 1 of this Annual Report on Form 10-K.

In addition, the TCJA, which went into effect in December 2017, made changes to the corporate tax rate, business-related deductions and taxation of foreign earnings, among others, U.S. federal and state regulatory and standard-setting bodies continue to issue guidance and regulations related to the TCJA that could have a material financial statement impact on our effective tax rate in future periods. The implementation by us of new practices and processes designed to comply with, and

benefit from, the TCJA and its rules and regulations could require us to make substantial changes to our business practices, allocate additional resources, and increase our costs, which could negatively affect our business, results of operations and financial condition.

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, including as a result of the COVID-19 pandemic, 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 do not maintain any "key person" life insurance policies with respect to any of our key personnel.

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, and the number of H1-B visas available, as well as the process to obtain them, may be subject to significant change. 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. On June 22, 2020, President Trump signed an executive order temporarily halting certain work visa programs, including the H1-B visa program. The executive order took effect on June 24, 2020 and was extended in December 2020 to remain in effect until March 31, 2021. While the executive order does not impact current employees that are working under Masimo-sponsored temporary work visas, including H1-B visas, the executive order could impact our ability to recruit and hire qualified skilled personnel.

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 33% 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. For example, we have had sales of medical products destined for Iran.

Although these activities have not been financially material to our business, financial condition or results of operations, and were undertaken in accordance with general licenses authorizing such activities issued by the U.S. Treasury Department's Office of Foreign Assets Control, we may not be successful in ensuring compliance with limitation or restrictions on business in Iran or any other countries subject to economic sanctions and embargoes imposed by the United States. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, manufacturing and sales activities. Any material decrease in our international sales would adversely affect our business, financial condition and results of operations.

In June 2016, the United Kingdom (UK) held a referendum pursuant to which voters elected to leave the EU, commonly referred to as Brexit. The UK formally left the EU on January 31, 2020 and began a transition period that ended on December 31, 2020. Although the long-term effects of Brexit have yet to be seen, and the UK is in the process of negotiating trade deals with other countries, 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 instituted or are considering imposing tariffs on certain U.S. goods. In addition, the U.S. has recently negotiated new trade agreements that could impact us, including the United States-Mexico-Canada Agreement (USMCA), which went into force on July 1, 2020 and replaced 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 healthcare 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.

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 the approximation of the exchange rates applied 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 an approximation of the average monthly exchange rates applicable 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 I, Item 3 of this Annual Report on Form 10-K.

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

We rely on manufacturing facilities in California, New Hampshire and Mexico 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 global manufacturing and distribution are dependent upon our manufacturing facilities in Mexico, and the expedient importation of raw materials and exportation of finished goods between the U.S. and Mexico. Undue delays and/or closures of the proximal cross-border transit facilities, or any restrictions by the U.S. federal administration related to the movement of goods across the U.S. and Mexico border, may adversely affect our ability to fulfill orders and supply our healthcare provider customers with essential replenishment supplies, as well as adversely impact our business, operating results and financial condition.

In addition, our manufacturing facilities in Mexico are authorized to operate under the Mexican Maquiladora (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.

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

We are required to prepare and disclose certain information under the Securities Exchange Act of 1934, as amended, 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 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 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 created, and will create, additional compliance requirements for us. For example, the Dodd-Frank Act includes provisions regarding, among other things, advisory votes on named executive officer compensation and "conflict minerals" reporting. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business, financial condition and results of operations. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses. 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.

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 being 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.

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. In addition, as we continue to expand our product portfolio, we may enter or create new markets, including consumer markets, that may expose us to additional product liability risks. For example, with the acquisition of TNI® in March 2020, we added TNI softFlow® technology to our product portfolio. While this technology provides efficient, quiet and comfortable respiratory support to patients, it may present increased risk of infection to caregivers.

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.

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 systems and networks, including the confidentiality, availability and integrity of any underlying information and data, and those of our customers, partners, suppliers and third-party service providers. 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.

Discontinuation, reform or replacement of LIBOR and other benchmark rates, or uncertainty related to the potential for any of the foregoing, may adversely affect our business.

The U.K. Financial Conduct Authority announced in 2017 that it intends to phase out the London Inter-Bank Offered Rate (LIBOR) by the end of 2021. In addition, other regulators have suggested reforming or replacing other benchmark rates. The discontinuation, reform or replacement of LIBOR or any other benchmark rates may have an unpredictable impact on contractual mechanics in the credit markets or cause disruption to the broader financial markets. Uncertainty as to the nature of such potential discontinuation, reform or replacement may also negatively impact interest expense related to borrowings under our Credit Facility.

Borrowings under our Credit Facility bear interest, at our election, either at the Alternate Base Rate (as defined in the Credit Facility), or at the Adjusted LIBO Rate (as defined in the Credit Facility), which is derived from LIBOR. We may in the future pursue amendments to our Credit Facility to provide for a transition mechanism or other reference rate in anticipation of LIBOR's discontinuation, but we may not be able to reach agreement with our lenders on any such amendments. As a result, additional financing to replace any then-outstanding LIBOR-based debt may be unavailable, more expensive or restricted by the terms of such outstanding indebtedness.

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 \$148.38 to \$271.35 per share from December 29, 2019 to January 2, 2021. Factors contributing to our stock price volatility may include our financial performance, as well as broader economic, political and market factors, including the COVID-19 pandemic. 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;
- 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;
- effects of public health crises, epidemics and pandemics, such as the COVID-19 pandemic;
- 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.

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 January 2, 2021, approximately 11.1 million shares of our common stock were reserved for issuance under our equity incentive plans, of which approximately 3.4 million shares were subject to options outstanding at such date at a weighted-average exercise price of \$77.44 per share, approximately 2.9 million shares were subject to outstanding RSUs, approximately 0.4 million shares were subject to outstanding PSUs and approximately 4.4 million shares were available for future awards under our 2017 Equity Incentive Plan. Over the past 36 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.

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.

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. In addition, under certain circumstances, our Credit Facility may limit our ability to pay cash dividends, repurchase our common stock or make other distributions to stockholders. 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.

Any repurchase of our common stock under the stock repurchase plan authorized by our Board in July 2018 (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 17 to our accompanying condensed consolidated financial statements included in Part I, Item 1 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.

ITEM 2. PROPERTIES

We own two facilities in Irvine, California with combined square footage of approximately 314,400 that house our corporate headquarters and the majority of our U.S. research and development activities. We also own approximately 86,500 square feet of property in Hudson, New Hampshire, which is used to develop and manufacture advanced light emitting diodes and other advanced component-level technologies, as well as warehousing and administrative operations. Additionally, we own approximately 79,300 square feet of property in Neuchatel, Switzerland, that houses our international headquarters.

We continue to lease and occupy various other buildings in California and other locations in the U.S. approximating a total of 168,800 square feet for product manufacturing, warehousing, distribution and sales support operations. These leases expire from February 2022 through September 2030. We also operate multiple facilities in Mexicali and San Luis Rio Colorado, Mexico with combined square footage of approximately 333,400 square feet, which are used for manufacturing and warehousing 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 that are guaranteed by us. These leases expire in August 2024.

We also lease and occupy various other facilities throughout the world to operate our business. We believe that our existing facilities are adequate to meet our needs and that existing needs and future growth can be accommodated by purchasing or leasing alternative or additional space.

ITEM 3. LEGAL PROCEEDINGS

The information set forth in Note 21 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.

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 16, 2021, the closing price of our stock was \$273.52 per share, and the number of stockholders of record, excluding persons whose stock is in nominee or “street name” accounts through brokers, was 18.

Dividend Policy

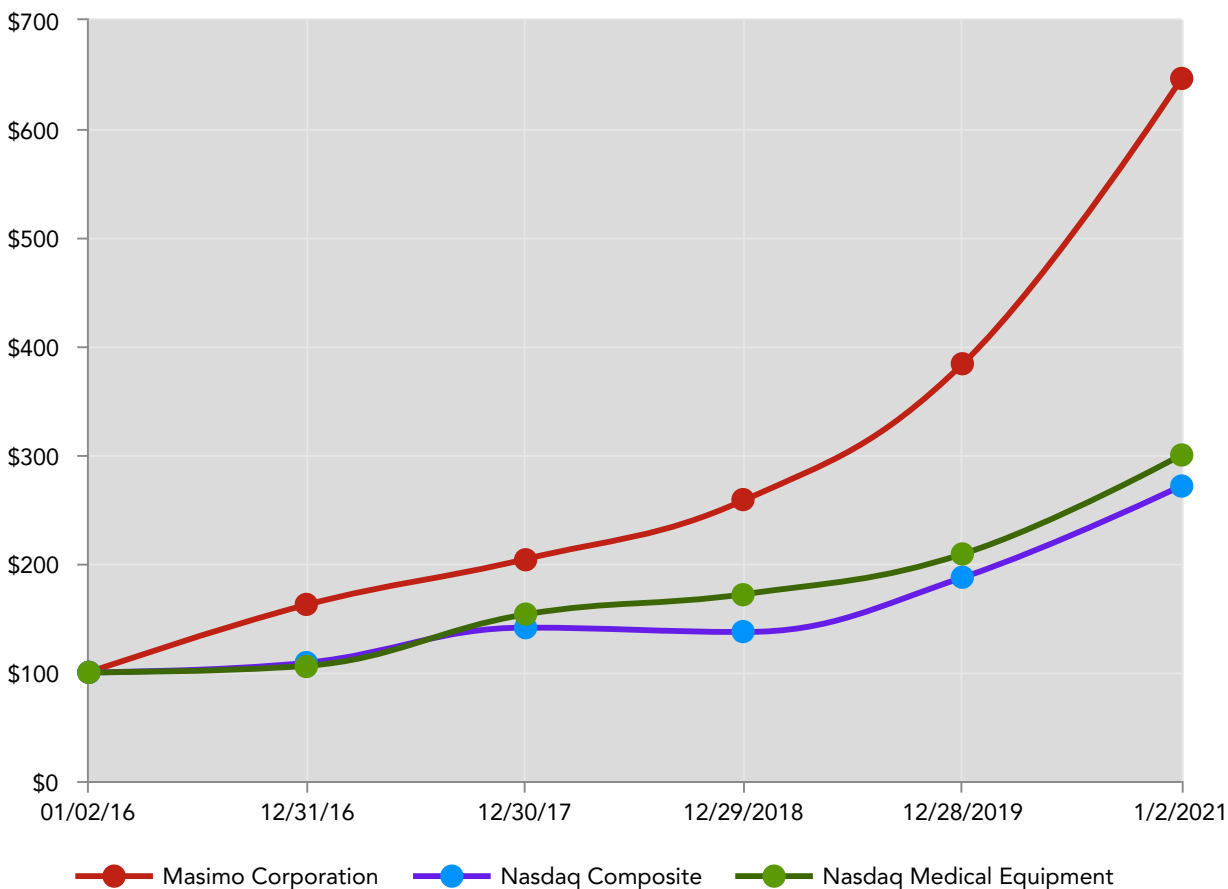
We have historically not paid dividends to our stockholders. Any determination to declare and pay dividends will be made by our Board and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our Board. In addition, under certain circumstances, our Credit Facility may limit our ability to pay cash dividends. In the event a dividend is declared, there is no assurance with respect to the amount, timing or frequency of any such dividends. The dividend declared in 2012 was deemed to be a special dividend and there is no assurance that special dividends will be declared again during the expected term.

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 our common stock from January 2, 2016 through January 2, 2021 against the Nasdaq Market Composite Index and Nasdaq Medical Equipment Index, assuming a \$100 investment made on January 2, 2016. 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.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
 Among Masimo Corporation, the Nasdaq Market Composite Index, and
 the Nasdaq Medical Equipment Index



*\$100 invested on 1/2/2016 in stock or in index, including reinvestment of dividends. Indexes calculated on month-end basis.

Repurchases and Withholdings of Issuer Securities

In July 2018, our Board of Directors (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 (Repurchase Program). The Repurchase Program became effective in September 2018. We expect to fund the Repurchase Program through its available cash, cash expected to be generated from future operations and other potential sources of capital. The 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 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. During the year ended January 2, 2021, we repurchased approximately 0.5 million shares under the Repurchase Program at an average cost of \$242.40 per share, totaling approximately \$110.5 million. The total remaining shares authorized for repurchase under the Repurchase Program approximated 4.3 million shares as of January 2, 2021.

Issuer Repurchases and Withholdings of Equity Securities

During the three months ended January 2, 2021, we effected stock repurchases pursuant to the Repurchase Program. Shares repurchased by us or withheld to satisfy tax withholding obligations during each fiscal month of the quarter ended January 2, 2021 were as follows:

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs ⁽¹⁾
September 27, 2020 to October 24, 2020.....	—	\$ —	—	4,722,518
October 25, 2020 to November 21, 2020.....	317,950	242.35	—	4,404,568
November 22, 2020 to January 2, 2021.....	135,512	244.37	—	4,269,056
Total.....	453,462	\$ 242.95	—	4,269,056

⁽¹⁾ In July 2018, our board of directors authorized the Repurchase Program, whereby we may repurchase up to 5.0 million shares of our common stock. The Repurchase Program can 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 privately negotiated transactions.

During the year ended January 2, 2021, we satisfied certain U.S. federal and state tax withholding obligations due upon the vesting of equity grants by withholding shares of our common stock, with an aggregate fair market value on the date of vesting equal to the tax withholding obligations, from the shares of our common stock actually issued in connection with such award. Shares withheld to satisfy tax withholding obligations for the year ended January 2, 2021 and December 28, 2019 were as follows (in thousands, except per share amounts):

	Three Months Ended		Year Ended	
	January 2, 2021 ⁽¹⁾	December 28, 2019	January 2, 2021 ⁽¹⁾	December 28, 2019
Shares withheld.....	8,464	—	18,750 ⁽¹⁾	1
Average cost per share.....	\$ 252.72	\$ —	\$ 203.01	\$ 105.52
Value of shares withheld.....	\$ 2,139	\$ —	\$ 3,807	\$ 123

⁽¹⁾ Also included here is the option cost due upon the exercise of stock options that was paid by delivering the shares previously owned by the participant.

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 January 2, 2021, December 28, 2019 and December 29, 2018 and the consolidated balance sheet data as of January 2, 2021 and December 28, 2019 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 December 30, 2017 and December 31, 2016, and the consolidated balance sheet data as of December 29, 2018, December 30, 2017 and December 31, 2016 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.

We adopted Accounting Standards Codification (ASC) Topic 842, *Leases* (ASC 842), effective December 30, 2018, using the modified retrospective approach and applying the current-period adjustment method of adoption. Pursuant to such adoption method, all periods beginning on or after December 30, 2018 are presented under ASC 842 with a cumulative effect adjustment to the opening balance sheet as of the first day of fiscal year 2019, and all prior period amounts are not adjusted and continue to be reported in accordance with the legacy accounting requirements under ASC Topic 840, *Leases*. 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.

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018	Year Ended December 30, 2017 ⁽¹⁾	Year Ended December 31, 2016 ⁽¹⁾
(in thousands, except per share amounts)					
Statement of Operations:					
Revenue:					
Product.....	\$ 1,143,744	\$ 936,408	\$ 829,874	\$ 738,242	\$ 673,962
Royalty and other revenue.....	—	1,429	28,415	52,006	38,936
Total revenue.....	1,143,744	937,837	858,289	790,248	712,898
Cost of goods sold.....	400,679	308,665	283,397	268,216	234,560
Gross profit.....	743,065	629,172	574,892	522,032	478,338
Operating expenses:					
Selling, general and administrative.....	369,057	314,661	285,417	273,011	254,707
Research and development.....	118,659	93,295	81,006	65,234	57,686
Litigation settlement, award and/or defense costs.....	(474)	—	425	—	(270,000)
Total operating expenses.....	487,242	407,956	366,848	338,245	42,393
Operating income.....	255,823	221,216	208,044	183,787	435,945
Non-operating income (expense).....	7,913	12,950	5,732	2,013	(2,429)
Income before provision for income taxes.....	263,736	234,166	213,776	185,800	433,516
Provision for income taxes.....	23,454	37,950	20,233	61,011	122,419
Net income including noncontrolling interest.....	240,282	196,216	193,543	124,789	311,097
Net loss attributable to noncontrolling interest.....	20	—	—	—	—
Net income attributable to Masimo Corporation stockholders.....	\$ 240,302	\$ 196,216	\$ 193,543	\$ 124,789	\$ 311,097
Net income per share attributable to Masimo Corporation stockholders:					
Basic.....	\$ 4.39	\$ 3.67	\$ 3.70	\$ 2.42	\$ 6.28
Diluted.....	\$ 4.14	\$ 3.44	\$ 3.45	\$ 2.23	\$ 5.85
Weighted-average number of common shares:					
Basic.....	54,700	53,434	52,296	51,516	49,530
Diluted.....	58,037	57,100	56,039	55,874	53,195

	January 2, 2021	December 28, 2019	December 29, 2018	December 30, 2017 ⁽¹⁾	December 31, 2016 ⁽¹⁾
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments.....	\$ 641,447	\$ 687,687	\$ 552,490	\$ 315,302	\$ 305,970
Working capital.....	867,329	823,843	642,722	430,041	289,830
Total assets.....	1,712,552	1,396,128	1,154,818	905,436	814,352
Total debt.....	—	—	—	—	71
Total equity.....	1,407,640	1,167,874	969,065	724,025	584,177

⁽¹⁾ Certain information presented as of and for the periods ended December 30, 2017 and December 31, 2016 have been previously restated to reflect the full retrospective application of Accounting Standards Update (ASU) No. 2014-09, *Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09)*, as of December 31, 2017. Information presented as of and for the period ended January 2, 2016 has not been restated and continues to reflect the prior revenue recognition guidance pursuant to ASC Topic 605, *Revenue Recognition*.

