MASIMO CORP
Form 10-Q
May 04, 2016
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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 April 2, 2016
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ý	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No 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 April 2, 2016
Common stock, $0.001 par value	48,985,489

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements
MASIMO CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except par values)

	April 2, 2016	January 2, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$139,901	$132,317
Accounts receivable, net of allowance for doubtful accounts of $2,017 and $1,967 at April 2, 2016 and January 2, 2016, respectively	93,284	80,960
Inventories	62,505	62,038
Prepaid income taxes	2,006	2,404
Other current assets	19,763	21,423
Total current assets	317,459	299,142
Deferred cost of goods sold	70,014	71,718
Property and equipment, net	133,262	132,466
Intangible assets, net	28,826	27,556
Goodwill	20,694	20,394
Deferred tax assets	41,683	44,320
Other assets	9,324	6,139
Total assets	$621,262	$601,735
LIABILITIES AND EQUITY		
Current liabilities		
Accounts payable	$25,310	$25,865
Accrued compensation	25,284	38,415
Accrued liabilities	35,144	44,222
Income taxes payable	7,129	2,777
Deferred revenue	26,747	21,280
Current portion of capital lease obligations	76	74
Total current liabilities	119,690	132,633
Deferred revenue	258	298
Long term debt	225,003	185,071
Other liabilities	8,328	8,021
Total liabilities	353,279	326,023
Commitments and contingencies		
Equity		
Masimo Corporation stockholders’ equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; 0 shares issued and outstanding at April 2, 2016 and January 2, 2016	—	—
Common stock, $0.001 par value; 100,000 shares authorized; 48,985 and 49,881 shares issued and outstanding at April 2, 2016 and January 2, 2016, respectively	49	50
Treasury stock, 13,855 and 12,759 shares at April 2, 2016 and January 2, 2016, respectively	(383,757)	(340,873)
Additional paid-in capital	338,893	332,417
Accumulated other comprehensive loss	(3,340)	(4,739)
Retained earnings	316,138	288,560
Total Masimo Corporation stockholders’ equity	267,983	275,415
Noncontrolling interest	—	297

Total equity	267,983	275,712
Total liabilities and equity	$621,262	$601,735

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	
	April 2, 2016	April 4, 2015
Revenue:		
Product	$163,290	$147,357
Royalty	7,877	7,180
Total revenue	171,167	154,537
Cost of goods sold	56,954	51,432
Gross profit	114,213	103,105
Operating expenses:		
Selling, general and administrative	62,511	60,799
Research and development	14,365	14,929
Total operating expenses	76,876	75,728
Operating income	37,337	27,377
Non-operating income	498	153
Income before provision for income taxes	37,835	27,530
Provision for income taxes	10,258	7,708
Net income including noncontrolling interest	27,577	19,822
Net loss attributable to the noncontrolling interest	—	701
Net income attributable to Masimo Corporation stockholders	$27,577	$20,523
Net income per share attributable to Masimo Corporation stockholders:		
Basic	$0.56	$0.39
Diluted	$0.53	$0.38
Weighted-average shares used in per share calculations:		
Basic	49,424	52,687
Diluted	51,949	53,964

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	
	April 2, 2016	April 4, 2015
Net income including noncontrolling interest	$27,577	$19,822
Other comprehensive (loss) income, net of tax:		
Foreign currency translation adjustments	1,399	(2,942)
Total comprehensive income	28,976	16,880
Comprehensive loss attributable to noncontrolling interest	—	701
Comprehensive income attributable to Masimo Corporation stockholders	$28,976	$17,581

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)

	Three Months Ended	
	April 2, 2016	April 4, 2015
Cash flows from operating activities:		
Net income including noncontrolling interest	$27,577	$19,822
Adjustments to reconcile net income including noncontrolling interest to net cash provided by operating activities:		
Depreciation and amortization	4,051	3,777
Stock-based compensation	3,027	2,894
Loss on disposal of property, equipment and intangibles	152	58
Gain on deconsolidation of variable interest entity	(273)	—
Provision for doubtful accounts	127	51
Provision for deferred income taxes	2,697	—
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	(12,266)	2,777
Increase in inventories	(326)	(88)
Decrease in deferred cost of goods sold	1,799	208
Decrease (increase) in prepaid income taxes	353	(104)
Increase in other assets	(621)	(6,464)
Increase (decrease) in accounts payable	198	(3,053)
Decrease in accounts payable to related party	(1,130)	—
Decrease in accrued compensation	(12,634)	(10,817)
(Decrease) increase in accrued liabilities	(4,220)	7,183
Increase in income tax payable	4,513	866
Increase in deferred revenue	5,427	1,949
Increase in other liabilities	352	67
Net cash provided by operating activities	18,803	19,126
Cash flows from investing activities:		
Purchases of property and equipment, net	(5,346)	(17,218)
Increase in intangible assets	(751)	(737)
Reduction in cash resulting from deconsolidation of variable interest entity	(763)	—
Net cash used in investing activities	(6,860)	(17,955)
Cash flows from financing activities:		
Borrowings under line of credit	45,000	(69)
Repayments on line of credit	(5,000)	—
Repayments of capital lease obligations	(67)	—
Proceeds from issuance of common stock	2,552	4,612
Repurchases of common stock	(47,699)	(2,154)
Issuance of equity by noncontrolling interest, net of equity issued	—	3
Net cash (used in) provided by financing activities	(5,214)	2,392
Effect of foreign currency exchange rates on cash	855	(2,296)
Net (decrease) increase in cash and cash equivalents	7,584	1,267
Cash and cash equivalents at beginning of period	132,317	134,453
Cash and cash equivalents at end of period	$139,901	$135,720

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 cost of care by taking noninvasive monitoring to new sites and applications. The Company's patient monitoring solutions generally incorporate a monitor or circuit board, proprietary single-patient use, reusable or resposable 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 noninvasive optical blood constituent monitoring, optical organ oximetry monitoring, electrical brain function monitoring, acoustic respiration monitoring and optical gas monitoring. The Company also developed the Root® patient monitoring and connectivity platform and the Masimo Patient SafetyNet™ 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 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 condensed consolidated balance sheet as of January 2, 2016 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 January 2, 2016 (fiscal year 2015), filed with the SEC on February 24, 2016. The results for the three months ended April 2, 2016 are not necessarily indicative of the results to be expected for the fiscal year ending December 31, 2016 (fiscal year 2016) or for any other interim period or for any future year.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company, its wholly-owned subsidiaries and through January 2, 2016, Cercaccor Laboratories, Inc. (Cercacor), the variable interest entity (VIE) of which the Company was the primary beneficiary. Effective January 3, 2016, the Company discontinued consolidating Cercacor within its consolidated financial statements based on its determination that the Company was no longer the primary beneficiary of Cercacor. 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.

Fiscal Periods

The Company follows a conventional 52/53 week fiscal year. Under a conventional 52/53 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 2016 is a 52 week

fiscal year. All references to years in these notes to condensed consolidated financial statements are fiscal years unless otherwise noted.

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

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, distributor channel inventory, royalty revenues, deferred revenue, uncertain income tax positions, litigation costs and related accruals. Actual results could differ from such estimates.

Reclassifications

Certain amounts in the 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 three months ended April 2, 2016. The Company carries cash and cash equivalents at cost, which approximates fair value. As of April 2, 2016 and January 2, 2016, the Company did not have any short-term investments.

The following tables represent the Company's financial assets (in thousands), measured at fair value on a recurring basis:

April 2, 2016	Adjusted Basis Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Estimated Fair Value	Cash and Cash Equivalents
Cash	$89,700	$ —	$ —	$89,700	$ 89,700
Level 1:					
Bank Time Deposits	50,000	—	—	50,000	50,000
Money Market Funds	201	—	—	201	201
Subtotal	50,201	—	—	50,201	50,201
Level 2:					
None	—	—	—	—	—
Level 3:					
None	—	—	—	—	—
Total assets measured at fair value	$139,901	$ —	$ —	$139,901	$ 139,901

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

January 2, 2016	Adjusted Basis Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Estimated Fair Value	Cash and Cash Equivalents
Cash	$57,168	$ —	$ —	$57,168	$ 57,168
Level 1:					
Bank Time Deposits	55,000	—	—	55,000	55,000
Money Market Funds	20,149	—	—	20,149	20,149
Subtotal	75,149	—	—	75,149	75,149
Level 2:					
None	—	—	—	—	—
Level 3:					
None	—	—	—	—	—
Total assets measured at fair value	$132,317	$ —	$ —	$132,317	$ 132,317

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 evaluation of the customer's financial condition. Collateral is generally not required. The allowance for doubtful accounts is determined based on historical write-off experience, current customer information and other relevant factors, including specific identification of past due accounts, based on the age of the receivable in excess of the contemplated or contractual due date. Accounts are charged off against the allowance when the Company believes they are uncollectible.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using a standard cost method, which approximates FIFO (first in, first out) 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
Buildings	39 years
Building improvements	7 to 15 years
Leasehold improvements	Lesser of useful life or term of lease
Machinery and equipment	5 to 7 years
Vehicles	5 years
Tooling	3 years
Computer equipment	2 to 6 years
Furniture and office equipment	2 to 6 years
Demonstration units	3 years

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

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

For the three months ended April 2, 2016 and April 4, 2015, depreciation and amortization expense of property and equipment was $3.3 million and $2.7 million, respectively.

Intangible Assets

The Company's policy is to renew its patents and trademarks. Total renewal costs for patents and trademarks were $0.2 million and $0.1 million for the three months ended April 2, 2016 and April 4, 2015, respectively. As of April 2, 2016, the weighted-average number of years until the next renewal was one year for patents and five 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 performing the two-step impairment test is unnecessary. However, if the Company concludes otherwise, then the Company is required to perform the first step of the two-step impairment test by comparing the fair value of the reporting unit, determined using future projected discounted operating cash flows, with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is not considered impaired; otherwise, goodwill is considered impaired and the loss is measured by performing step two. Under step two, the impairment loss is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill. The Company also has the option to bypass the qualitative assessment and proceed directly to performing the first step of the two-step goodwill impairment test. The Company may resume performing the qualitative assessment in any subsequent period. 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 the three months ended April 2, 2016 and April 4, 2015.

Revenue Recognition and Deferred Revenue

The Company follows the current authoritative guidance for revenue recognition. Based on these requirements, the Company recognizes revenue from the sale of products or services when: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. In the case of the license or sale of software that does not function together with hardware components to provide the essential functionality of the hardware, revenue is recognized pursuant to the software revenue recognition guidance.

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

The Company derives the majority of its revenue from four primary sources: (i) direct sales under long-term sensor purchase agreements with end-user hospitals where the Company provides certain monitoring-related equipment, software, installation, training and/or warranty support 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 direct customers, many of which have long-term sensor purchase agreements with the Company; and (iv) sales of integrated circuit boards to OEM customers who incorporate the Company's embedded software technology into their multi-parameter monitoring devices.

The Company enters into agreements to sell its noninvasive monitoring solutions and services, sometimes as part of multiple deliverable arrangements that include various combinations of products and services. While the majority of the Company's sales transactions contain standard business terms and conditions, there are some transactions that contain non-standard business terms and conditions. As a result, contract interpretation and analysis is sometimes required to determine the appropriate accounting, including: (i) how the arrangement consideration should be allocated among the deliverables when multiple deliverables exist, (ii) when to recognize revenue on the deliverables, and (iii) whether undelivered elements are essential to the functionality of the delivered elements. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

In the case of multiple deliverable arrangements, the authoritative guidance provides a hierarchy to determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor-specific objective evidence (VSOE) of fair value, (ii) third-party evidence of selling price (TPE), and (iii) best estimate of the selling price (ESP). VSOE of fair value is defined as the price charged when the same element is sold separately. VSOE generally exists only when the deliverable is sold separately and is the price actually charged for that deliverable. TPE generally does not exist for the majority of the Company's products. The objective of ESP is to determine the price at which the Company would transact a sale if the product was sold on a stand-alone basis. In the absence of VSOE and TPE, the Company determines ESP for its products 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 market conditions.

A deliverable in an arrangement qualifies as a separate unit of accounting if the delivered item has value to the customer on a stand-alone basis. Most of the Company's products in a multiple deliverable arrangement qualify as separate units of accounting. In the case of the Company's monitoring equipment containing embedded Masimo SET® or rainbow® SET software, the Company has determined that the hardware and software components function together to deliver the equipment's essential functionality and, therefore, represent a single deliverable. However, software deliverables, such as rainbow® parameter software, which do not function together with hardware components to provide the equipment's essential functionality, are accounted for under software revenue recognition guidance. The revenue for these multiple-element arrangements is allocated to the software deliverables and the non-software deliverables based on the relative selling prices of all of the deliverables in the arrangement using the hierarchy in the revenue recognition accounting guidance for arrangements with multiple deliverables.

