MASIMO CORP
Form 10-Q
October 31, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 29, 2018
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)

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

(949) 297-7000
(Registrant's Telephone Number, Including Area Code)
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 ý 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 ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ý	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company ¨
	Emerging growth company ¨

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	Number of Shares Outstanding as of September 29, 2018
Common stock, $0.001 par value	52,995,786

MASIMO CORPORATION
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 29, 2018
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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements
MASIMO CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except par values)

	September 29, 2018	December 30, 2017 As Adjusted
ASSETS		
Current assets		
Cash and cash equivalents	$ 493,488	$ 315,302
Accounts receivable, net of allowance for doubtful accounts of $1,681 and $2,116 at September 29, 2018 and December 30, 2017, respectively.	101,024	118,532
Inventories	92,952	92,259
Other current assets	48,283	33,601
Total current assets	735,747	559,694
Deferred costs and other contract assets	119,523	109,256
Property and equipment, net	164,605	164,096
Intangible assets, net	28,462	27,123
Goodwill	23,454	20,617
Deferred tax assets	20,209	19,981
Other non-current assets	3,859	4,668
Total assets	$ 1,095,859	$ 905,435
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities		
Accounts payable	$ 38,940	$ 33,780
Accrued compensation	41,293	39,515
Accrued and other current liabilities	27,802	24,254
Deferred revenue and other contract-related liabilities, current	35,592	32,105
Total current liabilities	143,627	129,654
Other non-current liabilities	39,834	51,757
Total liabilities	183,461	181,411
Commitments and contingencies		
Stockholders’ equity		
Preferred stock, $0.001 par value; 5,000 shares authorized; 0 shares issued and outstanding at September 29, 2018 and December 30, 2017	—	—
Common stock, $0.001 par value; 100,000 shares authorized; 52,996 and 51,636 shares issued and outstanding at September 29, 2018 and December 30, 2017, respectively	53	52
Treasury stock, 15,255 and 15,059 shares at September 29, 2018 and December 30, 2017, respectively	(489,026)	(472,536)
Additional paid-in capital	523,051	461,494
Accumulated other comprehensive loss	(5,818)	(2,941)
Retained earnings	884,138	737,955
Total stockholders’ equity	912,398	724,024
Total liabilities and stockholders’ equity	$ 1,095,859	$ 905,435

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

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MASIMO CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017 As Adjusted	September 29, 2018	September 30, 2017 As Adjusted
Revenue:				
Product	$202,068	$ 179,696	$608,461	$ 541,889
Royalty and other revenue	8,515	13,664	26,696	40,420
Total revenue	210,583	193,360	635,157	582,309
Cost of goods sold	69,830	69,295	208,596	198,929
Gross profit	140,753	124,065	426,561	383,380
Operating expenses:				
Selling, general and administrative	72,670	65,704	215,263	198,460
Research and development	19,442	15,300	57,160	45,859
Total operating expenses	92,112	81,004	272,423	244,319
Operating income	48,641	43,061	154,138	139,061
Non-operating income	1,028	287	4,080	1,319
Income before provision (benefit) for income taxes	49,669	43,348	158,218	140,380
Provision (benefit) for income taxes	(7,457)	7,495	11,609	7,856
Net income	$57,126	$ 35,853	$146,609	$ 132,524
Net income per share:				
Basic	$1.09	$ 0.69	$2.78	$ 2.57
Diluted	$1.02	$ 0.64	$2.59	$ 2.37
Weighted-average shares used in per share calculations:				
Basic	52,432	52,079	52,726	51,469
Diluted	56,237	56,163	56,555	55,967

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

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MASIMO CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(unaudited, in thousands)

	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017 As Adjusted	September 29, 2018	September 30, 2017 As Adjusted
Net income	$57,126	$ 35,853	$146,609	$ 132,524
Other comprehensive income, net of tax:				
Unrealized gains (losses) from foreign currency translation adjustments	179	1,404	(2,877)	4,270
Comprehensive income	$57,305	$ 37,257	$143,732	$ 136,794

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

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MASIMO CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

	Nine Months Ended	
	September 29, 2018	September 30, 2017 As Adjusted
Cash flows from operating activities:		
Net income	$146,609	$ 132,524
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	15,959	14,384
Stock-based compensation	19,695	11,192
Loss on disposal of property, equipment and intangibles	641	420
Benefit from doubtful accounts	(401)	—
Benefit from deferred income taxes	(6,747)	—
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	17,384	(17,277)
Increase in inventories	(1,069)	(26,354)
Increase in other current assets	(15,606)	(9,095)
Increase in deferred costs and other contract assets	(10,400)	(9,175)
Decrease (increase) in other non-current assets	496	(3,525)
Increase in accounts payable	4,090	3,748
Increase (decrease) in accrued compensation	1,919	(9,094)
Increase in accrued liabilities	5,695	393
Increase (decrease) in income tax payable	410	(71,177)
Increase (decrease) in deferred revenue and other contract-related liabilities	3,981	(11,039)
(Decrease) increase in other non-current liabilities	(6,351)	1,456
Net cash provided by operating activities	176,305	7,381
Cash flows from investing activities:		
Purchases of property and equipment, net	(12,299)	(37,830)
Increase in intangible assets	(4,718)	(2,220)
Business combination, net of cash acquired, and acquisitions of equity investments	(4,000)	(1,145)
Proceeds from sale of equity investments	453	—
Net cash used in investing activities	(20,564)	(41,195)
Cash flows from financing activities:		
Repayments of capital lease obligations	—	(71)
Proceeds from issuance of common stock	42,297	55,709
Payroll tax withholdings on behalf of employees for vested equity awards	(168)	—
Repurchases of common stock	(18,478)	(42,608)
Net cash provided by financing activities	23,651	13,030
Effect of foreign currency exchange rates on cash	(1,230)	3,112
Net increase in cash, cash equivalents, and restricted cash	178,162	(17,672)
Cash, cash equivalents and restricted cash at beginning of period	315,483	308,198
Cash, cash equivalents and restricted cash at end of period	$493,645	$ 290,526

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

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MASIMO CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Description of the Company

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

The Company invented Masimo Signal Extraction Technology® (SET®), which provides the capabilities of Measure-through Motion and Low Perfusion™ pulse oximetry to address the primary limitations of conventional pulse oximetry. Over the years, the Company's product offerings have expanded significantly to also include rainbow® Pulse CO-Oximetry, with its ability to measure and monitor carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), total hemoglobin concentration (SpHb®), fractional arterial oxygen saturation ($SpfO_2$™), Oxygen Content (SpOC™), Pleth Variability Index (PVi®), rainbow® Pleth Variability Index (RPVi™), respiration rate from the pleth (RRp®) and Oxygen Reserve Index (ORi™), as well as acoustic respiration monitoring (RRa®), electrical brain function monitoring (SedLine®) and optical gas monitoring. The Company also developed the Root™ patient monitoring and connectivity platform, the Radical-7® and Rad-97™ bedside and portable patient monitors, the Radius-7® wearable wireless patient monitor and the Masimo Patient SafetyNet[1] remote patient surveillance monitoring system. These solutions and related products are based upon Masimo SET®, rainbow® and other proprietary algorithms. These software-based technologies are incorporated into a variety of product platforms depending on customers' specifications. This technology is supported by a substantial intellectual property portfolio that the Company has built through internal development and, to a lesser extent, acquisitions and license agreements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and note disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) have been condensed or omitted pursuant to such rules and regulations. The accompanying condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, including normal recurring accruals, necessary to present fairly the Company's condensed consolidated financial statements. The accompanying condensed consolidated balance sheet as of December 30, 2017 was derived from the Company's audited consolidated financial statements at that date. The accompanying condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 30, 2017 (fiscal year 2017), filed with the SEC on February 28, 2018. The results for the nine months ended September 29, 2018 are not necessarily indicative of the results to be expected for the fiscal year ending December 29, 2018 (fiscal year 2018) or for any other interim period or for any future year.

As further discussed below in this Note 2 to these condensed consolidated financial statements, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) No. 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09) effective December 31, 2017. All prior period amounts and disclosures set forth in this Quarterly Report on Form 10-Q have been updated to comply with the new standard, as indicated by the "as adjusted" notation.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. In accordance with GAAP, current authoritative guidance is applied when determining whether an entity is subject to consolidation.

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

Fiscal Periods

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

Use of Estimates

The Company prepares its financial statements in conformity with GAAP, which requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates include the determination of accounts receivable allowances, inventory reserves, warranty reserves, rebate accruals, valuation of the Company's stock options, goodwill valuation, deferred taxes and any associated valuation allowances, royalty revenues, deferred revenue, deferred costs, uncertain income tax positions, litigation costs and related accruals. Actual results could differ from such estimates.

Reclassifications

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

Fair Value Measurements

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

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

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

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

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

Cash and Cash Equivalents

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

Accounts Receivable and Allowance for Doubtful Accounts

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

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MASIMO CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

Inventories

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

Property and Equipment

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

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

Land is not depreciated and construction-in-progress is not depreciated until placed in service. Normal repair and maintenance costs are expensed as incurred, whereas significant improvements that materially increase values or extend useful lives are capitalized and depreciated over the remaining estimated useful lives of the related assets. Upon sale or retirement of depreciable assets, the related cost and accumulated depreciation or amortization are removed from the accounts and any gain or loss on the sale or retirement is recognized in income.

Intangible Assets

The Company’s policy is to renew its patents and trademarks. Total renewal costs for patents and trademarks for the nine months ended September 29, 2018 and September 30, 2017 were $0.3 million and $0.4 million, respectively. As of September 29, 2018, the weighted-average number of years until the next renewal was one year for patents and six years for trademarks. Costs to renew patents and trademarks are capitalized and amortized over the remaining useful life of the intangible asset. The Company continually evaluates the amortization period and carrying basis of patents and trademarks to determine whether any events or circumstances warrant a revised estimated useful life or reduction in value. Capitalized application costs are charged to operations when it is determined that the patent or trademark will not be obtained or is abandoned.

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

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

(a) the amount that the carrying amount of a reporting unit exceeds its fair value; or (b) the amount of the goodwill allocated to that reporting unit. The annual impairment test is performed during the fourth fiscal quarter.

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

No impairment of goodwill, intangible assets or other long-lived assets was recorded during each of the three and nine months ended September 29, 2018 and September 30, 2017.

Revenue Recognition and Deferred Revenue

Effective December 31, 2017, the Company adopted ASU 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers. Accounting Standards Codification (ASC) Topic 606 (ASC 606) provides a single, principles-based five-step model to be applied to all contracts with customers. ASC 606 generally provides for the recognition of revenue in an amount that reflects the consideration to which the Company expects to be entitled, net of allowances for estimated returns, discounts or sales incentives, as well as taxes collected from customers that are remitted to government authorities, when control over the promised goods or services are transferred to the customer.

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

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

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

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

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

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

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

The majority of the Company's royalty and other revenue arises from an agreement with Medtronic plc (Medtronic, formerly Covidien Ltd.) that provides for quarterly royalty payments to the Company based upon U.S. sales of certain Medtronic products. An estimate of these royalty revenues is recorded quarterly in the period earned based on historical results, adjusted for any new information or trends known to management at the time of estimation. This estimated revenue is adjusted prospectively when the Company receives the Medtronic royalty report, approximately sixty days after the end of the previous quarter. For the three months ended September 29, 2018 and September 30, 2017, the Company recognized royalty revenue pursuant to this agreement of approximately $8.1 million and $8.4 million, respectively. For the nine months ended September 29, 2018 and September 30, 2017, the Company recognized royalty revenue pursuant to this agreement of approximately $25.3 million and $25.7 million, respectively.

From time-to-time, the Company also recognizes revenue related to non-recurring engineering (NRE) services provided to certain OEM customers. NRE revenue is generally recognized on a proportionate basis as the costs of performing such services are incurred by the Company.

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.

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MASIMO CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

Deferred Costs and Other Contract Assets
The costs of monitoring-related equipment leased to hospitals under LT Sensor Contracts are generally deferred and amortized to cost of goods sold over the life of the underlying contracts. Some of the Company's LT Sensor Contracts also contain provisions for certain payments to be made directly to the end-user hospital customer at the inception of the arrangement. These contractual incentive payments are generally deferred and amortized on a straight-line basis as contra-revenue over the life of the underlying LT Sensor Contract.
The Company records an unbilled contract receivable related to software delivered under LT Sensor Contracts with fixed annual commitments until such amounts are billed to the customer, which generally occurs at the time of delivery of the sensors over the term of the LT Sensor Contract.
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 LT Sensor Contracts 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 six to forty-eight months, depending on the product type. In traditional sales activities, including direct and OEM sales, the Company establishes an accrued liability for the estimated warranty costs at the time of revenue recognition, with a corresponding provision to cost of sales. Customers may also purchase extended warranty coverage separately or as part of a LT Sensor Contract. Revenue related to extended warranty coverage is recognized over the extended life of the contract, which is reasonably expected to be the period over which such services will be provided. The related extended warranty costs are expensed as incurred.
Changes in the product warranty accrual were as follows (in thousands):

	Nine Months Ended	
	September 29, 2018	September 30, 2017
Warranty accrual, beginning of period	$1,149	$ 910
Accrual for warranties issued	943	712
Changes to pre-existing warranties (including changes in estimates)	779	(116)
Settlements made	(974)	(486)
Warranty accrual, end of period	$1,897	$ 1,020

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.

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MASIMO CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
(unaudited)

Comprehensive Income

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

The change in accumulated other comprehensive loss was as follows (in thousands):

	Nine Months Ended September 29, 2018
Accumulated other comprehensive loss, beginning of period	$ (2,941)
Unrealized gains from foreign currency translation	(2,877)
Accumulated other comprehensive loss, end of period	$ (5,818)

Net Income Per Share

Basic net income per share is computed by dividing net income by the weighted-average number of shares outstanding during the period. Net income per diluted share is computed by dividing the net income by the weighted-average number of shares and potential shares outstanding during the period, if the effect of potential shares is dilutive. Potential shares include incremental shares of stock issuable upon the exercise of stock options and the vesting of both restricted share units (RSUs) and performance share units (PSUs). For the three and nine months ended September 29, 2018, weighted options to purchase 0.6 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 the three and nine months ended September 30, 2017, weighted options to purchase 0.6 million and 0.2 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. Certain RSUs are considered contingently issuable shares as their vesting is contingent upon the occurrence of certain future events. Since such events had not occurred and were not considered probable of occurring as of each of September 29, 2018 and September 30, 2017, 2.7 million weighted average shares related to such RSUs have been excluded from the calculation of potential shares for each of the three and nine months ended September 29, 2018 and September 30, 2017.

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

	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017 As Adjusted	September 29, 2018	September 30, 2017 As Adjusted
Net income	$57,126	$ 35,853	$146,609	$ 132,524
Basic net income per share:				
Weighted-average shares outstanding - basic	52,432	52,079	52,726	51,469
Net income per basic share	$1.09	$ 0.69	$2.78	$ 2.57
Diluted net income per share:				
Weighted-average shares outstanding - basic	52,432	52,079	52,726	51,469
Diluted share equivalent: stock options and RSUs	3,805	4,084	3,829	4,498
Weighted-average shares outstanding - diluted	56,237	56,163	56,555	55,967
Net income per diluted share	$1.02	$ 0.64	$2.59	$ 2.37

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

	Nine Months Ended			
	September 29, 2018		September 30, 2017	
Cash paid during the year for:				
Interest	$	184	$	432
Income taxes	29,003		86,759	
Noncash investing and financing activities:				
Unpaid purchases of property, plant and equipment	$	2,023	$	3,349
Unsettled common stock proceeds from option exercises	259		113	
Unsettled stock repurchases	—		2,653	
Reconciliation of cash, cash equivalents and restricted cash:				
Cash and cash equivalents	$	493,488	$	289,944
Restricted cash	157		582	
Total cash, cash equivalents and restricted cash shown in the statement of cash flow	$	493,645	$	290,526

Seasonality
The healthcare business in the United States and overseas is subject to quarterly fluctuations in hospital and other alternative care admissions. Historically, the Company has typically experienced higher product revenues during the traditional “flu season” that often increases hospital and acute care facility admissions in the Company’s first and fourth fiscal quarters. At the same time, the Company has frequently experienced a sequential decline in product revenues in its second and/or third fiscal quarters, primarily due to the summer vacation season during which the flu season has moderated and people tend to avoid and/or delay elective procedures. Because the Company’s non-sales variable operating expenses often do not fluctuate in the same manner as its quarterly product sales, its quarterly operating income may fluctuate disproportionately to its quarterly revenue.
Recently Adopted Accounting Pronouncements
In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Shares-Based Payment Accounting (ASU 2018-07). The new standard aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to

employees. Under this guidance, the measurement of the equity-classified nonemployee awards will be fixed at the grant date and the term used for measurement can be the expected term or the contractual term. ASU 2018-07 is effective for annual and interim fiscal reporting periods beginning after December 15, 2018. The Company early adopted this standard during the three months ended September 29, 2018 and such adoption did not have a material impact on its consolidated financial statements.

