MASIMO CORP
Form 10-Q
May 01, 2014
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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 March 29, 2014

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)
40 Parker 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 March 29, 2014
Common stock, $0.001 par value	56,737,132

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

	March 29, 2014	December 28, 2013
ASSETS		
Current assets		
Cash and cash equivalents	$117,529	$95,466
Accounts receivable, net of allowance for doubtful accounts of $1,868 and $1,833 at March 29, 2014 and December 28, 2013, respectively	74,065	76,759
Royalties receivable	7,500	7,300
Inventories	55,538	56,813
Prepaid expenses	10,437	9,243
Prepaid income taxes	908	3,740
Deferred tax assets	16,718	19,636
Other current assets	3,986	2,841
Total current assets	286,681	271,798
Deferred cost of goods sold	64,401	61,714
Property and equipment, net	25,486	24,866
Intangible assets, net	28,169	28,104
Goodwill	22,847	22,793
Deferred tax assets	22,552	22,565
Other assets	8,517	6,822
Total assets	$458,653	$438,662
LIABILITIES AND EQUITY		
Current liabilities		
Accounts payable	$33,685	$28,004
Accrued compensation	22,487	29,486
Accrued liabilities	16,448	23,028
Income taxes payable	2,533	2,406
Deferred revenue	21,680	20,755
Current portion of capital lease obligations	102	111
Total current liabilities	96,935	103,790
Deferred revenue	569	566
Capital lease obligations, less current portion	156	225
Other liabilities	7,550	7,680
Total liabilities	105,210	112,261
Commitments and contingencies		
Equity		
Masimo Corporation stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; 0 shares issued and outstanding at March 29, 2014 and December 28, 2013		—
Common stock, $0.001 par value; 100,000 shares authorized; 56,737 and 56,623 shares outstanding at March 29, 2014 and December 28, 2013, respectively	57	57
Treasury stock, 4,156 and 4,156 shares at March 29, 2014 and December 28, 2013, respectively	(83,454)	(83,454)
Additional paid-in capital	277,702	273,129

Accumulated other comprehensive income	4,014	3,995
Retained earnings	155,374	132,742
Total Masimo Corporation stockholders' equity	353,693	326,469
Noncontrolling interest	(250)	(68)
Total equity	353,443	326,401
Total liabilities and equity	$458,653	$438,662

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, except per share amounts)

	Three Months Ended	
	March 29, 2014	March 30, 2013
Revenue:		
Product	$132,232	$128,635
Royalty	7,582	7,307
Total revenue	139,814	135,942
Cost of goods sold	47,513	46,361
Gross profit	92,301	89,581
Operating expenses:		
Selling, general and administrative	56,122	52,273
Research and development	13,996	14,167
Litigation award and defense costs	(8,010)	—
Total operating expenses	62,108	66,440
Operating income	30,193	23,141
Non-operating income (expense)	200	(2,326)
Income before provision for income taxes	30,393	20,815
Provision for income taxes	7,902	4,413
Net income including noncontrolling interest	22,491	16,402
Net loss attributable to the noncontrolling interest	141	26
Net income attributable to Masimo Corporation stockholders	22,632	16,428
Other comprehensive income, net of tax:		
Foreign currency translation adjustments	19	153
Comprehensive income attributable to Masimo Corporation stockholders	$22,651	$16,581
Net income per share attributable to Masimo Corporation stockholders:		
Basic	$0.40	$0.29
Diluted	$0.39	$0.28
Weighted average shares used in per share calculations:		
Basic	56,705	57,240
Diluted	58,047	58,011

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	
	March 29, 2014	March 30, 2013
Cash flows from operating activities:		
Net income including noncontrolling interest	$22,491	$16,402
Adjustments to reconcile net income including noncontrolling interest to net cash provided by operating activities:		
Depreciation and amortization	3,043	2,783
Share-based compensation	2,601	3,413
Loss on disposal of property and equipment	2	78
Provision for doubtful accounts	232	142
Provision for deferred income taxes	2,926	—
Income tax benefit from exercise of stock options granted prior to January 1, 2006	24	12
Excess tax (benefit) deficit from share-based compensation arrangements	(31)	164
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	2,469	(72)
Increase in royalties receivable	(200)	(70)
(Increase) decrease in inventories	1,288	(1,109)
Increase in deferred cost of goods sold	(2,687)	(2,741)
Increase in prepaid expenses	(1,186)	(425)
Decrease in prepaid income taxes	2,832	1,492
(Increase) decrease in other assets	(2,831)	1,128
Increase in accounts payable	5,676	3,874
Decrease in accrued compensation	(6,996)	(3,405)
Increase (decrease) in accrued liabilities	(6,587)	341
Increase in income taxes payable	156	1,779
Increase in deferred revenue	929	1,102
Increase (decrease) in other liabilities	(130)	213
Net cash provided by operating activities	24,021	25,101
Cash flows from investing activities:		
Purchases of property and equipment	(2,840)	(1,839)
Increase in intangible assets	(886)	(1,107)
Net cash used in investing activities	(3,726)	(2,946)
Cash flows from financing activities:		
Repayments of capital lease obligations	(77)	(84)
Proceeds from issuance of common stock	1,918	463
Excess tax benefit (deficit) from share-based compensation arrangements	31	(164)
Repurchases of common stock	—	(12,431)
Repurchases of equity by noncontrolling interest	(42)	—
Net cash provided by (used in) financing activities	1,830	(12,216)
Effect of foreign currency exchange rates on cash	(62)	82
Net increase in cash and cash equivalents	22,063	10,021
Cash and cash equivalents at beginning of period	95,466	71,554
Cash and cash equivalents at end of period	$117,529	$81,575

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 (Masimo or the Company) is a global medical technology company that develops, manufactures and markets noninvasive patient monitoring products. 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 invented Masimo Signal Extraction Technology, or Masimo SET®, which provides the capabilities of Measure-Through Motion and Low Perfusion pulse oximetry to address the primary limitations of conventional pulse oximetry. The Company has also developed Masimo rainbow® SET products which monitor multiple blood measurements, including oxygen content, carboxyhemoglobin, methemoglobin and hemoglobin. Additional rainbow® SET measurements that assist clinicians are PVI®, RRa®, $SpfO_2$,™ Halo Index™ and In Vivo Adjustment.™ The Company develops, manufactures and markets a family of patient monitoring solutions which incorporate a monitor or circuit board and sensors, including proprietary single-patient use, reusable and resposable sensors, and cables. The Company sells to hospitals and the alternate care market through its direct sales force and distributors, and markets its circuit boards containing the Company's proprietary algorithm and software architecture to original equipment manufacturer (OEM) partners.

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, which include only normal recurring adjustments, necessary to present fairly the Company's condensed consolidated financial statements. The condensed consolidated balance sheet as of December 28, 2013 was derived from the Company's audited consolidated financial statements at that date. The accompanying condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 28, 2013, filed with the SEC on February 14, 2014. The results for the three months ended March 29, 2014 are not necessarily indicative of the results to be expected for the fiscal year ending January 3, 2015 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 the variable interest entity, or VIE, of which the Company is the primary beneficiary. All intercompany accounts 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 52-53 week fiscal year that ends on the Saturday closest to December 31. A 52 week 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 last 53 week fiscal year was fiscal year 2008. Fiscal year 2014 is a 53 week fiscal year. All references to years in these notes to condensed consolidated financial statements are fiscal years unless otherwise noted.

Use of Estimates

The Company prepares its financial statements in conformity with GAAP, which requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates include: determination of accounts receivable allowances, inventory reserves, warranty reserves, rebate reserves, 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, property taxes, litigation costs and related accruals. Actual results could differ from such estimates.

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

Reclassifications

Certain amounts in the condensed consolidated financial statements for prior periods have been reclassified to conform to 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 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 the fair value option under this guidance as to specific assets or liabilities. There were no transfers between Level 1, Level 2 and Level 3 inputs during the three months ended March 29, 2014. The Company carries cash and cash equivalents at cost, which approximates fair value. As of March 29, 2014 and December 28, 2013, the Company did not have any short-term investments.

The following tables represent the Company's fair value hierarchy for its financial assets (in thousands):

	Fair Value Measurement as of March 29, 2014 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
U.S. Treasuries	$36,998	$—	$—	$36,998
Money Market funds	1,792	—	—	1,792
Total	$38,790	$—	$—	$38,790

	Fair Value Measurement as of December 28, 2013 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
U.S. Treasuries	$25,997	$—	$—	$25,997
Money Market funds	1,793	—	—	1,793
Total	$27,790	$—	$—	$27,790

Accounts Receivable and Allowance for Doubtful Accounts

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

Intangible Assets

Costs to renew intangibles are capitalized and amortized over the remaining useful life of the intangible. As of March 29, 2014, the weighted average number of years until the next renewal is one year for patents and six years for trademarks.

The Company’s policy is to renew its patents and trademarks. 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.

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Impairment of Goodwill and Intangible 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 at least 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 March 29, 2014 or March 30, 2013.

Revenue Recognition

The Company follows the current authoritative guidance for revenue recognition. Based on these requirements, the Company recognizes revenue when: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. The Company enters into agreements to sell pulse oximetry and related products and services as well as multiple deliverable arrangements that include various combinations of products and services. While the majority of the Company's sales transactions contain standard business terms and conditions, there are some transactions that contain non-standard business terms and conditions. As a result, contract interpretation is sometimes required to determine the appropriate accounting including: (a) how the arrangement consideration should be allocated among the deliverables if there are multiple deliverables, (b) when to recognize revenue on the deliverables, and (c) whether undelivered elements are essential to the functionality of the delivered elements. Changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

The 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 of fair value (VSOE), (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, or 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® software, the Company has determined that the hardware and software components function together to deliver the equipment's essential functionality

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(unaudited)

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

The Company’s distributors primarily purchase sensor products which they then resell to hospitals that are typically fulfilling their purchase obligations to the Company under the end-user hospitals’ long-term sensor purchase commitments. Upon shipment to the distributor, revenue is deferred until the distributor ships the product to the Company’s customers based on an estimate of the inventory held by each distributor at the end of the accounting period. During the quarter ended March 29, 2014, the Company recorded a true-up to its deferred revenue estimate of approximately $2.6 million as a result of new information related to inventory on-hand at one distributor.

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

The Company also earns revenue from the sale of integrated circuit boards that use the Company’s software technology to OEMs as well as license fees for allowing certain OEMs the right to use the Company’s technology in their products. The license fee is recognized upon shipment of the OEM’s product to its customers, as represented to the Company by the OEM.

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 also records royalty revenue under a patent infringement settlement agreement with Covidien Ltd. (Covidien) based on the estimated U.S. sales of Covidien’s infringing products multiplied by the current royalty rate of 7.75%. This estimated revenue is adjusted prospectively when the Company receives the Covidien royalty report, approximately 60 days after the end of each quarter.

Product Warranty

The Company provides a warranty against defects in material and workmanship for a period ranging from six months to one year, depending on the product type. In the case of long-term sales agreements, the Company typically 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.

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MASIMO CORPORATION
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(unaudited)

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

	Three Months Ended	
	March 29, 2014	March 30, 2013
Warranty accrual, beginning of period	$1,161	$838
Provision for warranty costs	467	777
Warranty expenditures	(480)	(600)
Warranty accrual, end of period	$1,148	$1,015

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 related tax benefits, which have been excluded from net income including noncontrolling interest, and reflected in Masimo Corporation stockholders' equity.

The change in accumulated other comprehensive income is as follows (in thousands):

	Three Months Ended March 29, 2014
Accumulated other comprehensive income, beginning of period	$3,995
Foreign currency translation adjustments	19
Accumulated other comprehensive income, end of period	$4,014

Net Income Per Share

Basic net income per share attributable to Masimo Corporation for the three months ended March 29, 2014 and March 30, 2013 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 March 29, 2014 and March 30, 2013 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. For the three months ended March 29, 2014 and March 30, 2013, weighted options to purchase 2.8 million and 6.7 million shares of common stock, respectively, were outstanding, but were not included in the computation of diluted net income per share because the effect of including such shares would have been antidilutive in the periods presented. Based on authoritative accounting guidance, the Company adjusted its net income including noncontrolling interest by the amount of net loss attributable to the noncontrolling interest for the three months ended March 29, 2014 and March 30, 2013, to determine its net income attributable to its stockholders. A reconciliation of basic and diluted net income per share attributable to Masimo Corporation stockholders is as follows (in thousands, except per share amounts):

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

	Three Months Ended	
	March 29, 2014	March 30, 2013
Net income attributable to Masimo Corporation stockholders:		
Net income including noncontrolling interest	$22,491	$16,402
Net loss attributable to the noncontrolling interest	141	26
Net income attributable to Masimo Corporation stockholders	$22,632	$16,428
Basic net income per share attributable to Masimo Corporation stockholders:		
Net income attributable to Masimo Corporation stockholders	$22,632	$16,428
Weighted average shares outstanding - basic	56,705	57,240
Basic net income per share attributable to Masimo Corporation stockholders	$0.40	$0.29
Diluted net income per share attributable to Masimo Corporation stockholders:		
Weighted average shares outstanding	56,705	57,240
Diluted share equivalent: stock options	1,342	771
Weighted average shares outstanding - diluted	58,047	58,011
Diluted net income per share attributable to Masimo Corporation stockholders	$0.39	$0.28

Seasonality

The healthcare business in the United States and overseas is typically subject to quarterly fluctuations in hospital and other alternative care admissions. Over the past three years, the Company’s third fiscal quarter revenues have experienced a sequential decline from its second fiscal quarter revenues. The Company believes this is due primarily to the summer vacation season in which people throughout the world tend to shift their elective procedures out of the summer holiday season. Another factor affecting quarterly revenues is the traditional “flu season” that often increases hospital and acute care facility admissions during the Company’s first and/or fourth fiscal quarters. Because the Company's non-sales variable operating expenses often do not fluctuate in the same manner as its quarterly product sales, this may cause fluctuations in the Company’s quarterly operating income that are disproportionate to fluctuations in its quarterly revenue.