Sales under long-term sensor purchase 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 sensors are essential to the functionality of the monitoring equipment and, therefore, represent a substantive performance obligation. The Company generally does not recognize any revenue when the monitoring-related equipment and software are delivered to the hospitals, but rather recognizes revenue for these delivered elements on a pro-rata basis as the sensors are delivered under the long-term purchase commitment, when installation and training are complete. Accordingly, the cost of the monitoring-related equipment initially placed at the hospitals is deferred and amortized to cost of goods sold over the life of the underlying long-term sensor purchase

contract. Some of the Company's long-term 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 payments are generally treated as prepaid discounts that are deferred and amortized on a straight-line basis as contra-revenue over the life of the underlying long-term sensor purchase contract. Many of the Company's distributors purchase sensor products which they then resell to end-user hospitals that are typically fulfilling their purchase obligations to the Company under such end-user hospital's long-term sensor purchase commitments. Upon shipment to the distributor, revenue is deferred until the distributor ships the product to the Company's end-user customers based on an estimate of the inventory held by these distributors at the end of the accounting period.

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

The Company also earns revenue from the sale of integrated circuit boards and other products, as well as from rainbow® parameter software 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 also provides certain customers with the ability to purchase sensors under rebate programs. Under these programs, the customers may earn rebates based on their purchasing activity. The Company estimates and provides allowances for these programs at the time of sale as a reduction to revenue.
In general, customers do not have a right of return for credit or refund. However, the Company allows returns under certain circumstances. At the end of each period, the Company estimates and accrues for these returns as a reduction to revenue and accounts receivable. The Company estimates returns based on several factors, including contractual limitations and past returns history.
The Company's royalty revenue arises from one agreement with Medtronic plc (Medtronic, formerly Covidien), and is due and payable quarterly based on U.S. sales of Medtronic's infringing products. An estimate of these royalty revenues is recorded quarterly in the period earned based on the prior quarter's historical results, adjusted for any new information or trends known to management at the time of estimation. This estimated revenue is adjusted prospectively when the Company receives the royalty report from Medtronic, approximately 60 days after the end of the previous quarter.
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 the case of long-term sales agreements, the Company typically warrants the products for the term of the agreement, which generally ranges from three to six years. In traditional sales activities, including direct and OEM sales, the Company establishes an accrual for the estimated costs of warranty at the time of revenue recognition. Estimated warranty expenses are recorded as an accrued liability, with a corresponding provision to cost of sales. In long-term sales agreements, revenue related to extended warranty is recognized over the life of the contract, while the product warranty costs related to the long-term sales agreements are expensed as incurred.
Changes in the product warranty accrual were as follows (in thousands):

	Three Months Ended	
	April 2, 2016	April 4, 2015
Warranty accrual, beginning of period	$1,222	$1,416
Accrual for warranties issued	405	339
Changes to pre-existing warranties (including changes in estimates)	(50)	(17)
Settlements made	(290)	(258)
Warranty accrual, end of period	$1,287	$1,480

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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Comprehensive Income

Authoritative accounting guidance establishes requirements for reporting and disclosure of comprehensive income and its components. Comprehensive income includes foreign currency translation adjustments and any related tax benefits that have been excluded from net income including noncontrolling interest, and reflected in Masimo Corporation stockholders' equity.

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

	Three Months Ended April 2, 2016
Accumulated other comprehensive loss, beginning of period	$(4,739)
Foreign currency translation adjustments	1,399
Accumulated other comprehensive loss, end of period	$(3,340)

Net Income Per Share

Basic net income per share attributable to Masimo Corporation for the three months ended April 2, 2016 and April 4, 2015 is computed by dividing net income attributable to Masimo Corporation stockholders by the weighted-average number of shares outstanding during each period. The diluted net income per share attributable to Masimo Corporation stockholders for the three months ended April 2, 2016 and April 4, 2015 is computed by dividing the net income attributable to Masimo Corporation stockholders by the weighted-average number of shares and potential shares outstanding during each 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 restricted share units (RSUs). For the three months ended April 2, 2016 and April 4, 2015, 1.5 million and 3.2 million, respectively, weighted options to purchase shares of common stock were outstanding, but were not included in the computation of diluted net income per share because the effect of including such shares would have been antidilutive in the applicable period. For the three months ended April 2, 2016, certain RSUs were considered contingently issuable shares as their vesting is contingent upon the occurrence of certain future events. Since such events have not occurred and are not considered probable of occurring as of April 2, 2016, 2.7 million weighted average shares related to such RSUs have been excluded from the calculation of potential shares. Based on authoritative accounting guidance, the Company adjusted its net income including noncontrolling interest by the amount of net (income) loss attributable to the noncontrolling interest for the three months ended April 4, 2015 to determine its net income attributable to its stockholders. Since the Company discontinued consolidating Cercacor effective January 3, 2016, a similar adjustment was not required for the three months ended April 2, 2016.

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

	Three Months Ended	
	April 2, 2016	April 4, 2015
Net income attributable to Masimo Corporation stockholders:		
Net income including noncontrolling interest	$27,577	$19,822
Net loss attributable to the noncontrolling interest	—	701
Net income attributable to Masimo Corporation stockholders	$27,577	$20,523
Basic net income per share attributable to Masimo Corporation stockholders:		
Net income attributable to Masimo Corporation stockholders	$27,577	$20,523
Weighted-average shares outstanding - basic	49,424	52,687

Basic net income per share attributable to Masimo Corporation stockholders	$0.56	$0.39
Diluted net income per share attributable to Masimo Corporation stockholders:		
Weighted-average shares outstanding - basic	49,424	52,687
Diluted share equivalent: stock options and RSUs	2,525	1,277
Weighted-average shares outstanding - diluted	51,949	53,964
Diluted net income per share attributable to Masimo Corporation stockholders	$0.53	$0.38

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

	Three Months Ended	
	April 2, 2016	April 4, 2015
Cash paid during the year for:		
Interest (net of amounts capitalized)	$1,335	$ 413
Income taxes	2,303	6,673
Noncash investing and financing activities:		
Assets acquired under capital leases	$—	$ 36
Unpaid purchases of property, plant and equipment	3,600	4,346
Unsettled common stock proceeds from option exercises	896	395
Unsettled stock repurchases	—	6,079

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 often experienced a sequential decline in product revenues in its second and 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 March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). The new standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on stock-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU 2016-09 also clarifies the statement of cash flows presentation for certain components of stock-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. The Company early adopted this standard during the three months ended April 2, 2016 resulting in a $1.0 million reduction to the Company’s income tax provision for such period.
In February 2015, the FASB issued Accounting Standards Update No. 2015-02, Consolidation (Topic 810): Amendments to the Consolidation Analysis (ASU 2015-02). The amended standard applies to entities in all industries and eliminates the deferral of certain consolidation standards for entities considered to be investment companies, as well as modifies the consolidation analysis performed on certain types of legal entities. ASU 2015-02 is effective for annual and interim fiscal reporting periods beginning after December 15, 2015, and may be applied retrospectively, with early application permitted. The Company adopted this standard during the first quarter of the fiscal year ending December 31, 2016, and its adoption did not have a material impact on the Company’s consolidated financial statements by increasing assets and liabilities.
Recently Issued Accounting Pronouncements
In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases (Topic 842): (ASU 2016-02). The new standard requires lessees to recognize most leases on their balance sheets but continue to recognize lease expenses in their income statement in a manner similar to current practice. The new standard 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 income statement. ASU 2016-02 is effective for annual and interim fiscal reporting periods beginning after December 15, 2018, and early application is permitted. The Company is currently evaluating the expected impact of this standard on its consolidated financial statements, but anticipates that the required recognition of a lease

liability and related right-of-use asset will likely increase both the assets and liabilities recognized and reported on its balance sheet.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue (Topic 606): Revenue from Contracts with Customers (ASU 2014-09). The new standard provides a single, principles-based five-step model to be applied to all contracts with customers while enhancing disclosures about revenue, providing additional guidance for transactions that were not previously addressed comprehensively and improving guidance for multiple-element arrangements. ASU 2014-09 will replace most existing revenue recognition guidance under GAAP when it becomes effective. The standard permits the use of either the retrospective or cumulative effect transition method upon adoption. In August 2015, the FASB issued Accounting Standards Update No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which amended ASU 2014-09, providing for a one year deferral period for the implementation of ASU 2014-09. ASU 2014-09 will now be effective for annual and interim periods beginning on or after December 15, 2017. The Company is continuing to evaluate the expected impact of this standard on its consolidated financial statements but anticipates, among other things, that the adoption of such standard will result in the acceleration of certain revenue from product sales to distributors that is currently deferred under the “sell-through” method, as well as the deferral of certain contract-related costs that are currently expensed when incurred.

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

Cercacor is an independent entity spun off from the Company to its stockholders in 1998. Joe Kiani, the Company’s Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer 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. In addition, the Company entered into a Services Agreement with Cercacor effective January 1, 2007, which governs the general and administrative services the Company provides to Cercacor.

As a result of recent changes in the capital structure of Cercacor, as well as certain of its contractual relationships with the Company, the Company completed a re-evaluation of the authoritative consolidation guidance during the three months ended April 2, 2016 and determined that although Cercacor remains a VIE, the Company is no longer its primary beneficiary as it can no longer be deemed to have the power to direct the activities of Cercacor that most significantly impact Cercacor’s economic performance and can no longer be deemed to have an obligation to absorb Cercacor’s losses pursuant to the Company’s on-going contractual relationships with Cercacor. Based on such determination, the Company has discontinued consolidating Cercacor within its consolidated financial statements effective as of January 3, 2016. However, Cercacor will continue to be a related party following its deconsolidation. The Company recognized a gain of $0.3 million upon such deconsolidation, which has been reported within non-operating income in the condensed consolidated statement of operations. See Note 4 to these condensed consolidated financial statements for a description of the Company’s continuing business relationships with Cercacor.

Cercacor continues to be included within the Company’s condensed consolidated financial statements for all periods prior to January 3, 2016. Accordingly, for periods prior to January 3, 2016, all intercompany royalties, option and license fees and other charges between the Company and Cercacor, as well as all intercompany payables and receivables, have been eliminated in consolidation. However, for periods prior to January 3, 2016, all direct operating expenses that were incurred by the Company and charged to Cercacor, or that were incurred by Cercacor and charged to the Company, have not been eliminated and are included within operating expenses in the Company’s condensed consolidated statements of operations. The consolidating statement of operations for the three months ended April 4,

2015, which reflect the Company, Cercacor and related eliminations (in thousands), is included below:

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	Three Months Ended April 4, 2015					
Consolidating Statement of Operations:	Masimo Corp	Percentage of Revenue	Cercacor	Cercacor Elim	Total	Percentage of Revenue
Revenue:						
Product	$147,357	95.4 %	$ —	$ —	$147,357	95.4 %
Royalty	7,180	4.6	1,375	(1,375)	7,180	4.6
Total revenue	154,537	100.0	1,375	(1,375)	154,537	100.0
Cost of goods sold	52,682	34.1	—	(1,250)	51,432	33.3
Gross profit	101,855	65.9	1,375	(125)	103,105	66.7
Operating expenses:						
Selling, general and administrative	60,276	39.0	648	(125)	60,799	39.3
Research and development	13,501	8.7	1,428	—	14,929	9.7
Total operating expenses	73,777	47.7	2,076	(125)	75,728	49.0
Operating income (loss)	28,078	18.2	(701)	—	27,377	17.7
Non-operating income	153	0.1	—	—	153	0.1
Income (loss) before provision for income taxes	28,231	18.3	(701)	—	27,530	17.8
Provision for income taxes	7,708	5.0	—	—	7,708	5.0
Net income (loss) including noncontrolling interest	20,523	13.3	(701)	—	19,822	12.8
Net loss attributable to the noncontrolling interest	—	—	—	701	701	0.5
Net income (loss) attributable to Masimo Corporation stockholders	$20,523	13.3 %	$ (701)	$ 701	$20,523	13.3 %

4. Related Party Transactions

The Company's Chairman and Chief Executive Officer is also the Chairman and Chief Executive Officer of Cercacor. The Company is a party to the following agreements with Cercacor:

- Cross-Licensing Agreement - The Company is party to a Cross Licensing Agreement with Cercacor, (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. Actual aggregate royalty liabilities to Cercacor under the license were $1.5 million and $1.3 million for the three months ended April 2, 2016 and April 4, 2015, respectively, the latter of which was eliminated in consolidation. Pursuant to the terms of the Cross Licensing Agreement, the Company also had sales of certain integrated circuit boards to Cercacor of less than $0.1 million for the three months ended April 2, 2016. There were no similar sales during the three months ended April 4, 2015.
- 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 months ended April 2, 2016 and April 4, 2015.
- Consulting Services Agreement - The Company is also a party to a consulting services agreement (Consulting Agreement) with Cercacor that governs certain engineering consulting and clinical studies support services that Cercacor may provide to the Company from time-to-time. Expenses incurred by the Company related to this Consulting Agreement were less than $0.1 million for the three months ended April 2, 2016 and approximately $0.1 million for the three months ended April 4, 2015.