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

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

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Effective December 31, 2017, the Company adopted ASU 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09). ASC 606 provides a single, principles-based five-step model to be applied to all contracts with customers, and generally provides for the recognition of revenue in an amount that reflects the considerations to which the Company expects to be entitled when control over the promised goods or services are transferred to the customer. ASC 606 also enhances disclosures about revenue, provides additional guidance for transactions that were not previously addressed comprehensively and improves guidance for multiple-element arrangements. In addition, ASC 606 includes Subtopic 340-40, Other Assets and Deferred Costs - Contracts with Customers, which requires the deferral of incremental costs of obtaining a contract with a customer.
The Company adopted ASC 606 utilizing the full retrospective method of transition, which requires the Company to restate certain previously reported results, including the impact on the provision for income taxes. Adoption of the new standard resulted in changes to the Company’s accounting policies for revenue recognition and related cost of goods sold, as well as the capitalization and deferral of certain commission expenses, and a cumulative increase to retained earnings of approximately $23.9 million and $17.1 million as of December 31, 2016 and December 30, 2017, respectively. The areas impacted by ASC 606 include: (i) the acceleration of certain revenue from product sales to distributors that was previously deferred under the “sell-through” method; (ii) the acceleration of revenue related to certain software/parameter sales; (iii) the aggregation of all contract modifications occurring prior to the beginning of the earliest period presented; (iv) the acceleration of costs related to equipment for which control transfers up-front under certain contracts, the future consideration for which will now be treated as an optional purchase; (v) the capitalization and amortization of certain contract-related costs that were previously expensed when incurred; and (vi) the corresponding income tax effects related to these adjustments.
The Company applied the new standard using certain practical expedients, including: (i) excluding disclosures of transaction prices allocated to remaining performance obligations when the Company expects to recognize such revenue for all periods prior to the date of initial application of ASC 606; (ii) not adjusting the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company’s transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less; (iii) expensing costs as incurred for costs to obtain a contract when the amortization period would have been one year or less; (iv) not recasting revenue for contracts that begin and end in the same fiscal year; and (v) not assessing whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer.
Pursuant to the full retrospective method of adoption under ASC 606, the Company has adjusted certain amounts previously reported in its unaudited condensed consolidated financial statements.
During the fourth quarter of the fiscal year ended December 30, 2017, the Company early adopted ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18). The new standard was intended to reduce diversity in practice by adding or clarifying guidance on classification and presentation of changes in restricted cash on the statement of cash flows. The Company has restated interim periods prior to the date of adoption to reflect the adoption of this ASU.
The reconciliations below reflect the adoption of ASC 606, the adoption of ASU 2016-16, the adoption of ASU 2016-18 and certain other immaterial reclassifications (in thousands, except per share amounts):

Condensed Consolidated Balance Sheet:	December 30, 2017		
	As Previously Reported	Adjustments	As Adjusted
Accounts receivable	$121,309	$ (2,777)	$118,532
Inventories	95,944	(3,685)	92,259
Other current assets	31,563	2,038	33,601
Deferred costs and other contract assets	99,600	9,656	109,256

Deferred tax assets	23,898	(3,917)	19,981
Other non-current assets	10,782	(6,114)	4,668
Accrued and other liabilities	42,344	(18,090)	24,254
Deferred revenue and other contract liabilities, current	35,929	(3,824)	32,105
Retained earnings	720,842	17,113	737,955

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Condensed Consolidated Statement of Operations:	Three Months Ended September 30, 2017		
	As Previously Reported	Adjustments	As Adjusted
Product revenue	$181,271	$ (1,575)	$179,696
Royalty and other revenue	12,421	1,243	13,664
Cost of goods sold	65,027	4,268	69,295
Selling, general and administrative	65,390	314	65,704
Provision (benefit) for income taxes	9,027	(1,532)	7,495
Net income	39,235	(3,382)	35,853
Net income per share:			
Basic	$0.75	$ (0.06)	$0.69
Diluted	$0.70	$ (0.06)	$0.64

Condensed Consolidated Statement of Operations:	Nine Months Ended September 30, 2017		
	As Previously Reported	Adjustments	As Adjusted
Product revenue	$542,170	$ (281)	$541,889
Royalty and other revenue	30,757	9,663	40,420
Cost of goods sold	191,692	7,237	198,929
Selling, general and administrative	197,339	1,121	198,460
Provision (benefit) for income taxes	8,108	(252)	7,856
Net income	131,248	1,276	132,524
Net income per share:			
Basic	$2.55	$ 0.02	$2.57
Diluted	$2.35	$ 0.02	$2.37

Condensed Consolidated Statements of Cash Flows:	Nine Months Ended September 30, 2017		
	As Previously Reported	Adjustments	As Adjusted
Cash flows from operating activities:			
Net income	$131,248	$ 1,276	$132,524
Adjustments to reconcile net income to net cash provided by operating activities:			
Increase in inventories	(25,998)	(356)	(26,354)
Decrease in other current assets	(11,099)	2,004	(9,095)
Decrease in deferred costs and other contract assets	(16,166)	6,991	(9,175)
Increase in other non-current assets	(964)	(2,561)	(3,525)
Increase in accrued liabilities	(66,918)	67,311	393
Decrease in income taxes payable	—	(71,177)	(71,177)
Decrease in deferred revenue and other contract liabilities	(5,905)	(5,134)	(11,039)

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

Recently Issued Accounting Pronouncements

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

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

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU 2016-13). The new standard requires entities to use a current expected credit loss model, which is a new impairment model based on expected losses rather than incurred losses. Under this model, an entity would recognize an impairment allowance equal to its current estimate of all contractual cash flows that the entity does not expect to collect. The entity's estimate would consider relevant information about past events, current conditions, and reasonable and supportable forecasts. ASU 2016-13 is effective for annual and interim fiscal reporting periods beginning after December 15, 2019, with early adoption permitted for annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the expected impact of this standard but does not expect it to have a material impact on its consolidated financial statements upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (ASU 2016-02). ASU 2016-02 requires lessees to recognize most leases on their balance sheets but continue to recognize lease expenses in their statement of operations in a manner similar to current practice. ASU 2016-02 states that a lessee will recognize a lease liability for the obligation to make lease payments and a right-of-use asset for the right to use the underlying asset for the lease term. Expense related to leases determined to be operating leases will be recognized on a straight-line basis, while those determined to be financing leases will be recognized following a front-loaded expense profile in which interest and amortization are presented separately in the statement of operations. ASU 2016-02 is effective for annual and interim fiscal reporting periods beginning after December 15, 2018, and early application is permitted. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases (ASU 2018-10). ASU 2018-10 provides clarification on the rate implicit in the lease, impairment of the net investment in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase options, variable payments that depend on an index or rate and certain transition adjustments. ASU 2018-10 is effective for annual and interim fiscal reporting periods beginning after December 15, 2018. Also in July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements (ASU 2018-11). ASU 2018-11 provides a transition option and a practical expedient for lessors to aid in cost reductions and complexity of implementing the new standard. Under the transition option, entities can opt to continue to apply the legacy guidance in ASC Topic 840, Leases (ASC 840), including its disclosure requirements. Entities that elect this option will make only annual disclosures for the comparative periods because ASC 840 does not require interim disclosures.

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Entities that elect this transition option still adopt the new leases standard using the modified retrospective transition method required by the standard, but they recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption rather than in the earliest period presented. The optional practical expedient allows lessors to elect, by class of underlying asset, to not separate non-lease components from the associated lease components if the non-lease components otherwise would be accounted for in accordance with ASC 606 and both of the following criteria are met: (1) the lease component and the associated non-lease components have the same timing and pattern of transfer and(2) the lease component, if accounted for separately, would be classified as an operating lease. ASU 2018-11 is effective for annual and interim fiscal reporting periods beginning after December 15, 2018. The Company is currently evaluating the expected impact of these standards on its consolidated financial statements, but anticipates that, among other things, the required recognition by a lessee of a lease liability and related right-of-use asset for operating leases will increase both the assets and liabilities recognized and reported on its balance sheet as of the adoption date. In addition, the Company anticipates that the classification of certain leases for which the Company is the lessor will change under the new guidance for most circumstances, resulting in the acceleration of revenue under certain contracts, as well as the immediate expensing of certain costs that are currently deferred and expensed over the life of the lease. The Company currently expects to complete its assessment of the full financial impact of the new lease accounting guidance, as both a lessee and lessor, during the next three to six months.

3. Variable Interest Entity (VIE)

The Company follows authoritative guidance for the consolidation of a VIE, which requires an enterprise to determine whether its variable interest gives it a controlling financial interest in a VIE. Determination about whether an enterprise should consolidate a VIE is required to be evaluated continuously as changes to existing relationships or future transactions may result in consolidating or deconsolidating the VIE.

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. The Company is a party to a Cross-Licensing Agreement with Cercacor, which was most recently amended and restated effective January 1, 2007 (the Cross-Licensing Agreement), that governs each party’s rights to certain intellectual property held by the two companies. The Company is also a party to certain other agreements with Cercacor. See Note 4 to these condensed consolidated financial statements for a description of the Company’s various business relationships with Cercacor.

The Company has determined that it is not 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.

4. Related Party Transactions

The Company’s Chairman and CEO is also the Chairman and CEO of Cercacor. The Company is a party to the following agreements with Cercacor:

- Cross-Licensing Agreement - The Company and Cercacor are parties to the Cross-Licensing Agreement, which governs each party’s rights to certain intellectual property held by the two companies. The Company is subject to certain annual minimum aggregate royalty obligations for use of the rainbow® licensed technology. The current annual minimum royalty obligation is $5.0 million. Aggregate liabilities to Cercacor arising under the Cross-Licensing Agreement were $3.0 million and $2.1 million for the three months ended September 29, 2018 and September 30, 2017, respectively. Aggregate liabilities to Cercacor arising under the Cross-Licensing Agreement were $7.5 million and $5.6 million for the nine months ended September 29, 2018 and September 30, 2017, 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 less than $0.1 million for each of the three and nine months ended September 29, 2018 and September 30, 2017.

- Sublease Agreement - In March 2016, the Company entered into a sublease agreement with Cercacor for approximately 16,830 square feet of excess office and laboratory space located at 40 Parker, Irvine, California (Cercacor Sublease). The Cercacor Sublease began on May 1, 2016 and expires on November 30, 2019. The Company recognized $0.1 million in sublease income for each of the three months ended September 29, 2018 and September 30, 2017. The Company recognized $0.3 million in sublease income for each of the nine months ended September 29, 2018 and September 30, 2017.

Net amounts due to Cercacor at each of September 29, 2018 and December 30, 2017 were $2.1 million and $1.5 million, 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) and General Counsel is a Director and also serves as the Secretary of the Masimo Foundation and the Company's EVP, Chief Financial Officer (CFO) serves as the Treasurer of the Masimo Foundation. During the three and nine months ended September 29, 2018, the Company pledged $1.0 million to the Masimo Foundation.

The Company's CEO is the Chairman of both the Patient Safety Movement Foundation (PSMF), a non-profit organization that was founded in 2013 to work with hospitals, medical technology companies and patient advocates to unite the healthcare ecosystem and eliminate the more than 200,000 U.S. preventable hospital deaths that occur every year by 2020, and the Patient Safety Movement Coalition (PSMC), a not-for-profit social welfare organization that was founded in 2013 to promote patient safety legislation. The Company's EVP, CFO serves as the Treasurer of both PSMF and PSMC, and the Company's EVP and General Counsel serves as the Secretary of PSMC.

The Company's CEO also serves on the board of directors of Atheer Labs, which is working with the Company on the development of next generation Root™ applications. Further, he serves on the boards of directors of Children's Hospital of Orange County and CHOC Children's at Mission Hospital, two non-profit hospitals devoted exclusively to caring for children, both of which are also customers of the Company.

In August 2017, the Company entered into 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. For the three and nine months ended September 29, 2018, the Company charged the Company's CEO $0.1 million and $0.2 million, respectively, related to such reimbursements.

5. Inventories

Inventories consist of the following (in thousands):

	September 29, 2018	December 30, 2017 As Adjusted
Raw materials	$ 34,652	$ 31,200
Work-in-process	6,827	8,619
Finished goods	51,473	52,440
Total inventories	$ 92,952	$ 92,259

6. Other Current Assets

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

	September 29, 2018	December 30, 2017 As Adjusted
Prepaid income taxes	$ 15,377	$ 3,493
Prepaid expenses	10,859	10,517
Indirect taxes receivable	7,967	6,556
Royalties receivable	7,250	7,400
Customer notes receivable	2,647	2,777
Employee loans and advances	342	364
Other current assets	3,841	2,494
Total other current assets	$ 48,283	$ 33,601

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7. Deferred Costs and Other Contract Assets
Deferred costs and other contract assets consist of the following (in thousands):

	September 29, 2018	December 30, 2017 As Adjusted
Deferred cost of goods sold	$ 105,664	$ 93,261
Prepaid contract incentives	5,485	6,115
Deferred commissions	4,950	5,613
Unbilled contract receivables	3,424	4,267
Deferred costs and other contract assets	$ 119,523	$ 109,256

For the three months ended September 29, 2018 and September 30, 2017, $7.4 million and $7.6 million, respectively, of deferred cost of goods sold was amortized to cost of goods sold. For the nine months ended September 29, 2018 and September 30, 2017, $22.2 million and $21.5 million, respectively, of deferred costs of goods sold was amortized to cost of goods sold.
For the three months ended September 29, 2018 and September 30, 2017, $0.5 million and $0.6 million, respectively, of prepaid contract incentives was amortized as a reduction to revenue. For the nine months ended September 29, 2018 and September 30, 2017, $1.3 million and $1.5 million, respectively, of prepaid contract incentives was amortized as a reduction to revenue.
For the three months ended September 29, 2018 and September 30, 2017, $0.5 million and $0.6 million, respectively, of deferred commissions was amortized to selling, general and administrative expenses. For the nine months ended September 29, 2018 and September 30, 2017, $1.6 million and $1.9 million, respectively, of deferred commissions was amortized to selling, general and administrative expenses.
8. Property and Equipment
Property and equipment, net, consists of the following (in thousands):

	September 29, 2018	December 30, 2017
Building and building improvements	$ 88,403	$ 87,999
Machinery and equipment	53,160	47,556
Aircraft and vehicles	25,554	25,329
Land	23,762	23,762
Computer equipment	16,426	15,789
Leasehold improvements	16,323	15,326
Tooling	14,124	13,754
Furniture and office equipment	10,371	9,967
Demonstration units	471	486
Construction-in-progress (CIP)	9,698	6,365
Total property and equipment	258,292	246,333
Accumulated depreciation and amortization	(93,687)	(82,237)
Property and equipment, net	$ 164,605	$ 164,096

For the three months ended September 29, 2018 and September 30, 2017, depreciation expense of property and equipment was $4.0 million and $3.8 million, respectively. For the nine months ended September 29, 2018 and September 30, 2017, depreciation expense of property and equipment was $12.1 million and $10.8 million, respectively.
The balances in CIP at September 29, 2018 and December 30, 2017 related primarily to capitalized costs associated with the implementation of a new enterprise resource planning software system and manufacturing equipment, the underlying assets for which have not been completed or placed into service.

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9. Intangible Assets

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

	September 29, 2018	December 30, 2017
Patents	$ 20,924	$ 20,623
Customer relationships	7,669	7,669
Licenses-related party	7,500	7,500
Acquired technology	5,580	5,580
Trademarks	4,234	4,036
Capitalized software development costs	3,374	2,699
Other	5,466	3,691
Total intangible assets	54,747	51,798
Accumulated amortization	(26,285)	(24,675)
Intangible assets, net	$ 28,462	$ 27,123

Total amortization expense for each of the three months ended September 29, 2018 and September 30, 2017 was $1.1 million. Total amortization expense for the nine months ended September 29, 2018 and September 30, 2017 was $3.5 million and $3.2 million, respectively. All of these intangible assets have a 10 year weighted average amortization period.

Estimated amortization expense for future fiscal years is as follows (in thousands):

Fiscal year	Amount
2018 (balance of year)	$4,411
2019	3,959
2020	3,714
2021	3,333
2022	1,854
Thereafter	11,191
Total	$28,462

10. Goodwill

Changes in goodwill were as follows (in thousands):

	Nine Months Ended September 29, 2018
Goodwill, beginning of period	$ 20,617
Acquisition through business combination	3,490
Foreign currency translation	(653)
Goodwill, ending of period	$ 23,454

On September 21, 2018, the Company acquired all of the outstanding shares of a private patient monitoring software company for approximately $4.0 million. Based on the Company’s preliminary purchase price allocation, approximately $3.5 million of the purchase price has been assigned to goodwill. All of the assets and liabilities of the acquired company as of September 29, 2018, and its operating results from September 21, 2018 to September 29, 2018, are included in these condensed consolidated financial statements.