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 and hospital automation solutions. Our mission is to improve patient outcomes and reduce the cost of patient care. Our patient monitoring solutions generally incorporate a monitor or circuit board, proprietary single-patient use or reusable sensors, software and/or cables. We provide our products to hospitals, emergency medical service (EMS) providers, home care providers, long-term care facilities, physician offices, veterinarians and consumers through our direct sales force, distributors and original equipment manufacturers (OEM) partners. 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, 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 regional 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 hospital automation and connectivity solutions, such as the Masimo Patient SafetyNet™ 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; Iris® and Iris® Gateway, which allow the transfer of data from Masimo and third-party devices to hospital electronic medical records; and UniView™, which provides an integrated display of real-time data from Masimo and third-party devices. Please see Part I, Item 1 of this Annual Report on Form 10-K for additional information related to our business, products and technologies.

COVID-19 Pandemic

The COVID-19 pandemic has created significant uncertainty in the U.S. and around the globe, resulting in both challenges and opportunities for our business. We are committed to being as transparent as possible with our investors, employees, customers, suppliers and business partners as we collectively work to respond to this crisis. In response to this situation, we have implemented a number of precautionary measures at our facilities, including requiring certain personnel to work remotely from home and enacting social distancing, requiring face masks and mandatory screening for symptoms associated with COVID-19 for critical personnel that are required to report to our facilities to work.

We have recently introduced new products, such as Masimo SafetyNet™ and Masimo SafetyNet-Open™, to help combat the COVID-19 pandemic, and have made charitable pledges to various global health organizations to support global COVID-19 relief efforts. In response to the increased product demand that we are seeing from our customers as they respond to and prepare for COVID-19 patient volumes, we have continued to increase our manufacturing capacity. We currently believe that our existing liquidity position will be sufficient to fund these initiatives and our response efforts.

Given the uncertainties related to the COVID-19 pandemic, we cannot predict how long the increased product demand we have experienced or any resulting changes in our product mix, as well as the associated gross margin impact from increased boards/instruments sales, will continue. In addition, this increase in current demand could result in potential reductions in future demand if our customers have over purchased our products and need to consume their excess inventory before purchasing additional products. Furthermore, we continue to be exposed to potential disruptions to our manufacturing operations, disruptions in the supply of critical manufacturing components and in our workforce as circumstances surrounding the global impact of the COVID-19 pandemic continue to change. Please see “*Risks Related to Our Revenues*” and “*Risks Related to our Business and Operations*” in Part I, Item 1A of this Annual Report on Form 10-K for additional information on potential negative impacts to us resulting from the COVID-19 pandemic.

Adoption of Lease Accounting Standard

Effective December 30, 2018, we adopted ASC Topic 842, *Leases* (ASC 842). Our adoption of ASC 842 generally resulted in (a) the recognition of lessee right-of-use (ROU) assets for the right to use assets subject to operating leases; (b) the recognition of lessee lease liabilities for our obligation to make payments under operating leases; and (c) the acceleration of when we recognize certain revenue and costs as a lessor of equipment provided to end-user hospitals at no up-front charge under deferred equipment agreements with fixed multi-year sensor purchase commitments. See “*Critical Accounting Policies and Estimates*” below and Note 2 to our accompanying consolidated financial statements included in Part I, Item 1 of this Annual Report on Form 10-K for additional information related to our adoption of this accounting standard.

Stock Repurchase Program

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 17 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

Cercacor

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 (CEO), is also the Chairman and CEO 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. 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.

Results of Operations

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

	Year Ended January 2, 2021		Year Ended December 28, 2019		Year Ended December 29, 2018	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
(dollars in thousands)						
Revenue:						
Product.....	\$1,143,744	100.0 %	\$ 936,408	99.8 %	\$ 829,874	96.7 %
Royalty and other revenue.....	—	—	1,429	0.2	28,415	3.3
Total revenue.....	1,143,744	100.0	937,837	100.0	858,289	100.0
Cost of goods sold.....	400,679	35.0	308,665	32.9	283,397	33.0
Gross profit.....	743,065	65.0	629,172	67.1	574,892	67.0
Operating expenses:						
Selling, general and administrative.....	369,057	32.3	314,661	33.6	285,417	33.3
Research and development.....	118,659	10.4	93,295	9.9	81,006	9.4
Litigation awards, settlements/or defense costs	(474)	—	—	—	425	—
Total operating expenses.....	487,242	42.6	407,956	43.5	366,848	42.7
Operating income.....	255,823	22.4	221,216	23.6	208,044	24.2
Non-operating income.....	7,913	0.7	12,950	1.4	5,732	0.7
Income before provision for income taxes.....	263,736	23.1	234,166	25.0	213,776	24.9
Provision for income taxes.....	23,454	2.1	37,950	4.0	20,233	2.4
Net income including noncontrolling interest.....	240,282	21.0	196,216	20.9	193,543	22.5
Net loss attributable to noncontrolling interest.....	20	—	—	—	—	—
Net income attributable to Masimo Corporation stockholders.....	<u>\$ 240,262</u>	<u>21.0 %</u>	<u>\$ 196,216</u>	<u>20.9 %</u>	<u>\$ 193,543</u>	<u>22.5 %</u>

Comparison of the Year ended January 2, 2021 to the Year ended December 28, 2019

Revenue. Total revenue increased \$205.9 million, or 22.0%, to \$1,143.7 million for the year ended January 2, 2021, from \$937.8 million for the year ended December 28, 2019. The following table details our total product revenues by the geographic area to which the products were shipped for fiscal years 2020 and 2019 (dollars in thousands):

	Year Ended January 2, 2021		Year Ended December 28, 2019		Increase/ (Decrease)	Percentage Change
United States (U.S.).....	\$ 763,069	66.7 %	\$ 636,371	68.0 %	\$ 126,698	19.9 %
Europe, Middle East and Africa.....	238,681	20.9	183,363	19.6	55,318	30.2
Asia and Australia.....	103,756	9.1	87,961	9.4	15,795	18.0
North and South America (excluding U.S.).....	38,238	3.3	28,713	3.0	9,525	33.2
Total product revenue.....	<u>\$1,143,744</u>	<u>100.0 %</u>	<u>\$ 936,408</u>	<u>100.0 %</u>	<u>\$ 207,336</u>	<u>22.1 %</u>
Royalty and other revenue.....	—	—	1,429	—	(1,429)	(100.0)%
Total revenue.....	<u>\$1,143,744</u>		<u>\$ 937,837</u>		<u>\$ 205,907</u>	

Product revenues increased \$207.3 million, or 22.1%, to \$1,143.7 million for the year ended January 2, 2021 from \$936.4 million for the year ended December 28, 2019. This increase was primarily due to higher revenue from monitors, consumables, boards and services, a portion of which we believe is related to a continued overall demand for our products due to the global COVID-19 pandemic, as well as the impact of approximately \$0.5 million of favorable foreign exchange rate movements from the prior year that increased the U.S. Dollar translation of foreign sales that were denominated in various foreign currencies.

During the year ended January 2, 2021, we shipped approximately 472,300 noninvasive technology boards and monitors, an increase of approximately 226,100 units, or 91.8%, from approximately 246,200 units shipped during the year ended December 28, 2019.

Product revenue generated through our direct and distribution sales channels increased \$142.0 million, or 17.4%, to \$958.8 million for the year ended January 2, 2021, compared to \$816.8 million for the year ended December 28, 2019. Revenues from our OEM channel increased \$65.4 million, or 54.7%, to \$185.0 million for the year ended January 2, 2021 as compared to \$119.6 million for the year ended December 28, 2019.

Royalty and other revenue historically consisted primarily of royalties received from Medtronic plc (Medtronic) and revenue from non-recurring engineering services for a certain OEM customer. For the year ended January 2, 2021, there was no royalty and other revenue compared to \$1.4 million of royalty and other revenue reported for the year ended December 28, 2019, primarily due to a reduction in royalties from Medtronic as a result of the expiration of its obligation to pay us sales-based royalties after October 6, 2018. We received our final royalty payment from Medtronic during the three months ended March 30, 2019. We currently do not expect any significant royalty or other revenue in the future.

Gross Profit. Gross profit consists of total revenue less cost of goods sold. Our gross profit for fiscal years 2020 and 2019 was as follows (dollars in thousands):

Gross Profit						
	Year Ended January 2, 2021	Percentage of Revenues	Year Ended December 28, 2019	Percentage of Revenues	Increase/ (Decrease)	Percentage Change
Product gross profit.....	\$ 743,065	65.0 %	\$ 627,911	67.1 %	\$ 115,154	18.3 %
Royalty and other revenue gross profit...	—	—	1,261	88.2	(1,261)	(100.0)
Total gross profit.....	\$ 743,065	65.0 %	\$ 629,172	67.1 %	\$ 113,893	18.1 %

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 non-recurring engineering (NRE) services. Cost of goods sold increased \$92.0 million to \$400.7 million for the year ended January 2, 2021, from \$308.7 million for the year ended December 28, 2019, primarily due to higher material, manufacturing and distribution costs associated with the increase in product sales volumes, product mix, and increased manufacturing complexity associated with the impact of COVID-19.

Product gross margins decreased to 65.0% for the year ended January 2, 2021 from 67.1% for the year ended December 28, 2019, primarily due to unfavorable product mix associated with the increase in board and monitor sales, increased manufacturing complexity associated with the impact of COVID-19, and higher distribution costs. Royalty and other revenue gross profit decreased by \$1.3 million for the year ended January 2, 2021 compared to the year ended December 28, 2019 due to lower royalties from Medtronic as a result of the expiration of its obligation to pay us royalties after October 6, 2018.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of salaries, stock-based compensation 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 2020 and 2019 were as follows (dollars in thousands):

Selling, General and Administrative					
Year Ended January 2, 2021	Percentage of Revenues	Year Ended December 28, 2019	Percentage of Revenues	Increase/ (Decrease)	Percentage Change
\$369,057	32.3%	\$314,661	33.6%	\$54,396	17.3%

Selling, general and administrative expenses increased \$54.4 million, or 17.3%, to \$369.1 million for the year ended January 2, 2021 from \$314.7 million for the year ended December 28, 2019. This increase was primarily attributable to higher compensation and other employee-related costs of approximately \$28.3 million, higher advertising and marketing related expenses of approximately \$16.7 million, higher legal and professional fees of approximately \$12.5 million and higher contributions of approximately \$3.7 million, which were partially offset by a reduction in travel costs of approximately \$10.3 million.

Research and Development. Research and development expenses consist primarily of salaries, stock-based compensation 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 2020 and 2019 were as follows (dollars in thousands):

Research and Development

Year Ended January 2, 2021	Percentage of Revenues	Year Ended December 28, 2019	Percentage of Revenues	Increase/ (Decrease)	Percentage Change
\$118,659	10.4%	\$93,295	9.9%	\$25,364	27.2%

Research and development expenses increased \$25.4 million, or 27.2%, to \$118.7 million for the year ended January 2, 2021 from \$93.3 million for the year ended December 28, 2019, primarily due to higher compensation-related costs of approximately \$19.8 million, higher professional fees of approximately \$1.5 million, higher office equipment-related expenses of approximately \$1.3 million and higher occupancy and facilities-related expense of approximately \$1.0 million.

Non-operating Income. Non-operating income consists primarily of interest income, interest expense and foreign exchange losses. Non-operating income for fiscal years 2020 and 2019 was as follows (dollars in thousands):

Non-operating Income

Year Ended January 2, 2021	Percentage of Revenues	Year Ended December 28, 2019	Percentage of Revenues	Increase/ (Decrease)	Percentage Change
\$7,913	0.7%	\$12,950	1.4%	\$(5,037)	(38.9)%

Non-operating income was \$7.9 million for the year ended January 2, 2021, as compared to \$13.0 million of non-operating income for the year ended December 28, 2019. This net decrease of approximately \$5.0 million was primarily due to approximately \$8.4 million in lower interest income, which was offset by approximately \$3.3 million of net realized and unrealized gains on foreign currency denominated transactions during the year ended January 2, 2021.

Provision for Income Taxes. Our provision for income taxes for fiscal years 2020 and 2019 was as follows (dollars in thousands):

Provision for Income Taxes

Year Ended January 2, 2021	Percentage of Revenues	Year Ended December 28, 2019	Percentage of Revenues	Increase/ (Decrease)	Percentage Change
\$23,454	2.1%	\$37,950	4.0%	\$(14,496)	(38.2)%

Our provision for income taxes was \$23.5 million for the year ended January 2, 2021 compared to \$38.0 million for the year ended December 28, 2019. Our effective tax rate was 8.9% for the year ended January 2, 2021 compared to 16.2% for the year ended December 28, 2019. This decrease in our effective tax rate for the year ended January 2, 2021 resulted primarily from an increase in the amount of excess tax benefits realized from stock-based compensation pursuant to ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09) of approximately \$14.5 million compared to the year ended December 28, 2019, an increase in R&D tax credits, and a decrease in nondeductible compensation related expenses.

We have made no provision for U.S. income taxes or foreign withholding taxes on approximately \$142.8 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 28, 2019 to the Year ended December 29, 2018

For a discussion regarding our financial condition and results of operations for the year ended December 28, 2019 as compared to the year ended December 29, 2018, please refer to the discussion under the heading “Comparison of the Year ended December 28, 2019 to the Year ended December 29, 2018” in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 28, 2019, filed with the Securities and Exchange Commission on February 19, 2020.

Liquidity

Our principal sources of liquidity consist of our existing cash and cash equivalent balances, future funds expected to be generated from operations and available borrowing capacity under our credit facility. As of January 2, 2021, we had approximately \$867.3 million in working capital, of which approximately \$641.4 million was cash and cash equivalents. In addition to net working capital, we had approximately \$148.3 million of available borrowing capacity (net of outstanding letters of credit) under our Credit Agreement (Credit Facility) as compared to approximately \$823.8 million in working capital, approximately \$567.7 million in cash and cash equivalents and \$120.0 million in short-term investments at December 28, 2019.

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 January 2, 2021, we had cash totaling \$71.7 million held outside of the U.S., of which approximately \$32.8 million was accessible without additional tax cost and approximately \$38.9 million was accessible at an incremental estimated tax cost of up to \$0.4 million. We currently have sufficient funds on-hand and cash held outside the U.S. that is available without additional tax cost to fund our global 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.

Cash Flows

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

	Year Ended	
	January 2, 2021	December 28, 2019
Net cash provided by (used in):		
Operating activities.....	\$ 210,963	\$ 221,640
Investing activities.....	(82,787)	(197,681)
Financing activities.....	(54,307)	(9,339)
Effect of foreign currency exchange rates on cash.....	3,060	814
Increase in cash, cash equivalents, and restricted cash.....	<u>\$ 76,929</u>	<u>\$ 15,434</u>

Operating Activities. Cash provided by operating activities for the year ended January 2, 2021 was \$211.0 million and was primarily driven by net income including noncontrolling interests of \$240.3 million. This was increased by non-cash activities including stock-based compensation of \$42.2 million, depreciation and amortization of \$29.3 million and a deferred income tax benefit of \$5.0 million. Additional increases in operating cash resulted from increases in accrued compensation, deferred revenue and other contract-related liabilities, accrued liabilities and accounts payable of \$15.5 million, \$10.9 million, \$9.4 million and \$7.6 million, respectively, primarily due to the timing of payments. Partially offsetting this was \$94.4 million of purchases of inventory to both increase finished goods days on hand as well as secure raw material supply to ensure we are able to support higher customer demand during the COVID-19 pandemic, and to support product launches. Additional reductions to net income including noncontrolling interests were changes in operating assets, including an increase in other current assets of \$30.0 million, primarily due to the timing of various tax payments and refunds, and an increase in lease receivables of \$7.7 million.

Cash provided by operating activities for the year ended December 28, 2019 was \$221.6 million and was driven primarily by net income of \$196.2 million. Non-cash activity included stock-based compensation of \$39.2 million, depreciation and amortization of \$23.5 million and a deferred income tax benefit of \$6.0 million. Additional sources of cash related to changes in operating assets and liabilities included increases in accounts payable, deferred revenue and other contract-related liabilities, and accrued compensation of \$9.9 million, \$7.7 million and \$5.3 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 increases in accounts receivable and lease receivable of \$23.6 million and \$12.0 million, respectively, primarily due to the timing of cash receipts, an increase in inventory of \$21.3 million, primarily due to the growth in our business and the timing of shipments, and an increase in other current assets of \$8.5 million, primarily due to the timing of various tax payments and refunds.

Investing Activities. Cash used in investing activities for the fiscal year ended January 2, 2021 was \$82.8 million, consisting primarily of \$120.0 million for maturities of short-term investments, \$112.71 million of business combinations, \$72.5 million for purchases of property and equipment of which \$16.4 million related to the purchase of a building, \$6.8 million related to the acquisition of a strategic investment and \$7.4 million for intangible assets related to capitalized patent and trademark costs.

Cash used in investing activities for the fiscal year ended December 28, 2019 was \$197.7 million, consisting primarily of \$280.0 million for purchases of short-term investments, \$68.4 million for purchases of property and equipment of which \$35.6 million related to the purchase of two buildings, \$5.2 million related to the acquisition of a strategic investment and \$4.1 million for intangible assets related to capitalized patent and trademark costs, which were offset by \$160.0 million of maturities of short-term investments.

Financing Activities. Cash used in financing activities for the fiscal year ended January 2, 2021 was \$54.3 million, resulting primarily from cash paid for common stock repurchase transactions that settled during the year of \$110.5 million, which were partially offset by proceeds from the issuance of common stock (upon exercise of options) of \$58.4 million.