Recently Adopted Accounting Pronouncements

In July 2013, the FASB issued Accounting Standards Update No. 2013-11, or ASU 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. This update required companies to present an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, unless certain conditions exist. The Company adopted this update in fiscal year 2013 and such adoption did not have a material impact on the consolidated financial statements.

In July 2012, the FASB issued Accounting Standards Update No. 2012-2, or ASU 2012-2, Intangibles - Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment, to allow entities to use a qualitative approach to test indefinite-lived intangible assets for impairment. ASU 2012-2 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, then a quantitative impairment test that exists under current authoritative accounting guidance must be completed. Otherwise, the quantitative impairment test is not required. ASU 2012-2 was effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The Company adopted this update in fiscal year 2013 and such adoption did not have a material impact on the consolidated financial statements.

3. Variable Interest Entity (VIE)

The Company follows authoritative guidance for the consolidation of its 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.

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(unaudited)

Cercacor Laboratories, Inc. (Cercacor)

Cercacor is an independent entity spun off from the Company to its stockholders in 1998. Joe Kiani and Jack Lasersohn, members of the Company's board of directors, are also members of the board of directors of Cercacor. 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, or 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.

Under the Cross-Licensing Agreement, the Company granted Cercacor an exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET® owned by the Company, including all improvements on this technology, for the monitoring of non-vital signs measurements and to develop and sell devices incorporating Masimo SET® for monitoring non-vital signs measurements in any product market in which a product is intended to be used by a patient or pharmacist rather than a professional medical caregiver. The Company refers to this market as the Cercacor Market. The Company also granted Cercacor a non-exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET® for the measurement of vital signs in the Cercacor Market.

The Company exclusively licenses from Cercacor the right to make and distribute products in the professional medical caregiver markets, which the Company refers to as the Masimo Market, that utilize rainbow® technology for certain non-invasive measurements, including carbon monoxide, methemoglobin, fractional arterial oxygen saturation and hemoglobin. The Company also has the option to obtain exclusive licenses to make and distribute products that utilize rainbow® technology for the monitoring of other non-vital signs measurements, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver. To date, the Company has developed and commercially released devices that measure carbon monoxide, methemoglobin and hemoglobin using licensed rainbow® technology. The Company also markets certain other rainbow technologies, such as rainbow Acoustic Monitoring™, the rights to which are owned by the Company and for which no licensing fee is paid to Cercacor.

The Company's license to rainbow® technology for these parameters in these markets is exclusive on the condition that the Company continues to pay Cercacor royalties on its products incorporating rainbow® technology, subject to certain minimum aggregate royalty thresholds, and that the Company uses commercially reasonable efforts to develop or market products incorporating the licensed rainbow® technology. The royalty is up to 10% of the rainbow® royalty base, which includes handhelds, tabletop and multi-parameter devices. Handheld products incorporating rainbow® technology will carry up to a 10% royalty rate. For other products, only the proportional amount attributable for that portion of the Company's devices used to monitor non-vital signs measurements, rather than for monitoring vital signs measurements, and sensors and accessories for measuring only non-vital signs parameters, will be included in the 10% rainbow® royalty base. Effective January 2009, for multi-parameter devices, the rainbow® royalty base includes the percentage of the revenue based on the number of rainbow® enabled measurements. For hospital contracts where the Company places equipment and enters into a sensor contract, the Company pays a royalty to Cercacor on the total sensor contract revenues based on the ratio of rainbow® enabled devices to total devices.

The current annual minimum aggregate royalty obligation under the license 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 March 29, 2014 and March 30, 2013, respectively. In connection with a change in control of the Company, as defined in the Cross-Licensing Agreement, the minimum aggregate annual royalties for all licensed rainbow® measurements payable to Cercacor will increase to $15 million per year and up to $2 million per year for other rainbow® measurements.

In February 2009, in order to accelerate the product development of an improved hemoglobin spot-check measurement device, Pronto-7®, the Company's board of directors agreed to fund additional engineering expenses of Cercacor. Specifically, these expenses included third-party engineering materials and supplies expense as well as 50%

of Cercacor's total engineering and engineering-related payroll expenses, from April 2009 through June 2010, the original anticipated completion date of this product development effort. Since July 2010, Cercacor has continued to assist the Company with product development efforts and charged the Company accordingly. Beginning in 2012, due to a revised estimate of the support required by the Company to complete the various Pronto-7® related projects, the Company's board of directors approved an increase in the percentage of Cercacor's total engineering and engineering-related payroll expenses funded by the Company from 50% to 60%. During the three months ended March 29, 2014, and until both parties agree to end these services, Cercacor assisted and will continue to assist the Company with the continuing development efforts related to the new handheld noninvasive multi-parameter spot-

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check hemoglobin testing device. During the three months ended March 29, 2014 and March 30, 2013, the expenses for these additional services, materials and supplies totaled $0.9 million and $1.1 million, respectively.

Pursuant to authoritative accounting guidance, Cercacor is consolidated within the Company's financial statements for all periods presented. The Company is required to consolidate Cercacor since the Company is currently deemed to be the primary beneficiary of Cercacor's activities. This determination is based primarily on the Company's obligation to absorb Cercacor's expected losses, as well as the Company's ability to direct the activities that most significantly impact Cercacor's economic performance. Accordingly, 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 the consolidation. Also, all direct engineering expenses that have been incurred by the Company and charged to Cercacor, or that have been incurred by Cercacor and charged to the Company, have not been eliminated and are included as research and development expense in the Company's condensed consolidated statements of comprehensive income. Upon consolidation, $6.9 million and $7.0 million of deferred revenue related to technology licensed to the Company as of March 29, 2014 and December 28, 2013, respectively, were eliminated. In addition, a net receivable of $1.3 million and $2.0 million due from the Company as of March 29, 2014 and December 28, 2013, respectively, were eliminated.

Assets of Cercacor can only be used to settle obligations of Cercacor and creditors of Cercacor have no recourse to the general credit of the Company. The condensed consolidated balance sheets include a noncontrolling interest in Cercacor of $(0.2) million and ($0.1) million as of March 29, 2014 and December 28, 2013, respectively, which represents the value of common stock, additional paid in capital and retained earnings of Cercacor, which are not available to the Company. In addition, the condensed consolidated balance sheets include, net of intercompany eliminations, total assets of $6.9 million and $7.0 million as of March 29, 2014 and December 28, 2013, respectively, related to Cercacor. Cercacor's total assets as of March 29, 2014 included $4.8 million for intangible assets and $1.8 million for property and equipment. Its total assets as of December 28, 2013 included $4.7 million for intangible assets and $1.9 million for property and equipment. The Company's condensed consolidated balance sheets include total liabilities, net of intercompany eliminations, of $1.8 million and $2.3 million as of March 29, 2014 and December 28, 2013, respectively, related to Cercacor.

For the foreseeable future, the Company anticipates that it will continue to consolidate Cercacor pursuant to the current authoritative accounting guidance; however, in the event that Cercacor is no longer considered a VIE or in the event that the Company is no longer the primary beneficiary of Cercacor, the Company may discontinue consolidating the entity.

The changes in noncontrolling interest for Cercacor are as follows (in thousands):

	Three Months Ended March 29, 2014
Noncontrolling interest, beginning of period	$(68)
Increase in additional paid-in capital of noncontrolling interest	(41)
Net loss attributable to noncontrolling interest	(141)
Noncontrolling interest, end of period	$(250)

4. 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. As of March 29, 2014, the Company's cash balance was $78.7 million, which was comprised of checking accounts. Additionally, the Company had cash equivalents of $38.8 million, consisting of $37.0 million of U.S. Treasury bills and $1.8 million of money market funds. As of December 28, 2013, the Company's cash balance was $67.7 million, comprised of checking accounts. Additionally, the Company had cash equivalents of $27.8 million, consisting of $26.0 million of U.S. Treasury bills and $1.8 million of money market funds.

5. Royalties Receivable

The royalty receivable of $7.5 million as of March 29, 2014 represents the Company's estimated amount due for the three months ended March 29, 2014. Pursuant to the settlement agreement, as amended, with Nellcor Puritan Bennett, Inc. (currently Covidien Ltd., or Covidien), the royalties are paid to the Company based on a percentage of sales of Covidien U.S. based pulse oximetry products. The Company recognizes royalty revenue based on the royalty rate per the settlement agreement multiplied by its estimate of Covidien's sales for each quarter. Any adjustments to the quarterly estimate are recorded prospectively in the

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following quarter, when the Company receives the Covidien royalty report and payment, which is generally 60 days after the end of each of Covidien's fiscal quarters.

6. Inventories

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

	March 29, 2014	December 28, 2013
Raw materials	$27,533	$26,758
Work in-process	6,189	6,310
Finished goods	21,816	23,745
Total	$55,538	$56,813

7. Intangible Assets

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

	March 29, 2014	December 28, 2013
Cost		
Patents	$19,536	$18,750
Customer relationships	7,669	7,669
Acquired technology	5,580	5,580
Trademarks	3,366	3,338
Capitalized software development costs	1,611	1,612
Other	991	969
Total cost	$38,753	37,918
Accumulated amortization		
Patents	(5,931)	(5,679)
Customer relationships	(1,278)	(1,086)
Acquired technology	(973)	(834)
Trademarks	(705)	(653)
Capitalized software development costs	(1,315)	(1,270)
Other	(382)	(292)
Total accumulated amortization	(10,584)	(9,814)
Net carrying amount	$28,169	$28,104

Total amortization expense for the three months ended March 29, 2014 and March 30, 2013 was $0.8 million and $0.7 million, respectively. Estimated amortization expense for future fiscal years is as follows (in thousands):

Fiscal year	Amount
2014 (balance of year)	$3,033
2015	2,820
2016	2,561
2017	2,491
2018	2,333
Thereafter	14,931
Total	$28,169

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8. Stock Repurchase Program

In February 2013, the Company's board of directors authorized the repurchase of up to 6.0 million shares of the Company's common stock under a new stock repurchase program. The stock 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 10b5-1trading plans, block trades and in privately negotiated transactions. During the three months ended March 29, 2014, no shares were repurchased under the new repurchase program. During the three months ended March 30, 2013, 0.8 million shares were repurchased, at an average price of $19.77 per share, for a total repurchase price of $15.4 million.

9. Share-Based Compensation

On August 7, 2007, in connection with the Company's initial public offering, the 2007 Stock Incentive Plan, or the 2007 Plan, became effective. Under the 2007 Plan, 3.0 million shares of common stock were initially reserved for future issuance, plus shares available under the prior year equity incentive plans. The options generally vest annually over five years using the straight-line method, unless otherwise provided, and expire ten years from the date of grant. Options granted under the 2007 Plan and the prior year equity incentive plans that for any reason expire, are forfeited, are canceled or become unexercisable under any of the Company's stock incentive plans are automatically added to the share reserve of the 2007 Plan. Pursuant to the "evergreen" provision contained in the 2007 Plan, approximately 1.7 million additional shares of common stock were added to the share reserve of the 2007 Plan on each of January 4, 2009, January 3, 2010, January 1, 2012, December 30, 2012 and December 29, 2013, which represented 3% of the Company's total shares outstanding as of each of January 3, 2009, January 2, 2010, December 31, 2011, December 29, 2012 and December 28, 2013. No shares were added to the share reserve for the year ended January 1, 2011. Subject to applicable laws, the Company may terminate the 2007 Plan at any time. If not terminated sooner, the 2007 Plan will automatically terminate on August 7, 2017.

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

	Three Months Ended March 29, 2014	
	Shares	Average Exercise Price
Options outstanding, beginning of period	8,911	$22.76
Granted	824	$28.14
Canceled	(65)	$24.42
Exercised	(114)	$16.63
Options outstanding, end of period	9,556	$23.28
Options exercisable, end of period	5,598	$23.01
Options available for grant, end of period	6,472	

The Black-Scholes option pricing model is used to estimate the fair value of options granted under the Company's share-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	
	March 29, 2014	March 30, 2013
Risk-free interest rate	1.53% to 1.6%	0.9% to 1.0%
Expected term	5.1 years	5.5 years
Estimated volatility	32.5% to 32.8%	37.3% to 39.6%
Expected dividends	0%	0%
Weighted-average fair value of options granted	$8.89	$7.34

The total share-based compensation expense for the three months ended March 29, 2014 and March 30, 2013 was $2.6 million and $3.4 million, respectively. The aggregate intrinsic value of options outstanding, with an exercise price less than the closing price of the Company's common stock, as of March 29, 2014 was $44.1 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 March 29, 2014 was $29.9 million. The aggregate intrinsic value of options exercised during the three months ended March 29, 2014 was $1.5 million.

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The aggregate intrinsic value 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 unrecognized share-based compensation as of March 29, 2014 was $29.2 million related to unvested options granted after January 1, 2006. 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 March 29, 2014 was 6.2 years. The weighted average remaining contractual term of options exercisable, with an exercise price less than the closing price of the Company's common stock, as of March 29, 2014 was 4.3 years.