Net amounts due from (due to) Cercacor at April 2, 2016 and January 2, 2016 were approximately $0.1 million and $(1.1) million, respectively.

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The Company's Chief Executive Officer 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. The Company's Chief Financial Officer is also a Director of the Masimo Foundation.

The Company's Chief Executive Officer 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 Chief Financial Officer serves as the Treasurer and Secretary of PSMF, as well as the Secretary of PSMC.

The Company's Chief Executive Officer serves on the board of directors of Atheer Labs, which is working with the Company on the development of next generation Root® applications, as well as 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.

5. Inventories

Inventories consist of the following (in thousands):

	April 2, 2016	January 2, 2016
Raw materials	$29,128	$ 25,781
Work-in-process	4,617	4,337
Finished goods	28,760	31,920
Total inventories	$62,505	$ 62,038

6. Other Current Assets

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

	April 2, 2016	January 2, 2016
Prepaid expenses	$8,764	$ 9,930
Royalties receivable	7,200	7,200
Employee loans and advances	330	320
Due from related party	47	—
Other current assets	3,422	3,973
Total other current assets	$19,763	$ 21,423

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7. Property and Equipment

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

	April 2, 2016	January 2, 2016
Building and building improvements	$85,296	$78,877
Machinery and equipment	42,361	42,460
Land	23,737	23,738
Computer equipment	14,608	15,023
Tooling	12,893	13,079
Leasehold improvements	7,299	7,734
Furniture and office equipment	8,939	8,885
Demonstration units	984	973
Vehicles	45	45
Construction-in-progress	1,903	7,124
Total property and equipment	198,065	197,938
Accumulated depreciation and amortization	(64,803)	(65,472)
Property and equipment, net	$133,262	$132,466

During the quarter ended April 2, 2016, the Company completed construction on certain additional renovations to its new corporate headquarters and research and development facility in Irvine, California, resulting in the reclassification of approximately $6.2 million from construction-in-progress to building and improvements. Approximately $0.3 million of the remaining construction-in-progress relates to purchase and renovation costs for the corporate headquarters and research and development facility. Approximately $3.7 million of construction costs related to this facility are included in accounts payable as of April 2, 2016.

The gross value of furniture and office equipment under capital lease obligations was $0.4 million as of both April 2, 2016 and January 2, 2016, with accumulated depreciation of $0.3 million as of both April 2, 2016 and January 2, 2016.

8. Intangible Assets

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

	April 2, 2016	January 2, 2016
Patents	$18,633	$21,619
Customer relationships	7,669	7,669
Licenses[(1)]	7,500	—
Acquired technology	5,580	5,580
Trademarks	3,704	3,944
Capitalized software development costs	2,539	2,539
Other	2,535	2,541
Total intangible assets	48,160	43,892
Accumulated amortization	(19,334)	(16,336)
Intangible assets, net	$28,826	$27,556

(1) As a result of the deconsolidation of our prior VIE, Cercacor, $7.5 million of licenses that were previously eliminated in consolidation are now included as part of the Company's intangible assets at April 2, 2016.

Total amortization expense for the three months ended April 2, 2016 and April 4, 2015 was $0.9 million and $1.2 million, respectively. All of these intangible assets have a 10 year weighted average amortization period.

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

Fiscal year	Amount
2016 (balance of year)	$4,125
2017	3,865
2018	3,656
2019	3,272
2020	3,019
Thereafter	10,889
Total	$28,826

9. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	April 2, 2016	January 2, 2016
Accrued customer rebates, fees and reimbursements	$13,424	$ 11,857
Accrued arbitration award	5,391	5,391
Accrued legal fees	4,885	5,785
Accrued taxes	3,022	5,263
Accrued warranty	1,287	1,222
Accrued donations	532	5,612
Accrued stock repurchases	—	4,815
Accrued other	6,603	4,277
Total accrued liabilities	$35,144	$ 44,222

10. Long Term Debt

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

	April 2, 2016	January 2, 2016
Revolving line of credit	$225,000	$ 185,000
Long term portion of capital lease obligations acquisition	3	71
Total long term debt	$225,003	$ 185,071

In January 2016, the Company entered into an Amended and Restated Credit Agreement (Restated Credit Facility) with JPMorgan Chase Bank, N.A., as Administrative Agent and a Lender, Bank of America, N.A., as Syndication Agent and a Lender, Citibank, N.A., as Documentation Agent and a Lender, and various other Lenders (collectively, the Lenders). The Restated Credit Facility amends and restates the previous credit agreement and provides for up to $450.0 million in borrowings in multiple currencies, with an option, subject to certain conditions, for the Company to increase the aggregate borrowing capacity to up to $550.0 million in the future. The Restated Credit Facility also provides for a sublimit of up to $50.0 million for the issuance of letters of credit and a sublimit of $125.0 million in specified foreign currencies. All unpaid principal under the Restated Credit Facility will become due and payable on January 8, 2021.

Borrowings under the Restated Credit Facility will be deemed, at the Company’s election, either: (i) an Alternate Base Rate (ABR) Loan, which bears interest at the ABR plus a spread (ABR Spread) based upon a Company leverage ratio, or (ii) a Eurodollar Loan, which bears interest at the Adjusted LIBO Rate (as defined below) plus a spread (Eurodollar Spread) based upon a Company leverage ratio. The ABR Spread is 0.125% to 1.00% and the Eurodollar Spread is 1.125% to 2.0%. Subject to certain conditions, the Company may also request swingline loans from time to time (Swingline Loans) that bear interest similar to an ABR Loan.

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The ABR is determined by taking the greatest of (i) the prime rate, (ii) the federal funds effective rate plus 0.50%, and (iii) the one-month Adjusted LIBO Rate plus 1.0%. The Adjusted LIBO Rate is equal to LIBOR for the applicable interest period multiplied by the statutory reserve rate for such period.

The Company is obligated under the Restated Credit Facility to pay a fee ranging from 0.175% to 0.300% per annum, based upon a Company leverage ratio, with respect to any unused portion of the line of credit. This fee and interest on any ABR Loan are due and payable quarterly in arrears. Interest on any Eurodollar Loan is due and payable at the end of the applicable interest period (or at each three month interval in the case of loans with interest periods greater than three months). Interest on any Swingline Loan is due and payable on the date that the Swingline Loan is required to be repaid. The Company may prepay the loans and terminate the commitments in whole at any time, without premium or penalty, subject to reimbursement of certain costs in the case of Eurodollar Loans.

Pursuant to the terms of the Restated Credit Facility, the Company is subject to certain covenants, including financial covenants related to a leverage ratio and an interest charge coverage ratio, and other customary negative covenants. The Company's obligations under the Restated Credit Facility are secured by substantially all of the Company's personal property, including certain equity interests in U.S. domestic and first-tier foreign subsidiaries.

As of April 2, 2016, the Restated Credit Facility had outstanding Eurodollar Loan draws totaling $225.0 million at an effective interest rate of 1.7181%, and the Company was in compliance with all covenants under the Restated Credit Facility.

11. Other Liabilities, Long-Term

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

	April 2, 2016	January 2, 2016
Unrecognized tax benefit	$ 7,741	$ 7,747
Deferred tax liability, long-term	193	194
Other	394	80
Total other liabilities, long-term	$ 8,328	$ 8,021

The unrecognized tax benefit relates to the Company's long-term portion of tax liability. 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 15 to these condensed consolidated financial statements for further details.

12. Equity

Series A Junior Participating Preferred Stock and Stockholder Rights Plan

In November 2007, the Company authorized and declared a dividend of one preferred stock purchase right (Right) for each outstanding share of its common stock to stockholders of record at the close of business on November 26, 2007 (the Record Date) pursuant to a Rights Agreement, dated as of November 9, 2007, with Computershare Trust Company, N.A., as Rights Agent (the Rights Agreement). In addition, one Right was issued with each share of common stock that became outstanding after the Record Date. Each Right entitled the registered holder to purchase from the Company one thousandth of one share of the Company's Series A junior participating preferred stock, par value $0.001 per share, at a purchase price equal to $136.00 per Right, subject to adjustment.

On February 12, 2016, the Company entered into an amendment to the Rights Agreement (the Rights Amendment). The Rights Amendment accelerated the expiration of the Rights from the close of business on February 8, 2017 to the close of business on February 16, 2016, and had the effect of terminating the Rights Agreement on that date. Upon the termination of the Rights Agreement, all of the Rights distributed to holders of the Company's common stock pursuant to the Rights Agreement expired.

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Stock Repurchase Programs

In September 2015, the Board authorized a stock repurchase program, whereby the Company may purchase up to 5.0 million shares of its common stock over a period of up to three years (2015 Repurchase Program). The 2015 Repurchase Program may be carried out at the discretion of a committee comprised of the Company's Chief Executive Officer and Chief Financial Officer through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. The total remaining shares authorized for repurchase under the 2015 Repurchase Program approximated 3.3 million shares as of April 2, 2016. The Company expects to fund the 2015 Repurchase Program through its available cash, future cash from operations, funds available under the Restated Credit Facility or other potential sources of capital.

The following table provides a summary of the Company's stock repurchase activities during the three months ended April 2, 2016 and April 4, 2015 (in thousands, except per share amounts):

	Three Months Ended	
	April 2, 2016	April 4, 2015
Shares repurchased	1,096	250
Average cost per share	$39.13	$32.89
Value of shares repurchased	$42,884	$8,233

13. Stock-Based Compensation

Stock-Based Award Activity

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

	Three Months Ended April 2, 2016	
	Shares	Average Exercise Price
Options outstanding, beginning of period	9,202	$ 25.46
Granted	1,101	37.87
Canceled	(32)	24.72
Exercised	(199)	17.29
Options outstanding, end of period	10,072	$ 26.98
Options exercisable, end of period	5,870	$ 25.10

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

	Three Months Ended April 2, 2016	
	Units	Weighted Average Grant Date Fair Value
RSUs outstanding, beginning of period	2,703	$ 41.45
Granted	—	—
Canceled	—	—

Expired	—	—
Vested	—	—
RSUs outstanding, end of period	2,703	$ 41.45

Approximately 2.7 million of the total RSUs outstanding were awarded to the Company’s Chairman and Chief Executive Officer in connection with the previous amendment and restatement of his employment agreement (see “Employment and Severance Agreements” in Note 14 to these condensed consolidated financial statements for further details).

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At April 2, 2016, an aggregate of 17.2 million shares of common stock were reserved for future issuance under the 2007 Plan and prior equity incentive plans, of which 4.4 million shares were available for future grant under the 2007 Plan.

Valuation of Stock-Based Award Activity

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

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

	Three Months Ended	
	April 2, 2016	April 4, 2015
Risk-free interest rate	1.3% to 1.9%	1.3% to 1.8%
Expected term (in years)	5.7	5.5
Estimated volatility	34.6% to 35.7%	33.5% to 37.4%
Expected dividends	0%	0%
Weighted-average fair value of options granted	$13.13	$10.35

The total stock-based compensation expense for the three months ended April 2, 2016 and April 4, 2015 was $3.0 million and $2.9 million, respectively.

The aggregate intrinsic value of options is calculated as the positive difference, if any, between the market value of the Company's common stock on the date of exercise or the respective period end, as appropriate, and the exercise price of the options. The aggregate intrinsic value of options outstanding, with an exercise price less than the closing price of the Company's common stock, as of April 2, 2016 was $156.1 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 April 2, 2016 was $101.9 million. The aggregate intrinsic value of options exercised during the three months ended April 2, 2016 was $4.4 million.

The unrecognized stock-based compensation expense related to unvested options granted after January 1, 2006 was $32.3 million as of April 2, 2016. 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 April 2, 2016 was 3.5 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 April 2, 2016 was 4.0 years.

14. Commitments and Contingencies

Leases

The Company leases certain facilities in North America, Europe and Asia under operating lease agreements expiring at various dates through May 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 April 2, 2016 and January 2, 2016, rent expense accrued in excess of the amount paid aggregated $0.2 million, which is classified as other 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 March 2020. 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.