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11. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following (in thousands):

	September 29, 2018	December 30, 2017 As Adjusted
Accrued indirect taxes payable	$ 8,137	$ 6,711
Accrued expenses	4,727	4,022
Income tax payable	4,686	4,292
Related party payables	3,116	1,528
Accrued legal fees	2,009	975
Accrued warranty	1,897	1,149
Accrued customer rebates, fees and reimbursements	1,888	2,351
Accrued stock repurchases	—	1,988
Other	1,342	1,238
Total accrued and other current liabilities	$ 27,802	$ 24,254

12. Deferred Revenue and Other Contract-Related Liabilities

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

	September 29, 2018	December 30, 2017 As Adjusted
Accrued customer reimbursements	$ 18,969	$ 16,896
Deferred revenue	11,612	11,589
Accrued rebates and incentives	5,255	3,598
Other contract-related liabilities	481	259
Total deferred revenue and other contract-related liabilities	36,317	32,342
Less: Non-current portion of deferred revenue	(725)	(237)
Deferred revenue and other contract-related liabilities - current	$ 35,592	$ 32,105

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

Changes in deferred revenue for the nine months ended September 29, 2018 were as follows:

	Nine Months Ended September 29, 2018
Deferred revenue, beginning of the period	$ 11,589
Revenue deferred during the period	7,802
Recognition of revenue deferred in prior periods	(7,779)
Deferred revenue, end of the period	$ 11,612

Expected revenue from remaining contractual performance obligations (Unrecognized Contract Revenue) includes deferred revenue, as well as other amounts that will be invoiced and recognized as revenue in future periods, when the Company completes its performance obligations. While Unrecognized Contract Revenue is similar in concept to backlog, Unrecognized Contract Revenue excludes revenue allocable to monitoring-related equipment that is effectively leased to hospitals under LT Sensor Contracts and other contractual obligations for which neither party has performed. The following table summarizes the Company’s estimated Unrecognized Contract Revenue as of September 29, 2018 and the future periods within which the Company expects to recognize such revenue.

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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.

	Expected Future Revenue By Period (in thousands)				
	Less than 1 year	Between 1-3 years	Between 3-5 years	More than 5 years	Total
Unrecognized contract revenue	$198,090	$252,211	$103,468	$ 20,625	$574,394

13. Other Non-Current Liabilities

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

	September 29, 2018	December 30, 2017
Income tax payable, long-term	$ 23,446	$ 25,734
Unrecognized tax benefits	10,908	14,348
Deferred tax liabilities	3,430	9,880
Deferred rent, long-term	1,238	1,266
Deferred revenue, long-term	725	237
Other	87	292
Total other non-current liabilities	$ 39,834	$ 51,757

Unrecognized tax benefit relates to the Company's long-term portion of tax liability associated with uncertain tax positions. Authoritative guidance prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. See Note 18 to these condensed consolidated financial statements for further details.

14. Stock Repurchase Program

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

In July 2018, the Board approved a new stock repurchase program, authorizing the Company to purchase up to 5.0 million additional shares of its common stock over a period of up to three years (2018 Repurchase Program). The 2018 Repurchase Program became effective in September 2018 upon the expiration of the 2015 Repurchase Program. The Company expects to fund the 2018 Repurchase Program through its available cash, cash expected to be generated from future operations 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.

The following table provides a summary of the Company's stock repurchase activities during the three and nine months ended September 29, 2018 and September 30, 2017 (in thousands, except per share amounts):

	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
Shares repurchased	—	533	198	533
Average cost per share	$ —	$ 84.86	$84.14	$ 84.86
Value of shares repurchased	$ —	$ 45,261	$16,490	$ 45,261

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15. Stock-Based Compensation
Total stock-based compensation expense for the three months ended September 29, 2018 and September 30, 2017 was $7.6 million and $5.1 million, respectively. Total stock-based compensation expense for the nine months ended September 29, 2018 and September 30, 2017 was $19.7 million and $11.2 million, respectively. As of September 29, 2018, an aggregate of 12.0 million shares of common stock were reserved for future issuance under the Company's equity plans, of which 3.2 million shares were available for future grant under the Masimo Corporation 2017 Equity Incentive Plan (2017 Equity Plan). Additional information related to the Company's current equity incentive plans, stock-based award activity and valuation of stock-based awards is included below.
Equity Incentive Plans
2017 Equity Incentive Plan
On June 1, 2017, the Company's stockholders ratified and approved the 2017 Equity Plan. The 2017 Equity Plan permits the grant of stock options, restricted stock, RSUs, stock appreciation rights, PSUs, performance shares, performance bonus awards and other stock or cash awards to employees, directors and consultants of the Company and employees and consultants of any parent or subsidiary of the Company. The aggregate number of shares that may be awarded under the 2017 Equity Plan is 5.0 million shares.
The 2017 Equity Plan provides that at least 95% of the equity awards issued under the 2017 Equity Plan must vest over a period of not less than one year following the date of grant. 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.
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.
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 exercise prices):

	Nine Months Ended September 29, 2018	
	Shares	Average Exercise Price
Options outstanding, beginning of period	6,953	$ 36.26
Granted	480	96.13
Canceled	(170)	52.96
Exercised	(1,518)	27.68
Options outstanding, end of period	5,745	$ 43.04
Options exercisable, end of period	3,323	$ 29.22

Total stock option expense for the three months ended September 29, 2018 and September 30, 2017 was $3.5 million and $2.9 million, respectively. Total stock option expense for the nine months ended September 29, 2018 and September 30, 2017 was $10.3 million and $8.2 million, respectively. As of September 29, 2018, the Company had $41.4 million of unrecognized compensation cost related to non-vested stock options that are expected to vest over a weighted average period of approximately 3.6 years. The weighted-average remaining contractual term of options outstanding with an exercise price less than the closing price of the Company's common stock as of September 29, 2018 was 6.2 years. The weighted-average remaining contractual term of options exercisable, with an exercise price less than the closing price of the Company’s common stock as of September 29, 2018, was 4.9 years.

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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):

	Nine Months Ended September 29, 2018	
	Units	Weighted Average Grant Date Fair Value
RSUs outstanding, beginning of period	2,708	$ 95.51
Granted	7	99.05
Canceled	—	—
Expired	—	—
Vested	(8)	88.40
RSUs outstanding, end of period	2,707	$ 95.54

Total RSU expense for each of the three months ended September 29, 2018 and September 30, 2017 was $0.2 million. Total RSU expense for the nine months ended September 29, 2018 and September 30, 2017 was $0.5 million and $0.3 million, respectively. As of September 29, 2018, the Company had $0.5 million of unrecognized compensation cost related to non-vested RSU awards expected to be recognized and vest over a weighted-average period of approximately 0.7 years.

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):

	Nine Months Ended September 29, 2018	
	Units	Weighted Average Grant Date Fair Value
PSUs outstanding, beginning of period	233	$ 90.70
Granted	197	86.95
Canceled	(86)	90.71
Expired	—	—
Vested	(31)	90.70
PSUs outstanding, end of period	313	$ 88.34

During the nine months ended September 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 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 197,000 PSUs or 394,000 shares. Based on management’s estimate of the number of units expected to vest, total PSU expense for the three months ended September 29, 2018 and September 30, 2017 was $4.0 million and $2.0 million, respectively. Total PSU expense for the nine months ended September 29, 2018 and September 30, 2017 was $8.8 million and $2.6 million, respectively. As of September 29, 2018, the Company had $29.5 million of unrecognized compensation cost related to non-vested PSU awards expected to be recognized and vest over a weighted-average period of approximately 2.3 years.

Valuation of Stock-Based Award Activity

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:

	Three Months Ended		Nine Months Ended	
	September 29, 2018	September 30, 2017	September 29, 2018	September 30, 2017
Risk-free interest rate	2.7% to 3.0%	1.7% to 2.0%	2.3% to 3.0%	1.7% to 2.2%
Expected term (in years)	5.6	5.5	5.6	5.5
Estimated volatility	26.8% to 32.0%	30.3% to 32.1%	26.8% to 32.0%	29.7% to 32.1%
Expected dividends	0%	0%	0%	0%
Weighted-average fair value of options granted	$37.62	$27.70	$31.21	$27.74

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 September 29, 2018 was $468.2 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 September 29, 2018 was $316.7 million. The aggregate intrinsic value of options exercised during the nine months ended September 29, 2018 was $119.4 million.

The fair value of each RSU and PSU award is determined based on the closing price of the Company's common stock on the grant date, or the modification date, if any.

16. Commitments and Contingencies

Leases

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 November 2026. Certain facility leases contain predetermined price escalations and in some cases renewal options. The Company recognizes the lease costs using a straight-line method based on total lease payments. The Company has received leasehold improvement incentives in connection with certain leased facilities in the U.S. These leasehold improvement incentives have been recorded as deferred rent and are being amortized as a reduction to rent expense on a straight-line basis over the life of the lease. As of each of September 29, 2018 and December 30, 2017, accrued rent expense in excess of the amount paid aggregated $1.5 million, which is classified within other current and non-current liabilities in the accompanying condensed consolidated balance sheets. In addition, the Company leases automobiles in the U.S. and Europe that are classified as operating leases and expire at various dates through September 2021. The majority of these leases are non-cancellable. The Company also has outstanding capital leases for office equipment and computer equipment, all of which are non-cancellable.

As of September 29, 2018, estimated future minimum lease payments, including interest, for each of the following fiscal years are as follows (in thousands):

	Total Operating Leases
2018 (balance of year)	$ 2,040
2019	6,388
2020	3,964
2021	2,126
2022	1,561
Thereafter	5,424

Total	$ 21,503

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Rental expense related to operating leases was $1.7 million for each of the three months ended September 29, 2018 and September 30, 2017, and $5.2 million and $5.0 million for the nine months ended September 29, 2018 and September 30, 2017, respectively.

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 $0.5 million and $0.6 million to the MRSP for the three months ended September 29, 2018 and September 30, 2017, respectively, and $1.8 million to the MRSP for each of the nine months ended September 29, 2018 and September 30, 2017.

In addition, the Company also sponsors various defined contribution plans in certain locations outside of the United States (Subsidiary Plans). For each of the three months ended September 29, 2018 and September 30, 2017, the Company contributed $0.1 million to the Subsidiary Plans. For the nine months ended September 29, 2018 and September 30, 2017, the Company contributed $0.3 million and $0.2 million to the Subsidiary Plans, respectively.

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 and the full amount of the Cash Payment. 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 September 29, 2018, 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 September 29, 2018, 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 (the Severance 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. The executive officers are also required to give the Company six months' advance notice of their resignation under certain circumstances.

Purchase Commitments

Pursuant to contractual obligations with vendors, the Company had $80.6 million of purchase commitments as of September 29, 2018, which 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 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 September 29, 2018, the Company had approximately $1.1 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 September 29, 2018, 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 its excess cash in time deposits with major financial institutions. As of September 29, 2018, the Company had $493.5 million of bank balances, of which $3.4 million was covered by either the U.S. Federal Deposit Insurance Corporation limit or foreign countries' deposit insurance organizations.

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

The Company's ability to sell its products to U.S. hospitals depends in part on its relationships with 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 three and nine months ended September 29, 2018, revenue from the sale of the Company's products to U.S. hospitals that are members of GPOs amounted to $115.3 million and $350.2 million, respectively. During the three and nine months ended September 30, 2017, revenue from the sale of the Company's products to U.S. hospitals that are members of GPOs amounted to $102.7 million and $308.0 million, respectively.

For the three months ended September 29, 2018, the Company had sales through two just-in-time distributors that represented 12.3% and 9.4% of total revenue, respectively. For the three months ended September 30, 2017, the Company had sales through the same two just-in-time distributors that represented 12.3% and 10.9% of total revenue, respectively.

For the nine months ended September 29, 2018, the Company had sales to two just-in-time distributors that represented 12.4% and 10.4% of total revenue, respectively. For the nine months ended September 30, 2017, the Company had sales to the same two just-in-time distributors that represented 13.2% and 11.4% of total revenue, respectively.

As of September 29, 2018, one just-in-time distributor represented 5.3% of the Company's accounts receivable balance. As of December 30, 2017, one just-in-time distributor represented 6.5% of the Company's accounts receivable balance.

For the nine months ended September 29, 2018 and September 30, 2017, the Company recorded $25.3 million and $25.7 million, respectively, in royalty revenues from Medtronic. In exchange for these royalty payments, the Company has provided Medtronic the ability to ship its patent infringing product with a covenant not to sue Medtronic as long as Medtronic abides by the terms of the settlement agreement between the companies. Pursuant to the terms of the Third Amendment to Settlement Agreement and Release of Claims effective September 2016, Medtronic agreed to continue paying royalties to the Company through October 6, 2018, after which no more royalties are due.

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 $0.4 million was recovered during the nine months ended September 29, 2018. The arbitration hearing is scheduled to begin on February 11, 2019. Although the Company intends to vigorously pursue full recovery of the amounts owed by the foreign agent through these arbitration proceedings, as well as explore other avenues for recovery, there is no guarantee that the Company will be successful in these efforts.

On January 24, 2018, the Company was notified that its former insurance carrier was seeking reimbursement of certain defense costs previously advanced by such insurance carrier in connection with an employment-related arbitration. The Company had previously disputed the insurance carrier's claim for reimbursement in a letter dated December 14, 2016, and had not received any response from the insurance carrier. Although the insurance carrier is seeking approximately $2.6 million plus interest at a rate of 10% per year from January 15, 2014, the Company believes it has good and substantial grounds to dispute the insurance carrier's reimbursement claim. Therefore, the Company is currently unable to determine whether any loss will ultimately occur.

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 by Physicians Healthsource, Inc. (PHI). 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 April 14, 2014, the Company filed a motion to stay the case pending a decision on a related petition filed by the Company with the Federal Communications Commission (FCC). On May 22, 2014, the District Court granted the motion and stayed the case pending a ruling by the FCC on the petition. On October 30, 2014, the FCC granted some of the relief and denied some of the relief requested in the Company's petition. Both parties appealed the FCC's decision on the petition. On November 25, 2014, the District Court granted the parties' joint request that the stay remain in place pending a decision on the appeal. On March 31, 2017, the D.C. Circuit Court of Appeals vacated and remanded the FCC's decision, holding that the applicable FCC rule was unlawful to the extent it requires opt-out notices on solicited faxes. On April 28, 2017, PHI filed a petition seeking rehearing by the D.C. Circuit Court of Appeals. The D.C. Circuit Court of Appeals denied the requested rehearing on June 6, 2017. The plaintiff filed a petition for a writ of certiorari with the United States Supreme Court on September 5, 2017 seeking review of the D.C. Circuit Court of Appeals' decision. The Company and the FCC filed oppositions to this petition on January 16, 2018. On February 20, 2018, the Supreme Court denied certiorari. The District Court lifted the stay on April 9, 2018 and set a trial date of November 5, 2019. The deadline for PHI to file its motion for class certification is February 4, 2019. The Company believes it has good and substantial defenses to the claims in the District Court litigation, 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 condensed consolidated financial statements.

On January 31, 2014, an amended putative class action complaint was filed against the Company in the U.S. District Court for the Northern District of Alabama by and on behalf of two participants in the Surfactant, Positive Pressure, and Oxygenation Randomized Trial at the University of Alabama. On April 21, 2014, a further amended complaint was filed adding a third participant. The complaint alleges product liability and negligence claims in connection with pulse oximeters the Company modified and provided at the request of study investigators for use in the trial. On August 13, 2015, the U.S. District Court for the Northern District of Alabama granted summary judgment in favor of the Company on all claims. The plaintiffs appealed the U.S. District Court for the Northern District of Alabama's decision. The appellate hearing before the Eleventh Circuit Court of Appeals was held on December 13, 2016. On March 3, 2018, the Eleventh Circuit Court of Appeals affirmed the decision of the U.S. District Court for the Northern District of Alabama.

On May 30, 2012, a patent infringement complaint was filed against the Company in the U.S. District Court for the Northern District of California by Dominion Assets LLC (Dominion). The complaint alleged infringement of U.S. Patent No. 5,360,004 titled "Non-invasive determination of analyte concentration using non-continuous radiation" (the '004 patent), U.S. Patent No. 5,379,764 titled "Non-invasive determination of analyte concentration in body of mammals" (the '764 patent) and U.S. Patent No. 5,460,177 titled "Method for non-invasive measurement of concentration of analytes in blood using continuous spectrum radiation" (the '177 patent). On June 27, 2014, the Court dismissed the case for lack of standing. Dominion refiled the case on June 30, 2014, alleging infringement of the '764 patent and the '177 patent. The Company responded to the complaint on July 24, 2014, and requested declaratory judgment that the asserted patents are invalid, unenforceable, and not infringed. On January 20, 2017, the Court granted summary judgment that the ‘177 patent is invalid. On August 13, 2018, the Company and Dominion entered into a settlement agreement that included, among other things, a mutual release of claims and Dominion’s dismissal of the case against the Company without payment by the Company. The case was dismissed with prejudice on August 14, 2018.