10. Commitments and Contingencies

Leases

The Company leases its facilities in North America, Europe and Asia under operating lease agreements expiring at various dates through December 2020. Certain facilities 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 also received certain leasehold improvement incentives totaling $0.7 million for its headquarters facilities in the U.S. These leasehold improvement incentives have been recorded as deferred rent and are being amortized as a reduction to rent expense on a straight-line basis over the life of the lease. As of both March 29, 2014 and March 30, 2013, rent expense accrued in excess of the amount paid aggregated $0.7 million and is classified in other liabilities in the accompanying condensed consolidated balance sheets. In addition, the Company leases automobiles in Europe that are classified as operating leases and expire at various dates through June 2015. The majority of these leases are non-cancelable. The Company also has outstanding capital leases for office equipment and computer equipment, all of which are non-cancelable.

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 March 29, 2014		
	Operating Leases	Capital Leases	Total
2014 (balance of year)	$6,874	$37	$6,911
2015	7,272	87	7,359
2016	3,777	80	3,857
2017	1,698	75	1,773
2018	1,516	—	1,516
Thereafter	2,174	—	2,174
Total	$23,311	$279	$23,590

Rental expense related to operating leases was $1.6 million and $1.3 million for the three months ended March 29, 2014 and March 30, 2013, respectively. The Company leases office equipment and computer equipment, which have interest rates ranging from 4.3% to 12.0% per year and mature on various dates from July 2014 through October 2017.

Employee Retirement Savings Plan

In 1996, the Company adopted the Masimo Retirement Savings Plan, or the Plan, which is a 401(k) 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. The Company contributed $0.6 million and $0.4 million to the Plan for the three months ended March 29, 2014 and March 30, 2013, respectively.

Employment and Severance Agreements

As of March 29, 2014, the Company had an employment agreement with one of its key employees that provides for an aggregate annual base salary with annual increases at the discretion of the Compensation Committee of the board of directors. The employment agreement provides for an annual bonus based on the Company's attainment of certain objectives and goals. The agreement has an initial term of three years, with automatic daily renewal, unless either the

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

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As of March 29, 2014, the Company had severance plan participation agreements with six of its executive officers. The participation agreements, or Agreements, are governed by the terms and conditions of the Company's 2007 Severance Protection Plan, or Severance Plan, which became effective on July 19, 2007 and which was amended effective December 31, 2008. Under each of the Agreements, each 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 $60.7 million of purchase commitments as of March 29, 2014, which are expected to be purchased within one year. These purchase commitments were made for certain inventory items to secure better pricing and to ensure the Company will have raw materials when necessary.

Concentrations of Risk

The Company is exposed to credit loss for the amount of cash deposits with financial institutions in excess of federally insured limits. The Company invests its excess cash deposits in U.S. Treasury bills and money market accounts with major financial institutions. As of March 29, 2014, the Company had $78.7 million of bank balances, of which $2.6 million was covered by either the U.S. Federal Deposit Insurance Corporation limit or foreign countries' deposit insurance organizations. As of March 29, 2014, the Company had $1.8 million in money market funds 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 may be easily modified to use a different component. 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 March 29, 2014 and March 30, 2013, revenue from the sale of the Company's products to U.S. hospitals that are members of GPOs amounted to $75.2 million and $73.5 million, respectively.

As of March 29, 2014, two different just-in-time distributors each represented 7% and 8% of the accounts receivable balance. As of December 28, 2013, two different just-in-time distributors each represented 8% and 9% of the accounts receivable balance.

For the three months ended March 29, 2014, the Company had sales through two just-in-time distributors, which each represented 15% and 9% of the total revenue. For the three months ended March 30, 2013, the Company had sales through two just-in-time distributors, which each represented 14% and 11% of the total revenue. For both periods, the just-in-time distributors took and fulfilled orders from the Company's direct customers, many of whom have signed long-term sensor agreements with the Company.

For the three months ended March 29, 2014 and March 30, 2013, the Company recorded $7.6 million and $7.3 million, respectively, in royalty revenues from Covidien pursuant to the original settlement agreement and amendments. In exchange for these royalty payments, the Company has provided Covidien the ability to ship its patent infringing product with a covenant not to sue Covidien as long as Covidien abides by the terms of the agreement. The current royalty rate is 7.75% and the amended agreement can be terminated by Covidien upon sixty days written notice.

Litigation

On February 3, 2009, the Company 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. The suit was brought in the U.S. District Court for the District of Delaware. Two patents originally asserted in this suit, related to the Company’s Measure-Through Motion technology, were successfully enforced in the Company’s previous suit against Nellcor. 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 on 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, 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. On October 4, 2010, the Court limited the number of patents to be construed to four for the Company and three for Philips. Further, on October 6, 2010, the Court denied Philips' motion to bifurcate and stay damages in the patent case. On January 17, 2012, the District Court Judge issued a claim construction order. In 2012, the parties completed expert reports and discovery on some of the patents. In addition, in 2012, the Company asserted additional patents, and the Court ordered that these patents and some of the originally asserted patents be tried in a second phase. In 2013, the Magistrate Judge issued reports and recommendations relating to various summary judgment motions filed by the parties. On December 2, 2013, the Court heard oral argument on the parties' objections to the Magistrate Judge's reports and recommendations. On March 31, 2014, the District Court Judge ruled on the objections. On April 14, 2014, the parties filed motions for reconsideration of certain rulings. The parties have requested a trial date in September 2014. The Company believes that it has good and substantial defenses to the antitrust and patent infringement claims asserted by Philips. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

On December 21, 2012, the Company filed suit against Mindray DS USA, Inc. and Shenzhen Mindray Bio-Medical Electronics Co, Ltd. (Shenzhen Mindray) in the U.S. District Court for the Central District of California. The complaint alleges patent infringement, breach of contract and other claims. Mindray DS USA, Inc. was dismissed from this case based on venue. On June 3, 2013, Shenzhen Mindray answered the Company's complaint and filed antitrust and related counterclaims against the Company, as well as counterclaims seeking declaratory judgments of invalidity and non-infringement on the patents asserted by the Company against Shenzhen Mindray. On June 24, 2013, the Company filed its answer denying Shenzhen Mindray's counterclaims and asserting various defenses. On July 17, 2013, the Court granted Shenzhen Mindray's motion to dismiss the patent claims without prejudice to allow the Company to amend the complaint to provide additional detail supporting Shenzhen Mindray's direct and indirect infringement of the Company's patents. On the same day, the Court denied Shenzhen Mindray's motion to dismiss the Company's non-patent claims. On August 5, 2013, the Company filed a first amended complaint. On August 21, 2013, Shenzhen Mindray answered the Company's complaint and reasserted the counterclaims it asserted on June 3, 2013, as well as two additional counterclaims alleging patent infringement. On September 16, 2013, the Company filed its answer denying Shenzhen Mindray's counterclaims and asserting various defenses. On October 31, 2013, the Court issued a scheduling order setting a trial date of November 4, 2014. On December 10, 2013, Shenzhen Mindray filed a second amended answer and counterclaims, including a new counterclaim for tortious interference. On January 2, 2014, the Company filed a motion for judgment on the pleadings as to Shenzhen Mindray's antitrust counterclaims and inequitable conduct counterclaims and defenses. The Court granted judgment on the pleadings with leave to amend. On March 27, 2014, Shenzhen Mindray filed a third amended answer and counterclaims. On April 10, 2014, Shenzhen Mindray filed a fourth amended answer and counterclaims, which motion is pending before the Court. The Company believes that it has good and substantial defenses to the antitrust, patent infringement and other counterclaims asserted by Shenzhen Mindray. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

On December 10, 2013, the Company filed suit against Mindray DS USA, Inc., Shenzhen Mindray and Mindray Medical International Ltd. in the Superior Court of New Jersey. The complaint alleges breach of contract and related claims. On January 17, 2014, Mindray DS USA filed a notice of removal removing the case to the U.S. District Court for the District of New Jersey. On January 24, 2014, Mindray DS USA, Inc. filed a motion seeking to dismiss or stay the action in view of the Company's action against Shenzhen Mindray in the Central District of California. That

motion is pending before the Court and no order from the Court has issued. On April 15, 2014, Mindray Medical International filed a motion to dismiss based on lack of personal jurisdiction, challenging service of process, and alleging that the Company failed to state a claim. That motion is also pending before the Court. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

In September 2012, a shareholder derivative lawsuit was filed in the U.S. District Court for the District of Delaware by Joseph Ausikaitis naming the Company's directors and certain executive officers as defendants and the Company as the nominal defendant. The lawsuit alleges claims of breach of fiduciary duty and unjust enrichment in connection with the grant or receipt of stock options under the Company's 2007 Stock Incentive Plan and related policies. The lawsuit seeks unspecified money damages on the Company's behalf from the officer and director defendants, various forms of equitable and/or injunctive relief, attorneys' and other professional fees and costs and various other forms of relief. In November 2012, the defendants filed a

motion to dismiss the action, which was denied by the court in July 2013. Although the outcome in this case cannot be determined, the Company does not expect it to have a material financial impact on its results of operations.

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 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 the Company's favor. The former sales representatives are appealing the District Court's decision.

In September 2011, two of the same former sales representatives also 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, which the Company accrued in fiscal 2013. In addition, the Company's insurance carrier notified the Company that it believed certain defense costs related to the arbitration may no longer be reimbursable in view of the arbitration decision. As a result, the Company accrued a liability of $2.6 million in fiscal 2013 for the costs estimated to have been paid by the insurance carrier. 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. Accordingly, the Company reversed the $8.0 million charge in the quarter ended March 29, 2014. The former sales representatives are appealing the District Court's decision. The Company is unable to predict the final outcome of the qui tam and employment matters. A reversal of the District Court's decision in either matter could have a material adverse effect on the Company's financial condition or results of operations in the future.

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 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). The motion to stay is pending. The Company believes it has good and substantial defenses to the claims, but there is no guarantee that the Company will prevail.

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. A previous version of the complaint also alleged a wrongful death claim, which the court dismissed on January 22, 2014. The amended complaint seeks unspecified damages, costs, interest, attorney fees, and injunctive and other relief. The Company believes it has good and substantial defenses to the remaining claims, but there is no guarantee that the Company will prevail.

From time to time, the Company may be involved in other litigation relating to claims arising out of its operations in the normal course of business. The Company believes that it currently is not a party to any 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.

11. 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.

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(unaudited)

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					
	March 29, 2014			March 30, 2013		
Geographic Area by Destination						
North and South America	$92,652	70.1	%	$98,722	76.7	%
Europe, Middle East and Africa	27,012	20.4		18,836	14.6	
Asia and Australia	12,568	9.5		11,077	8.6	
Total product revenue	$132,232	100	%	$128,635	100	%
United States	$88,047			$94,269		

12. Income Taxes

The Company has provided for income taxes in fiscal 2014 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 management judgment. The Company’s judgment 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. A valuation allowance has been previously recorded against all of the deferred tax assets of Cercacor. On a quarterly basis, Cercacor's management reassesses the need for these valuation allowances based on operating results and its assessment of the likelihood of future taxable income and developments in the relevant tax jurisdictions. Cercacor continues to maintain a full valuation allowance as of March 29, 2014 against its net deferred tax assets.

As of March 29, 2014, the liability for income taxes associated with uncertain tax positions was approximately $6.7 million. If fully recognized, approximately $5.7 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 for each year through 2009. All material state, local and foreign income tax matters have been concluded for each year through 2006.

13. Subsequent Event

On April 23, 2014, the Company entered into a five-year revolving credit facility with JPMorgan Chase Bank, National Association (the Bank), that matures on April 23, 2019 (the Credit Facility). The Credit Facility provides for up to an aggregate of $125 million in borrowings in multiple currencies. Borrowings under the Credit Facility will be deemed, at the Company’s election, either: (i) an ABR Loan, which bears interest at the Alternate Base Rate (as defined below) plus a spread of 0.225% to 1.250% based on the Company’s Total Leverage Ratio (as defined in the Credit Facility), or (ii) a Eurodollar Loan, which bears interest at the Adjusted LIBO Rate (as defined below) plus a spread of 1.125% to 2.250% based on the Company's Total Leverage Ratio. The Company may also request swingline loans from time to time, subject to certain conditions (Swingline Loans) that bear interest similar to an ABR Loan.

The Alternate Base Rate 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 1.00%. The Adjusted LIBO Rate is equal to LIBOR for the applicable interest period multiplied by the statutory reserve rate for such period.

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(unaudited)

The Company is obligated under the Credit Facility to pay a fee ranging from to 0.225% to 0.300% per annum, based upon the Company's Total Leverage Ratio, with respect to any unused portion of the Credit Facility. 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 Credit Facility, the Company is subject to certain customary financial and negative covenants. The Company's obligations under the Credit Facility are secured by substantially all of the Company's personal property, including all equity interests in domestic subsidiaries and first-tier foreign subsidiaries. Proceeds from the Credit Facility will be used for general corporate, capital investment and working capital purposes.