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Future minimum lease payments under operating and capital leases for each of the following fiscal years ending on or about December 31 are (in thousands) (including interest):

	As of April 2, 2016		
	Operating Leases	Capital Leases	Total
2016 (balance of year)	$3,374	$ 7	$3,381
2017	4,393	75	4,468
2018	4,486	—	4,486
2019	3,726	—	3,726
2020	2,036	—	2,036
Thereafter	58,105	—	58,105
Total	$76,120	$ 82	$76,202

In January 2016, the Company entered into the Third Amendment to Lease with The Irvine Company LLC (Third Amendment) relating to the rental of space in a building located in Irvine, California. Pursuant to the terms of the Third Amendment, the Company's current lease of certain premises will be terminated in exchange for the Company's leasing of approximately 70,700 square feet of space in another building in Irvine, California, located near the Company's new corporate headquarters (New Premises). The Third Amendment also extends the term of the original lease to the end of the month in which the ten-year anniversary of the date of commencement (Commencement Date) of the lease for the New Premises occurs. The Commencement Date will occur following the completion of certain improvements to the New Premises, which the Company currently expects to be no later than November 2016. Rental expense related to operating leases was $1.2 million and $1.5 million for the three months ended April 2, 2016 and April 4, 2015, respectively. Included in the future capital lease payments as of April 2, 2016 is interest aggregating less than $0.1 million.

Employee Retirement Savings Plan

The Company maintains a 401(k) plan, the Masimo Retirement Savings Plan (the Plan), 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 Plan on a discretionary basis. For each of the three month periods ended April 2, 2016 and April 4, 2015, the Company contributed $0.5 million to the Plan.

Employment and Severance Agreements

On November 4, 2015, the Company entered into an Amended and Restated Employment Agreement with Joe Kiani, the Company's Chairman and Chief Executive Officer (the Restated Employment Agreement). The Restated Employment Agreement, among other things, eliminates the tax gross-up payments, "single trigger" change in control payments and certain survival provisions, as well as phases out the fixed annual stock option grants guaranteed to Mr. Kiani under his previous employment agreement. Pursuant to the terms of the Restated Employment Agreement, upon a "Qualifying Termination" (as defined in the Restated Employment Agreement, including a change in control), 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. In addition, upon a Qualifying Termination prior to 2018, Mr. Kiani will receive 2.7 million shares of common stock (subject to adjustment for recapitalizations, stock splits, stock dividends and the like) upon the vesting of certain RSUs granted to Mr. Kiani in connection with the Restated Employment Agreement, and an additional cash payment of $35.0 million related to a Non-Competition and Confidentiality Agreement between Mr. Kiani and the Company (collectively, the Special Payment). For any Qualifying Termination occurring on or after January 1, 2018, the number of shares to be issued to Mr. Kiani pursuant to the RSUs and the cash payment will each be reduced by 10% of the original amount each year so that after December 31, 2026, no Special Payment will be due to Mr. Kiani upon a Qualifying Termination. As of April 2, 2016, the expense related to the Special Payment that would be recognized in

the Company’s condensed consolidated financial statements upon the occurrence of a Qualifying Termination under the Restated Employment Agreement approximated $149.7 million.

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As of April 2, 2016, the Company had severance plan participation agreements with seven other 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 $54.1 million of purchase commitments as of April 2, 2016, 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 April 2, 2016, the Company had approximately $0.5 million in 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 April 2, 2016, the Company has 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 deposits in time deposits and money market accounts with major financial institutions. As of April 2, 2016, the Company had $89.7 million of bank balances, of which $3.0 million was covered by either the U.S. Federal Deposit Insurance Corporation limit or foreign countries' deposit insurance organizations. As of April 2, 2016, the Company had $0.2 million in money market funds and $50.0 million of bank time deposits that are not guaranteed by the U.S. Federal government.

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 months ended April 2, 2016 and April 4, 2015, revenue from the sale of the Company's products to U.S. hospitals that are members of GPOs amounted to $91.9 million and $86.3 million, respectively.

For the three months ended April 2, 2016, the Company had sales through two just-in-time distributors, which represented 16.0% and 11.2% of total revenue, respectively. For the three months ended April 4, 2015, the Company had sales through the same two just-in-time distributors, which represented 14.0% and 13.0% of total revenue, respectively. As of April 2, 2016, three just-in-time distributors represented 7.8%, 7.9% and 6.2% of the Company's accounts receivable balance, respectively. As of January 2, 2016, two of the same just-in-time distributors represented 5.5% and 5.3% of the Company's accounts receivable balance, respectively.

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For the three months ended April 2, 2016 and April 4, 2015, the Company recorded $7.9 million and $7.2 million, respectively, in royalty revenues from Medtronic pursuant to the original settlement agreement and amendments. 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 agreement. The current royalty rate is 7.75% and the amended agreement can be terminated by Medtronic upon 60 days written notice.

Litigation

On February 3, 2009, the Company filed a patent infringement suit in the U.S. District Court for the District of Delaware against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH (collectively, Philips) related to Philips' FAST pulse oximetry technology and certain of Philips' patient monitors. On June 15, 2009, Philips answered the Company's complaint and Philips Electronics North America Corporation filed antitrust and patent infringement counterclaims against the Company, as well as counterclaims seeking declaratory judgments of invalidity of the patents asserted by the Company against Philips. On July 9, 2009, the Company filed its answer denying Philips' counterclaims and asserting various defenses. The Company also asserted counterclaims against Philips for fraud and intentional interference with prospective economic advantage and for declaratory judgments of noninfringement and invalidity with respect to the patents asserted by Philips against the Company. Philips later added a claim for infringement of one additional patent. Subsequently, the Court bifurcated Philips' antitrust claims and its patent misuse defense, as well as stayed the discovery phase on those claims pending trial in the patent case. In addition, the Company asserted additional patents in 2012, and the Court ordered that these patents and some of the originally asserted patents be tried in a second phase. On May 23, 2014, Philips filed a motion for leave to amend its answer and counterclaims to allege inequitable conduct. The Court granted Philips' motion for leave to amend. A jury trial commenced on September 15, 2014 with respect to two of the Company's patents and one of Philips' patents. On October 1, 2014, the jury determined that both of the Company's patents were valid and that the damages amount for Philips' infringement was $466.8 million. The jury also determined that the Company did not infringe the Philips patent. Philips has indicated that it intends to appeal the damages award once a final judgment has been rendered in the case. On September 18, 2015, the Court set a schedule for the trials related to Masimo's second phase patents against Philips and Philips' antitrust counterclaims and patent misuse defense, with both trials scheduled to take place in the first quarter of 2017. On November 16, 2015, the Company asserted three antitrust claims against Philips. On December 9, 2015, the Court dismissed with prejudice Philips' sole remaining patent infringement claim against the Company. On January 4, 2016, the Court granted Philips' motion to strike the Company's antitrust counterclaims, ruling that the Company must bring these claims in a separate litigation. On March 4, 2016, the Company filed an additional case against Philips alleging antitrust violations and patent infringement in the District of Delaware. The Company believes that it has good and substantial defenses to the remaining antitrust claims asserted by Philips. The Company is unable to determine whether any loss will occur or to estimate the range of such potential loss; therefore, no amount of loss has been accrued by the Company as of the date of filing of this Quarterly Report on Form 10-Q. Furthermore, there is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

In April 2011, the Company was informed by the United States Attorney's Office for the Central District of California, Civil Division, that a qui tam complaint had been filed against the Company in the U.S. District Court for the Central District of California by three of the Company's former physician office sales representatives. The qui tam complaint alleged, among other things, that the Company's noninvasive hemoglobin products failed to meet their accuracy specifications, and that the Company misled the U.S. Food and Drug Administration (FDA) and customers regarding the accuracy of the products. In November 2011, the United States declined to intervene in the case, and in October 2013, the District Court granted summary judgment in favor of the Company. The former sales representatives appealed the District Court's decision and an argument on the appeal was held in the Ninth Circuit Court of Appeals on February 1, 2016. On February 19, 2016, the Ninth Circuit Court of Appeals affirmed the summary judgment of the District Court.

In September 2011, two of the same former sales representatives filed employment-related claims against the Company in arbitration also stemming from their allegations regarding the Company's noninvasive hemoglobin products. On January 16, 2014, the Company was notified that the arbitrator awarded the plaintiffs approximately $5.4 million in damages (the Arbitration Award). The Company challenged the Arbitration Award in the U.S. District Court for the Central District of California, and on April 3, 2014, the District Court vacated the award. The former sales representatives appealed the District Court's decision, and the appeal argument was held in the Ninth Circuit Court of Appeals on February 1, 2016. On February 19, 2016, the Ninth Circuit Court of Appeals reversed the decision of the District Court vacating the award, and remanded the case to the District Court with instructions to confirm the Arbitration Award. On March 23, 2016, the District Court entered final judgment confirming the Arbitration Award, and on April 8, 2016 the Company remitted $6.2 million to the plaintiffs in full payment of the Arbitration Award and related interest. On April 22, 2016, the Company filed a notice of appeal.

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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. 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. The Company believes it has good and substantial defenses to the claims, but there is no guarantee that the Company will prevail. The Company is unable to determine whether any loss will ultimately occur or to estimate the range of such loss; therefore, no amount of loss has been accrued by the Company as of the date of filing of this Quarterly Report on Form 10-Q.

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 have appealed the U.S. District Court for the Northern District of Alabama's decision. 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 as of the date of filing of this Quarterly Report on Form 10-Q.

On October 21, 2015, Medtronic plc (Medtronic) filed three separate inter partes review petitions (IPR Petitions) with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (PTO), challenging several of the claims of the Company's U.S. Patent Nos. 7,496,393 (the '393 Patent), titled "Signal processing apparatus", which expires in September 2016, and 8,560,034 (the '034 Patent), also titled "Signal processing apparatus", which expires in October 2018. On April 27, 2016, the PTAB denied Medtronic's IPR Petitions with respect to the '034 Patent. On April 28, 2016, the PTAB granted Medtronic's IPR Petition for review of certain claims of the '393 Patent, and denied Medtronic's IPR Petition for review of other claims of the '393 Patent. The Company intends to defend the claims of the '393 Patent for which review was granted. Although the Company believes it has good and substantial positions for the patentability review and trial of '393 Patent, there is no guarantee that the Company will prevail.

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.

15. Segment Information and Enterprise Reporting

The Company's chief decision maker, the Chief Executive Officer, reviews financial information presented on a consolidated basis, accompanied by disaggregated information about revenues by geographic region, for purposes of making operating decisions and assessing financial performance. Accordingly, the Company considers itself to be in a single reporting segment, specifically 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 including noncontrolling interest. 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.

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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			
	April 2, 2016		April 4, 2015	
Geographic area by destination				
United States	$113,505	69.5 %	$107,276	72.8 %
Europe, Middle East and Africa	31,970	19.6	24,061	16.3
Asia and Australia	13,582	8.3	11,818	8.0
North and South America (excluding the United States)	4,233	2.6	4,202	2.9
Total product revenue	$163,290	100.0%	$147,357	100.0%

The Company's consolidated long-lived assets and net assets by geographic area are:

	Three Months Ended			
	April 2, 2016		January 2, 2016	
Long-lived assets by geographic area				
United States	$206,385	96.6 %	$203,553	96.8 %
International	7,338	3.4	6,770	3.2
Total	$213,723	100.0%	$210,323	100.0%

16. Income Taxes

The Company has provided for income taxes in fiscal 2016 interim periods based on the estimated effective income tax rate for the complete fiscal year. The income tax provision is computed on the estimated pretax income of the consolidated entities located within each taxing jurisdiction based on legislation enacted as of the balance sheet date. 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 April 2, 2016, the liability for income taxes associated with uncertain tax positions was approximately $8.7 million. If fully recognized, approximately $7.3 million (net of federal benefit on state taxes) would impact the Company's effective tax rate. The remaining balance relates to timing differences. 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 2011. The Company's 2012 income tax return is currently under examination by the U.S. Internal Revenue Service. All material state, local and foreign income tax matters have been concluded through fiscal year 2008. The Company does not believe that the results of any tax authority examination would have a significant impact on its 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 program; 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 January 2, 2016, which we filed with the SEC on February 24, 2016. 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. We provide our products directly and through distributors and original equipment manufacturers (OEM) partners to hospitals, emergency medical service providers, physician offices, veterinarians, long-term care facilities and consumers. Our mission is to improve patient outcomes and reduce the cost of care by taking noninvasive monitoring to new sites and applications.™ We were incorporated in California in May 1989 and reincorporated in Delaware in May 1996.

Our core business is Measure-through-Motion and Low-Perfusion™ pulse oximetry monitoring, known as Masimo Signal Extraction Technology® (SET®) pulse oximetry. Our product offerings have expanded significantly over the years to also include monitoring blood constituents with an optical signature, optical organ oximetry monitoring, electrical brain function monitoring, acoustic respiration monitoring, exhaled gas monitoring, patient monitoring with connectivity platforms, bedside and portable patient monitors and wearable wireless patent monitors. We have also developed a remote patient surveillance monitoring system, which currently allows up to 200 patients to be monitored simultaneously and remotely through a PC-based viewing station or by care providers through their pagers, voice-over-IP phones or smartphones.