Cash used in financing activities for the fiscal year ended December 28, 2019 was \$9.3 million, resulting primarily from cash paid for common stock repurchase transactions that settled during the year of \$37.6 million, which were partially offset by proceeds from the issuance of common stock (upon exercise of options) of \$28.3 million.

Capital Resources and Prospective Capital Requirements

We currently maintain 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 15 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 17 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 primarily related to investments in infrastructure growth. Possible additional uses of cash may include the acquisitions and/or strategic investments in technologies or technology companies, investments in property and equipment as well as repurchases of stock under our authorized stock repurchase program. However, any repurchases of common 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 infrastructure expansion, stock repurchase activity and costs related to our domestic and international regulatory requirements. Despite these investment requirements and potential expenditures, 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 January 2, 2021 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				Total
	Less than 1 Year	Between 1-3 Years	Between 3-5 Years	More than 5 Years	
Operating leases ⁽¹⁾	\$ 6,610	\$ 11,810	\$ 8,116	\$ 11,055 ⁽³⁾	\$ 37,591
Purchase commitments ⁽²⁾	123,000	—	—	—	123,000
Total contractual obligations.....	\$ 129,610	\$ 11,810	\$ 8,116	\$ 11,055	\$ 160,591

⁽¹⁾ Undiscounted lease payments for operating leases.

⁽²⁾ Certain inventory items under non-cancellable purchase orders.

⁽³⁾ Includes optional renewal periods for certain leases.

Other obligations. As of January 2, 2021, our estimated liabilities related to uncertain tax positions, including interest, were \$11.8 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.

In addition, we had the following annual minimum royalty commitments to Cercacor, as of January 2, 2021 (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 2025, 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 judgements that affect the reported amounts of net revenues, expenses, assets and liabilities. These estimates and judgements 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

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 generally recognize revenue following a single, principles-based five-step model to be applied to all contracts with customers and generally provide for the recognition of revenue in an amount that reflects the consideration to which we expect 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.

Revenue related to equipment supplied under sales-type lease arrangements is recognized once control over the equipment is transferred to the customer, while revenue related to equipment supplied under operating-type lease arrangements is generally recognized on a straight-line basis over the term of the lease.

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) whether the arrangement contains an embedded lease, and if so, whether such embedded lease is a sales-type lease or an operating lease, (iii) the identification of the distinct performance obligations contained within the arrangement, (iv) how the arrangement consideration should be allocated to each performance obligation when multiple performance obligations exist, including the determination of standalone selling price, and (v) when to recognize revenue on the performance obligations. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

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 distinct 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, 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.

Sales under deferred equipment agreements are generally structured such that we agree to provide certain monitoring-related equipment, software, installation, training and/or warranty support at no up-front charge in exchange for the customer's commitment to purchase sensors over the term of the agreement, which generally ranges from three to six years. We allocate contract consideration under deferred equipment agreements containing fixed annual sensor purchase commitments to the underlying lease and non-lease components at contract inception. In determining whether any underlying lease components are related to a sales-type lease or an operating lease, we evaluate the customer's rights and ability to control the use of the underlying equipment throughout the contract term, including any equipment substitution rights retained by us, as well as our expectations surrounding potential contract/lease extensions or renewals and the customer's likelihood to exercise any purchase options. Revenue allocable to non-lease components is generally recognized as such non-lease components are satisfied. Revenue allocable to lease components under sales-type lease arrangements is generally recognized when control over the equipment is transferred to the customer. Revenue allocable to lease components under operating lease arrangements is generally recognized over the term of the operating lease. We generally do not expect to derive any significant value in excess of such asset's unamortized book value from equipment underlying our operating leases arrangements.

Revenue from direct sales of our products to end-user hospitals, emergency medical response organizations, other direct customers, distributors and OEM customers is generally recognized by us when control of such products transfer to the customer based upon the terms of the contract or underlying purchase order. Revenue related to OEM rainbow® parameter software licenses is recognized by us upon the OEM's shipment of its product to its customer, 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.

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 determine any required inventory valuation adjustments 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 record other specific inventory valuation adjustments 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, 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.

Lessee ROU Assets and Lease Liabilities

We determine if an arrangement contains a lease at inception. ROU assets represent our right to use an asset underlying an operating lease for the lease term and lease liabilities represent our obligation to make lease payments arising from an operating lease. ROU assets and lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. We generally estimate the applicable discount rate used to determine the net present value of lease payments based on available information at the lease commencement date. Many of our lessee agreements include options to extend the lease, which we do not include in our lease terms unless they are reasonably certain to be exercised. We utilize a portfolio approach to account for the ROU assets and liabilities associated with certain equipment leases. We have also made a policy election not to separate lease and non-lease components for our real estate leases and to exclude short-term leases with a term of twelve months or less from our ROU assets and lease liabilities. Rental expense for lease payments related to operating leases is recognized on a straight-line basis over the lease term.

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.

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 18 to our accompanying consolidated financial statements included in Part IV, Item 15(a) of this Annual Report on Form 10-K.

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 2016 and all material state, local and foreign income tax matters for years through 2013. 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.

Business Combinations

We account for business combinations using the acquisition method of accounting, which requires that once control is obtained, all the assets acquired, liabilities assumed and noncontrolling interest in the acquired entity, if applicable, are recorded at their respective fair values at the date of acquisition. The determination of fair values of identifiable assets and liabilities requires estimates and the use of valuation techniques when market value is not readily available.

For intangible assets acquired in a business combination, we typically use the income method. Significant estimates in valuing certain intangible assets include, but are not limited to, the amount and timing of future cash flows, growth rates, discount rates and useful lives. The excess of the purchase price over fair values of identifiable assets, liabilities, and noncontrolling interest in the acquired entity, if applicable, is recorded as goodwill.

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 January 2, 2021, 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 also 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 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. In addition, 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.

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

Our primary foreign currency exchange rate exposures are with the Canadian Dollar, Euro, Japanese Yen, Swedish Krona, the British Pound, Mexico Peso, Turkish Lira and Australian Dollar. Foreign currency exchange rates may experience significant volatility from one period to the next. Specifically, during the fiscal year ended January 2, 2021, we estimate that fluctuations in the exchange rates between the U.S. Dollar and other foreign currencies, including the Turkish Lira, Canadian Dollar and the Australian Dollar, favorably impacted our revenues by \$0.5 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 January 2, 2021 would have resulted in an estimated reduction of \$23.4 million in reported pre-tax income for the year ended January 2, 2021. As our foreign operations continue to grow, our exposure to foreign currency exchange rate risk may become more significant.

Inflation Risk

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in 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 January 2, 2021.

Grant Thornton LLP, an independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of January 2, 2021. Their attestation report, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of January 2, 2021, is included in Part IV, Item 15(a)(1) of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

During the quarter ended January 2, 2021 there were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

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 2021 (2021 Proxy Statement).

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2021 Proxy Statement.

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 2021 Proxy Statement.

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 2021 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2021 Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The Consolidated Financial Statements of Masimo Corporation and Reports 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)	Second Amended and Restated Bylaws adopted on October 24, 2019 (Exhibit 3.1)
4.1(1)	Form of Common Stock Certificate (Exhibit 4.1)
4.2(4)#	Masimo Retirement Savings Plan (Exhibit 4.7)
4.3*	Description of Securities of Masimo Corporation
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(13)	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(19)#	Offer Letter, dated March 31, 2011 between Tom McClenahan and the Registrant (Exhibit 10.7)
10.8(14)#	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(9)#	2007 Severance Protection Plan Participation Agreement, dated January 11, 2008, by and between the Registrant and Yongsam Lee (Exhibit 10.3)
10.13(19)#	Amended and Restated 2007 Severance Protection Plan Agreement, dated November 12, 2013, by and between the Registrant and Jon Coleman (Exhibit 10.13)
10.14(19)#	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(17)#	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)
10.17(1)#	2007 Stock Incentive Plan of the Registrant, and forms of agreements related thereto (Exhibit 10.33)
10.18(15)#	Masimo Corporation 2017 Equity Incentive Plan (Exhibit 10)
10.19(16)#	Masimo Corporation Executive Bonus Incentive Plan (Appendix D)
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†*	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

<u>Exhibit Number</u>	<u>Description of Document</u>
10.24†*	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
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(8)	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†*	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.
10.30(10)	Lease Agreement, dated July 15, 2012, related to the premises at 9600 Jeronimo, between the Registrant and The Irvine Company, LLC (Exhibit 10.45)
10.31(10)	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)
10.32(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)
10.33(10)	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)
10.34(11)	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)
10.35(12)	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)
10.36(12)+	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)
10.37(19)	Credit Agreement dated as of December 17, 2018, among Masimo Corporation, the Lenders party thereto and JPMorgan Chase Bank, N.A. as Administrative Agent (Exhibit 10.42)
10.38(18)#	Offer Letter, dated April 17, 2002, between the Company and Bilal Muhsin (Exhibit 10.1)
10.39(18)#	Offer Letter, dated December 15, 2017, between the Company and Tao Levy (Exhibit 10.2)
10.40(18)#	2007 Severance Protection Plan Participation Agreement, dated March 26, 2018, by and between the Company and Bilal Muhsin (Exhibit 10.3)
10.41(18)#	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.

<u>Exhibit Number</u>	<u>Description of Document</u>
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

Attached as Exhibit 101 to this report are the following formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of January 2, 2021 and December 28, 2019, (ii) Consolidated Statements of Operations for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, (iii) Consolidated Statements of Comprehensive Income for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, (iv) Consolidated Statements of Equity for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, (v) Consolidated Statements of Cash Flows for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, and (vi) Notes to Consolidated Financial Statements.

- (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 30, 2019. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
- (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 January 31, 2011. 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 17, 2008. 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 on February 24, 2016. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
- (11) 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.
- (12) Incorporated by reference to the exhibit to the Registrant's Current 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.
- (13) 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.
- (14) 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.
- (15) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on July 28, 2020. The number given in parentheses indicates the corresponding exhibit number in such Form 10-Q.
- (16) Incorporated by reference to Appendix D to the Registrant's Definitive Proxy Statement on Schedule 14A (File No. 001-33642) filed on April 16, 2020.

- (17) 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.
- (18) 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.
- (19) Incorporated by reference to the exhibit to the Registrant's Annual Report on Form 10-K filed February 26, 2019. The number given in parentheses indicates the corresponding exhibit number in such Form 10-K.

* Filed herewith.

Indicates management contract or compensatory plan.

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

† Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.

(b) Exhibits

See Item 15(a)(3) above.

(c) Financial Statement Schedules

See Item 15(a)(2) above.

ITEM 16. FORM 10-K SUMMARY

None.

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Consolidated
Financial Statements

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**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SCHEDULE
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 January 2, 2021 and December 28, 2019, the related consolidated statements of operations, comprehensive income, equity, and cash flows for each of the three years in the period ended January 2, 2021, and the related notes and financial statement schedule included under Item 15(a) (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 January 2, 2021 and December 28, 2019, and the results of its operations and its cash flows for each of the three years in the period ended January 2, 2021, 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 January 2, 2021, 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 23, 2021 expressed an unqualified opinion.

Change in accounting principle

As described in Note 2 to the financial statements, the Company has changed its method of accounting for leases in fiscal year 2019 due to the adoption of the new leasing standard. The Company adopted the new leasing standard using the modified 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 regarding 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.

Critical audit matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for Deferred Equipment Agreements

As described in Note 2 to the financial statements, the Company derives a portion of its product revenue from direct sales under deferred equipment agreements with end-user hospitals. Contract consideration under such agreements containing fixed annual sensor purchase commitments is allocated to the identified performance obligations, including lease components, on the basis of relative standalone selling prices.

We identified the accounting for deferred equipment agreements as a critical audit matter. The principal consideration for our determination that the accounting for deferred equipment agreements is a critical audit matter is that the identification and evaluation of performance obligations requires management judgment and interpretation of contract terms. Therefore, subjective and complex auditor judgment is necessary to evaluate the reasonableness of management's judgments and assumptions in this area.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. Our audit procedures related to deferred equipment agreements included the following, among others.

- Inspecting a sample of deferred equipment agreements with fixed sensor commitments and evaluating the reasonableness of performance obligations, including lease components, identified by management in accordance with the relevant authoritative guidance.
- Testing the design and operating effectiveness of internal controls related to the accounting for deferred equipment agreements, including controls over the identification of performance obligations.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2006.

Newport Beach, California

February 23, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Masimo Corporation

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of Masimo Corporation (a Delaware corporation) and subsidiaries (the “Company”) as of January 2, 2021, 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 January 2, 2021, 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 January 2, 2021, and our report dated February 23, 2021 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 23, 2021

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

	January 2, 2021	December 28, 2019
ASSETS		
Current assets		
Cash and cash equivalents.....	\$ 641,447	\$ 567,687
Short-term investments.....	—	120,000
Trade accounts receivable, net of allowance for doubtful accounts of \$1,603 and \$1,803 at January 2, 2021 and December 28, 2019, respectively.....	141,350	132,433
Inventories.....	215,952	115,871
Other current assets.....	102,416	60,071
Total current assets.....	1,101,165	996,062
Lease receivable, noncurrent.....	57,666	49,936
Deferred costs and other contract assets.....	20,076	16,214
Property and equipment, net.....	272,511	219,552
Intangible assets, net.....	73,923	27,251
Goodwill.....	103,206	22,350
Deferred tax assets.....	39,363	35,972
Other non-current assets.....	44,642	28,791
Total assets.....	<u>\$ 1,712,552</u>	<u>\$ 1,396,128</u>
LIABILITIES AND EQUITY		
Current liabilities		
Accounts payable.....	\$ 64,061	\$ 54,548
Accrued compensation.....	71,601	54,705
Deferred revenue and other contract-related liabilities, current.....	44,935	25,939
Other current liabilities.....	53,239	37,027
Total current liabilities.....	233,836	172,219
Other non-current liabilities.....	71,076	56,035
Total liabilities.....	304,912	228,254
Commitments and contingencies (Note 21)		
Masimo Corporation Stockholders' equity		
Preferred stock, \$0.001 par value; 5,000 shares authorized; 0 shares issued and outstanding.....	—	—
Common stock, \$0.001 par value; 100,000 shares authorized; 55,251 and 53,696 shares issued and outstanding at January 2, 2021 and December 28, 2019, respectively.....	55	54
Treasury stock, 15,993 and 15,530 shares at January 2, 2021 and December 28, 2019, respectively.....	(638,736)	(526,580)
Additional paid-in capital.....	703,693	600,624
Accumulated other comprehensive income (loss).....	1,413	(6,718)
Retained earnings.....	1,341,235	1,100,494
Total Masimo Corporation stockholders' equity.....	1,407,660	1,167,874
Noncontrolling interest.....	(20)	—
Total equity.....	1,407,640	1,167,874
Total liabilities and equity.....	<u>\$ 1,712,552</u>	<u>\$ 1,396,128</u>

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

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

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Revenue:			
Product.....	\$ 1,143,744	\$ 936,408	\$ 829,874
Royalty and other revenue.....	—	1,429	28,415
Total revenue.....	1,143,744	937,837	858,289
Cost of goods sold.....	400,679	308,665	283,397
Gross profit.....	743,065	629,172	574,892
Operating expenses:			
Selling, general and administrative.....	369,057	314,661	285,417
Research and development.....	118,659	93,295	81,006
Litigation awards, settlements/or defense costs.....	(474)	—	425
Total operating expenses.....	487,242	407,956	366,848
Operating income.....	255,823	221,216	208,044
Non-operating income.....	7,913	12,950	5,732
Income before provision for income taxes.....	263,736	234,166	213,776
Provision for income taxes.....	23,454	37,950	20,233
Net income including noncontrolling interest.....	240,282	196,216	193,543
Net loss attributable to noncontrolling interest.....	20	—	—
Net income attributable to Masimo Corporation stockholders.....	<u>\$ 240,302</u>	<u>\$ 196,216</u>	<u>\$ 193,543</u>
Net income per share attributable to Masimo Corporation stockholders:			
Basic.....	<u>\$ 4.39</u>	<u>\$ 3.67</u>	<u>\$ 3.70</u>
Diluted.....	<u>\$ 4.14</u>	<u>\$ 3.44</u>	<u>\$ 3.45</u>
Weighted-average shares used in per share calculations:			
Basic.....	<u>54,700</u>	<u>53,434</u>	<u>52,296</u>
Diluted.....	<u>58,037</u>	<u>57,100</u>	<u>56,039</u>

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

MASIMO CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in thousands)

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Net income including noncontrolling interest.....	\$ 240,282	\$ 196,216	\$ 193,543
Other comprehensive gain (loss), net of tax:			
Foreign currency translation gains (losses).....	8,131	(519)	(3,258)
Total comprehensive income.....	248,413	195,697	190,285
Comprehensive loss attributable to noncontrolling interest.....	20	—	—
Comprehensive income attributable to Masimo Corporation stockholders.....	<u>\$ 248,433</u>	<u>\$ 195,697</u>	<u>\$ 190,285</u>

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

MASIMO CORPORATION
CONSOLIDATED STATEMENTS OF EQUITY
(in thousands)