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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 December 28, 2013, which we filed with the SEC on February 14, 2014. 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 OEM partners to hospitals, emergency medical service (EMS) 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 arterial blood oxygen saturation and pulse rate monitoring, known Masimo Signal Extraction Technology® (Masimo SET®) pulse oximetry. Pulse oximetry enables the noninvasive measurement of the oxygen saturation level of arterial blood, which delivers oxygen to the body's tissues. Pulse oximetry also enables the measurement of pulse rate, which when measured by an electrocardiography (ECG) is called heart rate. Pulse oximetry is one of the most common measurements taken in and out of hospitals around the world. Most pulse oximeter technologies work well when patients are well perfused and not moving. However, when either or both of these conditions occur, conventional pulse oximeters frequently do not provide any measurements, or provide inaccurate measurements. We invented Masimo SET®, which, for the first time, allows pulse oximeters to provide accurate measurements even during patient motion and low perfusion conditions.

The performance of Masimo SET® pulse oximetry is proven by more than 100 independent and objective studies and thousands of clinical evaluations. We believe that Masimo SET® is trusted by clinicians to safely monitor approximately 100 million patients each year and is used hospital-wide by eight of the top ten hospitals on the U.S. News & World Report Best Hospitals Honor Roll (2013-2014). Compared to other pulse oximeters during patient motion and low perfusion, Masimo SET® provides measurements when other pulse oximeters cannot, dramatically reduces false alarms (specificity), and accurately detects true alarms (sensitivity) that can indicate a deteriorating patient condition. Masimo SET® pulse oximetry has also been shown to improve patient outcomes by helping clinicians reduce retinopathy of prematurity (ROP) in neonates, screen newborns for critical congenital heart disease (CCHD), 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.

After introducing Masimo SET®, we have continued to innovate by introducing breakthrough noninvasive measurements that go beyond arterial blood oxygen saturation and pulse rate, and which create new market opportunities in both the hospital and non-hospital care settings. Our product offerings have expanded significantly over the years to also include noninvasive blood constituent, brain and breath monitoring, including rainbow® Pulse CO-Oximetry, brain function electroencephalogram (EEG) monitoring, respiration rate, capnography and anesthetic agent monitoring. In addition, we have developed the Root™ patient monitoring and connectivity platform and Patient SafetyNet™ remote patient surveillance monitoring system.

Our rainbow® Pulse CO-Oximetry utilizes both Masimo SET® and licensed rainbow® technology. We believe rainbow® Pulse CO-Oximetry includes the first devices cleared by the U.S. Food and Drug Administration (FDA) to noninvasively and

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continuously monitor multiple blood-based measurements using multiple wavelengths of light, and which previously was only possible through intermittent invasive procedures. SpCO® provides noninvasive and continuous measurement of carboxyhemoglobin, or carbon monoxide levels in the blood. Carbon monoxide is the most common cause of poisoning in the world. When used with other clinical variables, SpCO® may help clinicians and emergency responders detect carbon monoxide poisoning and help determine treatment and additional test options. SpMet® provides noninvasive and continuous measurement of methemoglobin levels in the blood. Elevated methemoglobin in the blood leads to a dangerous condition known as methemoglobinemia, which occurs as a reaction to some common drugs used in hospitals and outpatient procedures. When used with other clinical variables, SpMet® may help clinicians detect methemoglobinemia and help determine treatment and additional test options. SpHb® provides noninvasive and continuous measurement of total hemoglobin. Hemoglobin is the oxygen-carrying component of red blood cells (RBC) and, along with oxygen saturation, determines the oxygen content of blood. Hemoglobin measurement is one of the most frequent invasive laboratory measurements in the world and is often measured as part of a complete blood count (CBC), which measures multiple other blood components. A low hemoglobin status is called anemia, which is generally caused by bleeding or the inability of the body to produce RBCs. SpHb® is available as a continuous monitor or a spot check measurement. Continuous SpHb® monitoring provides real-time visibility into the changes, or lack of changes, in hemoglobin, which can otherwise only be measured through intermittent, invasive blood testing. SpHb® has been shown to help clinicians reduce the number of RBC transfusions and, in multiple cases, has demonstrated its lifesaving ability in helping clinicians detect internal bleeding. Spot check SpHb® measurement, when used with other clinical variables, may help clinicians assess whether a patient's hemoglobin is lower or higher than may otherwise be assessed without any hemoglobin measurement, which in turn, may help determine additional test options.

Available in both Masimo SET® and rainbow® SET® sensors, Pleth Variability Index (PVI®), provides for the noninvasive and continuous measurement of fluid responsiveness in patients whose breathing is controlled through mechanical ventilation, such as in the operating room or intensive care unit. Fluid administration is critical to optimizing fluid status in surgery and critical care, but traditional invasive methods to guide fluid administration often fail to help clinicians assess fluid responsiveness. Newer methods are complicated and costly and considered appropriate only for the highest-risk patients. When used with other clinical variables, PVI® may help clinicians assess fluid responsiveness and help determine treatment options.

Our sound-based monitoring technology called rainbow Acoustic Monitoring™ (RAM™) enables noninvasive monitoring of respiration rate (RRa®). Respiration rate is the number of breaths per minute. A low respiration rate is indicative of respiratory depression and a high respiration rate is indicative of patient distress. Traditional methods used to measure respiration rate are often considered inaccurate, such as impedance pneumography, or are not tolerated well by certain patients, such as capnography. When used with other clinical variables, RRa® may help clinicians assess respiratory status and determine treatment options. RAM™ technology is available from the same circuit board as Masimo SET® and rainbow® Pulse CO-Oximetry measurements, which together we refer to as the rainbow® SET technology platform.

Our SedLine® brain function monitoring product measures the brain's electrical activity and provides information about a patient's response to anesthesia. SedLine® may help clinicians assess depth of anesthesia to optimize anesthesia and avoid over- or under-titration of anesthetics.

Although not currently available for sale in the U.S., we received the CE Mark for respiration rate from the plethysmograph waveform (RRp)™ in 2011. RRp™ enables monitoring of breathing status from a standard Masimo SET® pulse oximetry or rainbow® Pulse CO-Oximeter sensor®. The RRp™ measurement is determined by the variations in the plethysmograph waveform due to respiration, although the measurement is not possible in all patients or many conditions and may not immediately indicate changes in respiration rate. For patients requiring accurate and sensitive respiration rate monitoring, we believe that our acoustic respiration rate (RRa®) measurement is better at detecting pauses in breathing than RRp.™ The RRa® measurement also provides an important visual indication of breathing through the displayed acoustic waveform.

Patient SafetyNet™ provides a patient surveillance or remote monitoring and clinician notification solution which includes Masimo SET® or rainbow® SET platform measurements at the patient's bedside along with a central

assignment station and wired or wireless server. Patient SafetyNet™ wirelessly notifies clinicians caring for multiple patients in different rooms when one of their patients has an alarm, allowing them to become aware of changing conditions and intervene sooner, at times with life-saving support. Masimo SET®, along with Patient SafetyNet,™ is proven to help clinicians avoid deaths while preventing ICU transfers, rapid response activations and preventable deaths on the medical/surgical floors of the hospital. Today, the majority of medical/surgical floors in the hospital are not continuously monitored. Halo Index™ can be used with our Patient SafetyNet™ to allow continuous global trending and assessment of multiple physiological measurements of a patient with a single number displayed on the Patient SafetyNet™ screen. Halo Index™ is CE marked, but not currently available for sale in the U.S.

Our universal “Board-in-Cable” pulse oximetry solution, uSpO2,™ enables easier and faster integration of our products for OEM partners due to the ability to integrate Masimo SET® through software only. SpfO2,™ a new parameter not currently

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available for sale in the U.S., has received the CE mark and allows for the noninvasive measurement of fractional arterial oxygen saturation. Previously, pulse oximeters could only measure and display functional oxygen saturation (SpO2), so when patients had elevated carboxyhemoglobin and/or elevated methemoglobin, the displayed functional oxygen saturation overestimated the actual oxygen saturation value. SpfO2™ allows more precise arterial oxygenation assessment in patients with elevated dyshemoglobins, common throughout the hospital and pre-hospital setting, compared to functional oxygen saturation.

Our portfolio of Phasein™ capnography and gas monitoring products range from OEM solutions for external "plug-in-and-measure" analyzers and integrated modules to handheld devices. With multiple measurements delivered through either mainstream or sidestream options, our customers can benefit from CO_2, N_2O, O_2 and anesthetic agent monitoring in many hospital and pre-hospital environments, such as the operating room (OR), procedural sedation, ICU and EMS scenarios. In addition, our EMMA™ capnograph with waveform display offers clinicians greater assessment of end-tidal carbon dioxide (EtCO2) and respiration rate, as well as assists in recognition of return to spontaneous circulation, for a variety of clinical settings, including emergency medicine and transport, ORs, ICUs, patient rooms and clinics. EMMA™ fits in the palm of the hand, and we believe it is the smallest and most portable capnograph in the world.

iSpO2® uses Masimo SET® technology for Measure-Through Motion and Low Perfusion performance to deliver measurements through a pulse oximeter cable and sensor with technology to an iPhone, iPad or iPod touch. The first version of iSpO2® allows consumers to use their iPhone, iPad or iPod touch to check their own arterial blood oxygen saturation (SpO2), pulse rate and perfusion index measurements. In the U.S., iSpO2® is available online for sports and aviation use only, and is not intended for medical use. In October 2013, iSpO2® was released in Japan for iPhone, iPad and iPod touch. In December 2013, we received the CE mark on iSpO2® for the Android operating system, enabling functionality on select Android-based phones outside of the U.S. The iSpO2® Rx, the professional version for medical use, also received the CE mark in December 2013. The iSpO2® Rx product is not yet available in the U.S. but is available outside of the U.S.

In June 2013, we announced the CE Mark and limited international market release of our Root™ platform. Root™ is a powerful new patient monitoring and connectivity platform that integrates our breakthrough rainbow® and SET® measurements with multiple additional parameters being made available through Masimo Open Connect™ (MOC-9™) in an integrated, clinician-centric platform. The first two MOC-9™ technologies for Root™ were SedLine® brain function monitoring and Phasein™ capnography. In January 2014, we announced the CE Mark for O3™ regional oximetry, our third MOC-9™ technology for Root,™ which provides for continuous and simultaneous measurement of tissue oxygen saturation (rSO2) and SpO2 to help detect regional hypoxemia that pulse oximetry alone can miss. Iris™ connectivity in Root™ enables third-party devices such as intravenous pumps and ventilators to connect through Root™ enabling display, notification and documentation to the electronic medical record through Masimo Patient SafetyNet.™ In combination with a Radical-7® handheld device using rainbow® Pulse CO-Oximetry and rainbow® Acoustic Monitoring,™ Root™ will help clinicians instantly interpret and quickly change display of multiple measurements, helping to simplify patient care workflows and empower caregivers to help make quicker patient assessments, earlier interventions and better clinical decisions throughout the continuum of care. Phasein™ capnography, O3™ and certain other Root™ features such as wireless radio and Iris™ connectivity are not available for sale in the U.S.

Our pulse oximetry technology is generally contained on a circuit board which is placed inside a standalone pulse oximetry monitor, placed inside OEM multiparameter monitors or included as part of an external "Board-in-Cable" solution which is plugged into a port on an OEM or other device. All of these solutions use our proprietary single-patient use and reusable sensors and cables. We sell our products to end-users through our direct sales force and certain distributors, as well as our OEM partners, for incorporation into their products. In 2013, we also began selling our pulse oximetry products in the consumer market. As of March 29, 2014, we estimate that the worldwide installed base of our pulse oximeters and OEM monitors that incorporate Masimo SET® and rainbow® SET was more than 1.2 million units, excluding handheld devices. Our installed base is the primary driver for the recurring sales of our pulse oximeter and Pulse CO-Oximeter sensors, most notably single-patient adhesive sensors. Based on industry reports, we estimate that the worldwide pulse oximetry market is nearly $1.5 billion in 2014, the largest component being sensors. Our strategy is to utilize the accuracy and broad clinical benefits of our technologies to:

1) be the leading choice for pulse oximetry in traditionally monitored areas, in and out of the hospital;
2) expand the use of pulse oximetry beyond the critical care settings, including to the general floor of the hospital;
3) create demand for the use of breakthrough rainbow® measurements by our hospital customers;
4) offer rainbow® measurements to new markets such as EMS, and the physician office;
5) penetrate existing noninvasive specialty monitoring markets such as capnography, gas, brain function, and other modalities with technologies that offer clinical and financial advantages; and
6) leverage the revolutionary Root™ platform to provide open access to third-party developers for additional measurements, as well as connectivity to electronic health record systems and for third-party devices.

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Our solutions and related products are based upon our proprietary Masimo SET® and rainbow® 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. We have exclusively licensed from Cercacor Laboratories, Inc. (Cercacor) the right to OEM selected rainbow® technology and to incorporate selected rainbow® technology into our products intended to be used by professional caregivers, including, but not limited to, hospital caregivers and alternate care facility caregivers.

Cercacor

Cercacor is an independent entity spun off from us to our stockholders in 1998. Joe Kiani and Jack Lasersohn, members of our board of directors, are also members of the board of directors of Cercacor. 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.

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 measurements and to develop and sell devices incorporating Masimo SET® for monitoring non-vital signs measurements in any product market in which a product is intended to be used by a patient or pharmacist rather than a professional medical caregiver, which we refer to as the Cercacor Market. We also granted Cercacor a non-exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET® for the measurement of vital signs in the Cercacor Market.

We exclusively license from Cercacor the right to make and distribute products in the professional medical caregiver markets, which we refer to as the Masimo Market, that utilize rainbow® technology for certain non-invasive measurements, including carbon monoxide, methemoglobin, fractional arterial oxygen saturation and hemoglobin. We also have the option to obtain the exclusive license to make and distribute products that utilize rainbow® technology for the monitoring of other non-vital signs measurements, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver. To date, we have developed and commercially released devices that measure carbon monoxide, methemoglobin and hemoglobin using licensed rainbow® technology. Additionally, we make and distribute products that monitor respiration rate via rainbow Acoustic Monitoring™, which is not required to be licensed from Cercacor.