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.

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17. Segment Information and Enterprise Reporting

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

	Three Months Ended				Nine Months Ended			
	September 29, 2018		September 30, 2017 As Adjusted		September 29, 2018		September 30, 2017 As Adjusted	
Geographic area by destination:								
United States	$136,895	67.7 %	$118,065	65.7 %	$418,178	68.7 %	$370,119	68.3 %
Europe, Middle East and Africa	37,257	18.4	38,300	21.3	115,631	19.0	102,476	18.9
Asia and Australia	21,332	10.6	17,676	9.8	54,627	9.0	51,750	9.6
North and South America (excluding United States)	6,584	3.3	5,655	3.2	20,025	3.3	17,544	3.2
Total product revenue	$202,068	100.0%	$179,696	100.0%	$608,461	100.0%	$541,889	100.0%

The Company's consolidated long-lived assets (total non-current assets excluding deferred taxes, goodwill and intangible assets) by geographic area are (in thousands, except percentages):

	September 29, 2018		December 30, 2017 As Adjusted	
Long-lived assets by geographic area:				
United States	$272,998	94.8 %	$265,678	95.6 %
International	14,989	5.2	12,342	4.4
Total	$287,987	100.0%	$278,020	100.0%

18. Income Taxes

The Company has provided for income taxes in fiscal year 2018 interim periods based on the estimated effective income tax rate for the complete fiscal year and adjusted for discrete tax events, including excess tax benefits or deficiencies related to stock-based compensation, in the period such events occur. The estimated annual effective tax rate is computed based on the expected annual pretax income of the consolidated entities located within each taxing jurisdiction based on legislation enacted as of the balance sheet date. For the nine months ended September 29, 2018 and September 30, 2017, the Company recorded discrete tax benefits of approximately $21.7 million and $35.1 million, respectively, related to excess tax benefits realized from stock-based compensation. In addition, the Company recorded approximately $4.7 million and $0.8 million of discrete tax benefits related to the derecognition of uncertain tax positions due to the expiration of the statutes of limitations for the nine months ended September 29, 2018 and September 30, 2017, respectively.

Deferred tax assets and liabilities are determined based on the future tax consequences associated with temporary differences between income and expenses reported for accounting and tax purposes. A valuation allowance for deferred tax assets is recorded to the extent that the Company cannot determine that the ultimate realization of the net deferred tax assets is more likely than not. Realization of deferred tax assets is principally dependent upon the achievement of future taxable income, the estimation of which requires significant judgment by the Company’s management. The judgment of the Company’s management regarding future profitability may change due to many factors, including future market conditions and the Company’s ability to successfully execute its business plans or tax planning strategies. These changes, if any, may require material adjustments to these deferred tax asset balances.

As of September 29, 2018, the liability for income taxes associated with uncertain tax positions was approximately $13.5 million. If fully recognized, approximately $12.5 million (net of federal benefit on state taxes) would impact the Company’s effective tax rate. It is reasonably possible that the amount of unrecognized tax benefits in various jurisdictions may change in the next twelve 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 twelve months cannot currently be made.

The Company conducts business in multiple jurisdictions and, as a result, one or more of the Company’s subsidiaries files income tax returns in U.S. federal, various state, local and foreign jurisdictions. The Company has concluded all U.S. federal income tax matters through fiscal year 2014. All material state, local and foreign income tax matters have been concluded through fiscal year 2010. The Company does not believe that the results of any tax authority examination would have a significant impact on its consolidated financial statements.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, in connection with the Private Securities Litigation Reform Act of 1995 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. Such forward-looking statements include any expectation of earnings, revenues or other financial items; any statements of the plans, strategies and objectives of management for future operations; factors that may affect our operating results or financial condition; statements concerning new products, technologies or services; statements related to future capital expenditures; statements related to future economic conditions or performance; statements related to our stock repurchase programs; statements as to 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" or "will," the negative versions of these terms and similar expressions or variations. The statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause 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 in the section titled "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q and in our other Securities and Exchange Commission (SEC) filings, including our Annual Report on Form 10-K for the fiscal year ended December 30, 2017, which we filed with the SEC on February 28, 2018. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statements.

Executive Overview

We are a global medical technology company that develops, manufactures and markets a variety of noninvasive monitoring technologies. Our mission is to improve patient outcomes and reduce the cost of care. We provide our products directly and through distributors and original equipment manufacturers (OEM) partners to hospitals, emergency medical service (EMS) providers, home care providers, long-term care facilities, physician offices, veterinarians and consumers. 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 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. For an overview of our product offerings and technologies, please refer to "Business" in Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended December 30, 2017, filed with the SEC on February 28, 2018.

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

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

In January 2018, we announced the CE Mark and release of RD rainbow Lite SET™ sensors, which enable the monitoring of oxygen reserve index (ORi)™ and rainbow® pleth variability index (RPVi)™, an improved pleth variability index (PVi®) that allows clinicians to noninvasively and continuously assess fluid responsiveness at a fraction of the cost of invasive methods, and at a fraction of the cost of rainbow® sensors. RD rainbow Lite™ sensors utilize twice as many wavelengths of light as SET® sensors, allowing RD rainbow Lite™ sensors to provide ORi™ and RPVi™ along with Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry.

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We also announced in January 2018 that the Rad-97™ Pulse CO-Oximeter® had received FDA 510(k) clearance for home use. Rad-97™ offers noninvasive and continuous monitoring through Measure-through Motion and Low Perfusion™ SET® pulse oximetry, upgradeable rainbow® technologies and integrated noninvasive blood pressure in a compact, standalone monitor that combines advanced connectivity and communication capabilities for telehealth, with an interface easily customized for use at home.

Our Next Generation SedLine® brain function monitoring also received FDA 510(k) clearance in January 2018. SedLine® helps clinicians monitor the state of the brain under anesthesia with bilateral acquisition and processing of four leads of electroencephalogram (EEG) signals. Next Generation SedLine® features an enhanced signal processing engine, driving a variety of performance improvements and helping give clinicians a more complete picture of the brain.

In March 2018, we announced the release of Replica™, an application for smart phones and tablets that works in conjunction with Masimo Patient SafetyNet, a supplemental remote monitoring and clinician notification system. Replica™ allows clinicians to view continuous monitoring data for multiple patients, as well as view and respond to alarms and alerts, all from their smart phones, regardless of location.

We also announced the CE Mark of Eve™, a critical congenital heart disease (CCHD) newborn screening application for the Rad-97™ Pulse CO-Oximeter® in March 2018. Eve™ combines the power of Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry with a pre-ductal to post-ductal synchronization algorithm designed to reduce calculation errors.

In April 2018, we announced the release of UniView™, an integrated display of real-time data and alarms from multiple Masimo and third-party devices, designed to reduce clinician cognitive overload, improve patient safety and promote data sharing and team coordination among clinicians.

We also announced the CE Mark of the Rad-97™ Pulse CO-Oximeter® with integrated NomoLine® capnography in April 2018. With this clearance, Rad-97™ is now available both within and outside the United States in three configurations: Rad-97™, Rad-97™ with integrated noninvasive blood pressure and now Rad-97™ with NomoLine® capnography.

In June 2018, we announced the United States release of TIR-1™, a non-contact Bluetooth® enabled thermometer designed to integrate with the Root™ patient monitoring and connectivity platform. TIR-1™ was developed in conjunction with Thermomedics, a PositiveID Corporation.

In July 2018, we announced the worldwide release of the Vital Signs Check Application, an integrated patient data collection and workflow application for the Masimo Root™ patient monitoring and connectivity platform. Vital Signs Check, available for new and existing Root™ customers through a software upgrade, augments Root's™ versatility by helping to automate hospital vital signs testing workflows.

In September 2018, we announced FDA 510(k) clearance of RAS-45, an acoustic respiration sensor for rainbow Acoustic Monitoring® (RAM®), for infant and neonatal patients. RAM® could previously be used to monitor adult and pediatric patients greater than 10 kg using RAS-125c and RAS-45 sensors. With 510(k) clearance of the RAS-45 sensor for infant and neonatal patients, acoustic respiration rate measurement is now, for the first time, possible for patients of all sizes, including neonates, in the United States.

Cercacor Laboratories, Inc.

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 Notes 3 and 4 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information related to Cercacor.

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 Chief Financial Officer (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 Note 14 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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Results of Operations[(1)]

The following table sets forth, for the periods indicated, our unaudited results of operations expressed as dollar amounts and as a percentage of total revenues (in thousands, except percentages):

	Three Months Ended				Nine Months Ended			
	September 29, 2018	Percentage of Revenue	September 30, 2017 As Adjusted	Percentage of Revenue	September 29, 2018	Percentage of Revenue	September 30, 2017 As Adjusted	Percentage of Revenue
Revenue:								
Product	$202,068	96.0 %	$ 179,696	92.9 %	$608,461	95.8 %	$ 541,889	93.1 %
Royalty and other revenue	8,515	4.0	13,664	7.1	26,696	4.2	40,420	6.9
Total revenue	210,583	100.0	193,360	100.0	635,157	100.0	582,309	100.0
Cost of goods sold	69,830	33.2	69,295	35.8	208,596	32.8	198,929	34.2
Gross profit	140,753	66.8	124,065	64.2	426,561	67.2	383,380	65.8
Operating expenses:								
Selling, general and administrative	72,670	34.5	65,704	34.0	215,263	33.9	198,460	34.1
Research and development	19,442	9.2	15,300	7.9	57,160	9.0	45,859	7.9
Total operating expenses	92,112	43.7	81,004	41.9	272,423	42.9	244,319	42.0
Operating income	48,641	23.1	43,061	22.3	154,138	24.3	139,061	23.9
Non-operating income	1,028	0.5	287	0.1	4,080	0.6	1,319	0.2
Income before provision (benefit) for income taxes	49,669	23.6	43,348	22.4	158,218	24.9	140,380	24.1
Provision (benefit) for income taxes	(7,457)	(3.5)	7,495	3.9	11,609	1.8	7,856	1.3
Net income	$57,126	27.1 %	$ 35,853	18.5 %	$146,609	23.1 %	$ 132,524	22.8 %

Comparison of the Three Months ended September 29, 2018 to the Three Months ended September 30, 2017[(1)]

Revenue. Total revenue increased $17.2 million, or 8.9%, to $210.6 million for the three months ended September 29, 2018 from $193.4 million for the three months ended September 30, 2017. The following table details our total product revenues by the geographic area to which the products were shipped for each of the three months ended September 29, 2018 and September 30, 2017 (dollars in thousands):

	Three Months Ended					
	September 29, 2018		September 30, 2017 As Adjusted		Increase/ (Decrease)	Percentage Change
United States	$136,895	67.7 %	$118,065	65.7 %	$ 18,830	15.9 %
Europe, Middle East and Africa	37,257	18.4	38,300	21.3	(1,043)	(2.7)
Asia and Australia	21,332	10.6	17,676	9.8	3,656	20.7
North and South America (excluding United States)	6,584	3.3	5,655	3.2	929	16.4
Total product revenue	$202,068	100.0%	$179,696	100.0%	$ 22,372	12.4 %
Royalty and other revenue	8,515		13,664		(5,149)	(37.7)
Total revenue	$210,583		$193,360		$ 17,223	8.9 %

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(1) Certain information presented for periods ending prior to December 31, 2017 has been restated to reflect the full retrospective application of the new revenue accounting standard, Accounting Standards Update (ASU) No. 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09). See Note 2 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information related to our adoption of this new accounting standard.

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Product revenue increased $22.4 million, or 12.4%, to $202.1 million for the three months ended September 29, 2018, compared to $179.7 million for the three months ended September 30, 2017. This increase was primarily due to higher sales of consumables, monitors and parameters, which was partially offset by the impact of approximately $0.7 million of unfavorable foreign exchange rate movements from the prior year period that decreased the U.S. Dollar translation of foreign sales that were denominated in various foreign currencies, primarily in Australia, Europe and Canada. During the third quarter of 2018, we shipped approximately 59,100 noninvasive technology boards and monitors, an increase of 8,000 units, or 15.7%, from 51,100 units shipped during the third quarter of 2017.

Product revenue generated through our direct and distribution sales channels increased $16.3 million, or 10.3%, to $173.8 million for the three months ended September 29, 2018, compared to $157.5 million for the three months ended September 30, 2017. Revenues from our OEM channel increased $6.1 million, or 27.5%, to $28.3 million for the three months ended September 29, 2018 as compared to $22.2 million for the three months ended September 30, 2017.

Royalty and other revenue consists primarily of royalties received from Medtronic plc (Medtronic, formerly Covidien Ltd.) related to its U.S. sales pursuant to the terms of our settlement agreement, and revenue from non-recurring engineering (NRE) services for certain OEM customers. For the three months ended September 29, 2018, royalty and other revenue decreased by $5.1 million, which was primarily related to lower NRE service revenue, when compared to the three months ended September 30, 2017. Pursuant to the terms of the Third Amendment to Settlement Agreement and Release of Claims effective September 2016, Medtronic agreed to continue paying royalties through October 6, 2018, after which no more royalties are due.

Gross Profit. Gross profit consists of total revenue less cost of goods sold. Our gross profit for the three months ended September 29, 2018 and September 30, 2017 was as follows (dollars in thousands):

	Three Months Ended					
	September 29, 2018	Gross Profit Percentage	September 30, 2017 As Adjusted	Gross Profit Percentage	Increase/ (Decrease)	Percentage Change
Product gross profit	$132,389	65.5 %	$ 111,375	62.0 %	$ 21,014	18.9 %
Royalty and other revenue gross profit	8,364	98.2	12,690	92.9	(4,326)	(34.1)
Total gross profit	$140,753	66.8 %	$ 124,065	64.2 %	$ 16,688	13.5 %

Cost of goods sold includes labor, material, overhead and other similar costs related to the production, supply, distribution and support of our products. Cost of goods sold increased $0.5 million for the three months ended September 29, 2018, compared to the three months ended September 30, 2017, primarily due to increased product revenue. Product gross margins increased to 65.5% for the three months ended September 29, 2018 compared to 62.0% for the three months ended September 30, 2017, primarily due to favorable product mix and improved manufacturing efficiencies. Royalty and other revenue gross profit decreased by $4.3 million for the three months ended September 29, 2018 compared to the three months ended September 30, 2017, due to lower NRE service revenue, net of related costs.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of salaries and related expenses for sales, marketing and administrative personnel, sales commissions, advertising and promotion costs, professional fees related to legal, accounting and other outside services, public company costs and other corporate expenses. Selling, general and administrative expenses for the three months ended September 29, 2018 and September 30, 2017 were as follows (dollars in thousands):

Selling, General and Administrative

Three Months Ended September 29, 2018	Percentage of Net Revenues	Three Months Ended September 30, 2017 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$72,670	34.5%	$65,704	34.0%	$6,966	10.6%

Selling, general and administrative expenses increased $7.0 million, or 10.6%, for the three months ended September 29, 2018, compared to the three months ended September 30, 2017. This increase was primarily attributable to higher payroll-related costs of approximately $6.8 million. Approximately $6.0 million and $4.0 million of stock-based compensation expense was included in selling, general and administrative expenses for the three months ended September 29, 2018 and September 30, 2017, respectively.

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Research and Development. Research and development expenses consist primarily of salaries and related expenses for engineers and other personnel engaged in the design and development of our products. These expenses also include third-party fees paid to consultants, prototype and engineering supply expenses and the costs of clinical trials. Research and development expenses for the three months ended September 29, 2018 and September 30, 2017 were as follows (dollars in thousands):

Research and Development

Three Months Ended September 29, 2018	Percentage of Net Revenues	Three Months Ended September 30, 2017 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$19,442	9.2%	$15,300	7.9%	$4,142	27.1%

Research and development expenses increased $4.1 million, or 27.1%, for the three months ended September 29, 2018, compared to the three months ended September 30, 2017, primarily due to higher payroll-related costs of approximately $2.5 million, allocations to cost of goods sold for NRE service costs of approximately $0.8 million and higher engineering project expenses of approximately $0.4 million. Included in research and development expenses was approximately $1.6 million and $0.9 million of stock-based compensation expense for the three months ended September 29, 2018 and September 30, 2017, respectively.