	Masimo Corporation Stockholders							Total Equity		
	Common Stock		Treasury Stock			Additional Paid-In Capital	Accumulated Other Comprehensive Loss		Retained Earnings	Noncontrolling Interest
	Shares	Amount	Shares	Amount	Amount	\$	\$		\$	\$
Balance at December 30, 2017	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)	
Stock-based compensation.....	—	—	—	—	27,417	—	—	—	27,417	
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	
Stock options exercised.....	851	1	—	—	28,348	—	—	—	28,349	
Restricted/Performance stock units vested.....	36	—	—	—	—	—	—	—	—	
Shares paid for tax withholding.....	(1)	—	—	—	(123)	—	—	—	(123)	
Stock-based compensation.....	—	—	—	—	39,235	—	—	—	39,235	
Repurchases of common stock.....	(275)	—	275	(37,554)	—	—	—	—	(37,554)	
Net income.....	—	—	—	—	—	—	196,216	—	196,216	
Adoption of ASU 2016-02.....	—	—	—	—	—	—	(26,795)	—	(26,795)	
Foreign currency translation adjustment.....	—	—	—	—	—	(519)	—	—	(519)	
Balance at December 28, 2019	53,696	54	15,530	(526,580)	600,624	(6,718)	1,100,494	—	1,167,874	
Stock options exercised.....	1,945	1	—	—	63,035	—	—	—	63,036	
Restricted/Performance stock units vested.....	85	—	—	—	—	—	—	—	—	
Shares paid for tax withholding.....	(19)	—	7	(1,616)	(2,191)	—	—	—	(3,807)	
Stock-based compensation.....	—	—	—	—	42,225	—	—	—	42,225	
Repurchases of common stock.....	(456)	—	456	(110,540)	—	—	—	—	(110,540)	
Net income (loss).....	—	—	—	—	—	—	240,302	(20)	240,282	
Adoption of ASU 2016-13.....	—	—	—	—	—	—	439	—	439	
Foreign currency translation adjustment.....	—	—	—	—	—	8,131	—	—	8,131	
Balance at January 2, 2021	55,251	55	15,993	(638,736)	\$ 703,693	\$ 1,413	\$ 1,341,235	\$ (20)	\$ 1,407,640	

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

MASIMO CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Cash flows from operating activities:			
Net income including noncontrolling interest.....	\$ 240,282	\$ 196,216	\$ 193,543
Adjustments to reconcile net income including noncontrolling interest to net cash provided by operating activities:			
Depreciation and amortization.....	29,300	23,487	21,127
Stock-based compensation.....	42,225	39,233	27,417
Loss on disposal of equipment, intangibles and other assets.....	554	357	949
Benefit (provision) for doubtful accounts.....	82	687	(439)
(Benefit) for amount due from former foreign agent.....	—	—	(2,016)
(Benefit) from deferred income taxes.....	(4,964)	(5,965)	(8,274)
Changes in operating assets and liabilities:			
(Increase) decrease in trade accounts receivable.....	(2,229)	(23,580)	10,826
(Increase) in inventories.....	(94,434)	(21,257)	(1,885)
(Increase) decrease in other current assets.....	(29,984)	(8,536)	3,843
(Increase) in lease receivable, net.....	(7,749)	(11,958)	—
(Increase) decrease in deferred costs and other contract assets.....	(2,806)	3,308	(17,935)
(Increase) decrease in other non-current assets.....	(1,320)	(226)	407
Increase in accounts payable.....	7,637	9,934	5,211
Increase in accrued compensation.....	15,544	5,338	10,195
Increase in deferred revenue and other contract-related liabilities.....	10,871	7,739	1,420
(Decrease) increase in income taxes payable.....	(1,301)	4,079	(1,208)
Increase in accrued liabilities.....	9,391	746	3,923
(Decrease) increase in other non-current liabilities.....	(136)	2,038	(7,577)
Net cash provided by operating activities.....	210,963	221,640	239,527
Cash flows from investing activities:			
Maturities of short-term investments.....	120,000	160,000	—
Purchases of short-term investments.....	—	(280,000)	—
Purchases of property and equipment, net.....	(72,549)	(68,375)	(17,126)
Increase in intangible assets.....	(7,408)	(4,117)	(5,557)
Business combinations, net of cash acquired.....	(112,706)	—	(3,922)
Deposit to acquire noncontrolling interest.....	(3,374)	—	—
Other strategic investing activities.....	(6,750)	(5,189)	453
Net cash (used in) investing activities.....	(82,787)	(197,681)	(26,152)
Cash flows from financing activities:			
Proceeds from issuance of common stock.....	58,424	28,339	44,748
Repurchases of common stock.....	(110,540)	(37,555)	(18,478)
Payroll tax withholdings on behalf of employees for stock options.....	(2,191)	(123)	(168)
Debt issuance costs.....	—	—	(322)
Net cash (used in) provided by financing activities.....	(54,307)	(9,339)	25,780
Effect of foreign currency exchange rates on cash.....	3,060	814	(1,997)
Net increase in cash, cash equivalents and restricted cash.....	76,929	15,434	237,158
Cash, cash equivalents and restricted cash at beginning of period.....	568,075	552,641	315,483
Cash, cash equivalents and restricted cash at end of period.....	<u>\$ 645,004</u>	<u>\$ 568,075</u>	<u>\$ 552,641</u>

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

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 wide array of patient monitoring technologies, as well as automation and connectivity solutions. The Company's mission is to improve patient outcomes and reduce the cost of patient 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 monitor carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), total hemoglobin concentration (SpHb®), fractional arterial oxygen saturation (SpfO₂™), 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. These technologies are based upon Masimo SET®, rainbow® and other proprietary algorithms and are incorporated into a variety of product platforms depending on customers' specifications. The Company's current technology offerings also include remote patient monitoring, connectivity, and hospital automation solutions, including Masimo Patient SafetyNet™⁽¹⁾, Masimo Patient SafetyNet™ Surveillance⁽¹⁾, Masimo SafetyNet™, Masimo SafetyNet-Open™, Replica™, Iris®, MyView®, UniView™, Uniview : 60™, Trace™, Masimo Sleep™, Centroid™, and Bridge™. The Company's technologies are 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 or controlled subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

As further discussed below within this Note 2 to these consolidated financial statements, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)* (ASU 2016-02) effective December 30, 2018.

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 weeks while a 53 week fiscal year includes three 13 week fiscal quarters and one 14 week fiscal quarter. The Company's last 53 week fiscal year was fiscal year 2014. Fiscal year 2020 is a 53 week fiscal year ending January 2, 2021, with the fourth quarter having 14 weeks. All references to years in these notes to consolidated financial statements are fiscal years unless otherwise noted.

Reclassifications

Certain amounts in the accompanying consolidated financial statements have been reclassified to conform to the current period presentation, including previously reported selling, general and administrative expenses that have been reclassified as research and development expenses within the consolidated financial statements for the year ended December 29, 2018. Included in the consolidated financial statements were certain reclassifications of the short-term investments for the years ended January 2, 2021 and December 28, 2019.

⁽¹⁾ The use of the trademark Patient SafetyNet™ is under license from the University HealthSystem Consortium.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 standalone selling prices, variable consideration, total consideration allocated to each performance obligation within a contract, inventory valuation, valuation of the Company's equity awards, valuation of identifiable assets and liabilities connected with business combinations, deferred taxes and any associated valuation allowances, deferred revenue, uncertain income tax positions, and litigation costs and related accruals. Actual results could differ from such estimates.

Business Combinations

The Company accounts for business combinations using the acquisition method of accounting, which requires that once control is obtained, all the assets acquired, liabilities assumed and noncontrolling interests in the acquired entity, if applicable, are recorded at their respective fair values at the date of acquisition. The excess of the purchase price over fair values of identifiable assets, liabilities and noncontrolling interests in the acquired entity, if applicable, is recorded as goodwill.

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 January 2, 2021 or December 28, 2019. The Company carries cash and cash equivalents, as well as certificates of deposit with maturities of one year or less, at cost, which approximates fair value.

The following table represents the Company's financial assets (in thousands), measured at fair value on a recurring basis as of January 2, 2021:

	Adjusted Basis Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Estimated Fair Value	Reported as	
					Cash and Cash Equivalents	Short-Term Investments
Cash.....	\$ 641,447	\$ —	\$ —	\$ 641,447	\$ 641,447	\$ —
Level 1:						
None.....	—	—	—	—	—	—
Level 2:						
None.....	—	—	—	—	—	—
Level 3:						
None.....	—	—	—	—	—	—
Total assets measured at fair value.....	<u>\$ 641,447</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 641,447</u>	<u>\$ 641,447</u>	<u>\$ —</u>

MASIMO CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table represents the Company's financial assets (in thousands), measured at fair value on a recurring basis as of December 28, 2019.

	Adjusted Basis Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Estimated Fair Value	Reported as	
					Cash and Cash Equivalents	Short-Term Investments
Cash.....	\$ 567,687	\$ —	\$ —	\$ 567,687	\$ 567,687	\$ —
Level 1:						
Certificates of deposit.....	120,000	—	—	120,000	—	120,000
Subtotal.....	120,000	—	—	120,000	—	120,000
Level 2:						
None.....	—	—	—	—	—	—
Level 3:						
None.....	—	—	—	—	—	—
Total assets measured at fair value.....	\$ 687,687	\$ —	\$ —	\$ 687,687	\$ 567,687	\$ 120,000

For certain other financial assets and liabilities, including restricted cash, accounts receivable, accounts payable and other current assets and liabilities, the carrying amounts approximate their fair value primarily due to the relatively short maturity of these balances. The Company also measures certain non-financial assets at fair value on a non-recurring basis, primarily goodwill, intangible assets and operating lease right-of-use assets, in connection with periodic evaluations for potential impairment.

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.

Short-Term Investments

The Company classifies its investments in certificates of deposits maturing in greater than three months but less than one year on the date of the original investment as short-term investments. The carrying value of such investments approximates fair value and is accessible without any significant restrictions, taxes, or penalties. As of January 2, 2021, the Company had no investments in certificates of deposit.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of trade receivables recorded at the time of invoicing of product sales, 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 Company records an allowance for doubtful accounts that it does not expect to collect based on relevant information, including historical experience, current conditions, and reasonable and supportable forecasts. Accounts are charged off against the allowance when the Company believes they are uncollectible.

Inventory

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 valuation adjustments 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. The Company generally determines inventory valuation adjustments based on an evaluation of the expected future use of its inventory on an item by item basis and applies historical obsolescence rates to estimate the loss on inventory expected to have a recovery value below cost. The Company also records other specific inventory valuation adjustments when it becomes aware of unique events or circumstances that result in an expected recovery value below cost. For inventory items that have been written down, the reduced value becomes the new cost basis.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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.....	4 to 20 years
Buildings.....	39 years
Building improvements.....	7 to 15 years
Computer equipment and software.....	2 to 12 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.

Lessee Right-of-Use (ROU) Assets and Lease Liabilities

As further discussed below within this Note 2 to these consolidated financial statements, the Company adopted ASC 842 effective December 30, 2018. The Company determines if an arrangement contains a lease at inception. ROU assets represent the Company's right to use an asset underlying an operating lease for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from an operating lease. ROU assets and lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. The Company generally estimates the applicable discount rate used to determine the net present value of lease payments based on available information at the lease commencement date. Many of the Company's lessee agreements include options to extend the lease, which the Company does not include in its lease terms unless they are reasonably certain to be exercised. The Company utilizes a portfolio approach to account for the ROU assets and liabilities associated with certain equipment leases.

The Company has also made an accounting policy election not to separate lease and non-lease components for its real estate leases and to exclude short-term leases with a term of twelve months or less from its ROU assets and lease liabilities. Rental expense for lease payments related to operating leases is recognized on a straight-line basis over the lease term.

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 technologies, the useful life is determined largely by valuation estimates of remaining economic life.

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

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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, 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.

Revenue Recognition, Deferred Revenue and Other Contract Liabilities

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

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 generally recognizes revenue following 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. Revenue related to equipment supplied under sales-type lease arrangements is recognized once control over the equipment is transferred to the customer, while revenue related to equipment supplied under operating-type lease arrangements is generally recognized on a straight-line basis over the term of the lease.

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, as well as variable consideration, (ii) whether the arrangement contains an embedded lease, and if so, whether such embedded lease is a sales-type lease or an operating lease, (iii) the identification of the distinct performance obligations contained within the arrangement, (iv) how the arrangement consideration should be allocated to each performance obligation when multiple performance obligations exist, including the determination of standalone selling price, and (v) when to recognize revenue on the performance obligations. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

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.

Sales under deferred equipment agreements are generally structured such that the Company agrees to provide certain monitoring-related equipment, software, installation, training and/or warranty support at no up-front charge in exchange for the customer's commitment to purchase sensors over the term of the agreement, which generally ranges from three years to six years. The Company allocates contract consideration under deferred equipment agreements containing fixed annual sensor purchase commitments to the underlying lease and non-lease components at contract inception.

In determining whether any underlying lease components are related to a sales-type lease or an operating lease, the Company evaluates the customer's rights and ability to control the use of the underlying equipment throughout the contract term, including any equipment substitution rights retained by the Company, as well as the Company's expectations surrounding potential contract/lease extensions or renewals and the customer's likelihood to exercise any purchase options. Revenue allocable to non-lease performance obligations is generally recognized as such non-lease performance obligations are satisfied. Revenue allocable to lease components under sales-type lease arrangements is generally recognized when control over the equipment is transferred to the customer. Revenue allocable to lease components under operating lease arrangements is generally recognized over the term of the operating lease. The Company generally does not expect to derive any significant value in excess of such asset's unamortized book value from equipment underlying its operating lease arrangements after the end of the agreement.

Revenue from the sale of products to end-user hospitals, emergency medical response organizations, other direct customers, distributors and OEM customers, is recognized by the Company when control of such products transfer to the customer based upon the terms of the contract or underlying purchase order. Revenue related to OEM rainbow® parameter software licenses is recognized by the Company upon the OEM's shipment of its product to its customer, as reported to the Company by the OEM.

The Company provides certain customers with various sales incentives that may take the form of discounts or rebates. The Company records estimates related to 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

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 and other revenue arose from one agreement that was due and payable quarterly in arrears. An estimate of these royalty revenues was recorded 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 was adjusted prospectively when the Company received the underlying royalty report, approximately sixty days after the end of the previous quarter. The Company received its final royalty payment from this agreement during the three months ended March 30, 2019. For the years ended January 2, 2021, December 28, 2019 and December 29, 2018, the Company recognized royalty revenue pursuant to this agreement of approximately \$0.0 million, \$0.7 million and \$26.4 million, respectively.

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.

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.

Deferred Costs and Other Contract Assets

The costs of monitoring-related equipment provided to customers under operating lease arrangements within the Company's 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 allowances to be made directly to the end-user hospital customer at the inception of the arrangement. These allowances are generally allocated to the lease and non-lease components and recognized as a reduction to revenue as the underlying performance obligations are satisfied.

The Company generally invoices its customers under deferred equipment agreements as sensors are provided to the customer. However, the Company may recognize revenue for certain non-lease performance obligations under deferred equipment agreements with fixed annual commitments at the time such performance obligations are satisfied and prior to the customer being invoiced.

When this occurs, the Company records an unbilled contract receivable related to such revenue until the customer has been invoiced pursuant to the terms of the underlying deferred equipment 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 ranging from three months 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 goods sold. Customers may also purchase extended warranty coverage or service level upgrades separately or as part of a deferred equipment agreement. Revenue related to extended warranty coverage and service level upgrades is generally recognized over the life of the contract, which reasonably approximates the period over which such services will be provided. The related extended warranty and service level upgrade costs are expensed as incurred.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	Year Ended		
	January 2, 2021	December 28, 2019	December 29, 2018
Warranty accrual, beginning of period.....	\$ 3,395	\$ 1,910	\$ 1,149
Accrual for warranties issued.....	832	1,715	1,549
Changes in pre-existing warranties (including changes in estimates) ⁽¹⁾	196	1,130	551
Settlements made.....	(1,683)	(1,360)	(1,339)
Warranty accrual, end of period.....	<u>\$ 2,740</u>	<u>\$ 3,395</u>	<u>\$ 1,910</u>

⁽¹⁾ In connection with its adoption of ASC 842 on December 30, 2018, the Company recorded an adjustment to pre-existing warranties of \$2.5 million related to equipment previously capitalized under its deferred equipment agreements where the embedded leases were treated as operating leases under prior guidance. See “Recently Adopted Accounting Pronouncements” in Note 2 to these consolidated financial statements for additional information related to the Company’s adoption of ASC 842.

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 January 2, 2021, December 28, 2019 and December 29, 2018 were \$30.8 million, \$14.0 million and \$17.9 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.

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, and the largest transactions in foreign currency translations occur in Japanese Yen and the European Euro.

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.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Comprehensive Income

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

Net Income Per Share

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

	Year Ended		
	January 2, 2021	December 28, 2019	December 29, 2018
Net income attributable to Masimo Corporation stockholders:	\$ 240,282	\$ 196,216	\$ 193,543
Net loss attributable to noncontrolling interest.....	20	—	—
Net income attributable to Masimo Corporation stockholders.....	<u>\$ 240,302</u>	<u>\$ 196,216</u>	<u>\$ 193,543</u>
Basic net income per share attributable to Masimo Corporation stockholders:			
Net income attributable to Masimo Corporation stockholders.....	\$ 240,302	\$ 196,216	\$ 193,543
Weighted-average shares outstanding - basic.....	54,700	53,434	52,296
Net income per basic share attributable to Masimo Corporation stockholders.....	<u>\$ 4.39</u>	<u>\$ 3.67</u>	<u>\$ 3.70</u>
Diluted net income per share attributable to Masimo Corporation stockholders:			
Weighted-average shares outstanding - basic.....	54,700	53,434	52,296
Diluted share equivalents: stock options, RSUs and PSUs.....	3,337	3,666	3,743
Weighted-average shares outstanding - diluted.....	58,037	57,100	56,039
Net income per diluted share attributable to Masimo Corporation stockholders.....	<u>\$ 4.14</u>	<u>\$ 3.44</u>	<u>\$ 3.45</u>

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 share units (RSUs) and performance stock units (PSUs).