In February 2009, in order to accelerate the product development of our hemoglobin spot-check measurement device, we agreed to fund additional engineering expenses of Cercacor. Specifically, these expenses included third-party engineering materials and supplies expense, as well as 60% of Cercacor's total engineering and engineering-related payroll expenses, during both the three months ended March 29, 2014 and March 30, 2013. We expect this arrangement to continue in the future. During the three months ended March 29, 2014, the funding for Cercacor's additional expenses totaled $0.9 million. For additional discussion of Cercacor, see Note 3 to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and Part I, Item 1. "Business—Cercacor Laboratories, Inc." in our Annual Report on Form 10-K for the fiscal year ended December 28, 2013, filed with the SEC on February 14, 2014.

For the foreseeable future, we anticipate that we will continue to consolidate Cercacor pursuant to the current authoritative accounting guidance; however, in the event that Cercacor is no longer considered a VIE or in the event that we are no longer obligated to absorb Cercacor's expected losses, or do not have the ability to direct the activities that most significantly impact Cercacor's economic performance, we may discontinue consolidating the entity.

Stock Repurchase Program

In February 2013, our board of directors authorized us to repurchase up to 6.0 million shares of our common stock under a repurchase program. 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. We have paid for prior repurchases of stock with available cash and cash equivalents. During the three months ended March 29, 2014, no shares were

repurchased under the program. As of March 29, 2014, approximately 5.0 million shares remain authorized for repurchase under the program.

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Medical Device Excise Tax

In March 2010, the U.S. Congress adopted and President Obama signed into law comprehensive health care reform legislation. Among other initiatives, these laws impose new taxes on medical device makers in the form of a 2.3% excise tax on U.S. medical device sales, with certain exemptions, beginning on January 1, 2013. During the three months ended March 29, 2014, and March 30, 2013, our medical device excise tax expense was $1.6 million and $1.7 million, respectively, which was recorded within our selling, general and administrative expenses.

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					
	March 29, 2014	% of Revenue		March 30, 2013	% of Revenue	
Revenue:						
Product	$132,232	94.6	%	$128,635	94.6	%
Royalty	7,582	5.4		7,307	5.4	
Total revenue	139,814	100.0		135,942	100.0	
Cost of goods sold	47,513	34.0		46,361	34.1	
Gross profit	92,301	66.0		89,581	65.9	
Operating expenses:						
Selling, general and administrative	56,122	40.1		52,273	38.5	
Research and development	13,996	10.0		14,167	10.4	
Litigation award and defense costs	(8,010)	(5.7)		—	—	
Total operating expenses	62,108	44.4		66,440	48.9	
Operating income	30,193	21.6		23,141	17.0	
Non-operating income (expense)	200	0.1		(2,326)	(1.7)	
Income before provision for income taxes	30,393	21.7		20,815	15.3	
Provision for income taxes	7,902	5.6		4,413	3.2	
Net income including noncontrolling interest	22,491	16.1		16,402	12.1	
Net loss attributable to the noncontrolling interest	141	0.1		26	0.0	
Net income attributable to Masimo Corporation stockholders	$22,632	16.2	%	$16,428	12.1	%

Comparison of the Three Months ended March 29, 2014 to the Three Months ended March 30, 2013

Revenue. Total revenue increased $3.9 million, or 2.8%, to $139.8 million for the three months ended March 29, 2014 from $135.9 million for the three months ended March 30, 2013. Product revenues increased $3.6 million, or 2.8%, to $132.2 million for the three months ended March 29, 2014 from $128.6 million for the three months ended March 30, 2013. This increase was primarily due to rainbow technology revenues which rose from $10.5 million in the three month period ended March 30, 2013 to $12.9 million in the three month period ended March 29, 2014. Also contributing to higher product revenues were consumable sales resulting from an increase in our installed base of circuit boards and pulse oximeters, which we estimate totaled 1,231,000 units at March 29, 2014, up from 1,117,000 units at March 30, 2013. Such increase in revenue was partially offset by a current quarter true-up for deferred revenue of approximately $2.6 million resulting from new information related to inventory on-hand at one distributor. Revenue generated through our direct and distribution sales channels increased $3.1 million, or 2.9%, to $111.1 million for the three months ended March 29, 2014, compared to $108.0 million for the three months ended March 30, 2013. During the three months ended March 29, 2014, revenues from our OEM channel increased $0.5 million, or 2.4%, to $21.1 million from $20.6 million for the three months ended March 30, 2013. Our royalty revenue increased $0.3 million to $7.6 million for the three months ended March 29, 2014 from $7.3 million for the three months ended March 30, 2013.

Cost of goods sold. Cost of goods sold includes the cost of producing, supporting and managing our supply of finished products. Cost of goods sold increased $1.2 million compared to the three months ended March 30, 2013. Our total

gross margin increased slightly to 66.0% for the three months ended March 29, 2014 as compared to 65.9% for the three months

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ended March 30, 2013. Excluding royalties, product gross margin increased to 64.1% for the three months ended March 29, 2014 from 64.0% for the three months ended March 30, 2013. This net increase in product margin was primarily due to the benefit of our continued product cost reduction efforts and other improvements in our manufacturing processes offset slightly by lower average selling prices. We incurred $1.5 million and $1.3 million in Cercacor royalty expenses for the three months ended March 29, 2014 and March 30, 2013, respectively, which have been eliminated in our condensed consolidated financial statements for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 63.1% and 62.9% for the three months ended March 29, 2014 and March 30, 2013, respectively.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of salaries and related expenses for sales, marketing and administrative personnel, sales commissions, advertising and promotion costs, professional fees related to legal, accounting and other outside services, public company costs and other corporate expenses. Selling, general and administrative expenses increased $3.8 million, or 7.4%, for the three months ended March 29, 2014, compared to the three months ended March 30, 2013. This increase was due primarily to increased legal expenses. Approximately $2.6 million of share-based compensation expense was included in selling, general and administrative expenses for each of the three months ended March 29, 2014 and March 30, 2013, respectively. Also included in total selling, general and administrative expenses are $0.7 million and $0.8 million of direct expenses incurred by Cercacor for the three months ended March 29, 2014 and March 30, 2013, 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 decreased slightly by $0.2 million, or 1.2%, for the three months ended March 29, 2014 compared to the three months ended March 30, 2013. This decrease was primarily due to lower engineering project expenses in the three months ended March 29, 2014 as compared to the three months ended March 30, 2013 due to a shift in the timing of certain expected project expenses for fiscal year 2014 from the first quarter to the second and third quarters. Included in research and development expenses for the three months ended March 29, 2014 and March 30, 2013 was approximately $0.4 million and $0.7 million of share-based compensation expense, respectively. Also included in total research and development expenses were $0.9 million of engineering expenses incurred by Cercacor for each of the three months ended March 29, 2014 and March 30, 2013.

Litigation Award and Defense Costs. Two of our former physician office sales representatives filed employment-related claims against us in 2011 regarding our noninvasive hemoglobin monitoring products. In January 2014, an arbitrator awarded the plaintiffs approximately $5.4 million in damages. As a result of this award, we took a charge of $8.0 million in the fiscal quarter ended December 28, 2013, which included $5.4 million in damages and $2.6 million in defense-related costs. We challenged the award in the U.S. District Court for the Central District of California, and on April 3, 2014, the District Court vacated the award. Accordingly, we reversed the previous $8.0 million charge in the fiscal quarter ended March 29, 2014. We are unable to predict the final outcome of this matter, however, a reversal of the District Court’s ruling could have a material adverse effect on our financial condition or results of operations in the future. See Note 10 to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Non-operating income (expense). Non-operating income (expense) consists primarily of interest income, interest expense, and foreign exchange gains (losses). Non-operating income was $0.2 million for the three months ended March 29, 2014 as compared to non-operating expense of $2.3 million for the three months ended March 30, 2013. This net change of $2.5 million was primarily due to the recognition of net realized and unrealized gains on foreign currency denominated transactions during the three months ended March 29, 2014, as compared to the recognition of net realized and unrealized losses on foreign currency denominated transactions during the three months ended March 30, 2013. The net realized and unrealized gains on foreign currency denominated transactions recognized during the three months ended March 29, 2014 resulted primarily from the weakening of the U.S. Dollar against the Japanese Yen during the same three month period. The net realized and unrealized losses on foreign currency denominated transactions recognized during the three months ended March 30, 2013 resulted primarily from the strengthening of the U.S. Dollar against the Japanese Yen during the same three month period.

Provision for Income Taxes. Our provision for income taxes was $7.9 million, or an effective tax rate of 26.0%, for the three months ended March 29, 2014, compared to $4.4 million, or an effective tax rate of 21.2%, for the three months ended March 30, 2013. The lower prior year effective tax rate was due primarily to the discrete tax impact of the retroactive reinstatement of the federal research tax credit for year 2012 and the expiration of such tax credit at the end of year 2013. Our future effective income tax rate will depend on various factors, including changes to tax law, the recognition and derecognition of tax benefits associated with uncertain tax positions and the geographic composition of our pre-tax income.

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Liquidity and Capital Resources

Our principal sources of liquidity consist of our existing cash and cash equivalent balances, as well as funds expected to be generated from operations. At March 29, 2014, we had approximately $189.7 million in working capital and approximately $117.5 million in cash and cash equivalents as compared to approximately $168.0 million in working capital and approximately $95.5 million in cash and cash equivalents at December 28, 2013. 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 March 29, 2014, we had cash totaling $49.4 million held outside of the U.S., a portion of which was accessible without a significant tax cost. In managing our day-to-day liquidity and our capital structure, we do not rely on foreign earnings as a source of funds. We currently have sufficient funds for 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.

Cash Flows

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

	Three Months Ended	
	March 29, 2014	March 30, 2013
Net cash provided by (used in):		
Operating activities	$24,021	$25,101
Investing activities	(3,726)	(2,946)
Financing activities	1,830	(12,216)
Effect of foreign currency exchange rates on cash	(62)	82
Increase in cash and cash equivalents	$22,063	$10,021

Operating Activities. Cash provided by operating activities was $24.0 million in the three months ended March 29, 2014. This increase was due primarily to net income of $22.5 million, non-cash activity for depreciation and amortization of $3.0 million and share-based compensation of $2.6 million. In addition, accounts payable increased by $5.7 million due to the timing of payments. These sources of cash were primarily offset by an increase in deferred cost of goods sold of $2.7 million related to shipments of equipment to customers pursuant to long-term sensor contracts, an increase of $2.8 million in the prepayment of income taxes and a decrease of $7.0 million in accrued compensation due to the payment of the fiscal year 2013 annual bonuses.

Cash provided by operating activities was $25.1 million in the three months ended March 30, 2013. Sources of cash consisted primarily of net income including noncontrolling interest of $16.4 million, non-cash activity for depreciation and amortization of $2.8 million and share-based compensation of $3.4 million. In addition, accounts payable increased by $3.9 million and income taxes payable increased by $1.8 million, both due to the timing of payments. These sources of cash were offset by a decrease in accrued compensation of $3.4 million primarily as a result of the fiscal year 2012 annual bonus payouts, and an increase in deferred cost of goods sold of $2.7 million due to continued shipments of equipment to customers pursuant to long-term sensor contracts.

Investing Activities. Cash used in investing activities for the three months ended March 29, 2014 was $3.7 million, consisting of $2.8 million for purchases of property and equipment to support our manufacturing operations and $0.9 million for the increase in intangible assets related to capitalized patent and trademark costs. Cash used in investing activities for the three months ended March 30, 2013 was $2.9 million, consisting of $1.8 million for purchases of property and equipment to support our manufacturing operations and $1.1 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 March 29, 2014 was $1.8 million, primarily due to proceeds from the issuance of common stock (upon exercise of options) totaling $1.9 million. Cash used in financing activities for the three months ended March 30, 2013 was $12.2 million, primarily resulting from common stock repurchase transactions totaling $15.4 million, of which only $12.4 million actually settled prior to March 30, 2013.

Capital Resources and Prospective Capital Requirements.

On April 23, 2014, we entered into a five-year revolving credit facility with JPMorgan Chase Bank, National Association that matures on April 23, 2019 (the Credit Facility). The Credit Facility provides for up to an aggregate of $125.0 million in

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borrowings in multiple currencies that can be used for general corporate, capital investment and working capital purposes. Pursuant to the terms of the Credit Facility, we are subject to certain financial and non-financial covenants. See Note 13 to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

As of March 29, 2014, we had capital leases related to office and computer equipment with an outstanding balance of $0.3 million. We had no other debt obligations.

In the future, in addition to funding our working capital requirements, we anticipate our primary use of cash to be the equipment that we provide to hospitals under our long-term sensor purchase agreements. We anticipate additional capital purchases related to expanding our worldwide operations, including manufacturing, sales, marketing and other areas of necessary infrastructure growth. We also anticipate possible uses of cash for the acquisition of technologies or technology companies.

On March 12, 2014, we announced our intention to acquire a new corporate headquarters facility in Irvine, California for $56.0 million. We expect to close the transaction in the second fiscal quarter of 2014. Over the next twelve months, we expect to incur approximately $25 to $30 million in additional reconstruction and other building-related costs. We intend to fund the acquisition cost, additional reconstruction costs and other related costs through the Credit Facility and available cash and cash equivalents.