Masimo SET® was designed to overcome the primary limitations of conventional pulse oximetry by maintaining accuracy in the presence of motion artifact, low perfusion and weak signal-to-noise situations. Pulse oximetry is the noninvasive measurement of the oxygen saturation level of arterial blood, which delivers oxygen to the body's tissues, and pulse rate. Pulse oximetry is one of the most common measurements taken inside and outside of hospitals around the world. We believe that Masimo SET® is trusted by clinicians to safely monitor approximately 100 million patients each year. Masimo SET® pulse oximetry has been shown by more than 100 independent studies and thousands of clinical evaluations during patient motion and low-perfusion conditions to provide more accurate measurements than other non-Masimo pulse oximeters, as well as to significantly reduce false alarms (specificity) and accurately detect true alarms (sensitivity) that can indicate a deteriorating patient condition. The use of Masimo SET® pulse oximetry has also been shown to improve patient outcomes by helping clinicians reduce retinopathy of prematurity in neonates, screen newborns for critical congenital heart disease, reduce ventilator weaning time and arterial blood gas

measurements in the intensive care unit (ICU), and save lives and costs while reducing rapid response activations and ICU transfers on the general floor.

Our rainbow SET™ platform leverages Masimo SET® technology and incorporates licensed rainbow® technology to enable real-time monitoring of additional noninvasive measurements. Our rainbow SET™ platform includes our rainbow SET™ Pulse CO-Oximetry products, which we believe are the first devices cleared by the U.S. Food and Drug Administration (FDA) to noninvasively and continuously monitor multiple blood-based measurements using multiple wavelengths of light, which previously was only possible through intermittent invasive procedures. In addition to monitoring oxygen saturation (SpO_2), pulse rate (PR), perfusion index (PI), Pleth Variability Index (PVI®) and Respiration Rate (RRa)™, rainbow SET™ Pulse CO-Oximetry has the ability to provide noninvasive monitoring of total hemoglobin (SpHb®), carboxyhemoglobin (SpCO®) and methemoglobin (SpMet®), as well as the calculation of Oxygen Content (SpOC)™. The rainbow SET™ platform also allows for

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monitoring of arterial oxygen saturation, even under the presence of carboxyhemoglobin and methemoglobin, known as fractional arterial oxygen saturation ($SpfO_2$)™, Respiration Rate from the Pleth (RRp)™ and Oxygen Reserve Index™ (ORI)™. Although $SpfO_2$,™ RRp™ and ORI™ have received the CE Mark, they are not currently available for sale in the U.S. Following the introduction of our rainbow SET™ platform, we have continued to expand our technology offerings by introducing additional noninvasive measurements and technologies to create new market opportunities in both the hospital and non-hospital care settings. These offerings include:

- SedLine® - Brain function monitoring is most commonly used during surgery to help clinicians monitor sedation under anesthesia. SedLine® brain function monitoring technology measures the brain's electrical activity by detecting electroencephalogram (EEG) signals. Brain function monitors display the patient's EEG waveforms, but these are difficult for clinicians to interpret, so the EEG signals are processed and displayed as a single number called Patient State Index (PSI), which gives a continuous indication of the patient's depth of sedation. Our SedLine® brain function monitoring technology can now be delivered through the Masimo Open Connect™ (MOC-9)™ connectivity port within our Root® patient monitoring and connectivity platform, which integrates our rainbow® and SET® measurements with multiple additional parameters, such as SedLine®. In addition, our SedLine® brain function monitoring technology also displays raw EEG waveforms, the PSI trend and the Density Spectral Array view to allow clinicians to compare EEG power in both sides of the brain over time to facilitate the detection of asymmetrical activity.
- Capnography and Gas Monitoring - Our portfolio of capnography and gas monitoring products include external "plug-in-and-measure" capnography and gas analyzers, integrated modules and handheld capnograph and capnometer devices. These products have the ability to measure multiple expired gases, such as carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2) and other anesthetic agents. In the case of capnography, respiration rate is also calculated from the CO_2 waveform. These measurements are possible through either mainstream monitoring, which samples gases from a ventilated patient's breathing circuit, or sidestream monitoring, which samples gases from a breathing circuit in mechanically ventilated patients or through a cannula or mask in spontaneously breathing patients.
- O_3™ - Regional oximetry monitoring, also known as tissue oximetry and cerebral oximetry monitoring, uses near-infrared spectroscopy to provide for continuous measurement of tissue oxygen saturation (rSO_2) to help detect regional hypoxemia that pulse oximetry alone can miss. In addition, our Root® patient monitor and O_3™ sensors can automate the differential analysis of regional to central oxygen saturation. O_3™ monitoring involves applying O_3™ regional oximetry sensors to the forehead and connecting our O_3™ Masimo Open Connect™ (MOC-9)™ module to any Root® monitor through one of its three MOC-9™ ports. O_3™ regional oximetry is currently intended for use in subjects larger than 40 kg (approximately 88 lbs) and has received the CE Mark, but is not currently available for sale in the U.S.
- rainbow Acoustic Monitoring® (RAM)™ - Our sound-based monitoring technology enables noninvasive monitoring of respiration rate (RRa®). Compared to traditional capnography, which monitors exhaled carbon dioxide (CO_2), most often through a nasal cannula, multiple clinical studies have shown that the noninvasive measurement of RRa® provides as good or better accuracy to monitor respiration rate and detect respiratory pause episodes, defined as a cessation of breathing for 30 seconds or more. When used with other clinical variables, RRa® may help clinicians assess respiratory depression and respiratory distress earlier and more often to help determine treatment options and potentially enable earlier interventions.
- Root® - This powerful patient monitoring and connectivity platform integrates our breakthrough rainbow® and SET® measurements with multiple additional specialty measurements through its MOC-9™ connectivity ports in an integrated, clinician-centric platform. The first three Masimo MOC-9™ technologies for Root® were SedLine® brain function monitoring, Phasein™ capnography and O_3™ regional oximetry. In addition, Iris™ connectivity in Root® enables third party devices such as intravenous pumps and ventilators to connect through Root® and enables display, notification and documentation to the electronic medical record (EMR) through our Patient SafetyNet™ solution. In combination with a Radical-7® handheld monitor, Root® will display alarm information, thereby simplifying patient care workflows and potentially helping caregivers make quicker patient assessments. Root® can also be connected with monitoring devices from other medical device companies that develop their own MOC-9™ compatible modules. For example, our Root® connectivity and patient monitoring platform with noninvasive blood pressure from SunTech Medical® enables clinicians to measure arterial blood pressure for adult, pediatric and neonatal patients with three distinct measurement

modes: spot-check, automatic interval and stat interval. The temperature module from Welch Allyn® can measure the temperature of adult, pediatric and neonatal patients.

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In March 2016, we announced Iris Gateway,™ a server-based software solution for integrating medical device data. The Iris™ ports on our Root® patient monitor allow other medical devices (such as infusion pumps, ventilators, patient monitors and "smart" beds) to connect to Iris Gateway™ via Root®. Iris™ Gateway can provide a timely and cost-effective solution for the integration of medical device data by connecting to existing medical devices and performing the required translations to move the data from the devices into EMRs. Iris Gateway™ can be deployed on a remote server farm or as a server appliance in the hospital.

- Patient SafetyNet™ - Our patient surveillance, remote monitoring and clinician notification solution allows for monitoring of the oxygen saturation, pulse rate, perfusion index, hemoglobin, methemoglobin and respiration rate of up to 200 patients simultaneously. Patient SafetyNet™ offers a rich user interface with trending, real-time waveform capability at the central station and remote notification via pager or smart phone. Patient SafetyNet™ also features the Adaptive Connectivity Engine,™ which enables two-way, Health Level 7 (HL7) based connectivity to clinical/hospital information systems. The Adaptive Connectivity Engine™ significantly reduces the time and complexity to integrate and validate custom HL7 implementations and demonstrates our commitment to innovation that automates patient care with open, scalable and standards-based connectivity architecture.

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

In March 2016, we introduced SafetyNet Surveillance,™ a software option for our Patient SafetyNet™ solution that provides real-time video images of a patient's room, including the patient with connected monitoring devices, adding existing communication technology to central monitoring. Two-way audio is available to allow the caregiver to listen to and communicate with the patient. The system utilizes the existing hospital information technology network and can provide viewing of images in the same care area.

- MightySat™ - Our fingertip pulse oximeter provides oxygen saturation and pulse rate measurements and is designed for those who want accurate measurements even under challenging conditions such as movement and low perfusion. MightySat™ provides SpO_2, PR, RRp,™ PVI® and PI measurements in a compact, battery-powered design with a large color screen that can be rotated for real-time display of the pleth waveform as well as measurements. Its Bluetooth® wireless functionality enables measurement display via the free, downloadable Masimo Personal Health app on iOS and Android mobile devices, as well as the ability to trend and communicate measurements and interface with the Apple Health app. MightySat™ is also available with optional PVI®, a measure of the dynamic changes in the perfusion index that occur during one or more complete respiratory cycles. MightySat™ is available through online retailers such as Amazon.com. In the U.S., MightySat™ is intended for general health and wellness use and is not intended for medical use. However, MightySat™ Rx, the medical version of the product with optional Bluetooth®, received 510(k) clearance in late 2015. MightySat™ Rx with the RRp™ measurement is not currently available for sale in the U.S.
- MyView™ - This wireless, presence-detection system enables clinicians to automatically display customized clinical profiles on our devices, such as Root®, Radical-7® and the Patient SafetyNet™ View Station. When a clinician approaches the device, a clinician-worn MyView™ badge signals the device to display a preselected set of parameters and waveforms tailored to the individual clinician's preferences. MyView™ gives clinicians the ability to receive and review medical device information in a manner that is most conducive to optimizing their workflow, while the presence mapping data collected by all the Masimo devices can provide information on how clinicians spend time

with their patients. This provides nursing leadership and management with the opportunity to examine analytical data on patient and clinician interactions to optimize workflows across the unit, hospital or hospital system.

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Since inception, our mission has been to develop noninvasive monitoring solutions that improve patient outcomes and reduce the cost of patient care®. We intend to continue to grow our business and improve our market position by pursuing the following strategies:

(1) continue to expand our market share in pulse oximetry;
(2) expand the pulse oximetry market to other patient care settings;
(3) expand the use of rainbow® technology in hospital settings;
(4) expand the use of rainbow® technology in non-hospital settings;
(5) expand the use of Root® in hospital settings;
(6) utilize our customer base and OEM relationships to market our rainbow SET™ products incorporating our licensed rainbow® technology, as well as our other non-invasive specialty products including O_3,™ SedLine® and capnography monitoring; and
(7) continue to innovate and maintain our technology leadership position.

Our solutions and related products are based upon our Masimo SET®, rainbow® and other proprietary algorithms. This software-based technology is incorporated into a variety of product platforms depending on our customers' specifications. Our technology is supported by a substantial intellectual property portfolio that we have built through internal development and, to a lesser extent, acquisitions and license agreements. In addition, we have exclusively licensed certain rainbow® technology from Cercacor Laboratories, Inc. (Cercacor) and have the right to incorporate such rainbow® technology into products that are intended for use by professional caregivers, including, but not limited to, hospital caregivers and alternate care facility caregivers.

Cercacor Laboratories, Inc.

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

As a result of recent changes in the capital structure of Cercacor, as well as certain of its contractual relationships with us, we completed a re-evaluation of the authoritative consolidation guidance during the three months ended April 2, 2016 and determined that although Cercacor remains a VIE, we are no longer its primary beneficiary. Based on such determination, we have discontinued consolidating Cercacor within our consolidated financial statements effective as of January 3, 2016. However, Cercacor continues to be consolidated within our condensed consolidated financial information for all periods prior to January 3, 2016. See Note 3 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Stock Repurchase Program

In September 2015, our board of directors (Board) authorized a stock repurchase program, whereby we may purchase up to 5.0 million shares of our common stock over a period of up to three years. As of April 2, 2016, approximately 3.3 million shares remained authorized for repurchase under this program.