For the years ended January 2, 2021, December 28, 2019 and December 29, 2018, weighted options to purchase 0.4 million, 0.4 million and 1.1 million shares of common stock, respectively, were outstanding, but 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 each of the years ended January 2, 2021, December 28, 2019 and December 29, 2018, certain RSUs were 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 January 2, 2021, December 28, 2019 and 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 21 to these consolidated financial statements.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Supplemental Cash Flow Information

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

	Year Ended		
	January 2, 2021	December 28, 2019	December 29, 2018
Cash paid during the year for:			
Interest expense.....	\$ 270	\$ 211	\$ 193
Income taxes.....	39,491	42,270	36,589
Operating lease liabilities.....	6,276	6,676	—
Non-cash operating activities:			
ROU assets obtained in exchange for lease liabilities ⁽¹⁾	\$ 15,387	\$ 26,484	\$ —
Non-cash investing activities:			
Unpaid purchases of property and equipment.....	\$ 2,053	\$ 6,686	\$ 2,391
Settlement of promissory note receivable in connection with business combination.....	5,100	—	—
Non-cash financing activities:			
Unsettled common stock proceeds from option exercises.....	\$ 3,011	\$ 14	\$ 4
Fair value of common stock received for payment of stock option exercise price.....	1,616	—	—
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents.....	\$ 641,447	\$ 567,687	\$ 552,490
Restricted cash.....	3,557	388	151
Total cash, cash equivalents and restricted cash shown in the statement of cash flows.....	<u>\$ 645,004</u>	<u>\$ 568,075</u>	<u>\$ 552,641</u>

⁽¹⁾ In connection with its adoption of ASC 842 on December 30, 2018, the Company recorded a lessee operating lease ROU asset of \$22.5 million. See “Recently Adopted Accounting Pronouncements” in Note 2 to these consolidated financial statements for additional information related to the Company’s adoption of ASC 842.

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 2016, the (FASB) issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU 2016-13)*. Subsequent to the issuance of ASU 2016-13, the FASB clarified the guidance through several ASUs. The collective new guidance (ASC 326) generally 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 recognizes 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 considers relevant information about past events, current conditions, and reasonable and supportable forecasts. The Company’s adoption of this standard, effective December 29, 2019, did not have a material impact on its consolidated financial statements.

MASIMO CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In July 2019, the FASB issued ASU No. 2019-07, *Codification Updates to SEC Sections - Amendments to SEC Paragraphs Pursuant to SEC Final Rule Releases No. 33-10532, Disclosure Update and Simplification, and Nos. 33-10231 and 33-10442, Investment Company Reporting Modernization, and Miscellaneous Updates* (ASU 2019-07). The new standard aligns the guidance in various sections of the codification with the requirements of certain already effective SEC final rules. ASU 2019-07 is effective immediately and was adopted upon issuance. The Company's adoption of this standard did not have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 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 early adopted this standard during the three months ended September 28, 2019, and such adoption did not have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13). The new standard adds and modifies certain disclosure requirements for fair value measurements including when entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but will need to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. ASU 2018-13 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 early adopted this standard during the three months ended September 28, 2019, and such adoption did not have a material impact on its consolidated financial statements.

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 are effective upon issuance. The Company completed its adoption of all applicable items contained in ASU 2018-09 as of September 28, 2019, and such adoption did not have a material impact on its consolidated financial statements.

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 for certain stranded tax effects from accumulated other comprehensive income to retained earnings, and requires certain disclosures about stranded tax effects. ASU 2018-02 is effective for annual and interim periods beginning after December 15, 2018. The Company adopted this standard during the three months ended March 30, 2019, and such adoption did not have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASU 2016-02). Subsequent to the issuance of ASU 2016-02, the FASB clarified the guidance through several ASUs. The collective guidance was codified by the FASB in ASC 842, which, among other things (i) requires the Company to recognize an ROU asset and a lease liability for all operating leases for which the Company is the lessee; (ii) changes the classification of certain embedded leases within the Company's deferred equipment agreements with its customers from operating to sales-type leases, resulting in the acceleration of revenue under certain contracts, as well as the immediate expensing of certain costs that were previously deferred and expensed over the term of the lease; and (iii) requires disclosures by the Company as a lessor and lessee about the amount, timing and uncertainty of cash flows arising from its leases.

On December 30, 2018, the Company adopted ASC 842 using the modified retrospective method for all lease arrangements at the beginning of the period of adoption. Results for reporting periods beginning December 30, 2018 are presented under ASC 842, while prior period amounts were not adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 840, *Leases*. Adoption of this new accounting standard had a material impact on the Company's consolidated balance sheet upon adoption, but did not have a significant impact on the Company's consolidated net earnings and cash flows for the year ended December 28, 2019. For leases that commenced before the effective date of ASC 842, the Company did not elect any of the permitted practical expedients. However, the Company utilized a portfolio approach for purposes of determining the discount rate associated with certain equipment leases and made certain accounting policy elections not to separate lease and non-lease components for its real estate leases and to exclude short-term leases with a term of twelve months or less from its application of ASC 842.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In connection with its adoption of ASC 842, the Company recorded lessee operating lease ROU assets and lessee operating lease liabilities of \$22.5 million as of December 30, 2018, primarily related to real estate and equipment leases, based on the present value of the future lease payments on such date. As a lessor, the Company also recorded customer lease receivables of \$62.0 million, a reduction to equipment leased to customers (formerly titled deferred cost of goods sold) of \$103.5 million, an increase to deferred tax assets of \$8.6 million, a decrease to deferred revenue and contract-related liabilities of \$9.1 million, an increase in other current liabilities of \$3.0 million and a cumulative net decrease to retained earnings of \$26.8 million, all related to the reclassification of certain embedded leases in existing deferred equipment agreements from operating to sales-type leases as of December 30, 2018. See Notes 6, 7 and 11 to these consolidated financial statements for additional disclosures required by ASC 842.

Recently Issued Accounting Pronouncements

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting (ASU 2020-04)*. The new guidance provides temporary optional expedients and exceptions to the guidance in GAAP on contract modifications and hedge accounting to ease the financial reporting burdens related to the expected market transition from the London Interbank Offered Rate (LIBOR) and other interbank offered rates to alternative reference rates, such as the Secured Overnight Financing Rate (SOFR). Entities can make a one-time election to sell and/or reclassify held-to-maturity debt securities that reference an interest rate affected by reference rate reform. ASU 2020-04 is effective beginning on March 12, 2020, and the Company may elect to apply this guidance prospectively through December 31, 2022. The relief is temporary and generally cannot be applied to contract modifications that occur after December 31, 2022 or hedging relationships entered into or evaluated after that date. However, certain optional expedients can be applied to hedging relationships evaluated in periods after December 31, 2022. 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 December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12)*. The new standard simplifies the accounting for income taxes by removing exceptions to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items, to the requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment, to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary, and to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year.

In addition, the standard requires that an entity recognize a franchise tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction, reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, and specifying that an entity is not required to allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements, however, an entity may elect to do so (on an entity-by-entity basis) for a legal entity that is both not subject to tax and disregarded by the taxing authority. ASU 2019-12 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2020. 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.

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.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

- *Cross-Licensing Agreement* - The Company and Cercacor are parties to a cross-licensing agreement (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 \$13.3 million, \$12.1 million and \$10.9 million for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, respectively. The Company had sales to Cercacor in the amount of less than \$0.1 million, \$0.1 million, and less than \$0.1 million for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, respectively.
- *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 \$0.3 million, \$0.2 million and \$0.2 million for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, respectively.
- *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.
- *Lease and Sublease Agreements* - Effective December 14, 2019, the Company entered into a new lease agreement with Cercacor for approximately 34,000 of square feet of office, research and development space at one of the Company's owned facilities in Irvine (Cercacor Lease). The term of the Cercacor Lease expires on December 31, 2024. 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 expired on December 15, 2019. The Company recognized approximately \$1.1 million, \$0.4 million and \$0.4 million of combined lease and sublease income for the years ended January 2, 2021, December 28, 2019, and December 29, 2018, respectively.

Net amounts due to Cercacor were approximately \$3.6 million and \$2.9 million as of January 2, 2021 and December 28, 2019, 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), Chief Financial Officer (CFO) serves as the Treasurer of the Masimo Foundation and the Company's EVP, General Counsel and Corporate Secretary serves as the Secretary for the Masimo Foundation. For the fiscal years ended January 2, 2021, December 28, 2019 and December 29, 2018, the Company made cash contributions of approximately \$1.5 million, \$1.0 million and \$2.0 million, respectively, to the Masimo Foundation. In addition, for each of the years ended January 2, 2021, December 28, 2019 and December 29, 2018, the Company made various in-kind contributions to the Masimo Foundation, mainly in the form of donated administrative services.

The Company's CEO is also a co-founder and a member of the board of directors of Like Minded Media Ventures (LMMV), a team of storytellers that create content focused in the areas of true stories, social causes and science. LMMV creates stories with a multi-platform strategy, bridging the gap between film, television, digital and social media. The Company entered into a marketing service agreement with LMMV for audiovisual production services promoting brand awareness, including television commercials and digital advertising, during the second quarter of 2020. During the fiscal year ended January 2, 2021, the Company incurred approximately \$3.5 million in marketing expenses to LMMV under the marketing service agreement. At January 2, 2021, there was no amount due to LMMV for services rendered.

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 January 2, 2021, December 28, 2019 and December 29, 2018, the Company charged the Company's CEO less than \$0.1 million, \$0.1 million and \$0.2 million, respectively, related to such reimbursements.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

4. Inventories

Inventories consist of the following (in thousands):

	January 2, 2021	December 28, 2019
Raw materials.....	\$ 133,098	\$ 55,920
Work-in-process.....	15,985	10,966
Finished goods.....	66,869	48,985
Total Inventories.....	<u>\$ 215,952</u>	<u>\$ 115,871</u>

5. Other Current Assets

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

	January 2, 2021	December 28, 2019
Prepaid expenses.....	\$ 30,235	\$ 11,746
Lease receivable, current.....	23,206	20,250
Prepaid income taxes.....	14,782	7,330
Indirect taxes receivable.....	14,545	9,311
Deposits to acquire noncontrolling interest ⁽¹⁾	3,374	—
Prepaid rebates and royalties.....	3,081	1,801
Restricted cash ⁽²⁾	3,397	230
Customer notes receivable.....	2,283	4,847
Other current assets.....	7,513	4,556
Total other current assets.....	<u>\$ 102,416</u>	<u>\$ 60,071</u>

⁽¹⁾ During the fourth quarter of fiscal 2020, the Company obtained a controlling interest in a provider of advanced hemodynamic monitoring solutions. The Company made a deposit to acquire the noncontrolling interest of the acquiree.

⁽²⁾ Restricted cash includes funds received from the Bill and Melinda Gates Foundation. As the Company incurs costs associated with research and development related to this project, on a quarterly basis, the Company reclasses amounts from the grant to offset costs incurred.

6. Lease Receivable

Effective December 30, 2018, the Company adopted ASC 842, which resulted in changes to the classification of certain embedded leases within its deferred equipment agreements from operating-type leases to sales-type leases. As a result, the Company now recognizes revenue and costs, as well as a lease receivable, at the time the lease commences pursuant to deferred equipment agreements containing embedded sales-type leases. Lease revenue related to both operating-type and sales-type leases for the year ended January 2, 2021 and December 28, 2019 was approximately \$42.6 million and \$44.0 million, respectively, and is included within product revenue in the accompanying consolidated statements of operations. Costs related to embedded leases within the Company's deferred equipment agreements are included in cost of goods sold. See "Recently Adopted Accounting Pronouncements" in Note 2 to these consolidated financial statements for additional information related to the Company's adoption of ASC 842.

Lease receivable consists of the following (in thousands):

	January 2, 2021	December 28, 2019
Lease receivable.....	\$ 81,074	\$ 70,589
Allowance for credit loss.....	(202)	(403)
Lease receivable, net.....	80,872	70,186
Less: current portion of lease receivable.....	(23,206)	(20,250)
Lease receivable, noncurrent.....	<u>\$ 57,666</u>	<u>\$ 49,936</u>

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

As of January 2, 2021, estimated future maturities of customer sales-type lease receivables for each of the following fiscal years are as follows (in thousands):

Fiscal year	Amount
2021.....	\$ 23,206
2022.....	19,992
2023.....	15,493
2024.....	11,469
2025.....	6,238
Thereafter.....	4,474
Total.....	\$ 80,872

Estimated future operating lease payments expected to be received from customers under deferred equipment agreements are not material as of January 2, 2021.

7. Deferred Costs and Other Contract Assets

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

	January 2, 2021	December 28, 2019
Deferred commissions.....	\$ 7,477	\$ 5,260
Prepaid contract allowances.....	7,336	8,098
Unbilled contract receivables.....	3,925	2,482
Equipment leased to customers, net ⁽¹⁾	1,338	374
Deferred costs and other contract assets.....	\$ 20,076	\$ 16,214

⁽¹⁾ Formerly titled “Deferred cost of goods sold”. In connection with its adoption of ASC 842 on December 30, 2018, the Company recorded a reduction to equipment leased to customers, net, of \$103.5 million as a result of the reclassification of certain embedded leases within the Company’s deferred equipment agreements with its customers from operating to sales-type leases. See “Recently Adopted Accounting Pronouncements” under Note 2 to these consolidated financial statements for additional information related to the Company’s adoption of ASC 842.

For the years ended January 2, 2021, December 28, 2019, and December 29, 2018, \$0.4 million, \$1.0 million and \$30.0 million, respectively, of equipment leased to customers was amortized to cost of goods sold. As of January 2, 2021 and December 28, 2019, accumulated amortization of equipment leased to customers was \$0.9 million and \$0.7 million, respectively.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

8. Property and Equipment, net

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

	January 2, 2021	December 28, 2019
Building and building improvements.....	\$ 122,310	\$ 101,731
Machinery and equipment.....	72,610	58,864
Land.....	57,151	40,216
Aircraft and vehicles.....	33,175	29,934
Computer equipment and software.....	24,693	19,650
Leasehold improvements.....	19,295	15,921
Tooling.....	18,233	15,346
Furniture and office equipment.....	13,567	11,049
Demonstration units.....	1,024	836
Construction-in-progress (CIP).....	44,589	39,107
Total property and equipment	406,647	332,654
Accumulated depreciation.....	(134,136)	(113,102)
Property and equipment, net.....	<u>\$ 272,511</u>	<u>\$ 219,552</u>

In March 2020, the Company purchased a facility in Switzerland for its international headquarters for a purchase price of \$16.4 million, as well as land in Mexicali, Mexico for a purchase price of \$7.7 million to be used for the construction of a new manufacturing and distribution facility.

The balance in CIP at January 2, 2021 relates primarily to acquisition and improvement costs for a portion of a recently purchased building in Switzerland, capitalized implementation costs related to a new enterprise resource planning software system and costs related to manufacturing equipment and other facility improvements, the underlying assets for which have not been completed or placed into service. The balance in CIP at December 28, 2019 related primarily to acquisition and improvement costs for a portion of a recently purchased building in California, capitalized and implementation costs related to an enterprise resource planning software system and costs related to manufacturing equipment and other facility improvements, the underlying assets for which have not been placed into service.

For the years ended January 2, 2021, December 28, 2019 and December 29, 2018, depreciation expense of property and equipment was \$21.8 million, \$19.1 million and \$16.3 million, respectively.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

9. Intangible Assets, net

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

	January 2, 2021	December 28, 2019
Gross carrying amount		
Acquired technologies.....	\$ 29,039	\$ 5,580
Patents.....	26,875	23,242
Customer relationships.....	24,666	7,669
Trademarks.....	11,708	4,614
Licenses-related party.....	7,500	7,500
Capitalized software development costs.....	3,710	3,328
Other.....	7,091	5,466
Total gross carrying amount.....	<u>\$ 110,589</u>	<u>\$ 57,399</u>
Accumulated amortization		
Patents.....	\$ (10,763)	\$ (9,251)
Licenses-related party.....	(6,841)	(5,984)
Customer relationships.....	(6,486)	(5,688)
Acquired technologies.....	(5,259)	(4,182)
Trademarks.....	(3,999)	(2,195)
Capitalized software development costs.....	(2,319)	(2,137)
Other.....	(999)	(711)
Total accumulated amortization.....	<u>(36,666)</u>	<u>(30,148)</u>
Net carrying amount.....	<u>\$ 73,923</u>	<u>\$ 27,251</u>

Intangible assets have a weighted-average amortization period of twelve years. For the years ended January 2, 2021, December 28, 2019 and December 29, 2018, amortization of intangible assets was \$7.5 million, \$4.4 million and \$4.8 million, respectively. As of January 2, 2021 and December 28, 2019, the total costs of patents not yet amortizing was \$8.2 million and \$6.1 million, respectively. As of January 2, 2021 and December 28, 2019, the total costs of trademarks not yet amortizing was \$0.9 million and \$0.7 million, respectively.

For the years ended January 2, 2021 and December 28, 2019, total renewal costs capitalized for patents and trademarks was \$1.3 million and \$1.3 million, respectively. As of January 2, 2021, the weighted-average number of years until the next renewal was one year for patents and six years for trademarks.

During the first quarter of fiscal 2020, the Company completed an immaterial business combination. Based on the Company's preliminary purchase price allocation, approximately \$15.5 million, \$2.6 million and \$1.7 million of the purchase price was assigned to customer relationships, acquired technologies and trademarks, respectively.

During the second quarter of fiscal 2020, the Company completed another immaterial business combination. Based on the Company's preliminary purchase price allocation, approximately \$6.3 million, \$2.4 million, \$0.4 million and \$0.3 million of the purchase price was assigned to acquired technologies, trademarks, customer relationships and other intangibles, respectively.