In February 2013, our board of directors authorized the repurchase of up to 6.0 million shares of common stock under a repurchase program. During the three months ended March 29, 2014, no shares were repurchased. As of March 29, 2014, approximately 5.0 million shares remain authorized for repurchase under the program.

The amount and timing of our actual investing activities will vary significantly depending on numerous factors, including the timing of the acquisition, reconstruction, and other costs related to our new corporate headquarters facility, product development efforts, our timetable for international sales operations and manufacturing expansion and both domestic and international regulatory requirements. Despite these investment requirements, we anticipate that our existing cash and cash equivalents and amounts available under the 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 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 March 29, 2014, 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, share-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 December 28, 2014. There have been no material changes to any of our critical accounting policies during the three months ended March 29, 2014.

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Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of changes in the value of market risk sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. We are exposed to various market risks that may arise from adverse changes in market rates and prices, such as interest rates, foreign exchange fluctuations and inflation. We do not enter into derivatives, including forward contracts, or other financial instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our 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 Credit Facility. 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 March 29, 2014. 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 also 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 Sterling and the Australian Dollar, all relative to the U.S. Dollar. Foreign currency exchange rates have experienced significant movements recently and may continue to do so in the future. 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.

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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, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's 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.

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 March 29, 2014 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

On February 3, 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. The suit was brought in the U.S. District Court for the District of Delaware. Two patents originally asserted in this suit, related to our Measure-Through Motion technology, were successfully enforced in our previous suit against Nellcor. On June 15, 2009, Philips answered our complaint and Philips Electronics North America Corporation filed antitrust and patent infringement counterclaims against us as well as counterclaims seeking declaratory judgments of invalidity on the patents asserted by us against Philips. On July 9, 2009, we filed our answer denying Philips' counterclaims and asserting various defenses. We also asserted counterclaims against Philips for fraud, intentional interference with prospective economic advantage and for declaratory judgments of noninfringement and invalidity with respect to the patents asserted by Philips against us. 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. On October 4, 2010, the Court limited the number of patents to be construed to four for us and three for Philips. In addition, on October 6, 2010, the Court denied Philips' motion to bifurcate and stay damages in the patent case. On January 17, 2012, the District Court Judge issued a claim construction order. In 2012, the parties completed expert reports and discovery on some of the patents. In addition, in 2012, we asserted additional patents, and the Court ordered that these patents and some of the originally asserted patents be tried in a second phase. In 2013, the Magistrate Judge issued reports and recommendations relating to various summary judgment motions filed by the parties. On December 2, 2013, the Court heard oral argument on the parties' objections to the Magistrate Judge's reports and recommendations. On March 31, 2014, the District Court Judge ruled on the objections. On April 14, 2014, the parties filed motions for reconsideration of certain rulings. The parties have requested a trial date in September 2014. We believe that we have good and substantial defenses to the antitrust and patent infringement claims asserted by Philips. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

On December 21, 2012, we filed suit against Mindray DS USA, Inc. and Shenzhen Mindray Bio-Medical Electronics Co, Ltd. (Shenzhen Mindray) in the U.S. District Court for the Central District of California. The complaint alleges patent infringement, breach of contract and other claims. Mindray DS USA, Inc. was dismissed from this case based on venue. On June 3, 2013, Shenzhen Mindray answered our complaint and filed antitrust and related counterclaims against us, as well as counterclaims seeking declaratory judgments of invalidity and non-infringement on the patents asserted by us against Shenzhen Mindray. On June 24, 2013, we filed our answer denying Shenzhen Mindray's counterclaims and asserting various defenses. On July 17, 2013, the Court granted Shenzhen Mindray's motion to dismiss the patent claims without prejudice to allow us to amend the complaint to provide additional detail supporting Shenzhen Mindray's direct and indirect infringement of our patents. On the same day, the Court denied Shenzhen Mindray's motion to dismiss our non-patent claims. On August 5, 2013, we filed a first amended complaint. On August 21, 2013, Shenzhen Mindray answered our complaint and reasserted the counterclaims it asserted on June 3, 2013, as well as two additional counterclaims alleging patent infringement. On September 16, 2013, we filed our answer denying Shenzhen Mindray's counterclaims and asserting various defenses. On October 31, 2013, the Court issued a scheduling order setting a trial date of November 4, 2014. On December 10, 2013, Shenzhen Mindray filed a second amended answer and counterclaims, including a new counterclaim for tortious interference. On January 2, 2014, we filed a motion for judgment on the pleadings as to Shenzhen Mindray's antitrust counterclaims and inequitable conduct counterclaims and defenses. The Court granted judgment on the pleadings with leave to amend. On March 27, 2014, Shenzhen Mindray filed a third amended answer and counterclaims. On April 10, 2014, Shenzhen Mindray filed a fourth amended answer and counterclaims, which motion is pending before the Court. We believe that we have good and substantial defenses to the antitrust, patent infringement and other counterclaims asserted by Shenzhen Mindray. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

On December 10, 2013, we filed suit against Mindray DS USA, Inc., Shenzhen Mindray and Mindray Medical International Ltd. in the Superior Court of New Jersey. The complaint alleges breach of contract and related claims. On January 17, 2014, Mindray DS USA filed a notice of removal removing the case to the U.S. District Court for the District of New Jersey. On January 24, 2014, Mindray DS USA, Inc. filed a motion seeking to dismiss or stay the action in view of our action against Shenzhen Mindray in the Central District of California. That motion is pending before the Court and no order from the Court has issued. On April 15, 2014, Mindray Medical International filed a motion to dismiss based on lack of personal jurisdiction, challenging service of process, and alleging that we failed to state a claim. That motion is pending before the Court. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

In September 2012, a shareholder derivative lawsuit was filed in the U.S. District Court for the District of Delaware by Joseph Ausikaitis naming our directors and certain executive officers as defendants and us as the nominal defendant. The lawsuit

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alleges claims of breach of fiduciary duty and unjust enrichment in connection with the grant or receipt of stock options under our 2007 Stock Incentive Plan and related policies. The lawsuit seeks unspecified money damages on our behalf from the officer and director defendants, various forms of equitable and/or injunctive relief, attorneys' and other professional fees and costs and various other forms of relief. In November 2012, the defendants filed a motion to dismiss the action, which was denied by the court in July 2013. Although the outcome in this case cannot be determined, we do not expect it to have a material financial impact on our results of operations.

In April 2011, we were 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 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 United States declined to intervene in the case, and in October 2013, the District Court granted summary judgment in our favor. The former sales representatives are appealing the District Court's decision.

In September 2011, two of the same former sales representatives also filed employment-related claims against us in arbitration stemming from their allegations regarding our noninvasive hemoglobin products. On January 16, 2014, we were notified that the arbitrator awarded the plaintiffs approximately $5.4 million in damages. We 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 are appealing the District Court's decision. We are unable to predict the final outcome of the qui tam and employment matters. A reversal of the District Court's decision in either matter could have a material adverse effect on our financial condition or results of operations in the future.

On January 2, 2014, a putative class action complaint was filed against us in the U.S. District Court for the Central District of California by Physicians Healthsource, Inc. The complaint alleges that we 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 court finds the alleged violations to be knowing, plus interest, costs, and injunctive relief. On April 14, 2014, we filed a motion to stay the case pending a decision on a related petition filed by us with the Federal Communications Commission (FCC). The motion to stay is pending. We believe we have good and substantial defenses to the claims, but there is no guarantee that we will prevail.

On January 31, 2014, an amended putative class action complaint was filed against us 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 that we modified and provided at the request of study investigators for use in the trial. A previous version of the complaint also alleged a wrongful death claim, which the court dismissed on January 22, 2014. The amended complaint seeks unspecified damages, costs, interest, attorney fees, and injunctive and other relief. We believe we have good and substantial defenses to the remaining claims, but there is no guarantee that we will prevail.

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

Item 1A. Risk Factors

Before you decide to invest or maintain an interest in our common stock, you should consider carefully the risks described below, which have been updated since the filing of our Annual Report on Form 10-K for the fiscal year ended December 28, 2013, filed with the SEC on February 14, 2014, 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.

We have marked with an asterisk (*) those risk factors below that include a substantive change from or update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 28, 2013, filed with the SEC on February 14, 2014.

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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 to provide evidence to the medical community that our products are cost-effective and offer significantly improved performance compared to conventional pulse oximeters. Health care providers that currently have significant investments in competitive pulse oximetry products may be reluctant to purchase our products. If hospitals and other health care providers do not believe our Masimo SET® platform is cost-effective, safe or more accurate or reliable than competitive pulse oximetry products, they may not buy our products in sufficient quantities to enable us to be profitable. 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.

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 recently introduced into the market, including, but not limited to, those based on rainbow® technology, a technology that we license, may not be accepted in the market. If our products do not gain market acceptance or if our customers prefer our competitors' products, our potential growth would be limited, which would adversely affect our business, financial condition and results of operations.

Given that certain rainbow® technology products are new to the marketplace, we do not know to what degree the market will accept these products, if at all. Even if our customers recognize the benefits of our products, we cannot assure you that our customers will purchase them in quantities sufficient for us to be profitable or successful. We will need to invest in significant sales and marketing resources to achieve market acceptance of these products with no assurance of success. The degree of market acceptance of these products will depend on a number of factors, including:

- perceived advantages of our products and their sales prices;
- perceived safety and effectiveness of our products;
- reimbursement available through Centers for Medicare and Medicaid Services (CMS) programs for using 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 right to use rainbow® technology are each limited to certain markets by our Cross-Licensing Agreement with Cercacor, which may impair our growth and adversely affect our 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

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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 sign measurements consist of body fluid constituents other than vital sign 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 impair our growth and adversely affect our financial condition and results of operations.

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 non-invasive 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 new products or alternative technologies developed by others, we could lose revenue opportunities and customers, and our ability to grow our business would be impaired.

A number of our competitors have substantially greater capital resources, larger customer bases and larger sales forces, have established stronger reputations with target customers, and have built relationships with GPOs that are more effective than ours. We face substantial competition from companies developing products that compete with our Masimo SET® platform for use with third-party monitoring systems. We also face competition from companies currently marketing pulse oximetry monitors.

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for Masimo SET® and licensed rainbow® technology. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. In particular, we may not be able to successfully commercialize our products for applications other than arterial blood oxygen saturation and pulse rate monitoring, including respiration rate, hemoglobin, carboxyhemoglobin and methemoglobin monitoring. If we do not successfully adapt our products and applications both within and outside these measurements, we could lose revenue opportunities and customers. Furthermore, one or more of our competitors may develop products that are substantially equivalent to our FDA-cleared products, or those of our original equipment manufacturer, or OEM, partners, whereby they may be able to use our products or those of our OEM partners, as predicate devices to more quickly obtain FDA clearance of their competing products. Competition could result in reductions in the price of our products, fewer orders for our products, a reduction of our gross margins and a loss of our market share.

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 they have no contractual obligation, to do so. Because products that incorporate our technologies may represent a relatively small percentage of business for some of our OEM partners, they may have less incentive to promote these products rather than other products that do not incorporate these technologies. In addition, some of our OEM partners offer products that compete with ours. Therefore, we cannot guarantee that our OEM partners, or any company that might acquire

any of our OEM partners, will vigorously promote products incorporating Masimo SET® and licensed rainbow® technology. 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.

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*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 become members of GPOs. GPOs negotiate beneficial pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors.

These negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, the GPO's affiliated hospitals and other members may be less likely or unlikely to purchase our products. If a GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be prohibited from making sales to members of the GPO for the duration of such contractual arrangement. For the three months ended March 29, 2014 and March 30, 2013, shipments of our pulse oximetry products to customers that are members of GPOs represented approximately $75.2 million and $73.5 million, respectively, of our revenue from sales to U.S. hospitals. Our failure to renew our contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. In addition, if we are unable to develop new relationships with GPOs, our competitive position would likely suffer and our business would be harmed.

We have learned that 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 or purchase our products, resulting in lower market share and an adverse effect on our sales, 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 for the procedures in which our products are used, may impact our customers' purchasing decisions. Therefore, our customers' inability to obtain adequate coverage and reimbursement for our products would have a material adverse effect on our business.

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

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

We cannot guarantee a governmental or third-party payer will reimburse, or continue to reimburse, a customer for the cost of our products. 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. We are working with these payers to obtain reimbursement, but may not be successful. These trends could lead to pressure to reduce prices for our current products and product candidates and could cause a decrease in the size of the market or a potential increase in competition that could adversely affect our business, financial condition and results of operations.

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

Our customers are facing a growing level of uncertainties, such as lower overall hospital census for paying patients and the impact of that lower census on hospital budgets. In addition, there are specific portions of our business, such as our OEM customers, that, due to their capital equipment sales model, could be impacted by the ongoing economic

uncertainties and the resulting constraints on hospital budgets. These hospital budget constraints could cause our OEMs more difficulty in selling their large, relatively high priced multiparameter devices which, in turn, could reduce our board sales to our OEM customers. In addition, certain of our products, including our rainbow® measurements such as carbon monoxide, methemoglobin and hemoglobin, are sold with upfront license fees and more complex, and therefore, more expensive sensors could 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, our SpCO® monitoring devices may be subject to authorization by individual states as part of Emergency Medical Services (EMS), scope of practice procedures. The State of California recently categorized SpCO® as a laboratory test and therefore outside the scope of practice for EMS providers. Although a lack of inclusion into scope of practice procedures does not prohibit usage, it may limit adoption.