Our stock repurchase program may be carried out at the discretion of a committee comprised of our Chief Executive Officer and Chief Financial Officer 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 stock repurchase program, see Note 12 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

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					
	April 2, 2016	Percentage of Revenue		April 4, 2015	Percentage of Revenue	
Revenue:						
Product	$163,290	95.4	%	$147,357	95.4	%
Royalty	7,877	4.6		7,180	4.6	
Total revenue	171,167	100.0		154,537	100.0	
Cost of goods sold	56,954	33.3		51,432	33.3	
Gross profit	114,213	66.7		103,105	66.7	
Operating expenses:						
Selling, general and administrative	62,511	36.5		60,799	39.3	
Research and development	14,365	8.4		14,929	9.7	
Total operating expenses	76,876	44.9		75,728	49.0	
Operating income	37,337	21.8		27,377	17.7	
Non-operating income	498	0.3		153	0.1	
Income before provision for income taxes	37,835	22.1		27,530	17.8	
Provision for income taxes	10,258	6.0		7,708	5.0	
Net income including noncontrolling interest	27,577	16.1		19,822	12.8	
Net loss attributable to the noncontrolling interest[(1)]	—	—		701	0.5	
Net income attributable to Masimo Corporation stockholders	$27,577	16.1	%	$20,523	13.3	%

(1) Effective January 3, 2016, we determined that we are no longer the primary beneficiary of Cercacor, and, therefore, we discontinued consolidating Cercacor in our consolidated financial information. Pursuant to authoritative accounting guidance, all periods prior to January 3, 2016 continue to include Cercacor in our consolidated financial information. See Note 3 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Comparison of the Three Months ended April 2, 2016 to the Three Months ended April 4, 2015

Revenue. Total revenue increased $16.6 million, or 10.8%, to $171.2 million for the three months ended April 2, 2016 from $154.5 million for the three months ended April 4, 2015. The following chart details our total product revenues by the geographic area to which the products were shipped for each of the three month periods ended April 2, 2016 and April 4, 2015 (dollars in thousands):

	Three Months Ended								
	April 2, 2016			April 4, 2015			Increase/ (Decrease)	Percentage Change	
United States	$113,505	69.5	%	$107,276	72.8	%	6,229	5.8	%
Europe, Middle East and Africa	31,970	19.6		24,061	16.3		7,909	32.9	
Asia and Australia	13,582	8.3		11,818	8.0		1,764	14.9	
North and South America (excluding United States)	4,233	2.6		4,202	2.9		31	0.7	
Total Product Revenue	$163,290	100.0	%	$147,357	100.0	%	$ 15,933	10.8	%
Royalty	7,877			7,180			697		
Total Revenue	$171,167			$154,537			$ 16,630		

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Product revenue increased $15.9 million, or 10.8%, to $163.3 million for the three months ended April 2, 2016 from $147.4 million for the three months ended April 4, 2015. This increase was primarily due to higher sales of consumable products. This increase in product revenue was partially offset by the impact of approximately $1.4 million related to unfavorable movements in foreign exchange rates from the prior year period that reduced the U.S. Dollar translation of foreign sales that were denominated in various foreign currencies, primarily in Europe. We estimate that our installed base of circuit boards and pulse oximeters increased to 1,438,000 units at April 2, 2016 as compared to 1,340,000 units at April 4, 2015.

Product revenue generated through our direct and distribution sales channels increased $15.9 million, or 12.7%, to $140.9 million for the three months ended April 2, 2016, compared to $125.1 million for the three months ended April 4, 2015. Revenues from our OEM channel were unchanged at $22.3 million for the three months ended April 2, 2016 as compared to the three months ended April 4, 2015. Total rainbow® product revenue increased by $4.8 million, or 39.2%, to $16.9 million for the three months ended April 2, 2016, compared to $12.2 million for the three months ended April 4, 2015.

Royalty revenue consists of amounts received from Medtronic plc (Medtronic, formerly Covidien) related to its U.S. sales pursuant to the terms of our amended settlement agreement. Based on the terms of such agreement, Medtronic has the right to stop paying us royalties, subject to certain notice requirements. In addition, on October 21, 2015, Medtronic filed three separate inter partes review petitions (IPR Petitions) with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office, challenging several of the claims of two U.S. patents titled “Signal processing apparatus” that are owned by us. On April 27, 2016, the PTAB denied the IPR Petitions with respect to one patent. On April 28, 2016, the PTAB granted the IPR Petition for review of certain claims of the other patent while denying the IPR Petition for review of other claims with respect to such patent. We intend to defend the claims of the patent for which review was granted. See Note 14 to the condensed consolidated financial statements under the caption “Litigation” included in Part I, Item 1 and “Medtronic may seek to avoid paying any royalties to us, which would significantly reduce our royalty revenues and adversely affect our business, financial condition and results of operations” under Part II, Item 1A - Risk Factors, in this Quarterly Report on Form 10-Q for additional information.

Gross Profit. Gross profit consists of total revenue less cost of goods sold. Our gross profit for the three months ended April 2, 2016 and April 4, 2015 was as follows (dollars in thousands):

	Three Months Ended							
	April 2, 2016	Gross Profit Percentage		April 4, 2015	Gross Profit Percentage		Increase/ (Decrease)	Percentage Change	
Product Gross Profit	$106,336	65.1	%	$95,925	65.1	%	$ 10,411	10.9	%
Royalty Gross Profit	7,877	100.0		7,180	100.0		697	9.7	
Total Gross Profit	$114,213	66.7	%	$103,105	66.7	%	$ 11,108	10.8	%

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 $5.5 million for the three months ended April 2, 2016, compared to the three months ended April 4, 2015, primarily due to the increase in our product revenues and the impact of approximately $1.5 million of Cercacor royalty expense that is no longer eliminated in consolidation.

Product gross margins were unchanged at 65.1% for the three months ended April 2, 2016 as compared to the three months ended April 4, 2015, primarily due to the impact of the non-elimination of such Cercacor royalty expense for the three months ended April 2, 2016. We incurred $1.3 million in Cercacor royalty expenses for the three months ended April 4, 2015 that was eliminated in our condensed consolidated financial statements for such period. Had such royalty expenses not been eliminated in consolidation, product gross profit margin would have been 64.2% for the three months ended April 4, 2015, compared to our reported product gross profit margin of 65.1% for the three months ended April 2, 2016. This increase in product gross margin resulted primarily from our continued cost reduction efforts, as well as from differences in our product sales mix. See Note 3 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 the deconsolidation of Cercacor.

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, medical device taxes and other corporate expenses. Selling, general and administrative expenses for the three months ended April 2, 2016 and April 4, 2015 were as follows (dollars in thousands):

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Selling, General and Administrative

Three Months Ended April 2, 2016	Percentage of Net Revenues	Three Months Ended April 4, 2015	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$62,511	36.5%	$60,799	39.3%	$1,712	2.8%

Selling, general and administrative expenses increased $1.7 million, or 2.8%, for the three months ended April 2, 2016 compared to the three months ended April 4, 2015. This increase was primarily attributable to higher payroll related costs of approximately $3.1 million, higher marketing related fees of approximately $1.5 million and higher travel related costs of approximately $0.7 million, which were partially offset by a decrease of approximately $1.8 million in medical device excise tax as a result of the two year moratorium signed into law on December 18, 2015 under the Consolidated Appropriations Act, and lower legal and professional fees of approximately $1.0 million. Also offsetting these increases was the current period deconsolidation of Cercacor, which resulted in the exclusion of approximately $0.6 million of Cercacor's selling, general and administration expenses from our consolidated results of operations for the three months ended April 2, 2016, as compared to the inclusion of approximately $0.7 million of Cercacor's selling, general and administration expenses in our consolidated results of operations for the three months ended April 4, 2015. (See Note 3 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 the deconsolidation of Cercacor.) Stock-based compensation expense of approximately $2.2 million and $2.0 million was included in selling, general and administrative expenses for the three months ended April 2, 2016 and April 4, 2015, respectively.

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 April 2, 2016 and April 4, 2015 were as follows (dollars in thousands):

Research and Development

Three Months Ended April 2, 2016	Percentage of Net Revenues	Three Months Ended April 4, 2015	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$14,365	8.4%	$14,929	9.7%	$(564)	(3.8)%

Research and development expenses decreased $0.6 million for the three months ended April 2, 2016 compared to the three months ended April 4, 2015, primarily due to the current period deconsolidation of Cercacor, which resulted in the exclusion of approximately $1.3 million of Cercacor's research and development expenses from our consolidated results of operations for the three months ended April 2, 2016, as compared to the inclusion of approximately $1.4 million of Cercacor's research and development expenses in our consolidated results of operations for the three months ended April 4, 2015. (See Note 3 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 the deconsolidation of Cercacor.) Also contributing to the decrease in research and development expenses were lower project related supply costs of approximately $0.9 million during the three months ended April 2, 2016. Offsetting these decreases during the three months ended April 2, 2016 were higher payroll related costs of $0.9 million and higher occupancy related costs of $0.5 million. Included in research and development expenses was approximately $0.7 million of stock-based compensation expense for each of the three month periods ended April 2, 2016 and April 4, 2015.

Non-operating income. Non-operating income consists primarily of interest income, interest expense and foreign exchange losses. Non-operating income for the three months ended April 2, 2016 and April 4, 2015 was as follows (dollars in thousands):

Non-operating Income (Expense)

Three Months Ended April 2, 2016	Percentage of Net Revenues	Three Months Ended April 4, 2015	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$498	0.3%	$153	0.1%	$345	225.5%

Non-operating income increased by $0.3 million for the three months ended April 2, 2016 compared to the three months ended April 4, 2015. Non-operating income for the three months ended April 2, 2016 consisted of $0.7 million of interest expense offset by $0.9 million of net realized and unrealized gains on foreign currency denominated

transactions resulting primarily from the weakening of the U.S. Dollar against the Japanese Yen, Euro and Canadian Dollar, which were negatively impacted by losses due to the weakening of the U.S. Dollar against the Swedish Krona, and a $0.3 million gain resulting from our deconsolidation of Cercacor. See Note 3 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information on the deconsolidation of Cercacor.

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Non-operating income for the three months ended April 4, 2015 related primarily to $0.5 million of interest expense which was offset by $0.6 million of net realized and unrealized gains on foreign currency denominated transactions resulting primarily from the strengthening of the U.S. Dollar against the Swedish Krona, which were partially offset by losses due to the strengthening of the U.S. Dollar against the Euro and British Pound.

Provision for Income Taxes. Our provision for income taxes for the three months ended April 2, 2016 and April 4, 2015 was as follows (dollars in thousands):

Provision for Income Taxes

Three Months Ended April 2, 2016	Percentage of Net Revenues	Three Months Ended April 4, 2015	Percentage of Net Revenues	Increase/ (Decrease)	Percentage Change
$10,258	6.0%	$7,708	5.0%	$2,550	33.1%

Our provision for income taxes was $10.3 million, or an effective tax rate of 27.1%, for the three months ended April 2, 2016, compared to $7.7 million, or an effective tax rate of 28.0%, for the three months ended April 4, 2015. The lower effective tax rate for the three months ended April 2, 2016 is primarily due to a discrete tax benefit of $1.0 million during the three months ended April 2, 2016 related to excess tax benefits realized for stock-based compensation, pursuant to our adoption of Accounting Standards Update No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). No similar tax benefit was recognized in our provision for income taxes during the three months ended April 4, 2015. (See Note 2 to the condensed consolidated financial statements under the caption “Recently Adopted Accounting Pronouncements” included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information on our adoption of ASU 2016-09.) Partially offsetting this tax benefit was an increase on our effective tax rate resulting from differences in our expected fiscal 2016 geographic composition of our pre-tax income as compared to our expected fiscal 2015 geographic composition as of April 4, 2015.

Liquidity and Capital Resources

Our principal sources of liquidity consist of our existing cash and cash equivalent balances, funds expected to be generated from operations and funds available under our revolving credit agreement. At April 2, 2016, we had approximately $197.8 million in working capital and approximately $139.9 million in cash and cash equivalents as compared to approximately $166.5 million in working capital and approximately $132.3 million in cash and cash equivalents at January 2, 2016. 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 April 2, 2016, we had cash totaling $81.2 million held outside of the U.S., of which approximately $13.6 million was accessible without additional tax cost and approximately $67.5 million was accessible at an incremental estimated tax cost of approximately $20.4 million. In managing our day-to-day liquidity and capital structure, we do not rely on foreign earnings as a source of funds. We currently have sufficient funds on-hand and available under our line of credit to fund our domestic operations and do not anticipate the need to repatriate funds associated with our permanently reinvested foreign earnings. In the event funds that are treated as permanently reinvested are repatriated, we may be required to accrue and pay additional U.S. taxes with respect to any such repatriation.