During the fourth quarter of fiscal 2020, the Company obtained a controlling interest in a provider of advanced hemodynamic monitoring solutions. Based on the Company's preliminary purchase price allocation, approximately \$14.0 million, \$2.3 million, \$1.0 million and \$1.0 million of the purchase price was assigned to acquired technologies, trademarks, customer relationships and other intangibles, respectively. Subsequently, during the first quarter of fiscal 2021, the Company acquired the remaining minority interest. See Note 14 to these consolidated financial statements for further details.

The Company is still gathering additional information to finalize these preliminary estimates with respect to tax contingency matters and expects to finalize the purchase price allocations as soon as practicable, but no later than one year from the acquisition dates.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

Fiscal year	Amount
2021.....	\$ 8,761
2022.....	8,385
2023.....	7,334
2024.....	6,985
2025.....	5,974
Thereafter.....	36,484
Total.....	<u>\$ 73,923</u>

10. Goodwill

Changes in goodwill were as follows (in thousands):

	January 2, 2021	December 28, 2019
Goodwill, beginning of period.....	\$ 22,350	\$ 23,297
Increase from business combinations.....	79,862	—
Foreign currency translation and other adjustments.....	994	(947)
Goodwill, end of period.....	<u>\$ 103,206</u>	<u>\$ 22,350</u>

During the first quarter of fiscal 2020, the Company completed an immaterial business combination. Based on the Company’s preliminary purchase price allocation for this transaction, approximately \$31.4 million of the purchase price was assigned to goodwill.

During the second quarter of fiscal 2020, the Company completed another immaterial business combination. Based on the Company’s preliminary purchase price allocation for this transaction, approximately \$26.7 million of the purchase price was assigned to goodwill.

During the fourth quarter of fiscal 2020, the Company obtained a controlling interest in a provider of advanced hemodynamic monitoring solutions. Based on the Company’s preliminary purchase price allocation, approximately \$21.8 million of the purchase price was assigned to goodwill. Subsequently, during the first quarter of fiscal 2021, the Company acquired the remaining minority interest. See Note 14 to these consolidated financial statements for further details.

The Company is still gathering additional information to finalize these preliminary estimates with respect to tax contingency matters and expects to finalize the purchase price allocations as soon as practicable, but no later than one year from the acquisition dates.

11. Lessee ROU Assets and Lease Liabilities

Effective December 30, 2018, the Company adopted ASC 842. See “Recently Adopted Accounting Pronouncements” in Note 2 to these consolidated financial statements for additional information.

The Company leases certain facilities in North and South America, Europe, the Middle East and Asia-Pacific regions under operating lease agreements expiring at various dates through February 2031. In addition, the Company leases equipment in the U.S. and Europe that are classified as operating leases and expire at various dates through April 2024. The majority of these leases are non-cancellable and generally do not contain any material restrictive covenants, material residual value guarantees or other material guarantees. The Company recognizes lease costs under these agreements using a straight-line method based on total lease payments. Certain facility leases contain predetermined price escalations and in some cases renewal options, the longest of which is for five years.

The Company generally estimates the applicable discount rate used to determine the net present value of lease payments based on available information at the lease commencement date. As of January 2, 2021, the weighted average discount rate used by the Company for all operating leases was approximately 2.5%.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The balance sheet classifications for amounts related to the Company's operating leases for which it is the lessee are as follows (in thousands):

Balance sheet classification		January 2, 2021	December 28, 2019
Lessee ROU assets, net.....	Other non-current assets.....	\$ 32,324	\$ 19,137
Lessee current lease liabilities.....	Other current liabilities.....	5,975	4,653
Lessee non-current lease liabilities.....	Other non-current liabilities.....	28,373	15,834
Total operating lease liabilities.....		<u>\$ 34,348</u>	<u>\$ 20,487</u>

For the years ended January 2, 2021 and December 28, 2019, accumulated amortization for lessee ROU assets was \$9.2 million and \$4.7 million, respectively. The weighted average remaining lease term for the Company's operating leases was 7.1 years as of January 2, 2021.

As of January 2, 2021, estimated future operating lease payments for each of the following fiscal years were as follows (in thousands):

Fiscal year	Amount
2021.....	\$ 6,610
2022.....	6,048
2023.....	5,762
2024.....	4,540
2025.....	3,576
Thereafter ⁽¹⁾	11,055
Total.....	<u>37,591</u>
Imputed interest.....	(3,243)
Present value ⁽²⁾	<u>\$ 34,348</u>

⁽¹⁾ Includes optional renewal period for certain leases.

⁽²⁾ During fiscal 2020, the Company entered into lease agreements for two properties which have not commenced as of January 2, 2021. The future obligations for such leases are \$3.1 million in the aggregate and are not included in the estimated future operating lease payments.

Lease costs consist of the following (in thousands):

	January 2, 2021	December 28, 2019
Operating lease costs.....	\$ 6,945	\$ 6,790
Short-term lease costs.....	1	12
Sublease income.....	—	(232)
Total lease cost.....	<u>\$ 6,946</u>	<u>\$ 6,570</u>

For the year ended December 29, 2018, rental expense related to operating leases was \$6.9 million.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

12. Other Non-Current Assets

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

	January 2, 2021	December 28, 2019
Lessee ROU assets, net.....	\$ 32,324	\$ 19,137
Strategic investments.....	8,002	6,475
Prepaid deposits.....	3,816	3,022
Other non-current assets.....	500	157
Total non-current assets.....	<u>\$ 44,642</u>	<u>\$ 28,791</u>

13. Deferred Revenue and Other Contract Liabilities

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

	January 2, 2021	December 28, 2019
Deferred revenue ⁽¹⁾	\$ 33,221	\$ 13,998
Accrued rebates and allowances.....	12,127	8,436
Accrued customer reimbursements ⁽²⁾	3,829	5,739
Total deferred revenue and other contract liabilities.....	49,177	28,173
Less: Non-current portion of deferred revenue.....	(4,242)	(2,234)
Deferred revenue and other contract liabilities - current.....	<u>\$ 44,935</u>	<u>\$ 25,939</u>

⁽¹⁾ In connection with its adoption of ASC 842 on December 30, 2018, the Company recorded a reduction to deferred revenue of approximately \$1.1 million due to the acceleration of revenue as a result of the reclassification of certain embedded leases within the Company's deferred equipment agreements with its customers from operating to sales-type leases. See "Recently Adopted Accounting Pronouncements" in Note 2 to these consolidated financial statements for additional information related to the Company's adoption of ASC 842.

⁽²⁾ In connection with its adoption of ASC 842 on December 30, 2018, the Company recorded a reduction to accrued customer reimbursements of approximately \$12.3 million related to the derecognition of liabilities and leased equipment assets for certain OEM equipment reimbursements. See "Recently Adopted Accounting Pronouncements" in Note 2 to these consolidated financial statements for additional information related to the Company's adoption of ASC 842.

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 maintenance agreements.

Changes in deferred revenue for the year ended January 2, 2021 were as follows:

	Amount
Deferred revenue, beginning of the period.....	\$ 13,998
Increase from business combinations.....	9,778
Revenue deferred during the period.....	27,385
Recognition of revenue deferred in prior periods.....	(17,940)
Deferred revenue, end of the period.....	<u>\$ 33,221</u>

During the first quarter of fiscal 2020, the Company completed an immaterial business combination. Based on the Company's preliminary purchase price allocation for this transaction, approximately \$7.4 million of the purchase price was assigned to deferred revenue.

During the second quarter of fiscal 2020, the Company completed another immaterial business combination. Based on the Company's preliminary purchase price allocation for this transaction, approximately \$1.3 million of the purchase price was assigned to deferred revenue.

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

During the fourth quarter of fiscal 2020, the Company obtained a controlling interest in a provider of advanced hemodynamic monitoring solutions. Based on the Company's preliminary purchase price allocation, approximately \$1.1 million of the purchase price was assigned to deferred revenue. Subsequently, during the first quarter of fiscal 2021, the Company acquired the remaining minority interest. See Note 14 to these consolidated financial statements for further details.

The Company is still gathering additional information to finalize these preliminary estimates with respect to tax contingency matters and expects to finalize the purchase price allocations as soon as practicable, but no later than one year from the acquisition dates.

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 customers under deferred equipment agreements and other contractual obligations for which neither party has performed.

The following table summarizes the Company's estimated Unrecognized Contract Revenue as of January 2, 2021 and the future periods within which the Company expects to recognize such revenue.

	Expected Future Revenue By Period (in thousands)				Total
	Less than 1 Year	Between 1-3 Years	Between 3-5 Years	More than 5 Years	
Unrecognized contract revenue.....	\$ 231,982	\$ 370,779	\$ 176,835	\$ 44,862	\$ 824,458

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.

14. Other Current Liabilities

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

	January 2, 2021	December 28, 2019
Accrued indirect taxes payable.....	\$ 14,365	\$ 7,545
Accrued expenses.....	6,794	6,115
Lessee lease liabilities, current.....	5,975	4,653
Income tax payable.....	5,910	7,142
Accrued legal fees.....	4,058	1,839
Related party payables.....	3,655	3,024
Minority interest ⁽¹⁾	3,469	—
Accrued warranty.....	2,740	3,395
Accrued property taxes.....	1,682	1,629
Other current liabilities.....	4,591	1,685
Total other current liabilities.....	<u>\$ 53,239</u>	<u>\$ 37,027</u>

⁽¹⁾ During the fourth quarter of fiscal 2020, the Company obtained a controlling interest in a provider of advanced hemodynamic monitoring solutions. The noncontrolling interest of the acquiree was recorded within other current liabilities as of January 2, 2021, as the minority interest shares are mandatorily redeemable. During the first quarter of fiscal 2021, the Company acquired the remaining minority interest.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

15. Credit Facilities

The Company currently maintains a credit agreement (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 Credit Facility provides for up to \$150.0 million of unsecured borrowings, 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 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.

Borrowings under the 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 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 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 Credit Facility.

Pursuant to the terms of the 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 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 January 2, 2021 and December 28, 2019, the Credit Facility had no outstanding draws and as of January 2, 2021, the Credit Facility had \$1.7 million of outstanding letters of credit. The Company was in compliance with all covenants under the Credit Facility as of January 2, 2021.

The Company incurred total combined interest expense of \$0.3 million, \$0.3 million and \$0.6 million for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, respectively, under its current and previous credit facilities.

16. Other Non-Current Liabilities

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

	January 2, 2021	December 28, 2019
Lessee non-current lease liabilities.....	\$ 28,373	\$ 15,834
Income tax payable, non-current.....	19,245	21,509
Unrecognized tax benefits.....	11,777	13,184
Deferred tax liabilities.....	6,247	3,052
Other non-current liabilities.....	5,434	2,456
Total other non-current liabilities.....	<u>\$ 71,076</u>	<u>\$ 56,035</u>

Unrecognized tax benefits relate 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 20 to these consolidated financial statements for further details.

17. 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.

MASIMO CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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. As of January 2, 2021, 4.3 million shares remained available for repurchase pursuant the 2018 Repurchase Program.

The following table provides a summary of the Company’s stock repurchase activities during the years ended January 2, 2021, December 28, 2019 and December 29, 2018 (in thousands, except per share amounts):

	Years Ended		
	January 2, 2021	December 28, 2019	December 29, 2018
Shares repurchased.....	456 ⁽¹⁾	275 ⁽¹⁾	198
Average cost per share.....	\$ 242.40	\$ 136.61	\$ 84.12
Value of shares repurchased.....	\$ 110,540	\$ 37,554	\$ 16,490

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

18. Stock-Based Compensation

Total stock-based compensation expense for the years ended January 2, 2021, December 28, 2019 and December 29, 2018 was \$42.2 million, \$39.2 million and \$27.4 million, respectively. As of January 2, 2021, an aggregate of 11.1 million shares of common stock were reserved for future issuance under the Company’s equity plans, of which 4.4 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

2007 Stock Incentive Plan

Effective June 1, 2017, upon the approval and ratification of the 2017 Equity Plan, the Company’s 2007 Stock Incentive Plan (2007 Equity Plan) terminated, provided that awards outstanding under the 2007 Equity Plan will continue to be governed by the terms of that plan. In addition, upon the effectiveness of the 2017 Equity Plan, an aggregate of 5.0 million shares of the Company’s common stock registered under prior registration statements for issuance pursuant to the 2007 Equity Plan were deregistered and concurrently registered under the 2017 Equity Plan.

2017 Equity Incentive 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. Upon effectiveness, an aggregate of 5.0 million shares were available for issuance under the 2017 Equity Plan. In May 2020, the Company’s stockholders approved an increase of 2.5 million shares to the 2017 Equity Plan. The aggregate number of shares that may be awarded under the 2017 Equity Plan is 7.5 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. 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 closing price of the Company’s common stock on the Nasdaq Global Select Market on the grant date.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock-Based Award Activity

Stock Options

The number and weighted-average exercise price of options issued and outstanding under all of the Company's equity plans are as follows (in thousands, except for weighted-average exercise prices):

	Year Ended January 2, 2021		Year Ended December 28, 2019		Year Ended December 29, 2018	
	Shares	Average Exercise Price	Shares	Average Exercise Price	Shares	Average Exercise Price
Options outstanding, beginning of period.....	5,212	\$ 54.23	5,676	\$ 43.61	6,953	\$ 36.26
Granted.....	400	187.83	545	140.56	564	98.47
Canceled/Forfeited.....	(219)	126.98	(158)	83.14	(233)	67.45
Exercised.....	(1,945)	32.41	(851)	33.32	(1,608)	27.62
Options outstanding, end of period.....	<u>3,448</u>	\$ 77.44	<u>5,212</u>	\$ 54.23	<u>5,676</u>	\$ 43.61
Options exercisable, end of period.....	2,026	\$ 47.31	3,311	\$ 33.80	3,273	\$ 29.63

Total stock option expense for the years ended January 2, 2021, December 28, 2019 and December 29, 2018 was \$16.1 million, \$14.8 million, and \$13.8 million, respectively. As of January 2, 2021, the Company had \$40.8 million of unrecognized compensation cost related to non-vested stock options that are expected to vest over a weighted average period of approximately 5.9 years.

The number and weighted-average exercise price of outstanding and exercisable stock options segregated by exercise price ranges (in thousands, except range of exercise prices and remaining contractual life) were as follows:

Range of Exercise Prices	Year Ended January 2, 2021			Year Ended December 28, 2019		
	Options Outstanding		Options Exercisable	Options Outstanding		Options Exercisable
	Number of Options	Average Remaining Contractual Life	Number of Options	Number of Options	Average Remaining Contractual Life	Number of Options
\$15.00 to \$50.00.....	1,696	4.14	1,518	3,464	4.14	2,958
\$50.01 to \$80.00.....	42	5.80	26	68	5.56	30
\$80.01 to \$120.00.....	910	6.83	408	1,148	6.98	320
\$120.01 to \$160.00.....	476	8.41	74	532	8.46	3
\$160.01 to \$200.00.....	255	9.17	—	—	0.00	—
\$200.01 to \$230.00.....	37	9.50	—	—	0.00	—
\$230.01 to \$275.00.....	32	9.53	—	—	0.00	—
Total.....	<u>3,448</u>	5.90	<u>2,026</u>	<u>5,212</u>	5.60	<u>3,311</u>

As of January 2, 2021 and December 28, 2019, the weighted-average remaining contractual term of options outstanding was 5.9 years and 5.6 years, respectively. As of January 2, 2021 and December 28, 2019, the weighted average remaining contractual term of options exercisable with an exercise price less than the closing price of the Company's common stock was 4.7 years and 4.3 years, respectively.

RSUs

The number of RSUs issued and outstanding under all of the Company's equity plans are as follows (in thousands, except for weighted average grant date fair value amounts):

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	Year Ended January 2, 2021		Year Ended December 28, 2019		Year Ended December 29, 2018	
	Units	Weighted Average Grant Date Fair Value	Units	Weighted Average Grant Date Fair Value	Units	Weighted Average Grant Date Fair Value
RSUs outstanding, beginning of period.....	2,797	\$ 96.85	2,707	\$ 95.54	2,708	\$ 95.51
Granted.....	98	193.77	100	133.57	7	99.05
Canceled/Forfeited.....	(6)	165.03	(3)	133.50	—	—
Vested.....	(27)	134.78	(7)	99.05	(8)	88.40
RSUs outstanding, end of period.....	2,862	\$ 99.66	2,797	\$ 96.85	2,707	\$ 95.54

Total RSU expense for the years ended January 2, 2021, December 28, 2019 and December 29, 2018 was \$5.7 million, \$2.8 million and \$0.7 million, respectively. As of January 2, 2021, the Company had \$22.6 million of unrecognized compensation cost related to non-vested RSU awards expected to be recognized and vest over a weighted-average period of approximately 3.8 years, excluding any contingent compensation expense related to certain RSUs that were granted to the Company's Chairman and CEO in connection with the amendment and restatement of his employment agreement. See "Employment and Severance Agreements" in Note 21 to these consolidated financial statements for further details on the CEO's employment agreement.

PSUs

The number of PSUs outstanding under all of the Company's equity plans are as follows (in thousands, except for weighted average grant date fair value amounts):

	Year Ended January 2, 2021		Year Ended December 28, 2019		Year Ended December 29, 2018	
	Units	Weighted Average Grant Date Fair Value	Units	Weighted Average Grant Date Fair Value	Units	Weighted Average Grant Date Fair Value
PSUs outstanding, beginning of period.....	412	\$ 102.22	313	\$ 88.34	233	\$ 90.70
Granted.....	97	179.42	128	133.50	197	86.95
Canceled/Forfeited.....	(7)	122.13	—	—	(86)	90.71
Vested.....	(58)	90.69	(29)	90.69	(31)	90.70
PSUs outstanding, end of period.....	444	\$ 120.28	412	\$ 102.22	313	\$ 88.34

During the year ended December 29, 2018, the Company awarded 197,000 PSUs that will vest three years from the award date based on the achievement of certain 2020 performance criteria approved by the Compensation Committee. If earned, the PSUs granted will vest at the time the achievement level of the performance criteria is determined by the Compensation Committee. The number of shares that may be earned can range from 0% to 200% of the target amount; therefore, the maximum number of shares that can be issued under these awards is twice the original award of 197,000 PSUs or 394,000 shares. On February 22, 2021, the Compensation Committee determined that the performance criteria was achieved within the range.