Non-operating Income. Non-operating income consists primarily of interest income, interest expense and foreign exchange gains and losses. Non-operating income for the three months ended September 29, 2018 and September 30, 2017 was as follows (dollars in thousands):

Non-operating Income

Three Months Ended September 29, 2018	Percentage of Net Revenues	Three Months Ended September 30, 2017 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$1,028	0.5%	$287	0.1%	$741	258.2%

Non-operating income increased by $0.7 million for the three months ended September 29, 2018, compared to the three months ended September 30, 2017. Non-operating income for the three months ended September 29, 2018 consisted of approximately $2.3 million in net interest income, which was offset by approximately $1.3 million of net realized and unrealized losses on foreign currency denominated transactions. Non-operating income for the three months ended September 30, 2017 consisted of approximately $0.7 million in net interest income, which was offset by approximately $0.4 million of net realized and unrealized losses on foreign currency denominated transactions.

Provision (Benefit) for Income Taxes. Our provision (benefit) for income taxes for the three months ended September 29, 2018 and September 30, 2017 was as follows (dollars in thousands):

Provision (Benefit) for Income Taxes

Three Months Ended September 29, 2018	Percentage of Net Revenues	Three Months Ended September 30, 2017 As Adjusted	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$(7,457)	(3.5)%	$7,495	3.9%	$(14,952)	(199.5)%

For the three months ended September 29, 2018, we recorded a benefit for income taxes of approximately $7.5 million, or an effective tax benefit rate of 15.0%, as compared to a provision for income taxes of approximately $7.5 million, or an effective tax provision rate of 17.3%, for the three months ended September 30, 2017. The decrease in our effective tax rate for the three months ended September 29, 2018 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 $9.7 million compared to the three months ended September 30, 2017. Also contributing to the decrease in our effective tax rate for the three months ended September 29, 2018 was a discrete tax benefit of $4.7 million related to the derecognition of uncertain tax positions due to the expiration of the statutes of limitations, as well as the impact of a net decrease in our overall U.S. federal effective tax rate pursuant to various provisions within the Tax Cuts and Jobs Act of 2017.

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Comparison of the Nine Months ended September 29, 2018 to the Nine Months ended September 30, 2017

Revenue. Total revenue increased $52.8 million, or 9.1%, to $635.2 million for the nine months ended September 29, 2018 from $582.3 million for the nine months ended September 30, 2017. The following table details our total product revenues by the geographic area to which the products were shipped for each of the nine months ended September 29, 2018 and September 30, 2017 (dollars in thousands):

	Nine Months Ended					
	September 29, 2018		September 30, 2017		Increase/ (Decrease)	Percentage Change
United States	$418,178	68.7 %	$370,119	68.3 %	$48,059	13.0 %
Europe, Middle East and Africa	115,631	19.0	102,476	18.9	13,155	12.8
Asia and Australia	54,627	9.0	51,750	9.6	2,877	5.6
North and South America (excluding United States)	20,025	3.3	17,544	3.2	2,481	14.1
Total product revenue	$608,461	100.0%	$541,889	100.0%	$66,572	12.3 %
Royalty and other revenue	26,696		40,420		(13,724)	(34.0)%
Total revenue	$635,157		$582,309		$52,848	9.1 %

Product revenue increased $66.6 million, or 12.3%, to $608.5 million for the nine months ended September 29, 2018 from $541.9 million for the nine months ended September 30, 2017. This increase was primarily due to higher sales of consumables, monitors and parameters, as well as the impact of approximately $5.4 million of favorable foreign exchange rate movements from the prior year period that increased the U.S. Dollar translation of foreign sales that were denominated in various foreign currencies, primarily in Europe. During the nine months ended September 29, 2018, we shipped approximately 171,400 noninvasive technology boards and monitors, an increase of 22,400 units, or 15.0%, from 149,000 units shipped during the nine months ended September 30, 2017.

Product revenue generated through our direct and distribution sales channels increased $51.0 million, or 10.8%, to $525.2 million for the nine months ended September 29, 2018, compared to $474.1 million for the nine months ended September 30, 2017. Revenues from our OEM channel increased $15.5 million, or 22.9%, to $83.3 million for the nine months ended September 29, 2018 as compared to $67.8 million for the nine months ended September 30, 2017.

Royalty and other revenue decreased by $13.7 million for the nine months ended September 29, 2018 compared to the nine months ended September 30, 2017, primarily due to lower NRE service revenue and reduced royalty payments. Pursuant to the terms of the Third Amendment to Settlement Agreement and Release of Claims effective September 2016, Medtronic agreed to continue paying royalties through October 6, 2018, after which no more royalties are due.

Gross Profit. Gross profit consists of total revenue less cost of goods sold. Our gross profit for the nine months ended September 29, 2018 and September 30, 2017 was as follows (dollars in thousands):

	Nine Months Ended					
	September 29, 2018	Gross Profit Percentage	September 30, 2017	Gross Profit Percentage	Increase/ (Decrease)	Percentage Change
Product gross profit	$400,392	65.8 %	$345,916	63.8 %	$54,476	15.7 %
Royalty and other revenue gross profit	26,169	98.0	37,464	92.7	(11,295)	(30.1)
Total gross profit	$426,561	67.2 %	$383,380	65.8 %	$43,181	11.3 %

Cost of goods sold increased $9.7 million for the nine months ended September 29, 2018 compared to the nine months ended September 30, 2017, primarily due to higher product revenue. Product gross margins increased to 65.8% for the nine months ended September 29, 2018 compared to 63.8% for the nine months ended September 30, 2017, primarily due to favorable product mix and improved manufacturing efficiencies. Royalty and other revenue gross profit decreased by $11.3 million for the nine months ended September 29, 2018 compared to the nine months ended September 30, 2017, primarily due to lower NRE service revenue, net of related costs.

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Selling, General and Administrative. Selling, general and administrative expenses for the nine months ended September 29, 2018 and September 30, 2017 were as follows (dollars in thousands):

Selling, General and Administrative

Nine Months Ended September 29, 2018	Percentage of Net Revenues	Nine Months Ended September 30, 2017	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$215,263	33.9%	$198,460	34.1%	$16,803	8.5%

Selling, general and administrative expenses increased $16.8 million, or 8.5%, for the nine months ended September 29, 2018 compared to the nine months ended September 30, 2017. This increase was primarily attributable to higher payroll-related expenses of approximately $19.2 million, which were partially offset by approximately $3.7 million of lower legal fees. Stock-based compensation expense of approximately $15.3 million and $8.7 million was included in selling, general and administrative expenses for the nine months ended September 29, 2018 and September 30, 2017, respectively.

Research and Development. Research and development expenses for the nine months ended September 29, 2018 and September 30, 2017 were as follows (dollars in thousands):

Research and Development

Nine Months Ended September 29, 2018	Percentage of Net Revenues	Nine Months Ended September 30, 2017	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$57,160	9.0%	$45,859	7.9%	$11,301	24.6%

Research and development expenses increased $11.3 million, or 24.6%, for the nine months ended September 29, 2018 compared to the nine months ended September 30, 2017, primarily due to higher payroll-related costs of approximately $7.1 million, higher allocations to cost of goods sold for NRE service costs of approximately $2.4 million, higher occupancy costs of $1.1 million and higher supplies of $0.3 million. Included in research and development expenses was approximately $4.1 million and $2.3 million of stock-based compensation expense for the nine months ended September 29, 2018 and September 30, 2017, respectively.

Non-operating Income. Non-operating income consists primarily of interest income, interest expense and foreign exchange gains and losses. Non-operating income for the nine months ended September 29, 2018 and September 30, 2017 was as follows (dollars in thousands):

Non-operating Income

Nine Months Ended September 29, 2018	Percentage of Net Revenues	Nine Months Ended September 30, 2017	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$4,080	0.6%	$1,319	0.2%	$2,761	209.3%

Non-operating income increased by $2.8 million for the nine months ended September 29, 2018 compared to the nine months ended September 30, 2017. Non-operating income for the nine months ended September 29, 2018 consisted of approximately $4.6 million in net interest income, approximately $0.8 million of net realized and unrealized gains on foreign currency denominated transactions and approximately $0.3 million of net unrealized gains on equity-based investments. Non-operating income for the nine months ended September 30, 2017 consisted of approximately $1.6 million in net interest income, which was partially offset by approximately $0.2 million of net realized and unrealized gains on foreign currency denominated transactions.

Provision for Income Taxes. Our provision for income taxes for the nine months ended September 29, 2018 and September 30, 2017 was as follows (dollars in thousands):

Provision for Income Taxes

Nine Months Ended September 29, 2018	Percentage of Net Revenues	Nine Months Ended September 30, 2017	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$11,609	1.8%	$7,856	1.3%	$3,753	47.8%

For the nine months ended September 29, 2018, we recorded a provision for income taxes of approximately $11.6 million, or an effective tax rate of 7.3%, as compared to a provision for income taxes of approximately $7.9 million, or an effective tax rate of 5.6%, for the nine months ended September 30, 2017. The increase in our tax rate for the nine months ended September 29, 2018 resulted primarily from a decrease in the amount of excess tax benefits realized from stock-based compensation pursuant to ASU 2016-09 of approximately $13.4 million as compared to the nine months ended September 30, 2017. This increase was partially offset by a discrete tax benefit of approximately $4.7 million related to the derecognition of uncertain tax positions due to the expiration of the statutes of limitations, as well as the impact of a net decrease in our overall U.S. federal effective tax rate pursuant to various provisions within the Tax Cuts and Jobs Act of 2017.

Liquidity and Capital Resources

Our principal sources of liquidity consist of our existing cash and cash equivalent balances and future funds expected to be generated from operations. At September 29, 2018, we had approximately $592.1 million in working capital and approximately $493.5 million in cash and cash equivalents as compared to approximately $430.0 million in working capital, as adjusted, and approximately $315.3 million in cash and cash equivalents at December 30, 2017. We carry cash equivalents at cost that approximates fair value. We currently do not maintain an investment portfolio but have the ability to invest in various security holdings, types and maturities that meet credit quality standards in accordance with our investment guidelines.

As of September 29, 2018, we had cash totaling $72.6 million held outside of the U.S., all of which was accessible without additional tax cost. We currently have sufficient domestic funds on-hand and cash held outside the U.S. that is available without additional tax cost to fund our domestic operations.

Cash Flows[(2)]

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

	Nine Months Ended	
	September 29, 2018	September 30, 2017 As Adjusted
Net cash provided by (used in):		
Operating activities	$176,305	$ 7,381
Investing activities	(20,564)	(41.195)
Financing activities	23,651	13,030
Effect of foreign currency exchange rates on cash	(1,230)	3.112
Increase (decrease) in	$178,162	$ (17,672)

cash,
cash
equivalents
and
restricted
cash

Operating Activities. Cash provided by operating activities was approximately $176.3 million for the nine months ended September 29, 2018, generated primarily from net income from operations of $146.6 million. Non-cash activity included stock-based compensation of $19.7 million, depreciation and amortization of $16.0 million, and a decrease in deferred taxes of $6.7 million. Additional sources of cash included a decrease in accounts receivable of $17.4 million, primarily due to the timing of cash receipts; increases in accrued liabilities and accounts payable of $5.7 million and $4.1 million, respectively, primarily due to the timing of payments; and an increase in deferred revenue and other contract-related liabilities of $4.0 million. These sources of cash were partially offset by other changes in operating assets and liabilities, including an increase in prepaid income taxes of $11.9 million and a decrease in long-term income taxes payable of $2.3 million, primarily due to the timing of payments, an increase in deferred costs and other contract assets of $10.4 million; an increase in other current assets of $3.7 million; and a decrease in unrecognized tax benefits of $3.4 million.

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(2) Certain information presented for periods ending prior to December 31, 2017 has been restated to reflect the full retrospective application of the new revenue accounting standard, ASU 2014-09. See Note 2 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information related to our adoption of this new accounting standard.

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Cash provided by operating activities was approximately $7.4 million for the nine months ended September 30, 2017, arising primarily from net income of $132.5 million. Non-cash activity included depreciation and amortization of $14.4 million and stock-based compensation of $11.2 million. Additional sources of cash included an increase in accounts payable of $3.7 million, primarily due to the timing of payments. These sources of cash were partially offset by other changes in operating assets and liabilities, including decreases in incomes taxes payable and accrued compensation of $71.2 million and $9.1 million, respectively, primarily due to the timing of payments; an increase in accounts receivable of $17.3 million, primarily due to the timing of cash receipts; a decrease in deferred revenue and other contract-related liabilities of $11.0 million; and increases in inventory, deferred costs and other contract assets and and other current assets of $26.4 million $9.2 million and $9.1 million respectively.

Investing Activities. Cash used in investing activities for the nine months ended September 29, 2018 was approximately $20.6 million, consisting of $12.3 million for purchases of property and equipment, $4.0 million for a business combination, net of cash acquired, and capitalized intangible asset costs of $4.7 million, related primarily to patent and trademark costs. Cash used in investing activities for the nine months ended September 30, 2017 was approximately $41.2 million, consisting of $37.8 million for purchases of property and equipment and capitalized intangible asset costs of $2.2 million related to patent and trademark costs.

Financing Activities. Cash provided by financing activities for the nine months ended September 29, 2018 was approximately $23.7 million, driven primarily by proceeds from the issuance of common stock related to employee equity awards of $42.3 million, which were partially offset by settlements of common stock repurchase transactions totaling $18.5 million. Cash provided by financing activities for the nine months ended September 30, 2017 was approximately $13.0 million, primarily driven by proceeds from the issuance of common stock related to employee equity awards of approximately $55.7 million, which were partially offset by settlements of common stock repurchase transactions totaling $42.6 million.

Capital Resources and Prospective Capital Requirements

In September 2015, our Board authorized the 2015 Repurchase Program for the repurchase of up to 5.0 million shares of our common stock over a period of up to three years. A total of 3.1 million shares were purchased by the Company pursuant to the 2015 Repurchase Program prior to its expiration in September 2018. In July 2018, our Board approved the 2018 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. The 2018 Repurchase Program became effective in September 2018 upon the expiration of the 2015 Repurchase Program. For additional information regarding our stock repurchase programs, see Note 14 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

We anticipate funding our future operating, investing and financing activities through our available cash, cash expected to be generated from future operations and other potential sources of capital. In addition to funding our working capital requirements, we anticipate additional capital expenditures during fiscal year 2018, primarily related to investments in infrastructure growth. Possible additional uses of cash may include the acquisition of technologies or technology companies, as well as repurchases of stock under our authorized stock repurchase program. However, any repurchases of stock will be subject to numerous factors, including the availability of our stock, general market conditions, the trading price of our stock, available capital, alternative uses for capital and our financial performance. In addition, the amount and timing of our actual investing activities will vary significantly depending on numerous factors, including the timing and amount of capital expenditures, costs of product development efforts, our timetable for international sales operations and manufacturing expansion, stock repurchase activity and costs related to our domestic and international regulatory requirements. Despite these investment requirements, we anticipate that our existing cash and cash equivalents 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 engaged in these relationships. As of September 29, 2018, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

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Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of net revenues, expenses, assets and liabilities. We regularly evaluate our estimates and assumptions related to our critical accounting policies, including revenue recognition and deferred revenue, inventory and related reserves for excess or obsolete inventory, allowance for doubtful accounts, stock-based compensation, goodwill, deferred taxes and related valuation allowances, uncertain tax positions, tax contingencies, litigation costs and loss contingencies. We base our estimates and assumptions on current facts, historical experience and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue, costs and expenses that are not readily apparent from other sources. 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 on our condensed consolidated financial statements and future results of operations may be material. Effective December 31, 2017, we adopted ASU 2014-09. A description of our updated accounting policies pursuant to Accounting Standards Codification (ASC) Topic 606 (ASC 606) is included below:

Revenue Recognition and Deferred Revenue

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

We derive the majority of our product revenue from four primary sources: (i) direct sales under long-term sensor contracts (LT Sensor Contracts) 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 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.

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

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

Sales under LT Sensor Contracts are generally structured such that we agree to provide at no up-front charge certain monitoring-related equipment, software, installation, training and/or warranty support in exchange for the hospital’s agreement to purchase sensors over the term of the agreement, which generally ranges from three to six years. Pursuant to the authoritative guidance, we generally recognize revenue related to performance obligations related to software parameters under LT Sensor Contracts with fixed annual commitments at the time such software is delivered to the customer. Revenue allocable to performance obligations related to sensors and monitoring-related equipment under LT Sensor Contracts is generally recognized as the sensors are delivered to the customer over the life of the contract.

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

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

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

The majority of our royalty revenue arises from one agreement and is due and payable quarterly in arrears. An estimate of these royalty revenues is recorded quarterly in the period earned based on historical results, adjusted for any new information or trends known to management at the time of estimation.

This estimated revenue is adjusted prospectively when we receive the royalty report, approximately sixty days after the end of the previous quarter. We also recognize revenue from time-to-time related to NRE services provided to certain OEM customers. NRE revenue is generally recognized on a proportionate basis as the costs of performing such services are incurred by the Company.