On January 8, 2016, we entered into an Amended and Restated Credit Agreement (Restated Credit Facility) with JPMorgan Chase Bank, N.A., as Administrative Agent and a Lender, Bank of America, N.A., as Syndication Agent and a Lender, Citibank, N.A., as Documentation Agent and a Lender, and various other Lenders (collectively, the Lenders). The Restated Credit Facility amends and restates the Amended Credit Agreement and provides for up to $450.0 million in borrowings in multiple currencies, with an option, subject to certain conditions, for us to increase the aggregate borrowing capacity to up to $550.0 million in the future. The Restated Credit Facility also provides for a sublimit of up to $50.0 million for the issuance of letters of credit and a sublimit of $125.0 million in specified foreign currencies. All unpaid principal under the Restated Credit Facility will become due and payable on January 8, 2021. See Note 10 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

During the three months ended April 2, 2016, we received $7.9 million from Medtronic for royalties related to its U.S. sales pursuant to the terms of our amended settlement agreement. Based on the terms of such agreement, Medtronic

has the right to stop paying us royalties, subject to certain notice requirements. In addition, on October 21, 2015, Medtronic filed three separate inter partes review petitions (IPR Petitions) with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office, challenging several of the claims of two U.S. patents titled “Signal processing apparatus” that are owned by us. On April 27, 2016, the PTAB denied the IPR Petitions with respect to one patent. On April 28, 2016, the PTAB granted the IPR Petition for review of certain claims of the other patent while denying the IPR Petition for review of other claims with

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respect to such patent. We intend to defend the claims of the patent for which review was granted. See Note 14 to the condensed consolidated financial statements under the caption “Litigation” included in Part I, Item 1 and “Medtronic may seek to avoid paying any royalties to us, which would significantly reduce our royalty revenues and adversely affect our business, financial condition and results of operations” under Part II, Item 1A - Risk Factors, in this Quarterly Report on Form 10-Q for additional information.

Cash Flows

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

	Three Months Ended	
	April 2, 2016	April 4, 2015
Net cash provided by (used in):		
Operating activities	$18,805	$19,126
Investing activities	(6,860)	(17,955)
Financing activities	(5,214)	2,392
Effect of foreign currency exchange rates on cash	855	(2,296)
(Decrease) increase in cash and cash equivalents	$7,584	$1,267

Operating Activities. Cash provided by operating activities was $18.8 million in the three months ended April 2, 2016, arising primarily from net income of $27.6 million, non-cash activity for depreciation and amortization of $4.1 million, stock-based compensation of $3.0 million and deferred income taxes of $2.7 million. In addition, deferred revenue and income taxes payable increased by $5.4 million and $4.5 million, respectively. These sources of cash were primarily offset by other changes in operating assets and liabilities related to a decrease in accrued compensation of $12.6 million and a decrease in accrued liabilities of $4.2 million, both due to the timing of related payments, and an increase in accounts receivable of $12.3 million due to the timing of collections.

Cash provided by operating activities was $19.1 million for the three months ended April 4, 2015, arising primarily from net income of $19.8 million, non-cash activity for depreciation and amortization of $3.8 million and stock-based compensation of $2.9 million. In addition, deferred revenue and accrued liabilities increased by $1.9 million and $7.2 million, respectively, and accounts receivable decreased by $2.8 million due to the timing of collections. These

sources of cash were primarily offset by other changes in operating assets and liabilities related to an increase in other assets of $6.4 million primarily due to an increase in prepaid discounts, a decrease in accounts payable of $3.1 million related to the timing of payments and a decrease in accrued compensation of $10.8 million due to the payment of fiscal year 2014 annual bonuses.

Investing Activities. Cash used in investing activities for the three months ended April 2, 2016 was $6.9 million, consisting primarily of $5.3 million for purchases of property and equipment, $0.8 million of intangible assets related to capitalized patent and trademark costs and $0.8 million related to the deconsolidation of Cercacor. See Note 3 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 the deconsolidation of Cercacor.

Cash used in investing activities for the three months ended April 4, 2015 was $18.0 million, consisting of $17.2 million for purchases of property and equipment and $0.7 million for the increase in intangible assets related to capitalized patent and trademark costs.

Financing Activities. Cash used in financing activities for the three months ended April 2, 2016 was $5.2 million, primarily resulting from common stock repurchase transactions during the quarter totaling $47.7 million, offset by net borrowings under our Restated Credit Facility of $40.0 million and proceeds from the issuance of common stock (upon exercise of options) totaling $2.6 million.

Cash provided by financing activities for the three months ended April 4, 2015 was $2.4 million, primarily due to proceeds from the issuance of common stock (upon exercise of options) totaling $4.6 million, offset by common stock repurchase transactions that settled during the quarter totaling $2.2 million.

Capital Resources and Prospective Capital Requirements

As of April 2, 2016, we had $225.0 million in outstanding loan draws under our Restated Credit Facility, leaving available borrowing capacity of $225.0 million. We also had outstanding capital lease obligations of $0.1 million related primarily to office and computer equipment. We had no other debt obligations and are in compliance with all bank covenants.

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In September 2015, the Board authorized a stock repurchase program for the repurchase of up to 5.0 million shares of our common stock over a period of up to three years. The stock repurchase program may be carried out at the discretion of a committee comprised of our Chief Executive Officer and Chief Financial Officer through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. As of April 2, 2016, approximately 3.3 million shares remain authorized for repurchase under this stock repurchase program. For additional information regarding our stock repurchase program, see Note 12 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

We expect to fund our future operating, investing and financing activities through our available cash, future cash from operations, funds available under our Restated Credit Facility and other potential sources of capital. In addition to funding our normal working capital requirements, we anticipate additional capital purchases related to renovating our new corporate headquarters. We also anticipate that we will continue to repurchase stock under our authorized stock repurchase program subject to the availability of our stock, general market conditions, the trading price of our stock, available capital, alternative uses for capital and our financial performance. Possible additional uses of cash may include the acquisition of technologies or technology companies. The amount and timing of our actual investing activities will vary significantly depending on numerous factors, including the timing and amount of costs related to the renovation of our new corporate headquarters facility and other capital expenditures, costs of product development efforts, 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, as well as amounts available under the Restated Credit Facility, will be sufficient to meet our working capital requirements, capital expenditures and other operational funding needs for at least the next 12 months.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we engaged in these relationships. As of April 2, 2016, 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.

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. For a description of our 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 January 2, 2016, filed with the SEC on February 24, 2016. There have been no material changes to any of our critical accounting policies during the three months ended April 2, 2016.

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.

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Interest Rate Risk

Our exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense we must pay with respect to our various outstanding debt instruments. Our risk associated with fluctuations in interest expense is limited to interest associated with our outstanding capital lease arrangements, which have fixed interest rates, and any borrowings under our Restated Credit Facility and any amendments thereto. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities. A hypothetical 100 basis point change in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest-sensitive financial instruments at April 2, 2016. Declines in interest rates over time will, however, reduce our interest income and expense while increases in interest rates will increase our interest income and expense.

Foreign Currency Exchange Rate Risk

A majority of our assets and liabilities are maintained in the United States in U.S. Dollars and a majority of our sales and expenditures are transacted in U.S. Dollars. 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 exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables and payables, as well as intercompany transactions. 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, Mexican Peso and Australian Dollar, against the U.S. Dollar. Foreign currency exchange rates have experienced significant movements recently, particularly when compared to the same prior year period, and such volatility may continue in the future. Specifically, during the three months ended April 2, 2016, we estimate that changes in the exchange rates of the U.S. Dollar relative primarily to the Euro, Japanese Yen, Swedish Krona, Canadian Dollar, British Pound and Australian Dollar, negatively impacted our revenues by $1.4 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 a 10% change in foreign currency exchange rates could have a material effect on our future operating results or cash flows, depending on which foreign currency exchange rates change and depending on the directional change (either a strengthening or weakening against the U.S. Dollar). As our foreign operations continue to grow, our exposure to foreign currency exchange rate risk may become more significant.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the periods presented. 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 and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

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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 Chief Executive Officer and Chief Financial Officer, 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 Chief Executive Officer and Chief Financial Officer 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. There has been no change in our internal control over financial reporting during the quarter ended April 2, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The information set forth in Note 14 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 January 2, 2016, filed with the Securities and Exchange Commission (SEC) on February 24, 2016, 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 January 2, 2016, filed with the SEC on February 24, 2016.

Risks Related to Our Revenues

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

We are dependent upon the success and market acceptance of our proprietary Masimo SET® technology. Currently, our primary product offerings are based on the Masimo SET® platform. Continued market acceptance of products incorporating Masimo SET® will depend upon our ability to continue providing 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, including those based on licensed rainbow® technology, are in development or have been recently introduced into the market and may not achieve market acceptance, which could limit our growth and adversely affect our business, financial condition and results of operations.

Products that we have introduced into the market in recent years, including, but not limited to, those based on rainbow® technology, a technology that we license, may not be accepted in the market. 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.

Given that certain rainbow® technology products are relatively new to the marketplace, we do not know to what degree the market will accept these products, if at all. Even if our customers recognize the benefits of our products, we cannot assure you that our customers will purchase them in quantities sufficient for us to be profitable or successful. We 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:

- perceived clinical benefits from our products;
- perceived cost effectiveness of our products;

- perceived safety and effectiveness of our products;

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- 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.

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, if we do, we expect them to become more useful in more environments and to become more widely adopted. While this is the adoption pattern experienced historically with other new noninvasive measurements, such as oxygen saturation, we are unable to guarantee that such adoption pattern will apply to our recent and future technologies.

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.

In May 1998, we spun off a newly-formed entity, Cercacor, and provided it rights to use Masimo SET® to commercialize non-vital signs monitoring applications, while we retained the rights to Masimo SET® to commercialize vital signs monitoring applications. On May 2, 1998, we entered into a cross-licensing agreement with Cercacor, which has been amended several times, most recently in an Amended and Restated Cross-Licensing Agreement, effective January 1, 2007 (the Cross-Licensing Agreement). Under the Cross-Licensing Agreement, we granted Cercacor:

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

Non-vital 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 customer bases and larger sales forces, have established stronger reputations with specific customers, and have built relationships with Group Purchasing Organizations (GPOs) that are 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.

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

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commercialize. In particular, we may not be able to successfully commercialize our products for applications other than arterial blood oxygen saturation and pulse rate monitoring, including 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, whereby they 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 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 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. 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.

*Medtronic may seek to avoid paying any royalties to us, which would significantly reduce our royalty revenues and adversely affect our business, financial condition and results of operations.

Pursuant to our settlement agreement with Medtronic plc (Medtronic, formerly Covidien Ltd.), we earn royalties on Medtronic's total U.S. based pulse oximetry sales. For the three months ended April 2, 2016 and April 4, 2015, our royalties from the Medtronic settlement agreement totaled approximately $7.9 million and $7.2 million, respectively. Because these royalty payments do not carry any significant cost, they result in significant improvements to our reported gross profit, operating income levels and earnings per share.

On January 28, 2011, we entered into a second amendment to the settlement agreement, which became effective on March 15, 2011. Pursuant to the second amendment, in exchange for a specified royalty payment, we agreed not to sue Medtronic for its current pulse oximetry products, but not for any other technologies that Medtronic may add. On October 21, 2015, Medtronic filed three separate inter partes (IPR) review petitions (the IPR Petitions) with the Patent Trial and Appeal Board (the PTAB) of the U.S. Patent and Trademark Office (PTO), challenging several of the claims of our U.S. Patent Nos. 7,496,393 (the '393 Patent), titled "Signal processing apparatus", which expires in September 2016, and 8,560,034 (the '034 Patent), also titled "Signal processing apparatus", which expires in October 2018. On April 27, 2016, the PTAB denied Medtronic's IPR Petitions with respect to the '034 Patent. On April 28, 2016, the PTAB granted Medtronic's IPR Petition for review of certain claims of the '393 Patent, and denied Medtronic's IPR Petition for review of other claims of the '393 Patent. We intend to defend the claims of the '393 Patent for which review was granted. (See Note 14 to our accompanying consolidated financial statements under the caption "Litigation" included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information on the IPR Petitions.) Although we believe that we have good and substantial positions for the patentability review and trial of '393 Patent, there is no guarantee that we will prevail. Furthermore, Medtronic has the right to stop paying royalties to us, subject to certain notice requirements, under our existing settlement agreement with them. If Medtronic ceases paying royalties to us under the settlement agreement, our revenue, gross margins, operating income and earnings per share would be materially and adversely affected.

*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.

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These negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, the GPO's affiliated hospitals and other members may be less likely or unlikely to purchase our products. If a GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be prohibited from making sales to members of such GPO for the duration of such contractual arrangement. For the three months ended April 2, 2016 and April 4, 2015, shipments of our pulse oximetry products to customers that are members of GPOs represented approximately $91.9 million and $86.3 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 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. While we are working with these payers to obtain reimbursement, we may not be successful. These trends could lead to pressure to reduce prices for our current and future products and could cause a decrease in the size of the market or a potential increase in competition that could have a material adverse effect on our business, financial condition and results of operations.

*Our customers may reduce, delay or cancel purchases due to a variety of factors, such as lower hospital census levels or third-party guidelines, 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. In addition, although not yet fully understood, the impact of the Patient Protection and Affordable Care Act may force hospitals to reevaluate 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.

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In addition, states and other local regulatory authorities may issue guidelines regarding the appropriate scope and use of our products from time to time. For example, 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. 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. Also, 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. For the three months ended April 2, 2016 and April 4, 2015, we had sales through two just-in-time distributors, which in total represented approximately 27.2% and 26.7% of our total revenue, respectively. 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.