During the year ended December 28, 2019, the Company awarded 128,000 PSUs that will vest three years from the award date, based on the achievement of certain 2021 performance criteria approved by the Board. If earned, the PSUs granted will vest upon achievement of the performance criteria after the year in which the performance achievement level has been determined. The number of shares that may be earned can range from 0% to 200% of the target amount; therefore, the maximum number of shares that can be issued under these awards is twice the original award of 128,000 PSUs or 256,000 shares.

During the year ended January 2, 2021, the Company awarded 97,000 PSUs that will vest three years from the award date, based on the achievement of certain 2023 performance criteria approved by the Board. If earned, the PSUs granted will vest upon achievement of the performance criteria after the year in which the performance achievement level has been determined. The number of shares that may be earned can range from 0% to 200% of the target amount; therefore, the maximum number of shares that can be issued under these awards is twice the original award of 97,000 PSUs or 194,000 shares.

Based on management's estimate of the number of units expected to vest, total PSU expense for the years ended January 2, 2021, December 28, 2019 and December 29, 2018 was \$20.4 million, \$21.6 million and \$12.9 million, respectively. As of

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

January 2, 2021, the Company had \$31.6 million of unrecognized compensation cost related to non-vested PSU awards expected to be recognized and vest over a weighted-average period of approximately 0.9 years.

Valuation of Stock-Based Award Activity

The fair value of each RSU and PSU is determined based on the closing price of the Company's common stock on the grant date.

The Black-Scholes option pricing model is used to estimate the fair value of options granted under the Company's stock-based compensation plans. The range of assumptions used and the resulting weighted-average fair value of options granted at the date of grant were as follows:

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Risk-free interest rate.....	0.2% to 1.7%	1.4% to 2.6%	2.3% to 3.1%
Expected term.....	5.1 years to 5.1 years	5.1 years to 5.2 years	5.2 years to 5.6 years
Estimated volatility.....	26.9% to 35.5%	28.2% to 30.0%	26.8% to 32.0%
Expected dividends.....	0%	0%	0%
Weighted-average fair value of options granted...	\$51.10 per share	\$42.29 per share	\$31.85 per share

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

Expected term. The expected term represents the average period that the Company's stock options are expected to be outstanding. The expected term is based on both the Company's specific historical option exercise experience, as well as expected term information available from a peer group of companies with a similar vesting schedule.

Estimated volatility. The estimated volatility is the amount by which the Company's share price is expected to fluctuate during a period. The Company's estimated volatilities for fiscal years 2020, 2019 and 2018 are based on historical and implied volatilities of the Company's share price over the expected term of the option.

Expected dividends. The Board may from time to time declare, and the Company may pay, dividends on its outstanding shares in the manner and upon the terms and conditions provided by law. Any determination to declare and pay dividends will be made by the Board and will depend upon the Company's results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by the Board. In the event a dividend is declared, there is no assurance with respect to the amount, timing or frequency of any such dividends. The dividend declared in 2012 was deemed to be a special dividend and there is no assurance that special dividends will be declared again during the expected term. Based on this uncertainty and unknown frequency, for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, no dividend rate was used in the assumptions to calculate the stock-based compensation expense.

The Company has elected to recognize stock-based compensation expense on a straight-line basis over the requisite service period for the entire award. The total fair value of all options that vested during fiscal years 2020, 2019 and 2018 was \$15.1 million, \$14.2 million and \$13.7 million, respectively.

The aggregate intrinsic value of options is calculated as the positive difference, if any, between the market value of the Company's common stock on the date of exercise or the respective period end, as appropriate, and the exercise price of the options. The aggregate intrinsic value of options outstanding, with an exercise price less than the closing price of the Company's common stock, as of January 2, 2021 was \$658.5 million. The aggregate intrinsic value of options exercisable, with an exercise price less than the closing price of the Company's common stock, as of January 2, 2021 was \$447.8 million. The aggregate intrinsic value of options exercised during the years ended January 2, 2021, December 28, 2019 and December 29, 2018 was \$355.3 million, \$93.9 million and \$127.1 million, respectively.

The total income tax benefit recognized in the consolidated statements of operations for stock-based compensation expense was \$30.4 million, \$15.7 million and \$22.0 million for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, respectively.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table presents the total stock-based compensation expense that is included in each functional line item of the consolidated statements of operations (in thousands):

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Cost of goods sold.....	\$ 714	\$ 445	\$ 334
Selling, general and administrative.....	31,462	30,450	21,391
Research and development.....	10,049	8,340	5,692
Total.....	<u>\$ 42,225</u>	<u>\$ 39,235</u>	<u>\$ 27,417</u>

The increase in total stock-based compensation expense during the year ended January 2, 2021 was due to both the composition of the equity awards granted and a significant increase in the fair market value of the Company's stock from the prior year, which increased the value of the equity awards granted during such year.

19. Non-operating Income

Non-operating income consists of the following (in thousands):

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Interest income.....	\$ 5,534	\$ 13,917	\$ 8,178
Realized and unrealized foreign currency gain (loss).....	2,631	(627)	(2,027)
Interest expense.....	(338)	(328)	(706)
Other.....	86	(12)	287
Total non-operating income.....	<u>\$ 7,913</u>	<u>\$ 12,950</u>	<u>\$ 5,732</u>

20. Income Taxes

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

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
United States.....	\$ 214,816	\$ 181,664	\$ 173,848
Foreign.....	48,920	52,502	39,928
Total.....	<u>\$ 263,736</u>	<u>\$ 234,166</u>	<u>\$ 213,776</u>

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Current:			
Federal.....	\$ 13,901	\$ 30,218	\$ 20,418
State.....	6,444	5,273	3,075
Foreign.....	8,073	8,424	5,014
Subtotal.....	<u>\$ 28,418</u>	<u>\$ 43,915</u>	<u>\$ 28,507</u>
Deferred:			
Federal.....	\$ 1,354	\$ (3,732)	\$ (6,678)
State.....	(6,191)	(1,985)	(1,258)
Foreign.....	(127)	(248)	(338)
Subtotal.....	<u>(4,964)</u>	<u>(5,965)</u>	<u>(8,274)</u>
Total.....	<u>\$ 23,454</u>	<u>\$ 37,950</u>	<u>\$ 20,233</u>

Included in the fiscal year 2020 and 2019 tax provisions are increases of \$0.2 million and \$1.8 million, respectively, for tax and accrued interest related to uncertain tax positions for each fiscal year. Fiscal year 2018 included a tax benefit of \$1.6 million for tax and accrued interest related to uncertain tax positions.

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

	Year Ended January 2, 2021	Year Ended December 28, 2019	Year Ended December 29, 2018
Statutory regular federal income tax rate.....	21.0 %	21.0 %	21.0 %
State provision, net of federal benefit.....	0.1	1.1	0.7
Nondeductible executive compensation.....	1.8	2.1	1.9
Research and development tax credits.....	(2.2)	(1.1)	(1.4)
Foreign income taxed at different rates.....	(1.0)	(1.7)	(2.0)
U.S. tax on foreign income, net.....	1.0	0.1	0.7
Impact of 2017 Tax Act.....	—	—	0.1
Withholding taxes on undistributed foreign earnings, net.....	—	—	(0.6)
Excess stock-based compensation.....	(10.4)	(6.0)	(9.4)
Derecognition of uncertain tax position.....	(2.2)	—	(1.5)
Other.....	0.8	0.7	—
Total.....	<u>8.9 %</u>	<u>16.2 %</u>	<u>9.5 %</u>

During the year ended December 29, 2018, the Company completed its analysis of the income tax effects of the Tax Cuts and Jobs Act of 2017 (2017 Tax Act) and, pursuant to Staff Accounting Bulletin No. 118, recorded an adjustment of approximately \$0.9 million to reduce its previously estimated accrual based on additional information and guidance that became available with respect to the application of certain provisions of the 2017 Tax Act. The U.S. Treasury Department, the Internal Revenue Service, and other standard-setting bodies will continue to interpret or issue guidance on how provisions of the 2017 Tax Act will be applied or otherwise administered. As future guidance is issued, the Company may make adjustments to amounts that it has previously recorded that may materially impact its provision for income taxes in the period in which such adjustments are made.

As of January 2, 2021, the Company has accumulated undistributed earnings generated by its foreign subsidiaries of approximately \$229.3 million. Because such earnings have previously been subject to U.S. tax, any additional taxes due with respect to such earnings or the excess of the amount for financial reporting over the tax basis of its foreign investments would generally be limited to foreign withholding and state taxes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company considers \$86.5 million of these accumulated undistributed earnings as no longer permanently reinvested and has accrued foreign withholding and state taxes, net of estimated foreign tax credits, of \$1.6 million. The Company intends, however, to indefinitely reinvest the remaining \$142.8 million of earnings. If the Company decides to distribute such permanently reinvested earnings, the Company would accrue estimated additional income tax expense of up to approximately \$6.8 million.

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

	January 2, 2021	December 28, 2019
Deferred tax assets:		
Deferred revenue.....	\$ 19,769	\$ 13,948
Net operating losses.....	19,140	724
Accrued liabilities.....	16,534	13,273
Tax credits.....	9,398	6,438
Stock-based compensation.....	8,385	7,926
Operating lease assets.....	5,782	4,174
Other.....	—	867
Total.....	79,008	47,350
Valuation allowance.....	(15,660)	—
Total deferred tax assets.....	\$ 63,348	\$ 47,350
Deferred tax liabilities:		
Property and equipment.....	\$ (12,818)	\$ (6,604)
Acquired intangibles.....	(5,465)	—
Operating lease liabilities.....	(5,429)	(3,845)
Withholding taxes on undistributed foreign earnings.....	(3,108)	(2,829)
State taxes and other.....	(2,302)	(1,152)
Other.....	(1,110)	—
Total deferred tax liabilities.....	(30,232)	(14,430)
Net deferred tax assets.....	\$ 33,116	\$ 32,920

As of January 2, 2021, the Company has \$1.9 million and \$2.9 million of net operating losses from federal and various state jurisdictions, which will begin to expire in 2036 and 2039, respectively. Additionally, the Company has \$76.8 million of net operating losses from foreign jurisdictions which will carryover indefinitely. The Company also has state research and development tax credits of \$14.9 million that will carry forward indefinitely and \$0.3 million of Canadian investment tax credits on research and development expenditures that will begin to expire in 2033. In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that all or some portion of the deferred tax assets will not be realized. In making this determination, the Company considered all available positive and negative evidence, including scheduled reversals of liabilities, projected future taxable income, tax planning strategies and recent financial performance. During the year ended January 2, 2021, the Company established a valuation allowance to reduce the deferred tax assets relating to certain acquired operating losses in certain foreign jurisdictions that the Company believes are not likely to be realized.

As a result of certain business and employment actions undertaken by the Company, income earned in a certain European country is subject to a reduced tax rate through 2022, which, upon meeting certain requirements, can be extended through 2026. For the year ended January 2, 2021 and December 29, 2018, the estimated income tax benefit related to such business arrangement was \$0.9 million and \$1.7 million, respectively, and favorably impacted net income per diluted share by \$0.02 for each year.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits (in thousands):

	Year Ended January 2, 2021	Year Ended December 28, 2019
Unrecognized tax benefits (gross), beginning of period.....	\$ 17,009	\$ 15,412
Increase from tax positions in prior period.....	471	81
Increase from tax positions in current period.....	6,565	2,636
Lapse of statute of limitations.....	(6,040)	(1,120)
Unrecognized tax benefits (gross), end of period.....	<u>\$ 18,005</u>	<u>\$ 17,009</u>

The amount of unrecognized benefits which, if ultimately recognized, could favorably affect the tax rate in a future period was \$16.3 million and \$15.7 million as of January 2, 2021 and December 28, 2019, respectively. It is reasonably possible that the amount of unrecognized tax benefits in various jurisdictions may change in the next 12 months due to the expiration of statutes of limitation and audit settlements. However, due to the uncertainty surrounding the timing of these events, an estimate of the change within the next 12 months cannot be made at this time.

For the years ended January 2, 2021 and December 29, 2018, the Company recorded a benefit of \$0.5 million and \$0.8 million, respectively, for interest and penalties related to unrecognized tax benefits as part of income tax expense. For the year ended December 28, 2019, the Company recorded an expense of \$0.5 million for interest and penalties related to unrecognized tax benefits as part of income tax expense.

Total accrued interest and penalties related to unrecognized tax benefits as of January 2, 2021 and December 28, 2019 were \$0.7 million and \$1.3 million, respectively.

The Company conducts business in multiple jurisdictions, and as a result, one or more of the Company's subsidiaries files income tax returns in the U.S. federal, various state, local and foreign jurisdictions. The Company has concluded all U.S. federal income tax matters for years through 2016. All material state, local and foreign income tax matters have been concluded for years through 2013.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) was enacted and signed into law in response to the market volatility and instability resulting from the COVID-19 pandemic. It includes a significant number of tax provisions and lifts certain deduction limitations originally imposed by the 2017 Tax Act. The changes are primarily related to: (1) the business interest expense disallowance rules for 2019 and 2020; (2) net operating loss rules; (3) charitable contribution limitations; (4) employee retention credit; and (5) the realization of corporate alternative minimum tax credits.

The Company has reviewed the tax provision in the CARES Act and did not identify any material impact to the Company's consolidated financial statements.

21. Commitments and Contingencies

Employee Retirement Savings Plan

The Company sponsors a qualified defined contribution plan or 401(k) plan, the Masimo Retirement Savings Plan (MRSP), covering the Company's full-time U.S. employees who meet certain eligibility requirements. In general, the Company matches an employee's contribution up to 3% of the employee's compensation, subject to a maximum amount. The Company may also contribute to the MRSP on a discretionary basis. The Company contributed \$3.2 million, \$2.5 million and \$2.3 million to the MRSP for the years ended January 2, 2021, December 28, 2019 and December 29, 2018, respectively, all in the form of matching contributions. In addition, the Company sponsors various defined contribution plans in certain locations outside of the United States, the contributions to which were not material for any period.

Employment and Severance Agreements

In July 2017, the Company entered into the First Amendment to the certain Amended and Restated Employment Agreement entered into between the Company and Mr. Kiani on November 4, 2015 (as amended, the Amended Employment Agreement). Pursuant to the terms of the Amended Employment Agreement, upon a "Qualifying Termination" (as defined in the Amended Employment Agreement), Mr. Kiani will be entitled to receive a cash severance benefit equal to two times the sum of his then-current base salary and the average annual bonus paid to Mr. Kiani during the immediately preceding three years, the full amount of the "Award Shares" (as defined in the Amended Employment Agreement) and the full amount of the "Cash Payment" (as defined in the Amended Employment Agreement).

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In addition, in the event of a “Change in Control” (as defined in the Amended Employment Agreement) prior to a Qualifying Termination, on each of the first and second anniversaries of the Change in Control, 50% of the Cash Payment and 50% of the Award Shares will vest, subject in each case to Mr. Kiani’s continuous employment through each such anniversary date; however, in the event of a Qualifying Termination or a termination of Mr. Kiani’s employment due to death or disability prior to either of such anniversaries, any unvested amount of the Cash Payment and all of the unvested Award Shares shall vest and be paid in full. Additionally, in the event of a Change in Control prior to a Qualifying Termination, Mr. Kiani’s stock options and any other equity awards will vest in accordance with their terms, but in no event later than in two equal installments on each of the one year and two year anniversaries of the Change in Control, subject in each case to Mr. Kiani’s continuous employment through each such anniversary date.

As of January 2, 2021, the expense related to the Award Shares and Cash Payment that would be recognized in the Company’s consolidated financial statements upon the occurrence of a Qualifying Termination under the Restated Employment Agreement was approximately \$292.9 million.

As of January 2, 2021, the Company had severance plan participation agreements with eight executive officers. The participation agreements (the Agreements) are governed by the terms and conditions of the Company’s 2007 Severance Protection Plan, which became effective on July 19, 2007 and which was amended effective December 31, 2008.

Under each of the Agreements, the applicable executive officer may be entitled to receive certain salary, equity, medical and life insurance benefits if he is terminated by the Company without cause or if he terminates his employment for good reason under certain circumstances. Each executive officer is also required to give the Company six months advance notice of his resignation under certain circumstances.

Cercacor Cross-Licensing Agreement Provisions

The Company’s Cross-Licensing Agreement with Cercacor contains annual minimum aggregate royalty obligations for use of the rainbow® licensed technology. The current annual minimum royalty obligation is \$5.0 million. Upon a change in control (as defined in the Cross-Licensing Agreement) of the Company or Cercacor: (i) all rights to the “Masimo” trademark will be assigned to Cercacor if the surviving or acquiring entity ceases to use “Masimo” as a company name and trademark; (ii) 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 (iii) the minimum aggregate annual royalties payable to Cercacor for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, hemoglobin and/or glucose measurements 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 vital sign measurement with no maximum ceiling for non-vital sign measurements.

Purchase Commitments

Pursuant to contractual obligations with vendors, the Company had \$123.0 million of purchase commitments as of January 2, 2021, that are expected to be purchased within one year. These purchase commitments have been made for certain inventory items in order to secure sufficient levels of those items, other critical inventory and manufacturing supplies and to achieve better pricing.