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

We have a concentration of OEM, distribution and direct customers. 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 or 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 March 29, 2014 and March 30, 2013, we had sales through two just-in-time distributors, which in total represented approximately 24% and 25% of our total revenue, respectively. The loss of any large customer or distributor could have a material adverse effect on our financial condition and results of operations.

Organizations that manufacture imitation Masimo sensors and third-party medical device reprocessors that reprocess our single-patient-use sensors and then resell them to hospitals at a cost lower than our new sensors may harm our reputation and cause our revenue to decline. Our development of a new technology designed to provide hospitals, clinicians and their patients with sensors that reflect true Masimo quality and performance may not be accepted by all of our customers, which may adversely affect our business, financial condition and results of operations.

We are aware that other organizations are manufacturing 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 for other patients. Over the past two years, there has been an increase in our customers' awareness of these imitation sensors and reprocessing programs. Our experience with both these imitation sensors and reprocessed sensors is that they provide inferior performance, increased sensor utilization, reduced comfort and a number of monitoring problems. Notwithstanding these limitations and despite our customers' acknowledged preference for genuine Masimo single-patient-use adhesive sensors due to performance and risk of contamination, 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 overall operating costs. These imitation and reprocessed sensors have led to 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 up to our performance level and to their expectations, and enforcing our proprietary rights against the imitation manufacturers and reprocessors and under our customer contracts.

We have developed a new technology that is designed to ensure our customers get the performance they expect by using genuine Masimo sensors. This new technology has been included in sensors shipped since the fourth quarter of 2011. While most customers will not observe any difference when compared to our prior sensors, 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. Although we believe that this technology will be viewed favorably by the overwhelming majority of hospitals and clinicians, there are no assurances that all of our customers will view it positively, which may reduce certain customer demand for our new sensors and, as a result, have a material adverse effect on our business, financial condition and results of operations.

*From time to time we may carry out strategic initiatives that are not viewed favorably by our customers, which may reduce demand for our products.

We expect to continue to implement new technologies and take action to protect and enforce our contractual, intellectual property and other rights. For example, during fiscal 2013, we began to build a new worldwide blood management sales force, whose primary focus is working with hospitals to identify new opportunities for our noninvasive hemoglobin measurement, SpHb®. Although we believe implementing new technologies and taking these actions are, and will continue to be, in the best interest of patient care, the Company and our stockholders, there are no assurances that the market will perceive their benefits or that these actions will yield favorable results for us, which may result in reduced customer demand for our products, cause our revenue to decline and have a material adverse effect on our operating results.

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

We are party to a settlement agreement with Covidien. Under the current settlement agreement, we earn royalties on Covidien's total U.S. based pulse oximetry sales. For the three months ended March 29, 2014 and March 30, 2013, our royalties from the Covidien settlement agreement totaled approximately $7.6 million and $7.3 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. As a result, an elimination of royalties that we earn under the settlement agreement in the future will have a significant impact on our revenue, gross margins, operating income and earnings per share.

On January 28, 2011, we entered into a second amendment to this settlement agreement with Covidien. As part of this amendment, which became effective on March 15, 2011, Covidien agreed to pay us a royalty at a rate of 7.75% of its U.S. pulse oximetry revenue, as that term is defined in the January 28, 2011 second amendment. In exchange for this royalty payment, we have provided Covidien with a covenant not to sue for its current pulse oximetry products, but not for any other technologies that Covidien may add, pursuant to the second amendment. As of March 15, 2014, Covidien has the right to stop paying us royalties, subject to certain notice requirements, which would have a material adverse impact on our total revenue, gross margins, operating income and earnings per share.

Risks Related to Our Intellectual Property

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

Our success depends significantly on our ability to protect our rights to the technologies used in our products, including Masimo SET® and licensed rainbow® technology. We rely on patent protection, trade secrets and a combination of copyright and trademark laws, as well as nondisclosure, confidentiality and other contractual arrangements, to protect our technology and rights. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or maintain any competitive advantage. In addition, we cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The U.S. Patent and Trademark Office (PTO) may deny or require 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. Our issued and licensed patents and those that may be issued or licensed in the future, may expire or may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related technologies. 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. There is no assurance that competitors will not be able to design around our patents. We also rely on contractual rights with the third parties that license technology to us to protect our rights in the technology licensed to us. In addition, we rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology.

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

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

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 availability searches. In addition, many of our employees were previously employed at other medical device companies. We may be subject to claims that our employees have disclosed, or that we have used, trade secrets or other proprietary information of our employees' former employers. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement against us, even those without merit, could:

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

In addition, new patents obtained by our competitors could threaten the continued commercialization of our products in the market even after they have already been introduced. Philips Electronics North America Corporation and Shenzhen Mindray Bio-Medical Electronics Co., Ltd. have filed antitrust and patent infringement counterclaims against us, as further explained in Part II, Item 1 of this Quarterly Report on Form 10-Q.

*We believe competitors may currently be violating and may in the future violate our intellectual property rights, and we may bring additional litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert our attention from implementing our business strategy.

We believe that the success of our business depends, in significant part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets. We were previously involved in significant litigation to protect our patent position and may be required to engage in further litigation. In 2006, we settled a costly, six-year lawsuit against Mallinckrodt, Inc., part of Tyco Healthcare (currently Covidien Ltd.), and one of its subsidiaries, Nellcor Puritan Bennett, Inc., in which we claimed that Covidien was infringing some of our pulse oximetry signal processing patents.

In February 2009, we filed a patent infringement suit against Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH related to Philips' FAST pulse oximetry technology and certain of Philips' patient monitors. In December 2012 and December 2013, we filed patent infringement and breach of contract suits against Mindray DS USA, Inc., Shenzhen Mindray Bio-Medical Electronics Co, Ltd., and Mindray Medical International Ltd. These suits are described in Part II, Item 1 of this Quarterly Report on Form 10-Q, and Note 10 to our accompanying condensed consolidated financial statements. Both Philips and Mindray are OEM partners of ours. There is no guarantee that we will prevail in these suits 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.

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Risks Related to Our Regulatory Environment

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

Each medical device that we wish to market in the U.S. generally must first receive either 510(k) clearance from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act by filing a 510(k) pre-market notification (PMA) through submitting a PMA application. Even if regulatory clearance or approval of a product is granted, the clearance or approval may be subject to limitations on the indicated uses for which the product may be marketed. We cannot 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 FDA's 510(k) clearance process of our products and uses has historically taken approximately four to six months. However, over the past two years we have experienced a significantly longer 510(k) clearance review process. Our more recent experience in seeking FDA 510(k) clearance, along with information we have received from other medical device manufacturers, suggests that the FDA is requiring applicants to provide much more information and data than in prior periods, that the FDA is not consistently relying upon prior precedents thereby leading to more review cycles or, in some cases, to non-substantially equivalent decisions, and that the FDA has broadened the scope of its reviews. As a result, we have experienced lengthier FDA 510(k) review periods over the past two years, which has delayed the 510(k) clearance process for our products and uses over this period compared to prior periods.

In connection with our most recent 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 intend to work with the FDA to address whatever remaining concerns the agency has, but we cannot be sure we will be able to resolve those concerns.

To date, the FDA has regulated pulse oximeters incorporating Masimo SET® and licensed rainbow® technology, and our sensors, cables and other products incorporating Masimo SET® and licensed rainbow® technology for pulse oximetry under the 510(k) process. Although 510(k) clearances have been obtained for all of our current products, these clearances may be withdrawn by the FDA at any time if substantial safety or effectiveness problems develop with our devices. Furthermore, our new products or significantly modified marketed products could be denied 510(k) clearance and be required to undergo the more burdensome PMA process. The process of obtaining PMA is much more costly, lengthy and uncertain than the process for obtaining 510(k) clearance and generally takes one to three years, but may be longer.

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

Our OEM partners will be required to obtain their own FDA clearances for products incorporating Masimo SET® and licensed rainbow® technology to market these products in the U.S. We cannot 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 ever grant clearances on a timely basis, if at all, for any future product incorporating Masimo SET® and licensed rainbow® technology that our OEM partners propose to market.

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

Our products, along with the manufacturing processes and promotional activities for such products, are subject to continual review and periodic inspections by the FDA and other regulatory bodies. Among other requirements, we and our suppliers are required to comply with the FDA's Quality System Regulation, or 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.

The FDA inspected our facility in Irvine, California, in 2013 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 (MDR), and corrective and preventative action

(CAPA) procedures. The FDA also inspected our facility in Mexicali, Mexico, in 2014 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. The observations do not represent final agency determinations. We have submitted responses to both Form 483s and are awaiting responses from the FDA. We do not know what further actions, if any, the FDA will take in connection with the inspections.

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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 could result in, among other things, any of the following actions:

- warning letters or untitled letters issued by the FDA;
- fines, civil penalties, injunctions and criminal prosecution;
- unanticipated expenditures to address or defend such actions;
- delays in clearing or approving, or refusal to clear or approve, our products;
- withdrawal or suspension of clearance or approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;
- product recall or seizure;
- orders for physician notification or device repair, replacement or refund;
- interruption of production or inability to export to certain foreign countries; and
- operating restrictions.

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

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

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

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

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 PMA approval. We may not be able to obtain such clearances or approvals in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business, financial condition and results of operations. If the FDA disagrees with our conclusion and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could have an adverse effect on our business, financial conditions and results of operations.

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

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

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

Under the FDA medical device reporting regulations, we are required to report to the FDA any incident in which a product of ours may have caused or contributed to a death or serious injury or in which a product of ours malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally required to report to the relevant authority in whose jurisdiction any serious or potentially serious incidents involving devices produced or sold by the manufacturer 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 we become aware of a safety issue involving a marketed product. A government-mandated or voluntary recall by us or by one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. We may initiate certain voluntary recalls involving our products in the future. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations.

From our inception through March 29, 2014, we initiated six voluntary recalls of our products, none of which was material to our operating results. Each of these recalls was 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.

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

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

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

Although we do not provide health care services or receive payments directly from Medicare, Medicaid or other third-party payers for our products or the procedures in which our products are used, health care regulation by federal

and state governments will impact our business. Health care fraud and abuse laws potentially applicable to our operations include, but are not limited to:

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

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- federal false claims laws which prohibit, among other things, knowingly and willfully presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal provisions of the HIPAA established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services; 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 non-governmental third-party payers, including commercial insurers, and
- state laws governing the privacy of certain PHI.

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 who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and Medicare. Some suits filed under the 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 United States 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 United States declined to intervene in the case, and in October 2013, the District Court granted summary judgment in our favor. The former sales representatives are appealing the District Court’s decision.

In September 2011, two of the same former sales representatives also filed employment-related claims against us in arbitration stemming from their allegations regarding our noninvasive hemoglobin products. On January 16, 2014, we were notified that the arbitrator awarded the plaintiffs approximately $5.4 million in damages. We 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 are appealing the District Court’s decision. We are unable to predict the final outcome of the qui tam and employment matters. A reversal of the District Court’s decision in either matter could have a material adverse effect on our financial condition or results of operations in the future.

In the third quarter of 2013, we were notified that the FDA and the United States Attorney’s Office for the Central District of California, Criminal Division, are investigating the allegations regarding our noninvasive hemoglobin products. The government has made informal requests for the production of documents and other information, and we are cooperating with the government in connection with the investigation. The Company and various Company executives signed agreements tolling the statute of limitations as to any charges that may be brought by the government. We have not received grand jury subpoenas in connection with the investigation, but we expect to receive them in the future. We cannot predict the outcome of the investigation. The investigation may be a distraction to management and cause us to incur significant expenses, and could result in criminal, civil, or regulatory proceedings against us and/or our officers or other employees.

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 Law's safe harbor requirements, which may result in increased scrutiny by government authorities that are responsible for enforcing these laws.

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

Further, we are required to comply with federal and state laws governing the transmission, security and privacy of individually identifiable patient-identifiable health information (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 Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security requirements. Our failure to comply may result in criminal and civil liability because the potential for enforcement action against business associates is greater as a result of the Health Information Technology for 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.

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 breakthrough 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 the 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 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 recent years, 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. We currently estimate our medical device excise tax to be in the range of $6.0 million to $7.0 million for fiscal year 2014.

Moreover, the Physician Payment Sunshine Act (Sunshine Act) which was enacted by Congress as part of the Patient Protection and Affordable Care Act on March 23, 2010, required medical device companies to track and publicly report, with limited exception, 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. In addition, medical device companies are also be required to report payments to the government by March 31, 2014, and annually thereafter. 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 government's role in the U.S. health care industry may lower reimbursements for our products, reduce demand for innovative products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly materially. In addition, as a result of the continued focus on health care reform, there is 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. 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

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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, the 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 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 product promotional practices. 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 period 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

Cercacor has conducted most of the research and development of rainbow® technology and we are largely dependent upon Cercacor to develop improvements to certain rainbow® technologies.

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

*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 March 29, 2014, a number of stockholders of Cercacor continued to own shares of our stock. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Cercacor.

Jack Lasersohn, another member of our board of directors, also serves on the board of directors 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, development of products and technology, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Cercacor. 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.