Other Critical Accounting Policies

There have been no material changes to any of our other critical accounting policies during the nine months ended September 29, 2018. For a description of these critical accounting policies, please refer to "Critical Accounting Estimates" in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 30, 2017, filed with the SEC on February 28, 2018.

Recent Accounting Pronouncements

See Note 2 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for a description of recently issued or adopted accounting standards.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of changes in the value of market risk sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. 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, including forward contracts, 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 September 29, 2018, the carrying value of our cash equivalents approximated fair value. We currently do not have any significant risks associated with interest rates fluctuations related to interest expense. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. Therefore, declines in interest rates over time will reduce our interest income while increases in interest rates will increase our interest income. A hypothetical 100 basis point change in interest rates along the entire interest rate yield curve would increase or decrease our interest rate yields on our investments and interest by approximately $0.1 million for each $10.0 million in interest-bearing investments.

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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 vary depending on the average exchange rates during a respective period.

We are also exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables and payables that arise in connection with such revenues and costs for the period of time between when these receivables and payables arise and the time that they are settled in cash. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of comprehensive income as incurred. Furthermore, other transactions between us or our subsidiaries and a third-party, denominated in a currency different from the functional currency, are foreign currency transactions. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of comprehensive income as incurred, and are converted to U.S. Dollars at the average exchange rates for a respective period.

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 the average monthly exchange rate during the period. Any foreign exchange gain or loss as a result of translating the balance sheets of our foreign subsidiaries whose functional currency is not the U.S. Dollar is included in equity as a component of accumulated other comprehensive income.

Our primary foreign currency exchange rate exposures are with the Euro, Japanese Yen, Swedish Krona, Canadian Dollar, British Pound and Mexican Peso against the U.S. Dollar. Foreign currency exchange rates have experienced significant movements in recent years, and such volatility may continue in the future. During the nine months ended September 29, 2018, we estimate that changes in the exchange rates of the U.S. Dollar, related primarily to the Euro and British Pound, favorably impacted our revenues by $5.4 million when compared to foreign exchange rates from the prior year period. 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 September 29, 2018 would have resulted in an estimated reduction of $12.2 million in reported pre-tax income for the nine months ended September 29, 2018. 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 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's (SEC) regulations, rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our CEO and CFO concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

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There has been no change in our internal controls over financial reporting during the quarter ended September 29, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The information set forth in Note 16 to the condensed consolidated financial statements under the caption "Litigation" included in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference.

Item 1A. Risk Factors

Before you decide to invest or maintain an interest in our common stock, you should consider carefully the risks described below, which have been updated since the filing of our Annual Report on Form 10-K for the fiscal year ended December 30, 2017, filed with the Securities and Exchange Commission (SEC) on February 28, 2018, together with the other information contained in this Quarterly Report on Form 10-Q, and any recent Current Reports on Form 8-K. We believe the risks described below are the risks that are material to us as of the date of this Quarterly Report on Form 10-Q. Other risks and uncertainties, including those not presently known to us or that we do not currently consider material, may also impair our business operations. If any of the following risks comes to fruition, our business, financial condition, results of operations and 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 or interest.

Risk factors marked with an asterisk (*) below include a substantive change from or an update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 30, 2017, filed with the SEC on February 28, 2018.

Risks Related to Our Revenues

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

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

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.

Products that we have introduced into the market in recent years may not be accepted in the market. In general, our recent noninvasive measurement technologies are considered disruptive. These recent technologies have performance levels that we believe are acceptable for many clinical environments but may be insufficient in others. In addition, these technologies may perform better in some patients and settings than others. 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. While this is the adoption pattern experienced historically with other new noninvasive measurements, such as regional oximetry, we are unable to guarantee that such adoption pattern will apply to our recent and future technologies.

Even if our customers recognize the benefits of our products, we cannot assure you that our customers will purchase them in quantities sufficient for us to be profitable or successful. We are continuing to invest in significant sales and marketing resources to achieve market acceptance of these products with no assurance of success.
The degree of market acceptance of these products will depend on a number of factors, including:

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- perceived clinical benefits from our products;
- perceived cost effectiveness of our products;
- perceived safety and effectiveness of our products;
- reimbursement available through Centers for Medicare and Medicaid Services (CMS) programs for using some of our products; and
- introduction and acceptance of competing products or technologies.

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

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

We are party to a cross-licensing agreement with Cercacor, which has been amended several times, most recently in an Amended and Restated Cross-Licensing Agreement, effective January 1, 2007 (the Cross-Licensing Agreement). Under the Cross-Licensing Agreement, we granted Cercacor:

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

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Rapid product development and technological advances within the medical device industry place our products at risk of obsolescence. Our long-term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for Masimo SET® and licensed rainbow® technology. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. In particular, we may not be able to successfully commercialize our products for applications other than arterial blood oxygen saturation and pulse rate monitoring, such as for respiration rate, hemoglobin, carboxyhemoglobin and methemoglobin monitoring.
If we do not successfully adapt our products and applications both within and outside these measurements, we could lose revenue opportunities and customers. Furthermore, one or more of our competitors may develop products that are substantially equivalent to our U.S. Food and Drug Administration (FDA) cleared products, or those of our original equipment manufacturer (OEM) partners, in which case a competitor of ours may use our products or those of our OEM partners as predicate devices to more quickly obtain FDA clearance of their competing products. Competition could result in pressure from our customers to reduce the price of our products and in 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.
We also believe that some of the world’s largest technology companies that have not historically operated in the healthcare or medical device space, such as Apple, Alphabet, Samsung and others, have developed or are developing 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 Masimo SET® and licensed rainbow® technology, our business would be harmed.
We are, and will continue to be, dependent upon our domestic and international OEM partners for a portion of our revenue through their marketing, selling and distribution of certain of their products that incorporate Masimo SET® and licensed rainbow® technology. Although we expect that our OEM partners will accept and actively market, sell and distribute products that incorporate licensed rainbow® technology, they may not elect, and have no contractual obligation, to do so. Because products that incorporate our technologies may represent a relatively small percentage of business for some of our OEM partners, they may have less incentive to promote these products 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 Masimo SET® and licensed rainbow® technology. The failure of our OEM partners to successfully market, sell or distribute products incorporating these technologies, the termination of OEM agreements, the loss of OEM partners or the inability to enter into future OEM partnership agreements would have a material adverse effect on our business, financial condition and results of operations.
*If we fail to maintain or develop relationships with GPOs, sales of our products would decline.
Our ability to sell our products to U.S. hospitals depends, in part, on our relationships with GPOs. Many existing and potential customers for our products are members of GPOs. GPOs negotiate beneficial pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors.
These negotiated prices are made available to a GPO’s affiliated hospitals and other members. If we are not one of the providers selected by a GPO, the GPO’s affiliated hospitals and other members may be less likely or unlikely to purchase our products. If a GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer’s products, we may be prohibited from making sales to members of such GPO for the duration of such contractual arrangement. For the nine months ended September 29, 2018 and September 30, 2017, shipments of our pulse oximetry products to customers that are members of GPOs represented approximately $350.2 million and $308.0 million, respectively, of our revenue from sales to U.S. hospitals. Our failure to renew our contracts with GPOs may cause us to lose market share and could have a material adverse effect on our 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.

Certain GPOs are creating, coordinating and facilitating regional purchasing coalition (RPC) supply chain networks that include anti-competitive practices such as sole sourcing and bundling. These RPCs circumvent and potentially violate rules of conduct for GPOs and have the effect of reducing product purchasing decisions available to the hospitals that belong to these regional organizations. If the GPOs and RPCs are permitted to continue practices that limit, reduce or eliminate competition, we could lose customers who are no longer able to choose to purchase our products, resulting in lower sales that could adversely affect our business, financial condition and results of operations.

Inadequate levels of coverage or reimbursement from governmental or other third-party payers for our products, or for procedures using our products, may cause our revenue to decline.

Sales of our products depend in part on the reimbursement and coverage policies of governmental and private health care payers. The ability of our health care provider customers, including hospitals, to obtain adequate coverage and reimbursement for our products or the procedures in which our products are used may impact our customers' purchasing decisions. Therefore, our customers' inability to obtain adequate coverage and reimbursement for our products or reimbursement for the procedures in which our products are used would have a material adverse effect on our business.

Third-party payers have adopted, and are continuing to adopt, health care policies intended to curb rising health care costs. These policies include, among others:

- controls on reimbursement for health care services and price controls on medical products and services;
- limitations on coverage and reimbursement for new medical technologies and procedures; and
- the introduction of managed care and prospective payment systems in which health care providers contract to provide comprehensive health care for a fixed reimbursement amount per person or per procedure.

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

We do not control payor decision-making with respect to coverage and payment levels for our products. Additionally, we expect many payors to continue to explore cost-containment strategies (e.g., comparative and cost-effectiveness analyses, so-called "pay-for-performance" programs implemented by various public government health care programs and private third-party payors, 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.

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

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This has resulted in, and will likely continue to result in, greater pricing pressures and the exclusion of certain suppliers from important market segments as GPOs, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals. 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.

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

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

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

States and other local regulatory authorities may issue guidelines regarding the appropriate scope and use of our products from time to time. For example, some of our noninvasive monitoring devices may be subject to authorization by individual states as part of the Emergency Medical Services scope of practice procedures. Although a lack of inclusion into scope of practice procedures does not prohibit usage, it may limit adoption.

Additionally, as a result of the continued consolidation in the health care industry, we may experience decreasing prices for our products due to the potential increased market pricing power of our health care provider customers. If these and other competitive forces drive down the price of our products, and we are not able to counter that pressure with cost reductions to our existing products or the introduction of new higher priced products, our product gross profit margins will decline. This, in turn, could have a material adverse effect on 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.

We have a concentration of OEM, distribution and direct customers. We cannot provide any assurance that we will retain our current customers, groups of customers or distributors, or that we will be able to attract and retain additional customers in the future. If for any reason we were to lose our ability to sell to a specific group or class of customers, or through a distributor, we could experience a significant reduction in revenue, which would adversely impact our operating results. For the nine months ended September 29, 2018 and September 30, 2017, we had sales through two just-in-time distributors, which in total represented approximately 22.8% and 24.6% of our total revenue, respectively. 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 currently consists primarily of royalties received from Medtronic plc (Medtronic, formerly Covidien Ltd.) related to its U.S. sales pursuant to the terms of our settlement agreement, and revenue from non-recurring engineering (NRE) services for a certain OEM customer. Pursuant to the terms of the Third Amendment to Settlement Agreement and Release of Claims effective September 2016, Medtronic agreed to continue paying royalties through October 6, 2018, after which no more royalties are due from Medtronic. In addition, we expect to complete the remaining contracted NRE services for our OEM customer next year. We currently do not expect to replace this royalty and NRE services revenue with revenue from other sources, and such loss of revenue will have an adverse effect on our future results of operations.

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

We believe that other organizations are manufacturing and selling imitation Masimo sensors. In addition, certain medical device reprocessors have been collecting our used single-patient-use sensors from hospitals and then reprocessing, repackaging and reselling those sensors to hospitals. These imitation and third-party reprocessed sensors are sold at lower prices than new Masimo sensors. Our experience with both these imitation sensors and third-party reprocessed sensors is that they provide inferior performance, increased sensor consumption, reduced comfort and a number of monitoring problems. Notwithstanding these limitations, some of our customers have indicated a willingness to purchase some of their sensor requirements from these imitation manufacturers and third-party reprocessors in an effort to reduce their sensor costs.

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

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

In response to these imitation sensors and third-party reprocessors, we offer to our customers our own Masimo reprocessed sensors, which we re-manufacture and test to ensure that they meet the same performance specifications as our new Masimo sensors. In addition, 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.

We believe this technology will help ensure that hospitals, clinicians and, ultimately, their patients receive true Masimo measurement quality and performance, and will curtail some of the harm to us that results when customers experience performance and other problems with imitation and reprocessed sensors. However, some customers may object to the X-Cal® technology, potentially resulting in the loss of customers and revenues. In addition, reprocessed sensors sold by us are generally offered at a lower price and, therefore, may reduce certain customer demand for our new sensors. As a result, increased sales of genuine Masimo reprocessed sensors may result in lower revenues, which could negatively impact our business, financial condition and results of operations.

From time to time, we may carry out strategic initiatives that may not be viewed favorably by our customers, or that could negatively impact our business, financial condition and results of operations.

We expect to continue to carry out strategic initiatives and investments that we believe are necessary to grow our revenues and expand our business, both in the U.S. and abroad. For example, we have continued to make incremental investments in additional sales force resources and invest in international expansion programs designed to increase our worldwide presence and take advantage of market expansion opportunities around the world. Although we believe these initiatives and investments continue to be in the long-term best interests of Masimo and our stockholders, there are no assurances that such initiatives and investments will yield favorable results for us. Accordingly, if these initiatives and investments are not viewed favorably by our customers, our business, financial condition and results of operations could be adversely affected.

Risks Related to Our Intellectual Property

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

Our success depends significantly on our ability to protect our rights to the technologies used in our products, including Masimo SET® and licensed rainbow® technology. We rely on patent protection, trade secrets and a combination of copyright and trademark laws, as well as nondisclosure, confidentiality and other contractual arrangements, to protect our technology and rights. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or maintain any competitive advantage. In addition, we cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The U.S. Patent and Trademark Office (PTO) may deny or require a significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or may not be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO.

In addition, third parties may challenge our issued patents through procedures such as Inter-Partes Review (IPR). In many IPR challenges, the 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.

Our patents related to Masimo SET® algorithm technology began to expire in 2011. Certain other patents related to our ProCal sensor technology began to expire in 2015. Additionally, upon the expiration of other issued or licensed patents, we may lose some of our rights to exclude competitors from making, using, selling or importing products using the technology based on the expired patents. While we seek to secure additional patents on commercially desirable improvements, there can be no assurance that we will be successful in securing such additional patents, or that such additional patents will adequately protect our innovations or offset the effect of expiring patents.

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For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. Additionally, there is no assurance that competitors will not be able to design around our patents.

We also rely on contractual rights with the third parties that license technology to us to protect our rights in such licensed technology. In addition, we rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology.

We seek to protect our know-how and other unpatented proprietary technology with confidentiality agreements and intellectual property assignment agreements with our employees, OEM partners, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Common law trademarks provide less protection than registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S. If we fail to apply for intellectual property protection or if we cannot adequately protect our intellectual property rights in these foreign countries, our competitors may be able to compete more effectively against us, which could adversely affect our competitive position, as well as our business, financial condition and results of operations.

If third parties claim that we infringe their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling certain products.

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:

- increase the cost of our products;
- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- force us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, product candidates and technologies;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third-party's intellectual property on terms that may not be favorable or acceptable to us;
- require us to indemnify third parties pursuant to contracts in which we have agreed to provide indemnification for intellectual property infringement claims;
- divert the attention of our management and other key employees;
- result in our customers or potential customers deferring or limiting their purchase or use of the affected products impacted by the claims until the claims are resolved; and
- otherwise have a material adverse effect on our business, financial condition and results of operations.

In addition, new patents obtained by our competitors could threaten the continued commercialization of our products in the market even after they have already been introduced.

We believe competitors may currently be violating and may in the future violate our intellectual property rights. As a result, we may initiate litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert management's attention from implementing our business strategy.

We believe that the success of our business depends, in part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets. We were previously involved in significant litigation to protect our patent positions related to some of our pulse oximetry signal processing patents that resulted in various settlements, most recently in 2016, and in view of some of the new market entrants, may be required to engage in additional litigation to protect our intellectual property in the future. In addition, we believe that an individual who previously held a high level technical position with the Company misappropriated our intellectual property for the benefit of himself and other companies. Our ongoing and future litigation could result in significant additional costs and further divert the attention of our management and key personnel from our business operations and the implementation of our business strategy and may not be successful or adequate to protect our intellectual property rights.

Risks Related to Our Regulatory Environment

*Our failure to obtain and maintain FDA clearances or approvals on a timely basis, or at all, would prevent us from commercializing our current or upgraded products in the U.S., which could severely harm our business.

Unless an exemption applies, each medical device that we wish to market in the U.S. must first undergo premarket review pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA) by receiving clearance of a 510(k) premarket notification, receiving clearance through the de novo review process, or obtaining approval of a premarket approval (PMA) application. Even if regulatory clearance or approval of a product is granted, the FDA may clear or approve our products only for limited indications for use, limiting our ability to market the product for only the FDA approved or cleared indications for use. The FDA may not grant 510(k) clearance on a timely basis, if at all, for new products or uses that we propose for Masimo SET® or licensed rainbow® technology.

The traditional FDA 510(k) clearance process for our products has generally taken between three to six months. However, our more recent experience and interactions with the FDA, along with information we have received from other medical device manufacturers, suggests that, in some cases, the FDA is requiring applicants to provide additional or different information and data for 510(k) clearance than it had previously required, and that the FDA may not rely on approaches that it had previously accepted to support 510(k) clearance.