Other Contractual Commitments

In the normal course of business, the Company may provide bank guarantees to support government hospital tenders in certain foreign jurisdictions. As of January 2, 2021, the Company had approximately \$2.5 million in outstanding unsecured bank guarantees.

In certain circumstances, the Company also provides limited indemnification within its various customer contracts whereby the Company indemnifies the parties to whom it sells its products with respect to potential infringement of intellectual property, and against bodily injury caused by a defective Company product. It is not possible to predict the maximum potential amount of future payments under these or similar agreements, due to the conditional nature of the Company’s obligations and the unique facts and circumstances involved. As of January 2, 2021, the Company had not incurred any significant costs related to contractual indemnification of its customers.

Concentrations of Risk

The Company is exposed to credit loss for the amount of its cash deposits with financial institutions in excess of federally insured limits. The Company invests a portion of its excess cash in time deposits with major financial institutions. As of

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

January 2, 2021, the Company had \$641.4 million of bank balances of which \$4.8 million was covered by either the U.S. Federal Deposit Insurance Corporation limit or foreign countries' deposit insurance organizations.

The Company's ability to sell its products to U.S. hospitals depends in part on its relationships with GPOs. Many existing and potential customers for the Company's products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes exclusively, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. During the years ended January 2, 2021, December 28, 2019 and December 29, 2018, revenue from the sale of the Company's products to customers that are members of GPOs approximated 49.3%, 55.3% and 56.7% of total product revenue, retrospectively.

For the years ended January 2, 2021, December 28, 2019 and December 29, 2018, the Company had sales through two just-in-time distributors that represented 11.5% and 10.1%, 11.1% and 13.0%, and 10.4% and 12.9% of total product revenue, respectively. As of January 2, 2021 and December 28, 2019, one just-in-time distributor represented 6.7% and 6.2% of the Company's accounts receivable balance, respectively.

As of January 2, 2021 and December 28, 2019, one customer represented 9.1% and 19.0%, respectively, of the Company's accounts receivable balance. The receivable balance related to such customer is fully secured by letters of credit.

The majority of the Company's historical royalty revenue arose from one agreement with Medtronic plc (Medtronic). For the year ended January 2, 2021, the Company recognized no royalty revenue pursuant to this agreement. For the years ended December 28, 2019 and December 29, 2018, the Company recognized royalty revenue pursuant to this agreement of \$0.7 million and \$26.4 million, respectively. Pursuant to the agreement, Medtronic is not obligated to pay royalties to the Company for its sales occurring after October 6, 2018.

Litigation

During the third quarter of fiscal year 2017, the Company became aware that certain amounts had been paid by a foreign government customer to the Company's former appointed foreign agent in connection with a foreign government tender, but had not been remitted by such agent to the Company in accordance with the agency agreement. On December 28, 2017, the Company initiated arbitration proceedings against this foreign agent after unsuccessful attempts to recover such remittances. As a result, the Company recorded a net charge of approximately \$10.5 million during the fourth quarter of fiscal year 2017 in connection with this dispute, of which \$2.0 million was recovered during the year ended December 28, 2019. An arbitration hearing was held on February 11, 2019. On July 8, 2019, the arbitrator awarded the Company \$10.5 million in damages, fees and costs. On January 12, 2020, the Company received notice that bankruptcy restructuring proceedings had been initiated for the foreign agent. The Company filed its claim with the bankruptcy trustee on January 16, 2020. In July 2020, the Company was notified that a bankruptcy reorganization proposal had been submitted for voting by creditors in August 2020. The reorganization proposal was rejected by a vote of the creditors on August 26, 2020. On October 22, 2020, the Company filed a petition seeking to enforce the arbitration award. Although the Company intends to vigorously pursue the collection of the arbitration award, there is no guarantee that the Company will be successful in these efforts.

On January 2, 2014, a putative class action complaint was filed against the Company in the U.S. District Court for the Central District of California (District Court) by Physicians Healthsource, Inc. The complaint alleges that the Company sent unsolicited facsimile advertisements in violation of the Junk Fax Protection Act of 2005 and related regulations. The complaint seeks \$500 for each alleged violation, treble damages if the District Court finds the alleged violations to be knowing, plus interest, costs and injunctive relief. On March 26, 2019, an amended complaint was filed adding Radha Geismann, M.D. PC as an additional named plaintiff. On June 17, 2019, the plaintiffs filed their motion for class certification. On September 10, 2019, the parties filed motions for summary judgment. On September 30, 2019, the Company filed its opposition to the motion for class certification, and the plaintiffs filed their reply on October 7, 2019.

On November 21, 2019, the District Court issued an order denying the plaintiffs' motion for class certification, and granting in part and denying in part the Company's motion for summary judgment, and deferring ruling on the plaintiffs' motion for summary judgment. On December 5, 2019, the plaintiffs filed a petition for permission to appeal the order denying class certification, which was denied on January 24, 2020. Trial of the individual plaintiffs' claims was scheduled for June 2, 2020, but on April 1, 2020, the District Court vacated the trial date and directed the parties to conduct an in-person mediation. The mediation has not occurred and no new trial date has been set. On July 13, 2020, the District Court issued an order granting in part and denying in part the plaintiffs' motion for summary judgment. The Company believes it has good and substantial defenses to the claims, but there is no guarantee that the Company will prevail. The Company is unable to determine whether any loss will ultimately occur or to estimate the range of such loss; therefore, no amount of loss has been accrued by the Company in the accompanying consolidated financial statements.

MASIMO CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

On January 9, 2020, the Company filed a complaint against Apple Inc. (Apple) in the District Court for infringement of a number of patents, for trade secret misappropriation, and for ownership and correction of inventorship of a number of Apple patents listing one of its former employees as an inventor. Apple filed petitions for Inter Partes Review of the asserted patents in the U.S. Patent and Trademark Office (PTO). The PTO has not yet acted on the petitions. On October 14, 2020, the District Court stayed the patent infringement claims pending completion of the Inter Partes review proceedings. On November 13, 2020, the Company filed a third amended complaint. On December 1, 2020, Apple filed a partial motion to dismiss the trade secrets claim in the third amended complaint. On January 6, 2021, the District Court granted the motion in part and denied it in part, with leave to amend within 30 days. On February 3, 2021, Apple filed its answer to the third amended complaint. The Company is seeking damages, injunctive relief, and declaratory judgment regarding ownership of the Apple patents. Although the Company intends to vigorously pursue all of its legal remedies, there is no guarantee that the Company will be successful in these efforts.

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

22. Segment Information and Enterprise Reporting

The Company operates in one segment based upon the Company’s organizational structure and the way in which the Company’s chief operating decision maker, the CEO, reviews financial information, including gross profit, operating expenses, operating income, and net income including noncontrolling interests presented on a consolidated basis, accompanied by disaggregated information about revenues by geographic region for purposes of making operating decisions and assessing financial performance. In addition, the Company’s assets are primarily located in the U.S. The Company does not produce reports for, or measure the performance of, its geographic regions on any asset-based metrics. Therefore, geographic information is presented only for revenues and long-lived assets.

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

	Year Ended January 2, 2021		Year Ended December 28, 2019		Year Ended December 29, 2018	
Geographic area by destination:						
United States (U.S.).....	\$ 763,069	66.7 %	\$ 636,371	68.0 %	\$ 566,816	68.3 %
Europe, Middle East and Africa.....	238,681	20.9	183,363	19.6	160,910	19.4
Asia and Australia.....	103,756	9.1	87,961	9.4	75,534	9.1
North and South America (excluding U.S.).....	38,238	3.3	28,713	3.0	26,614	3.2
Total product revenue.....	<u>\$ 1,143,744</u>	<u>100.0 %</u>	<u>\$ 936,408</u>	<u>100.0 %</u>	<u>\$ 829,874</u>	<u>100.0 %</u>

The Company’s consolidated long-lived assets (tangible non-current assets) by geographic area are (in thousands, except percentages):

	Year Ended January 2, 2021		Year Ended December 28, 2019		Year Ended December 29, 2018	
Long-lived assets by geographic area:						
United States.....	\$ 238,094	86.9 %	\$ 216,650	98.5 %	\$ 262,373	95.6 %
International.....	35,755	13.1	3,276	1.5	12,016	4.4
Total.....	<u>\$ 273,849</u>	<u>100.0 %</u>	<u>\$ 219,926</u>	<u>100.0 %</u>	<u>\$ 274,389</u>	<u>100.0 %</u>

MASIMO CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

23. Quarterly Financial Data

The following tables contain selected unaudited consolidated statements of operations data for each quarter of 2020 and 2019 (in thousands, except per share data):

	Quarters Ended			
	March 28, 2020	June 27, 2020	September 26, 2020	January 2, 2021
Fiscal 2020				
Total revenue.....	\$ 269,625	\$ 300,953	\$ 278,112	\$ 295,054
Gross profit.....	185,629	191,584	178,926	186,926
Operating income.....	69,010	62,220	59,698	64,895
Net income.....	64,456	55,772	49,405	70,669
Net income per share				
Basic ⁽¹⁾	\$ 1.20	\$ 1.02	\$ 0.90	\$ 1.28
Diluted ⁽¹⁾	\$ 1.12	\$ 0.96	\$ 0.85	\$ 1.21

	Quarters Ended			
	March 30, 2019	June 29, 2019	September 28, 2019	December 28, 2019
Fiscal 2019				
Total revenue.....	\$ 231,664	\$ 229,652	\$ 229,011	\$ 247,510
Gross profit.....	151,642	154,339	156,268	166,923
Operating income.....	56,023	52,004	51,632	61,557
Net income.....	49,322	44,888	49,085	52,921
Net income per share				
Basic ⁽¹⁾	\$ 0.93	\$ 0.84	\$ 0.92	\$ 0.99
Diluted ⁽¹⁾	\$ 0.87	\$ 0.79	\$ 0.86	\$ 0.92

⁽¹⁾ The sum of the basic and diluted earnings per share numbers for each quarter may not equal the basic and diluted earnings per share number for the entire year due to quarterly rounding.

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Schedule II -
Valuation and Qualifying Accounts

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MASIMO CORPORATION
VALUATION AND QUALIFYING ACCOUNTS
Years ended January 2, 2021, December 28, 2019 and December 29, 2018
(in thousands)

Description	Balance at Beginning of Period	Additions Charged to Expense and Other Accounts	Amounts Charged Against Reserve	Balance at End of Period
Year ended January 2, 2021				
Allowance for doubtful accounts.....	\$ 2,206	\$ 128 ⁽¹⁾	\$ (529)	\$ 1,805
Allowance for sales returns and allowances.....	700	814 ⁽¹⁾	(292)	1,222
Year ended December 28, 2019				
Allowance for doubtful accounts ⁽²⁾	1,535	1,021	(350)	2,206
Allowance for sales returns and allowances.....	432	1,696	(1,428)	700
Year ended December 29, 2018				
Allowance for doubtful accounts.....	2,116	(486)	(95)	1,535
Allowance for sales returns and allowances.....	424	1,416	(1,408)	432

⁽¹⁾ Additions charged to expense and other accounts include amounts from immaterial business combinations.

⁽²⁾ In connection with its adoption of ASC 842 on December 30, 2018, the Company recorded allowance for credit loss for lease receivable, which is included in the allowance for doubtful accounts for the year ended December 28, 2019. See "Recently Adopted Accounting Pronouncements" in Note 2 to these consolidated financial statements for additional information related to the Company's adoption of ASC 842.

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Exhibits

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Subsidiaries of the Registrant - 2020

The following are wholly-owned subsidiaries of the registrant, Masimo Corporation, a Delaware corporation:

<u>Name of Subsidiary</u>	<u>State or Jurisdiction of Incorporation or Organization</u>
Masimo Americas, Inc.	Delaware
Masimo de Mexico Holdings I LLC	Delaware
Masimo de Mexico Holdings II LLC	Delaware
Masimo Holdings LLC	Delaware
SpO2.com, Inc.	Delaware
SEDLIne, Inc.	Delaware
Masimo Australia Pty Ltd	Australia
Masimo Österreich GmbH	Austria
Masimo Importacao e Distribuicao de Produtos Medicos Ltda	Brazil
Masimo Holdings LP	Cayman
Masimo China Medical Technology Co., Ltd.	China
Masimo Europe Ltd.	England and Wales
Masimo Hong Kong Limited	Hong Kong
Masimo Medical Technologies India Private Limited	India
Masimo Japan Kabushiki Kaisha	Japan
Masimo Mexico, S. de R.L. de C.V.	Mexico
Masimo Canada ULC	Nova Scotia
Masimo Peru Srl	Peru
Masimo Asia Pacific PTE. Ltd.	Singapore
Masimo International SARL	Switzerland
Masimo International Technologies SARL	Switzerland
Masimo Medikal Ürünler Ticaret Limited Şirketi	Turkey
Masimo Semiconductor, Inc.	Delaware
Masimo Sweden AB	Sweden
52 Discovery, LLC	California
Masimo 25 Sagamore, LLC	New Hampshire
Masimo Korea, LLC	South Korea
Masimo Polska sp. Z.o.o.	Poland
Masimo 17, LLC	California
Masimo (Shanghai) Industrial Co., Ltd.	China
Patient Doctor Technologies, Inc.	Delaware

Subsidiaries of the Registrant - 2020 - (Continued)

The following are wholly-owned subsidiaries of the registrant, Masimo Corporation, a Delaware corporation:

<u>Name of Subsidiary</u>	<u>State or Jurisdiction of Incorporation or Organization</u>
Alton Office Property, LLC	Delaware
Alton Office Holdings, LLC	Delaware
OC Property Ventures LLC	Delaware
OC Property Shelter LLC	Delaware
Masimo Saudi Arabia for Trading, LLC	Saudi Arabia
VCCB Holdings, Inc.	Delaware
TNI medical AG	Germany
Masimo Technology Café LLC	California
Masimo LHC, Limited	United Kingdom
LiDCO Group, Plc	United Kingdom
LiDCO Limited	United Kingdom
Cassette Analytical Systems Limited	United Kingdom
LiDCO Netherlands B.V.	Netherlands

**CONSENT OF INDEPENDENT REGISTERED PUBLIC
ACCOUNTING FIRM**

We have issued our reports dated February 23, 2021, with respect to the consolidated financial statements, financial statement schedule, and internal control over financial reporting included in the Annual Report of Masimo Corporation on Form 10-K for the year ended January 2, 2021. We consent to the incorporation by reference of said reports in the Registration Statements of Masimo Corporation on Forms S-8 (File No. 333-148149, effective December 19, 2007; File No. 333-157673, effective March 4, 2009; File No. 333-168534, effective August 4, 2010; File No. 333-179557, effective February 17, 2012; File No. 333-186692, effective February 15, 2013; File No. 333-194089, effective February 24, 2014; File No. 333-219207, effective July 10, 2017; File No. 333-234386, effective October 30, 2019, and File No. 333-240152, effective July 28, 2020) and Form S-3 (File No. 333-229892, effective February 26, 2019).

/s/ GRANT THORNTON LLP

Newport Beach, California
February 23, 2021

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joe Kiani, certify that:

1. I have reviewed this annual report on Form 10-K of Masimo Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 23, 2021

/s/ JOE KIANI

Joe Kiani

Chairman of the Board and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Micah Young, certify that:

1. I have reviewed this annual report on Form 10-K of Masimo Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 23, 2021

/s/ MICAH YOUNG

Micah Young

Executive Vice President, Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joe Kiani, Chief Executive Officer of Masimo Corporation (the “Company”), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

1. The Annual Report on Form 10-K of the Company for the period ended January 2, 2021 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 23, 2021

/s/ JOE KIANI

Joe Kiani

Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

I, Micah Young, Executive Vice President and Chief Financial Officer of Masimo Corporation (the “Company”), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

1. The Annual Report on Form 10-K of the Company for the period ended January 2, 2021 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 23, 2021

/s/ MICAH YOUNG

Micah Young

Executive Vice President, Chief Financial Officer

(Principal Financial Officer)

A signed original of these certifications has been provided to Masimo Corporation and will be retained by Masimo Corporation and furnished to the Securities and Exchange Commission or its staff upon request.

These certifications are being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of Masimo Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Corporate Information

Masimo Corporation

Headquarters

The principal executive office of Masimo Corporation (the Company) are located at 52 Discovery, Irvine, CA 92618.

Stock Listing

The Company's common stock is listed on the Nasdaq Stock Market, under the symbol "MASI". As of January 2, 2021, there were 18 registered holders of the Company's common stock.

Investor Relations

Analysts, portfolio managers and other investors seeking additional information about Masimo stock should contact our V.P. Investor Relations at (949) 297-7077 or investorrelations@masimo.com. Visit the Investor Relations area of the Masimo website, <https://investor.masimo.com/overview/default.aspx> for stock information, financial news releases, links to Masimo's SEC filings, electronic versions of our annual reports and other items of interest to the Company's shareholders.

News Media

News media seeking information should visit our online newsroom at <https://investor.masimo.com/news/default.aspx> for new releases, press kits, and other items related to the Company.

Annual Report on Form 10-K

The Company's 2020 Annual Report on Form 10-K is available at <https://investor.masimo.com/financials/annual-reports/default.aspx>. The Company also will provide a copy of the 2020 Annual Report on Form 10-K (without exhibits) upon written request addressed to:

Masimo Corporation
Attn: Investor Relations
52 Discovery
Irvine, CA 92618

Shareholder Inquiries

For inquiries concerning tax statements, electronic delivery, transferring ownership, address changes or lost or stolen stock certificates, contact Masimo Corporation Shareholder Services at Computershare Trust Company, N.A. at (800) 642-9855. For general shareholder information, contact Masimo Corporation Corporate Secretary at (949) 297-7000.



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