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

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

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

Currently, we are required to consolidate Cercacor within our financial statements. Accordingly, the royalties that we owe to Cercacor are eliminated in our condensed consolidated financial statements presented within this Quarterly Report on Form 10-Q and our other periodic reports, and the gross profit margins reported in our consolidated financial results do not include the royalty expense that we pay to Cercacor. We are also obligated to include, and have included, Cercacor’s engineering and administrative expenses in our reported engineering and administrative expenses. If our financial statements were not consolidated with Cercacor, our reported cost of goods sold would increase and our reported engineering and administrative expenses would decrease. To date, the amount of royalty expense has approximated the amount of engineering and administrative expense. In the future, depending upon the success of rainbow® products and the royalties earned by Cercacor on those revenues, it is possible that the royalty expense will grow at a rate higher than the growth of engineering and administrative expenses. Should this occur, and if we were not required to consolidate Cercacor’s financial results within our financial statements, then our unconsolidated cost of sales could grow at a faster rate than our unconsolidated engineering expenses.

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

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

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

As a result of the royalties that we must pay to Cercacor, it is generally more expensive for us to make products that incorporate licensed rainbow® technology than products that do not include licensed rainbow® technology, We cannot assure you that we will be able to sell products incorporating licensed rainbow® technology at a price the market is willing to accept. If we cannot commercialize our products incorporating licensed rainbow® technology successfully, we may not be able to generate sufficient

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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, but is not limited to, the resignation or termination of Joe Kiani from his position of Chief Executive Officer of either Masimo or Cercacor. 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 all licensed rainbow® measurements payable to Cercacor will increase to $15.0 million for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, hemoglobin and blood glucose, plus up to $2.0 million per other rainbow® measurements. Also, if the surviving or acquiring entity ceases to use “Masimo” as a company name and trademark following a change in control, all rights to the “Masimo” trademark will automatically be assigned to 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 affect our reported results of operations.

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

- delays or interruptions in manufacturing and shipping of our products;
- varying demand for and market acceptance of our technologies and products;
- 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;
- market seasonality of our sales;
- ability to renew existing long-term sensor contract commitments;
- changes in the total dollar amount of annual contract renewal activities;
- changes in the mix, and therefore, the related costs of products that we supply at no upfront costs to our customers as part of their long-term sensor commitments;
- changes in hospital and other alternative care admission levels;
- inability to efficiently scale operations and establish processes to accommodate business growth;
- unanticipated delays or problems in the introduction of new products, including delays in obtaining clearance or approval from the FDA;
- high levels of returns and repairs; and
- change in reimbursement rates for SpHb®, SpCO® and SpMet® parameters.

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

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

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

The methods, estimates, and judgments that we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates, and judgments are, by their nature, subject to substantial risks, uncertainties, and assumptions, and factors may arise over time that lead us to change our methods, estimates, and judgments. Changes in those methods, estimates, and judgments could significantly affect our results of operations. See “Critical Accounting Policies and Estimates” contained in Part I, Item 2 of this Quarterly Report on Form 10-Q.

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

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

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

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

- difficulties in integrating any acquired companies, personnel, products and other assets into our existing business;
- delays in realizing the benefits of the acquired company, products or other assets;
- diversion of our management’s time and attention from other business concerns;
- limited or no direct prior experience in new markets or countries we may enter;
- higher costs of integration than we anticipated;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions; and
- changes in the overall financial model as certain acquired companies may have a different revenue, gross profit margin or operating expense profile.

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

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

We derive a portion of our net sales from international operations. In the three months ended March 29, 2014 and March 30, 2013, approximately 33% and 27%, respectively, of our product revenue was derived from our international operations. In addition, we purchase a portion of our raw materials and components on the international market. The sale and shipping of our products across international borders, as well as the purchase of materials and components from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and we would be exposed to potentially significant penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping, manufacturing and sales activities. Any material decrease in our international sales would adversely affect our business, financial condition and results of operations.

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

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

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

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

We market our products in certain foreign markets through our subsidiaries and other international distributors. The related sales agreements may provide for payments in a foreign currency. While a majority of our sales and expenditures are transacted in U.S. Dollars, some of our sales agreements with foreign customers provide for payment in currencies other than the U.S. Dollar. These foreign currency revenues, when converted into U.S. Dollars, can vary depending on average exchange rates during a respective period. In addition, we are exposed to foreign currency gains

or losses on outstanding foreign currency denominated receivables. When converted to U.S. Dollars, these receivables can vary depending on the monthly exchange rates at the end of the period. Similarly, certain of our foreign sales support subsidiaries transact business in their respective

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country's local currency, which is also their functional currency. As a result, expenses of these foreign subsidiaries when converted into U.S. Dollars can vary depending on average monthly exchange rates during a respective period. In addition, certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses. Accordingly, our operating results are subject to fluctuations in foreign currency exchange rates.

The balance sheets of our foreign subsidiaries whose functional currency is not the U.S. Dollar are translated into U.S. Dollars at the rate of exchange at the balance sheet date and the statements of 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.

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

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

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

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

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

If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934 and Section 404 of the Sarbanes-Oxley Act of 2002, or if we fail to maintain adequate internal control over financial reporting, our business,

results of operations and financial condition and investors' confidence in us could be materially and adversely affected. As a public company, we are required to comply with the periodic reporting obligations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner and meet our reporting obligations in their entirety could subject us to

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penalties under federal securities laws and regulations of The NASDAQ Stock Market LLC, expose us to lawsuits and restrict our ability to access financing on favorable terms, or at all.

In addition, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, we are required to evaluate and provide a management report of our systems of internal control over financial reporting and our independent registered public accounting firm is required to attest to our internal control over financial reporting. During the course of the evaluation of our internal control over financial reporting, we may identify areas requiring improvement and may be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time from other activities. In addition, if we fail to maintain the adequacy of our internal controls over financial reporting, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. Any failure to maintain compliance with the requirements of Section 404 could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business, negatively impact the trading price of our stock, and adversely affect investors' confidence in our company and our ability to access capital markets for financing.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and new regulations of the SEC and The NASDAQ Stock Market LLC, have and will create additional compliance requirements for companies such as ours. To maintain high standards of corporate governance and public disclosure, we have invested in, and intend to continue to invest in, reasonably necessary resources to comply with evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future. For example, the Dodd-Frank Wall Street Reform and Consumer Protection Act included provisions regarding certain minerals and metals, known as conflict minerals, mined from the Democratic Republic of Congo and adjoining countries. These provisions require companies to undertake due diligence procedures and report on the use of conflict minerals in their products, including products manufactured by third parties. Compliance with these provisions will cause us to incur costs to certify that our supply chain is conflict free and we may face difficulties if our suppliers are unwilling or unable to verify the source of their materials. Our ability to source these minerals and metals may also be adversely impacted. In addition, our OEM customers may require that we provide them with a certification and any inability to do so may disqualify us as a supplier.

To maintain high standards of corporate governance and public disclosure, we have invested in, and intend to continue to invest in, reasonably necessary resources to comply with such evolving standards. These investments have resulted in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities and may continue to do so in the future.

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

The manufacture and sale of products using Masimo SET® and licensed rainbow® technology expose us to product liability claims and product recalls, including but not limited to, those that may arise from unauthorized off-label use, which is use of a device in a manner outside the measurement or measurements cleared by the FDA, malfunctions, design flaws or manufacturing defects related to our products or the use of our products with incompatible components or systems. For example, on April 21, 2014, an amended putative class action complaint was filed against us alleging product liability and negligence claims in connection with pulse oximeters that we modified and provided at the request of the study investigators for use in a randomized trial at the University of Alabama. The amended complaint seeks unspecified damages, costs, interest, attorney fees and injunctive and other relief. While we believe we have good and substantial defenses to the claims, there is no guarantee that we will prevail. In addition, we cannot be certain that our product liability insurance will be sufficient to cover any or all damages or claims asserted in this case or any other product liability claims that may be brought against us in the future. Furthermore, we may not be

able to obtain or maintain insurance in the future at satisfactory rates or in adequate amounts to protect us against any product liability claims. Any losses that we may suffer from product liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our technology and products, together with the corresponding diversion of the attention of our key employees, may subject us to significant damages and could adversely affect our business, financial condition and results of operations.

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

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

Products that we sell in Europe are subject to regulation in European Union, or EU, markets under the Restriction of the Use of Hazardous Substances Directive, or RoHS. RoHS prohibits companies from selling products which contain certain hazardous materials, including lead, mercury, cadmium, chromium, polybrominated biphenyls and polybrominated diphenyl ethers, in EU member states. In addition, the EU's Registration, Evaluation, Authorization, and Restriction of Chemicals Directive also restricts substances of very high concern in products. Complying with this regulation may result in significant product transition costs including potential risk to the carrying value of the related inventory, or delays in sales of our products in the EU.

From time to time, new regulations are enacted, and it is difficult to anticipate how such regulations will be implemented and enforced. We continue to evaluate the necessary steps for compliance with environmental regulations as they are enacted. Future environmental laws may significantly affect our operations by, for example, requiring our manufacturing processes to be altered or requiring us to use different types of materials in manufacturing our products. Any changes to our operations may increase our manufacturing costs, detrimentally impact the performance of our products, add greater testing lead-times for product introductions or have other similar effects. In our research and manufacturing activities, we use, and our employees, may be exposed to, materials that are hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury to our employees or contamination from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any resulting damages and any such liability could exceed our reserves. Although we maintain general liability insurance, we do not specifically insure against environmental liabilities. If an enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action on terms favorable to us.

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

Our ability to effectively manage and maintain our internal business information, and to ship products to customers and invoice them on a timely basis depends significantly on our enterprise resource planning system and other information systems. Portions of our information technology systems may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The failure of these systems to operate effectively or to integrate with other systems, or a breach in security or other unauthorized access of these systems, may also result in delays in product fulfillment and reduced efficiency of our operations, and could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, financial condition and results of operations.

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

Many of the countries in which we operate, including the United States and several of the members of the European Union, have experienced and continue to experience uncertain economic conditions. Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, tax laws or tax rates; inflation; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; the effects of government initiatives to manage economic conditions; and reduced demand for our products resulting from a slow-down in the general global economy.

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

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Risks Related to Our Stock

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

There has been significant volatility in the market price and trading volume of equity securities, which is often unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our stock. From December 30, 2013 to March 28, 2014, our closing stock price ranged from $25.37 to $31.88 per share. You may not be able to resell your shares at or above the price you paid for them due to fluctuations in the market price of our stock caused by changes in our operating performance or prospects and other factors.

In addition to the other risk factors previously discussed above, there are many other factors that we may not be able to control that could have a significant effect on our stock market price These include but are not limited to:

- actual or anticipated fluctuations in our operating results or future prospects;
- our announcements or our competitors' announcements of new products;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidance, interpretations or principles;
- changes in our growth rates or our competitors' growth rates;
- developments regarding our patents or proprietary rights or those of our competitors;
- ongoing legal proceedings;
- our inability to raise additional capital as needed;
- concerns or allegations as to the safety or efficacy of our products;
- changes in financial markets or general economic conditions, including the effects of recession or slow economic growth in the U.S. and abroad;
- sales of stock by us or members of our management team, our board of directors or certain institutional stockholders; and
- changes in stock market analyst recommendations or earnings estimates regarding our stock, other comparable companies or our industry generally.

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

As of March 29, 2014, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned nearly 14% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, these stockholders may be able to exercise a significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have some control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of our Company, or otherwise discourage a potential acquirer from attempting to obtain control of our Company, which in turn could reduce the price of our stock. In addition, these stockholders could use their voting influence to maintain our existing management and directors in office or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

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

As of March 29, 2014, an aggregate of approximately 16.0 million shares of our stock were reserved for future issuance under our three equity incentive plans, approximately 9.6 million of which were subject to options outstanding as of that date at a weighted average exercise price of $23.28 per share. To the extent outstanding options are exercised, our existing stockholders may incur dilution. We rely heavily on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

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

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

We have registered and expect to continue to register shares reserved under our equity plans under a Registration Statement on Form S-8. All shares issued pursuant to a Registration Statement on Form S-8 can be freely sold in the public market upon issuance, subject to restrictions on our affiliates under Rule 144. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our stock.

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

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

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

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

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

Our board of directors (Board) may from time to time declare, and we may pay, dividends on our outstanding shares in the manner and upon the terms and conditions provided by law. However, we may elect to retain all future earnings for the operation and expansion of our business, rather than paying cash dividends on our stock. Any payment of cash dividends on our stock will be at the discretion of our Board and will depend upon our results of operations, earnings,

capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our board of directors. In the event our Board declares any dividends, there is no assurance with respect to the amount, timing or frequency of any such dividends.

In February 2013, our Board authorized a stock repurchase program, whereby we may purchase up to 6.0 million shares of our common stock over a period of up to three years. As of March 29, 2014, approximately 5.0 million shares remain authorized for repurchase under the program. Any repurchase of our common stock will be at the discretion of a committee comprised of our Chief Executive Officer and Chief Financial Officer, and will depend on several factors including, but not limited to, results of

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operations, capital requirements, financial conditions, available capital from operations or other sources, and the market price of our common stock. Therefore, there is no assurance with respect to the amount, price or timing of any such repurchases. We may elect to retain all future earnings for the operation and expansion of our business, rather than repurchasing additional outstanding shares. In the event we pay dividends, or make any stock repurchases in the future, our ability to finance any material expansion of our business, including through acquisitions, investments or increased capital spending, or to fund our operations, may be limited. In addition, any repurchases we may make in the future may not prove to be at optimal prices. Our Board may modify or amend our stock repurchase program at any time at its discretion without stockholder approval.

Item 6. Exhibits

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Quarterly Report on Form 10-Q and such Exhibit Index is incorporated herein by reference.

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SIGNATURES

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

MASIMO CORPORATION