These changes could lead to more review cycles or to decisions by the FDA that our products are not substantially equivalent or require greater amounts of information to demonstrate substantial equivalence. As a result, we have experienced lengthier FDA 510(k) review periods over the past few years, which have delayed the 510(k) clearance process for our products.

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

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

We sell consumer versions of our iSpO_2® and MightySat® pulse oximeters that are not intended for medical use. We believe we are marketing these products in accordance with legal requirements that apply to products that are intended for general wellness or fitness uses. Some of our products or product features may also be exempted from the 510(k) process and/or other regulatory requirements in accordance with specific FDA guidance and policies, such as the FDA guidance related to mobile medical applications.

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In addition, some of our products or product features may not be subject to device regulation under Section 520(o) of the FDCA, which was enacted as part of the 21st Century Cures Act (Cures Act) in December 2016 and excludes certain software functions from the statutory definition of a device. Laws affecting our products may change or the FDA may change its enforcement policy regarding the regulation of these products. If the FDA changes its policy or concludes that our marketing of these products is not in accordance with its current policy and/or Section 520(o) of the FDCA, we may be required to seek clearance or approval of these devices through the 510(k), de novo or PMA processes.

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

Our OEM partners are required to obtain their own FDA clearances for products incorporating Masimo SET® and licensed rainbow® technology to market these products in the U.S. 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 product incorporating Masimo SET® and licensed rainbow® technology that our OEM partners propose to market.

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

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

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

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

- warning letters or untitled letters issued by the FDA;
- fines, civil penalties, in rem forfeiture proceedings, injunctions, consent decrees and criminal prosecution;
- import alerts;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawals or suspensions of clearance or approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;
- product recalls or seizures;
- orders for physician notification or device repair, replacement or refund;
- interruptions of production or inability to export to certain foreign countries; and
- operating restrictions.

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

Failure to obtain regulatory authorizations in foreign jurisdictions may prevent us from marketing our products abroad.

We currently market and intend to continue to market our products internationally. Outside of the U.S., we can generally market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The regulatory registration/licensing process varies among international jurisdictions and may require additional or different product testing than required to obtain FDA clearance. FDA clearance does not ensure new product registration/licensing by foreign regulatory authorities, and we may be unable to obtain foreign regulatory registration/licensing on a timely basis, if at all.

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

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

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

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

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

In addition, the FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business or products. It is impossible to predict whether additional legislative changes will be enacted or whether FDA regulations, guidance or interpretations will be changed, and what the impact of such changes, if any, may be. However, any future regulatory changes could make it more difficult for us to maintain or attain approval to develop and commercialize our products and technologies.

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

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

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. A correction is a repair, modification, adjustment, relabeling, destruction or inspection of a device, without its physical removal from its point of use to some other location. A removal is the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction or inspection. If a correction or removal is initiated to reduce a health risk posed by our device, or to remedy a violation of the FDCA caused by the device that may present a risk to health, the correction or removal 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.

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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.

From time to time, we have initiated various field actions related to our products as required by applicable law and regulations, including device corrections and removals, none of which were material to our operating results. These field actions were reported to the FDA and other foreign regulatory agencies, when required, within the appropriate regulatory timeframes. Because of our dependence upon patient and physician perceptions, any negative publicity associated with these or any future voluntary recalls could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

Obtaining 510(k) clearance permits us to promote our products for the uses cleared by the FDA. Use of a device outside its cleared or approved indications is known as “off-label” use. Physicians may use our products off-label because the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. While we may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. If the FDA determines that our products were promoted for off-label use or that false, misleading or inadequately substantiated promotional claims have been made by us or our OEM partners, it could request that we or our OEM partners modify those promotional materials or take regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our communications, including promotional or training materials, to constitute promotion of an uncleared or unapproved use. Although, depending on the facts and circumstances, such promotion might be protected speech under the First Amendment to the U.S. Constitution, we cannot be sure that government authorities or a court would not find us in violation of the law. 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. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the regulatory standards regarding off-label promotion are ambiguous, and the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

In addition to promoting our products in a manner consistent with our clearances, 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.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the purchase, order or recommendation of an item or service reimbursable under a federal health care program (such as the Medicare or Medicaid programs);
- the federal False Claims Act and other federal laws which prohibit, among other things, knowingly and willfully presenting, or causing to be presented, claims for payment from Medicare, Medicaid, other government payers or other third-party payers that are false or fraudulent;
-

the provisions of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services; and

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

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Some suits filed under the Civil False Claims Act, known as “qui tam” actions, can be brought by a private individual, referred to as a “whistleblower” or “relator,” on behalf of the government, and such individuals may share in any amounts paid by the entity to the government in fines or settlement. Such complaints are filed under seal and remain sealed until the applicable court orders otherwise. In recent years, the number of suits brought by private individuals has increased dramatically. Manufacturers, like us, can be held liable under false claims laws, even if they do not submit claims to the government, if they are found to have caused medical care providers to have submitted claims to the government for payment for a service or the use of a device that is not properly covered for government reimbursement. A number of states also have false claims laws, which may apply to claims for items or services reimbursed under Medicaid, other state government health care programs, and/or commercial insurance.

Sanctions under these federal and state fraud and abuse laws may include fines, civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs and imprisonment. In particular, when an entity is determined to have violated the federal Civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $10,957 to $21,916 (adjusted for inflation) for each separate false claim.

We have certain arrangements with hospitals that may be affected by health care fraud and abuse laws. For instance, under our standard customer arrangements, we provide hospitals with pulse oximetry monitoring devices at no up-front charge as part of their agreement to purchase future pulse oximetry sensors from us. In addition, we occasionally provide our customers with rebates in connection with their annual purchases. While we believe that these arrangements are structured such that we are currently in compliance with applicable federal and state health care laws, one or more of these arrangements may not meet the federal Anti-Kickback Statute’s safe harbor requirements, which may result in increased scrutiny by government authorities that are responsible for enforcing these laws.

The Physician Payment Sunshine Act (the Sunshine Act) requires medical device companies to track and publicly report, with limited exceptions, all payments and transfers of value to physicians and teaching hospitals in the U.S. If we fail to comply with the data collection and reporting obligations imposed by the Sunshine Act, we may be subject to substantial civil monetary penalties.

Further, we may be required to comply with certain federal and state laws governing the transmission, security and privacy of individually identifiable PHI that we may obtain or have access to in connection with the manufacture and sale of our products. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements. In addition, if we do not properly comply with applicable laws and regulations related to the protection of health information, we could be subject to criminal or civil sanctions.

Numerous other federal and state laws protect the confidentiality of PHI, including state medical information privacy laws, state social security number protection laws and state and federal consumer protection laws. More protective state privacy and security laws are not preempted by HIPAA, and the interpretation of such laws by various governmental authorities and courts may result in potentially complex compliance issues for us and our customers. In addition, state and federal human subject protection laws apply to our clinical research. These laws could create liability for us if one of our research collaborators fails to obtain appropriate informed consent or otherwise violates laws intended to protect research subjects.

If we are found to have violated any of such laws or other similar governmental regulations which are directly or indirectly applicable to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion of our products from reimbursement under Medicare, Medicaid and other federal health care programs, and the curtailment or restructuring of our operations. Any penalties could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against such action, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

We may incur significant costs and potential liabilities in defending our new products and technologies in various legal and other proceedings.

Our noninvasive measurement technologies are new and not yet widely understood or accepted. These new technologies may become the subject of various legal and other proceedings. We may incur significant costs in explaining and defending our new products and technologies in these proceedings, often to non-technical audiences. As these new products are introduced into the market and become more widely adopted, we may discover flaws or errors, which could result in product recalls, fines or harm to our reputation, each of which could adversely affect our business, financial condition and results of operations. In addition, the outcomes of these proceedings are unpredictable and may result in significant liabilities, regardless of the merits of the claims made in the proceedings.

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

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

In general, an expansion in the government's role in the U.S. health care industry may lower reimbursements for our products, reduce demand for innovative products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly in a material manner. In addition, as a result of the continued focus on health care reform, there is a risk that Congress may implement changes in laws and regulations governing health care service providers, including measures to control costs or reduce reimbursement levels, which could result in pricing pressures, have an adverse effect on the demand for our products and/or negatively impact the prices that the market is willing to accept for our current and future products. Furthermore, many private payers look to Medicare's coverage and reimbursement policies in setting their coverage policies and reimbursement amounts such that federal reforms could influence the private sector as well. Finally, many states also may attempt to reform their Medicaid programs such that either coverage for certain items or services may be narrowed or reimbursement for them could be reduced. These health care reforms may adversely affect our business. In addition, the requirements or restrictions imposed on us or our products may change, either as a result of administratively adopted policies or regulations or as a result of the enactment of new laws. We cannot predict what health care initiatives, if any, will be implemented at the federal or state levels or the effect any future legislation or regulation will have on us.

There have also been recent U.S. Congressional actions to repeal and replace the ACA, and future actions are possible. Even if the ACA is not amended or repealed in its entirety, proposed changes impacting implementation or existing provisions of the ACA could materially and adversely affect our financial position or operations. For example, the Tax Cuts and Jobs Act of 2017 (the 2017 Tax Act), among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. The repeal of the individual mandate, as well as similar laws or changes in other jurisdictions, may decrease the number of people who are insured, which could decrease overall demand for our products and adversely affect our business and future results of operations. Although we cannot predict the ultimate content or timing of any healthcare reform legislation, potential changes resulting from any amendment, repeal or replacement of these programs, including any reduction in the future availability of healthcare insurance benefits, could adversely affect our business and future results of operations.

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

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

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Our medical devices and business activities are subject to rigorous regulation by the FDA and other federal, state and international governmental authorities. These authorities and members of Congress have been increasing their scrutiny over the medical device industry. In recent years, Congress, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, and the Department of Defense have issued subpoenas and other requests for information to medical device manufacturers, primarily related to financial arrangements with health care providers, regulatory compliance and marketing and product promotional practices. Furthermore, certain state governments have enacted legislation to limit and/or increase transparency of interactions with health care providers, pursuant to which we are required by law to disclose payments and other transfers of value to health care providers licensed by certain states. We anticipate that the government will continue to scrutinize our industry closely, and any new regulations or statutory provisions could result in delays or increased costs during the periods of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance.

Risks Related to Our Business and Operations

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

Prior to our initial public offering in August 2007, our stockholders owned 99% of the outstanding shares of capital stock of Cercacor and we believe that, as of September 29, 2018, 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 will 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 materially and 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.

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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.

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

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

- predatory pricing and bundling practices by our competitors targeted to dissuade customers from using our technology;
- delays, delivery performance issues or interruptions in manufacturing and shipping of our products;
- varying demand for and market acceptance of our technologies and products;
- delayed acceptance of our new products, negatively impacting the carrying value of our inventory;
- design, technology or other market changes that could negatively impact the carrying value of our inventory;
- the effect of competing technological and market developments resulting in lower selling prices or significant promotional costs;
- changes in the timing of product orders and the volume of sales to our OEM partners;
- actions taken by GPOs;
- delays in hospital conversions to our products and declines in hospital patient census;
- our legal expenses, particularly those related to litigation matters;
- changes in our product or customer mix;
- movements in foreign currency exchange rates;
- market seasonality of our sales due to quarterly fluctuations in hospital and other alternative care admissions;
- our ability to renew existing long-term sensor contract commitments;
- changes in the total dollar amount of annual contract renewal activities;
- changes in the mix and, therefore, the related costs of products that we supply at no upfront costs to our customers as part of their long-term sensor commitments;
- changes in hospital and other alternative care admission levels;
- our inability to efficiently scale operations and establish processes to accommodate business growth;

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- unanticipated delays or problems in the introduction of new products, including delays in obtaining clearance or approval from the FDA;
- high levels of returns and repairs; and
- changes in reimbursement rates for SpHb®, SpCO® and SpMet® parameters.

In addition, a change in accounting pronouncements or taxation rules or practices, or the interpretation of them by the SEC or other regulatory bodies, could have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements or taxation rules and varying interpretations of accounting pronouncements or taxation practice have occurred and may occur in the future. Specifically, on December 22, 2017, the 2017 Tax Act was signed into law. The 2017 Tax Act, which took effect on January 1, 2018, includes a number of changes to existing tax law impacting businesses including, among other things, a permanent reduction in the corporate income tax rate from 35% to 21%, a one-time transition tax on the "deemed repatriation" of cumulative undistributed foreign earnings as of December 31, 2017 and changes in the prospective taxation of the foreign operations of U.S. multinational companies. Moreover, Congressional leaders have recognized that the process of adopting extensive tax legislation in a short amount of time without hearings and substantial time for review is likely to have led to drafting errors, issues needing clarification and unintended consequences that will have to be reviewed in subsequent tax legislation. At this point, it is not clear when Congress will address these issues or when the Internal Revenue Service will be able to issue administrative guidance on the changes made in the 2017 Tax Act. Accordingly, given the complexity and lack of specificity related to certain provisions of the 2017 Tax Act, we made certain estimates and assumptions in connection with the calculation of our provision for income taxes for the year ended December 30, 2017. We continue to evaluate the impact of the 2017 Tax Act on our business, financial condition and results of operations. For additional information related to the impact of the 2017 Tax Act on our tax provision and tax rate, please see Note 16 of our consolidated financial statements included in Part IV, Item 15(a) of our Annual Report on Form 10-K for the fiscal year ended December 30, 2017, filed with the SEC on February 28, 2018.

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

Our results of operations could be harmed if we fail to effectively manage our growth or, alternatively, our spending during economic downturns.

Our ability to offer our products and implement our business plan in evolving markets successfully requires an effective planning and management process. We must effectively manage our spending and operations to ensure our competitive position during economic downturns, and must preserve our future opportunities when the economy improves. A failure to manage our spending and operations effectively could disrupt our business and harm our operating results. A growth in sales, combined with the challenges of managing geographically dispersed operations, can place a significant strain on our management systems and resources, and growth in future operations could continue to place such a strain. The failure to manage our growth effectively could disrupt our business and harm our operating results.

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

The methods, estimates and judgments that we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates and judgments are, by their nature, subject to substantial risks, uncertainties and assumptions and factors may arise over time that lead us to change our methods, estimates and judgments. Changes in those methods, estimates and judgments could significantly affect our results of operations. See "Critical Accounting Estimates" contained in Part I, Item 2 of this Quarterly Report on Form 10-Q and Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 30, 2017, which we filed with the SEC on February 28, 2018, for additional information about these methods, estimates and judgments.

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

We are highly dependent on our senior management, especially Joe Kiani, our CEO, and other key officers. We are also heavily dependent on our engineers and field sales team, including sales representatives and clinical specialists. Additionally, from time to time, some of our key personnel may hold stock options with an exercise price that is greater than our recent closing prices, which may minimize the retention value of these options.

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The loss of the services of members of our key personnel or the inability to attract and retain qualified personnel in the future could prevent the implementation and completion of our objectives, including the development and introduction of our products. In general, our key personnel may terminate their employment at any time and for any reason without notice, unless the individual is a participant in our 2007 Severance Protection Plan, in which case the individual has agreed to provide us with six months' notice if such individual decides to voluntarily resign.

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

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

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

We recruit professionals on a global basis and must comply with the immigration laws in the countries in which we operate, including the U.S. Some of our employees are working under Masimo-sponsored temporary work visas, including H1-B visas. The H-1B visa classification enables U.S. employers to hire certain qualified foreign workers in positions that require an education at least equal to a four-year bachelor degree in the United States in specialty occupations such as engineering. Statutory law limits the number of new H1-B temporary work permit petitions that may be approved in a fiscal year, and if we are unable to obtain H1-B visas for our employees in sufficient quantities or at a sufficient rate for a significant period of time, our business, operating results and financial condition could be adversely affected.

The subject of H1-B visas has recently become a topic of political discussion, and there are indications that the H1-B visa program may be significantly overhauled. If a new or revised visa program is implemented, there could be elements of any new or revised visa program that may impact our ability to recruit, hire and retain qualified skilled personnel, which could adversely impact our business, operating results and financial condition.

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

We derive a portion of our net sales from international operations. For the nine months ended September 29, 2018 and September 30, 2017, approximately 31.3% and 31.7%, respectively, of our product revenue was derived from our international operations. In addition, we purchase a portion of our raw materials and components on the international market. The sale and 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. Compliance with such regulations is costly and we could be exposed to potentially significant penalties if we are found not to be in compliance with such regulations. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, manufacturing and sales activities. Any material decrease in our international sales would adversely affect our business, financial condition and results of operations.

In June 2016, the United Kingdom (UK) held a referendum pursuant to which voters elected to leave the EU, commonly referred to as Brexit. As a result of UK voters' election to leave the EU, the British government is expected to begin negotiating the terms of the UK's future relationship with the EU.