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 are aware that other organizations are manufacturing and selling imitation Masimo sensors. In addition, we are aware that 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 utilization, reduced comfort and a number of monitoring problems. Notwithstanding these limitations, some of our customers have indicated a willingness to consider purchasing some of their sensor requirements from these imitation manufacturers and third-party reprocessors in an effort to reduce their sensor costs. These imitation and reprocessed sensors have led and may continue to lead to confusion with our genuine Masimo products; have reduced and may continue to reduce our revenue; and, in some cases, have harmed and may continue to harm our reputation if customers conclude incorrectly that these imitation or reprocessed sensors are original Masimo sensors. 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.

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*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, since 2013, we have made investments in additional sales force resources whose primary focus is to work with hospitals to identify new opportunities for certain noninvasive measurement technologies. Although we believe strategic initiatives and investments, including our investment in the new worldwide blood management sales force, are, and will 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 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 be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO.

As part of the Leahy-Smith America Invents Act (the Leahy-Smith Act), which was enacted in 2011, the PTO has introduced procedures that provide additional administrative pathways for third parties to challenge issued patents. IPR is one of these procedures. The number of IPR challenges filed is increasing, and in many cases, the PTO is canceling or significantly narrowing issued patent claims. Accordingly, even if a patent is granted by the PTO, there is a risk that it may not withstand an IPR challenge. 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. In addition, recent case law has increased uncertainty regarding the availability of patent protection for certain technologies and the costs associated with obtaining patent protection for those technologies.

On October 21, 2015, Medtronic filed three separate IPR Petitions with the PTAB challenging several of the claims of our ‘393 Patent, which expires in September 2016, and our ‘034 Patent, which expires in October 2018. On April 27, 2016, the PTAB denied Medtronic’s IPR Petitions with respect to the ‘034 Patent. On April 28, 2016, the PTAB granted Medtronic’s IPR Petition for review of certain claims of the ’393 Patent, and denied Medtronic’s IPR Petition for review of other claims of the ’393 Patent. We intend to defend the claims of the ’393 Patent for which review was granted. (See Note 14 to our accompanying consolidated financial statements under the caption “Litigation” included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information on the IPR Petitions.) Although we believe that we have good and substantial positions for the patentability review and trial of ‘393 Patent, there is no guarantee that we will prevail.

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

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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.

Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage in the marketplace. We face the risk of claims that we have infringed on third parties' intellectual property rights. Searching for existing intellectual property rights may not reveal important intellectual property and our competitors may also have filed for patent protection, which is not publicly-available information, or claimed trademark rights that have not been revealed through our 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, and we may bring additional 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 significant part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets. We were previously involved in significant litigation to protect our patent position and may be required to engage in further litigation. In 2006, we settled a costly, six-year lawsuit against Mallinckrodt, Inc., part of Tyco Healthcare, and one of its subsidiaries, Nellcor Puritan Bennett, Inc., in which we claimed infringement of some of our pulse oximetry signal processing patents. In November 2015, we settled multiple

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litigations with Mindray DS USA, Inc., Shenzhen Mindray Bio-Medical Electronics Co., Ltd. and Mindray Medical International Ltd.

In February 2009, we filed a patent infringement suit against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH (collectively, Philips) related to Philips' FAST pulse oximetry technology and certain of Philips' patient monitors. This suit is described in Note 14 to our accompanying consolidated financial statements under the caption "Litigation" included in Part I, Item 1 of this Quarterly Report on Form 10-Q. Philips is an OEM partner of ours. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

Our ongoing and future litigation could result in significant additional costs and further divert the attention of our management and key personnel from our business operations and the implementation of our business strategy and may not be adequate to protect our intellectual property rights.

Risks Related to Our Regulatory Environment

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

Each medical device that we wish to market in the U.S. generally must first undergo premarket review by the FDA and receive clearance or approval pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA) by receiving clearance of a 510(k) pre-market notification, receiving clearance through the de novo review process, or obtaining approval of a pre-market 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, which would limit our ability to market the product to only such indications for use. We cannot guarantee that the FDA will grant 510(k) clearance on a timely basis, if at all, for new products or uses that we propose for Masimo SET® or licensed rainbow® technology. The 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 much more 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, thereby leading 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 during this period as compared to prior periods.

In connection with an FDA 510(k) filing for certain improvements to our Pronto-7® product, the FDA expressed concerns and requested additional information regarding the methods we used to validate the SpHb® parameter. We responded to the FDA's request for additional information on March 25, 2014. The FDA responded that the remaining issues would not likely be resolved in the time remaining, so we voluntarily withdrew the application on March 31, 2014. We have since had further submissions and meetings with the FDA and believe we have a better understanding of the FDA's expectations on validation methodologies for future 510(k) filings for SpHb spot-check devices such as Pronto® and Pronto-7®. We intend to work with the FDA to address their remaining concerns, but we cannot be sure we will be able to resolve all such concerns.

To date, the FDA has regulated pulse oximeters incorporating Masimo SET® and licensed rainbow® technology, patient monitor devices, sensors, cables and other products under the 510(k) process. Although 510(k) clearances have been obtained for such products, if safety or effectiveness problems are identified with our devices, 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 are marketing these products in accordance with the FDA's current policy for products that are intended for wellness or

fitness uses. In addition, some of our products may also be exempted from the 510(k) process in accordance with specific FDA guidance and policies, such as the FDA guidance related to mobile medical applications. We cannot assure you that the FDA will not change its 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, we may be required to seek clearance or approval of these devices through the 510(k), de novo or PMA processes.

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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. We cannot guarantee that the FDA clearances we have obtained will make it easier for our OEM partners to obtain clearances of products incorporating these technologies, or that the FDA will 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 covers 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 2013, the FDA inspected our facility in Irvine, California and issued an FDA Form 483 listing observations the investigator believed may constitute violations of statutes or regulations administered by the FDA, including observations relating to complaint handling, medical device reporting and corrective and preventative action (CAPA) procedures. In 2014, the FDA also inspected our facility in Mexicali, Mexico and issued a Form 483 listing observations relating to our CAPA procedures, documentation practices associated with our device history records and procedures for employee training. We submitted responses to both Form 483s. In August 2014, we received from the FDA a final inspection report closing out the Mexicali inspection and a warning letter (the Warning Letter) related to the Irvine inspection. We submitted a response (the Response Letter) to the Warning Letter on September 5, 2014 and attended a regulatory meeting with the FDA on September 19, 2014. At the meeting, in addition to discussing our Response Letter, the FDA raised issues beyond the scope of the Warning Letter in the areas of Good Manufacturing Practices, quality, bioresearch monitoring and labeling/promotion. We have been in communication with the FDA since the meeting and are working to resolve the issues raised by the FDA. Although the FDA has yet to close out the Warning Letter, the FDA resumed issuing certificates to foreign governments (CFGs) for products manufactured in our Irvine, California facility in January 2016, which allows us to continue to register and import products into certain countries that require CFGs. We do not know what further actions, if any, the FDA will take in connection with these issues. If we are unable to resolve the issues raised by the FDA, our business, financial condition and results of operations could be adversely affected.

In December 2014, the California Department of Public Health, Food and Drug Branch (Food and Drug Branch) conducted an inspection of our facility in Irvine, California, and issued a Notice of Violation listing observations relating to complaint handling and CAPA procedures that the investigator believed may constitute violations of California statutes or regulations. We responded to the Notice of Violation in January 2015 and have completed various actions to address and resolve the issues raised by the Food and Drug Branch. The Food and Drug Branch did not respond to our communications from January 2015. We do not know what further actions, if any, the Food and Drug Branch will take in connection with these issues.

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 items:

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

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

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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 approval in foreign jurisdictions will prevent us from marketing our products abroad.

We currently market and intend to continue to market our products internationally. Outside of the U.S., we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The regulatory registration/licensing process varies among international jurisdictions and may require additional product testing. The time required for international registration of new products may differ from that required for obtaining FDA clearance. The foreign registration/licensing process may include similar risks to those associated with obtaining FDA clearance in addition to other risks. We may not obtain foreign regulatory registration/licensing on a timely basis, if at all. FDA clearance does not ensure new product registration/licensing by foreign regulatory authorities. 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 would 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 make it difficult to maintain or attain approval 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. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations 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 European Union (EU) markets 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 governmental authorities have the authority to require the recall of our commercialized products in the event of material deficiencies or defects in, for example, design, labeling or manufacture. In the case of the FDA, the authority to require a recall generally must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a

product if any material deficiency in a device is found or 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.

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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 recall must be reported to the FDA. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. From 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. Some of these field actions involved "reportable events" that were reported to the FDA and other foreign regulatory agencies 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. Although we may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. If the FDA determines that we or our OEM partners have promoted our products for off-label use or have made false or misleading or inadequately substantiated promotional claims, it could request that we or our OEM partners modify those promotional materials or take regulatory or enforcement actions, including the issuance of an untitled letter, 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 promotional or training materials to constitute promotion of an uncleared or unapproved use, which could also result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In either event, in addition to potential extensive fines and penalties, our reputation could be damaged and adoption of our products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

In addition 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 either false, misleading or deceptive, our products could be considered to be misbranded under the FDCA or to violate the Federal Trade Commission Act.

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

Although we do not provide health care services or receive payments directly from Medicare, Medicaid or other third-party payers for our products or the procedures in which our products are used, health care regulation by federal and state governments will impact our business. Health care fraud and abuse 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 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, and state laws governing the privacy of certain patient identifiable health information (PHI).

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Federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payers that are false or fraudulent. For example, the federal Civil False Claims Act imposes liability on any person or entity that, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and Medicare. Some suits filed under the 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, and some of these laws may apply to claims for items or services reimbursed under Medicaid and/or commercial insurance. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs and imprisonment. 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 $5,500 to $11,000 for each separate false claim.

In April 2011, we were informed by the U.S. Attorney's Office for the Central District of California, Civil Division, that a qui tam complaint had been filed against us in the U.S. District Court for the Central District of California by three of our former physician office sales representatives. The qui tam complaint alleged, among other things, that our noninvasive hemoglobin products failed to meet their accuracy specifications, and that we misled the FDA and customers regarding the accuracy of the products. In November 2011, the U.S. declined to intervene in the case, and in October 2013, the District Court granted summary judgment in our favor. The former sales representatives appealed the District Court's decision and an argument on the appeal was held in the Ninth Circuit Court of Appeals on February 1, 2016. On February 19, 2016, the Ninth Circuit Court of Appeals affirmed the summary judgment of the District Court.

In the third quarter of 2013, we were notified that the FDA and the U.S. Attorney's Office for the Central District of California, Criminal Division (USAO) were investigating the allegations regarding our noninvasive hemoglobin products. In the second quarter of 2014, we received grand jury subpoenas requesting documents pertaining to, among other things, the testing, marketing and sales of our Pronto® and Pronto-7® products. On May 7, 2015, we received a letter from the USAO stating that, as of the date of the letter, the USAO had decided not to initiate any criminal charges against us or any of our current or former employees in connection with its investigation. The USAO reserved the right to revisit its decision at any time.

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

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

Further, we are required to comply with 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 existing or new laws and regulations related to the protection of health information, we could be subject to criminal or civil sanctions, the potential enforcement of which is greater as a result of the Health Information Technology of Economic and Clinical Health Act.

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. In some cases, more protective state privacy and security laws are not preempted by HIPAA and may be subject to interpretation by various governmental authorities and courts, resulting in potentially complex compliance issues for us and our customers.

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

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. The outcomes of these proceedings are unpredictable and may result in significant liabilities, regardless of the merits of the claims made in the proceedings.

*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 as well as the way in which we conduct our business. In 2010, President Obama signed health care reform legislation into law that 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. Beginning on January 1, 2013, this legislation 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. Although President Obama signed into law a bill that included a two-year suspension of the medical device tax beginning January 1, 2016, such tax may be reimposed on medical device makers beginning on January 1, 2018 if such suspension is not extended or the medical device tax is not permanently repealed.

Moreover, the Physician Payment Sunshine Act (the Sunshine Act), which was enacted by Congress as part of the Patient Protection and Affordable Care Act on March 23, 2010, 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. Implementing regulations for these tracking and reporting obligations were finalized in 2013, and companies are now required to track payments made since August 1, 2013. 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.

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 reductions in 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. We cannot predict the effect any future legislation or regulation will have on us or what health care initiatives, if any, will be implemented at the state level. 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.

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

such legislation, regulation or policies that affect the coverage and reimbursement of our current or future products, or the procedures utilizing our current or future products, could cause our sales to decrease and our revenue to decline. 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

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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.

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. 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, the U.S. Congress, 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 increase transparency of interactions with health care providers, pursuant to which we are required by law to disclose payments and other transfers for 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 April 2, 2016, 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, is also the Chairman and Chief Executive Officer 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 and 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 Chief Executive Officer 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 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:

- delays 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 rene