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

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

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- a shortage of high-quality sales people and distributors;
- 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;
- scrutiny of foreign tax authorities, which could result in significant fines, penalties and additional taxes being imposed on us;
- pricing pressure that we may experience internationally;
- 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 such as the Zika virus;
- 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.

We are subject to certain other laws and regulations affecting our international operations, including laws and regulations such as the North American Free Trade Agreement (NAFTA), which, among other things, provide certain beneficial duties and tariffs for qualifying imports and exports, subject to compliance with the applicable classification and other requirements. The U.S. government has indicated its intent to make substantial changes to U.S. trade policy, including NAFTA, and has recently initiated certain tariffs, and is considering imposing additional tariffs, on certain foreign goods. In response to these actions, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U.S. goods. 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, to adversely affect our business, financial condition and results of operations.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from promising or making improper payments to non-U.S. officials for the purpose of obtaining an advantage to secure or retain business. Because of the predominance of government-sponsored health care systems around the world, many of our customer relationships outside of the U.S. are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws.

Personal privacy and data security have become significant issues in the United States, Europe and in many other jurisdictions where we offer our products. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Future laws, regulations, standards and other obligations, and changes in the interpretation of existing laws, regulations, standards and other obligations could result in increased regulation, cost of compliance and limitations on data collection, use, disclosure and transfer.

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For example, in October 2015, the Court of Justice of the EU ruled that the US-EU Safe Harbor framework that had been in place since 2000, which allowed companies to meet certain European legal requirements for the transfer of personal data from the European Economic Area to the United States, was invalid. In July 2016, a new data transfer framework referred to as the EU-U.S. Privacy Shield was adopted, which may provide a new mechanism for companies to transfer EU personal data to the U.S. While we have adopted the EU-U.S. Privacy Shield framework for the transfer of personal data from the EU to the U.S., our means for transferring personal data from the EU may not be adopted by all of our customers and suppliers and may be subject to legal challenge or risk of enforcement actions by data protection authorities. In addition, in April 2016, the EU approved a new data protection regulation, known as the General Data Protection Regulation (GDPR), which became effective in May 2018. The GDPR includes new operational requirements for companies that receive or process personal data of EU residents, as well as significant penalties for non-compliance. Complying with the GDPR may cause us to incur substantial operational costs or require us to change our business practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could subject us to cash and non-cash penalties, disrupt our operations, involve significant management distraction and result in a material adverse effect on our business, financial condition and results of operations.

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

We market our products in certain foreign markets through our subsidiaries and other international distributors. 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.

For example, the announcement of Brexit caused significant volatility in global economic markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. Dollar relative to certain other foreign currencies in which we conduct business. While a majority of our sales are transacted in U.S. Dollars, some of our sales agreements with foreign customers provide for payment in currencies other than the U.S. Dollar. These foreign currency revenues, when converted into U.S. Dollars, can vary depending on average exchange rates during a respective period. Similarly, certain of our foreign sales support 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. When converted to U.S. Dollars, these receivables and payables can vary depending on the monthly exchange rates at the end of the period. In addition, certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses based on the currency underlying such intercompany transactions. Accordingly, our operating results are subject to fluctuations in foreign currency exchange rates.

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

We currently do not hedge our foreign currency exchange rate risk. Should we decide in the future to hedge such exchange rate risk by entering into forward contracts, these contracts may not mitigate the potential adverse impact on our financial results due to the variability of timing and amount of payments under these contracts. In addition, our failure to sufficiently hedge, forecast or otherwise manage such foreign currency risks properly could have a material adverse effect on our business, financial condition and results of operations.

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

We rely on manufacturing facilities in Mexicali and San Luis Rio Colorado, Mexico; Irvine, California; Hudson, New Hampshire; and Danderyd, Sweden. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial time to repair. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since some of our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist or terrorist organizations, epidemics, communication failures, fire, floods and similar events.

In the event that one of our facilities is 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 we may 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 such manufacturing facilities, we may not be able to meet our customers' demands.

Our two manufacturing facilities in Mexico are authorized to operate under the Mexican Maquiladora or IMMEX program. The IMMEX program allows us to import certain items from the U.S. into Mexico duty-free, provided that such items, after processing, are exported from Mexico within a stipulated timeframe. Maquiladora status, which is renewed periodically, is subject to various restrictions and requirements, including compliance with the terms of the IMMEX program and other local regulations, which have become stricter in recent years. Failure to comply with the IMMEX program regulations could adversely affect our business, operating results and financial condition because we could, for example, be required to pay tax on material imported into Mexico. In addition, if the Mexican government adopts changes to the IMMEX program or if our Mexican facilities cease to qualify for Maquiladora status, our business, financial condition and results of operations could be adversely affected as our manufacturing costs in Mexico would increase.

We also purchase materials and components from international sources. Any disruption in the supply of such materials, including transportation or port delays, could adversely impact our manufacturing operations. Disruptions may also occur as a result of local, regional and worldwide health risks. Such disruptions may include the inability to manufacture and distribute our products due to the direct effects of illness on individuals or due to constraints on supply and distribution that may result from either voluntary or government imposed restrictions.

Any disruption or delay at such manufacturing facilities, any expansion of our operations to additional locations, or any changes in market conditions could create operational hurdles and have an adverse impact on our ability to produce sufficient inventory of our products or may require us to incur additional expenses in order to produce sufficient inventory, depending on changes in product demand. Furthermore, if we are unable to meet the demand of our customers, our customers may cancel orders or purchase products from our competitors, which could adversely affect our business, financial condition and results of operations. 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.

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

We depend on certain sole or limited source suppliers for key materials and components of our noninvasive patient monitoring solutions, and if we are unable to obtain these materials and components on a timely basis, we will not be able to deliver our noninvasive patient monitoring solutions to customers. Also, we cannot guarantee that any of the materials or components that we purchase, if available at all, will be of adequate quality and at acceptable price levels. From time to time, there are industry-wide shortages of several electronic components that we use in our noninvasive blood constituent patient monitoring solutions. We may 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.

We may experience delays in production of our products if we fail to identify alternate vendors for materials and components, if any parts supply is interrupted or reduced or if there is a significant increase in production costs, each of which could adversely affect our business, financial condition and results of operations. In addition, we rely on third party manufacturers to supply some of our products and components, including digital signal processor chips and analog to digital converter chips.

Manufacturing problems may occur with these and other outside sources, as a supplier may fail to develop and supply products and components to us on a timely basis, or may supply us with products and components that do not meet our quality, quantity and cost requirements. 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.

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If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934, as amended, and Section 404 of the Sarbanes-Oxley Act of 2002, 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 materially and adversely affected.

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

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

Any failure to maintain compliance with the requirements of Section 404 of the Sarbanes-Oxley Act or any material weakness in our internal control environment could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business, negatively impact the trading price of our stock, and adversely affect investors' confidence in our company and our ability to access capital markets for financing.

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

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

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

Furthermore, our ongoing compliance with these rules could affect the pricing, sourcing and availability of minerals used in the manufacture of our products. We may also encounter challenges with our customers and stockholders if we are unable to certify that our products are free of conflict minerals. 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 such evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

In addition, stockholder litigation surrounding executive compensation and disclosure of executive compensation has increased with the passage of the Dodd-Frank Act. Furthermore, our stockholders may not continue to approve our advisory vote on named executive officer compensation that is required to be voted on by our stockholders annually pursuant to the Dodd-Frank Act. If we are involved in a lawsuit related to compensation matters or any other matters not covered by our directors' and officers' liability insurance, we may incur significant expenses in defending against such lawsuits, or be subject to significant fines or required to take significant remedial actions, each of which could adversely affect our business, financial condition and results of operations.

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

Our products are predominantly used in patient care and expose us to product liability claims and product recalls, including, but not limited to, those that may arise from unauthorized off-label use, which is use of a device in a manner outside the indications for use cleared by the FDA, malfunctions, design flaws or manufacturing defects related to our products or the use of our products with incompatible components or systems. We cannot be certain that our product liability insurance will be sufficient to cover any or all damages for product liability claims that may be brought against us in the future. Furthermore, we may not be able to obtain or maintain insurance in the future at satisfactory rates or in adequate amounts to protect us against any product liability claims.

Additionally, the laws and regulations regarding product liability are constantly evolving, both through the passage of new legislation at the state and federal levels and through new interpretations of existing legislation. For example, in February 2017, the Washington Supreme Court determined that, under the Washington Product Liability Act, medical device manufacturers have a duty to warn hospitals of any potential risks posed by their products. As the legal and regulatory landscape surrounding product liability change, we may become exposed to greater liability than currently anticipated.

Any losses that we may suffer from product liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our technology and products, together with the corresponding diversion of the attention of our key employees, may subject us to significant damages and could adversely affect our business, financial condition and results of operations.

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

We have acquired seven businesses since our inception and we may acquire additional businesses in the future, which may be larger in magnitude than our previous acquisitions. Successful acquisitions depend upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. 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, we may experience:

- payment of above-market prices for acquisitions and incurring higher than anticipated acquisition costs;
- a need to issue shares 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 as future acquisitions may not result in accretive contributions to the business over either the short-term or the long-term;
- difficulties in integrating any acquired companies, personnel, products and other assets into our existing business;
- delays in realizing the benefits of the acquired company, products or other assets;
- regulatory challenges;
- cybersecurity and compliance related issues;
- diversion of our management’s time and attention from other business concerns;
- limited or no direct prior experience in new markets or countries we may enter;
- unanticipated issues dealing with unfamiliar suppliers, service providers or other collaborators of the acquired company;
- higher costs of integration than we anticipated;
- write-downs or impairments of goodwill or other intangible assets associated with the acquired company;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions;
- negative impacts on our relationships with our employees, clients or collaborators;
- litigation or other claims in connection with the acquisition; and
- changes in the overall financial model as certain acquired companies may have a different revenue, gross profit margin or operating expense profile.

Further, our ability to benefit from future acquisitions depends on our ability to successfully conduct due diligence, negotiate acceptable acquisition terms, evaluate prospective acquisitions and bring acquired technologies and/or products to market at acceptable margins and operating expense levels.

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Our failure in any of these tasks could result in unforeseen liabilities associated with an acquired company, acquiring a company on unfavorable terms or selecting and eventually acquiring a suboptimal acquisition target. We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance and product liabilities that we did not uncover prior to our acquisition of such businesses, which could result in us becoming subject to penalties or other liabilities. If we do not achieve the anticipated benefits of an acquisition as rapidly as expected, or at all, investors or analysts may not perceive the same benefits of the acquisition as we do. If these risks materialize, our stock price could be materially adversely affected. Any difficulties in the integration of acquired businesses or unexpected penalties or liabilities in connection with such businesses could have a material adverse effect on our business, financial condition and results of operations.

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

Certain manufacturing processes for our products may involve the use, generation and disposal of certain hazardous materials and wastes, including silicone adhesives, solder and solder paste, sealants, epoxies and various solvents such as methyl ethyl ketone, acetone and isopropyl alcohol. As a result, we are subject to stringent federal, state and local laws relating to the protection of the environment, including those governing the use, handling and disposal of hazardous materials and wastes. 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, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in EU member states. In addition, the EU's Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products. Compliance with such regulations may be costly and, therefore, we may be forced to incur significant costs to comply with environmental regulations.

From time to time, new regulations are enacted and it is difficult to anticipate how such regulations will be implemented and enforced. We continue to evaluate the necessary steps for compliance with environmental regulations as they are enacted. Future environmental laws may significantly affect our operations by, for example, requiring our manufacturing processes to be altered or requiring us to use different types of materials in manufacturing our products. Any 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 our research and manufacturing activities, we use, and our employees may be exposed to, materials that are hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal.

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

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

Increased global cybersecurity vulnerabilities, threats, and more sophisticated and targeted cybersecurity attacks pose a risk to the security of Masimo's and our customers', partners', suppliers' and third-party service providers' products, systems and networks, and the confidentiality, availability and integrity of any underlying information and data. Our ability to effectively manage and maintain our internal business information, and to ship products to customers and invoice them on a timely basis, depends significantly on our enterprise resource planning system and other information systems. Portions of our information technology systems may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In addition, interfaces between our products and our customers' computer network 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.

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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.

Our operating results may be adversely affected by unfavorable economic and market conditions.

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, such as Brexit. In addition, continuing strength and growth in the U.S. economy is raising the probability of inflationary pressures and future interest rate hikes that have not been experienced in the U.S. for more than a decade. Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions.

In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition.

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

Joe Kiani, our Chairman and CEO, founded the Patient Safety Movement Foundation in 2013 with the aim of eliminating the third leading cause of death in the U.S., preventable deaths due to medical errors. While reception to his work in this area has been high and great progress is being made, conflicts of interest issues may arise between our business and customers and the objectives of the Patient Safety Movement Foundation. For example, one of the objectives of the Patient Safety Movement Foundation is to request that hospitals implement Actionable Patient Safety Solutions to overcome some of the leading patient safety challenges that hospitals currently face. Some hospitals and other healthcare providers may disagree with the Patient Safety Movement Foundation’s recommendations or may determine that these steps and other actions encouraged by the Patient Safety Movement Foundation may not be practicable or may be too costly or burdensome to implement. Although Mr. Kiani’s role in the Patient Safety Movement Foundation is separate from his role as our President and CEO, hospitals and healthcare providers that do not agree with the actions or recommendations of the Patient Safety Movement Foundation may nonetheless disfavor Masimo products, which could adversely affect our business, financial condition and results of operations.

Risks Related to Our Stock

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

There has been significant volatility in the market price and trading volume of equity securities, which is often unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our stock. From January 2, 2018 to September 29, 2018, our closing stock price ranged from $82.06 to $124.54 per share. You may not be able to resell your shares at or above the price you paid for them due to fluctuations in the market price of our stock caused by changes in our operating performance or prospects and other factors.

In addition to the other risk factors previously discussed above, 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;
- 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.

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

As of September 29, 2018, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 11.2% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, these stockholders may be able to exercise significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have some control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of us, or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our stock.

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

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

As of September 29, 2018, approximately 12 million shares of our common stock were reserved for issuance under our equity incentive plans, of which approximately 5.7 million shares were subject to options outstanding at such date at a weighted-average exercise price of $43.04 per share, approximately 2.7 million shares were subject to outstanding RSUs, approximately 0.3 million shares were subject to outstanding PSUs and approximately 3.2 million shares were available for future awards under our 2017 Equity Incentive Plan. Over the past 24 months, we have experienced higher rates of stock option exercises compared to many earlier periods, and this trend may continue. To the extent outstanding options are exercised or outstanding RSUs or PSUs vest, our existing stockholders may incur dilution. We rely on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

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

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

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.

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

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our amended and restated certificate of incorporation authorizes our Board to issue up to 5.0 million shares of "blank check" preferred stock. As a result, without further stockholder approval, our Board has the authority to attach special rights, including voting and dividend rights, to this preferred stock, including pursuant to a stockholder rights plan. With these rights, preferred stockholders could make it more difficult for a third-party to acquire us. In addition, our amended and restated certificate of incorporation provides for a staggered board of directors, whereby directors serve for three year terms, with one-third of the directors coming up for reelection each year. A staggered Board will make it more difficult for a third-party to obtain control of our Board through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our Board.

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

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

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

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

In July 2018, our Board approved a stock repurchase program, authorizing us to purchase up to 5.0 million additional shares of our common stock over a period of up to three years (2018 Repurchase Program). The 2018 Repurchase Program became effective in September 2018. Any repurchase of our common stock under either 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. 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.

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Item 6. Exhibits
EXHIBIT INDEX

Exhibit Number		Description of Document
3.1	(1)	Amended and Restated Certificate of Incorporation (Exhibit 3.1)
3.2	(2)	Amended and Restated Bylaws adopted on October 20, 2011 (Exhibit 3.2)
4.1	(1)	Form of Common Stock Certificate (Exhibit 4.1)
4.2	(1)	Fifth Amended and Restated Registration Rights Agreement made and entered into as of September 14, 1999, between Masimo Corporation and certain of its stockholders (Exhibit 4.2)
4.3#	(3)	Masimo Retirement Savings Plan (Exhibit 4.7)
12.1*		Statement Regarding the Computation of Ratio of Earnings to Fixed Charges
21.1*		List of Registrant’s Subsidiaries
31.1*		Certification of Joe Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
31.2*		Certification of Micah Young, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
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, as amended
101.INS*		XBRL Instance Document
101.SCH*		XBRL Taxonomy Extension Schema Document
101.CAL*		XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*		XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*		XBRL Taxonomy Extension Label Linkbase Document
101.PRE*		XBRL Taxonomy Extension Presentation Linkbase Document

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

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

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

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

# Indicates management or compensatory plan.

* Filed herewith.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

	MASIMO CORPORATION	
Date: October 31, 2018	By:	/s/ JOE KIANI Joe Kiani Chief Executive Officer and Chairman
Date: October 31, 2018	By:	/s/ MICAH YOUNG Micah Young Executive Vice President and Chief Financial Officer