

MASIMO CORP
Form 10-Q
May 05, 2010
Table of Contents

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended April 3, 2010

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)

Edgar Filing: MASIMO CORP - Form 10-Q

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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 <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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

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

Edgar Filing: MASIMO CORP - Form 10-Q

Class	Number of Shares Outstanding as of April 3, 2010
Common stock, \$0.001 par value	58,759,831

Table of Contents

MASIMO CORPORATION
FORM 10-Q FOR THE QUARTER ENDED APRIL 3, 2010

TABLE OF CONTENTS

PART I. Financial Information

Item 1.	<u>Financial Statements (unaudited):</u>	
	<u>Condensed Consolidated Balance Sheets as of April 3, 2010 and January 2, 2010</u>	3
	<u>Condensed Consolidated Statements of Income for the three months ended April 3, 2010 and April 4, 2009</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended April 3, 2010 and April 4, 2009</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	26
Item 4.	<u>Controls and Procedures</u>	27

PART II. Other Information

Item 1.	<u>Legal Proceedings</u>	28
Item 1A.	<u>Risk Factors</u>	28
Item 6.	<u>Exhibits</u>	46
	<u>Signatures</u>	47

Table of Contents**PART 1. FINANCIAL INFORMATION****Item 1. Financial Statements****MASIMO CORPORATION****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited, in thousands, except share amounts)**

	April 3, 2010	January 2, 2010
ASSETS		
Current assets		
Cash and cash equivalents	\$ 36,153	\$ 132,054
Short-term investments	75,986	56,989
Accounts receivable, net of allowance for doubtful accounts of \$2,076 and \$1,972 at April 3, 2010 and January 2, 2010, respectively	46,038	38,897
Royalties receivable	12,000	11,500
Inventories	33,699	31,559
Prepaid expenses	4,057	5,447
Deferred tax assets	11,586	11,585
Other current assets	1,550	1,357
Total current assets	221,069	289,388
Deferred cost of goods sold	30,026	28,163
Property and equipment, net	12,302	11,682
Deferred tax assets	11,520	11,500
Intangible assets, net	9,780	9,829
Other assets	6,577	5,783
Total assets	\$ 291,274	\$ 356,345
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	\$ 20,949	\$ 16,716
Accrued compensation	15,061	17,793
Accrued liabilities	9,614	9,754
Income taxes payable	10,498	477
Deferred revenue	17,261	14,641
Current portion of capital lease obligation	61	60
Total current liabilities	73,444	59,441
Deferred revenue	2,079	270
Capital lease obligation, less current portion	155	171
Other liabilities	7,076	6,775
Total liabilities	82,754	66,657
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at April 3, 2010 and January 2, 2010		

Edgar Filing: MASIMO CORP - Form 10-Q

Common stock, \$0.001 par value; 100,000,000 shares authorized; 58,759,831 and 57,876,450 shares issued and outstanding at April 3, 2010 and January 2, 2010, respectively	59	58
Treasury stock, 156,240 shares at April 3, 2010 and January 2, 2010	(1,209)	(1,209)
Additional paid-in capital	205,782	195,690
Accumulated other comprehensive income	127	63
Retained earnings	3,316	94,112
Total Masimo Corporation stockholders' equity	208,075	288,714
Noncontrolling interests	445	974
Total stockholders' equity	208,520	289,688
Total liabilities and stockholders' equity	\$ 291,274	\$ 356,345

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

Table of Contents

MASIMO CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(unaudited, in thousands, except share amounts)

	Three Months Ended	
	April 3, 2010	April 4, 2009
Revenue:		
Product	\$ 85,866	\$ 74,497
Royalty	12,899	10,995
Total revenue	98,765	85,492
Cost of goods sold	29,228	24,745
Gross profit	69,537	60,747
Operating expenses:		
Research and development	9,410	7,767
Selling, general and administrative	49,311	32,880
Antitrust litigation expense (proceeds)	(29,968)	14
Total operating expenses	28,753	40,661
Operating income	40,784	20,086
Non-operating expense	(347)	(287)
Income before provision for income taxes	40,437	19,799
Provision for income taxes	14,273	6,535
Net income including noncontrolling interests	26,164	13,264
Net (income) loss attributable to the noncontrolling interests	546	(243)
Net income attributable to Masimo Corporation	\$ 26,710	\$ 13,021
Net income per share attributable to Masimo Corporation stockholders:		
Basic	\$ 0.46	\$ 0.23
Diluted	\$ 0.44	\$ 0.22
Cash dividend declared per share	\$ 2.00	\$

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

Table of Contents**MASIMO CORPORATION****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited, in thousands)**

	Three Months Ended	
	April 3, 2010	April 4, 2009
Cash flows from operating activities:		
Net income including noncontrolling interests	\$ 26,164	\$ 13,264
Adjustments to reconcile net income including noncontrolling interests to net cash provided by operating activities:		
Depreciation and amortization	1,577	1,508
Share-based compensation	2,818	2,640
Provision for doubtful accounts	233	199
Provision for obsolete inventory	249	127
Provision for warranty costs	619	495
Income tax benefit from exercise of stock options granted prior to January 1, 2006	555	435
Excess tax benefit from share-based payment arrangements	(1,383)	(65)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(7,375)	(5,467)
(Increase) decrease in royalties receivable	(500)	547
Increase in inventories	(2,388)	(2,585)
Increase in deferred cost of goods sold	(1,902)	(253)
Decrease in prepaid expense	1,375	1,065
Increase in other assets	(1,013)	(940)
Increase in accounts payable	4,256	71
Decrease in accrued compensation	(2,646)	(2,349)
Increase (decrease) in accrued liabilities	(724)	342
Increase (decrease) in income taxes payable	11,401	(6,130)
Increase in deferred revenue	4,429	2,678
Increase in other liabilities	313	137
Net cash provided by operating activities	36,058	5,719
Cash flows from investing activities:		
Purchase of short-term investments	(75,986)	
Proceeds from sale and maturities of short-term investments	56,989	
Purchases of property and equipment	(1,885)	(676)
Increase in intangible assets	(264)	(340)
Decrease in restricted cash		21
Net cash used in investing activities	(21,146)	(995)
Cash flows from financing activities:		
Repayments on long-term debt	(15)	(79)
Proceeds from issuance of common stock	5,354	739
Excess tax benefit from share-based payment arrangements	1,383	65
Dividends paid	(117,506)	
Net cash provided by (used in) financing activities	(110,784)	725
Effect of foreign currency exchange rates on cash	(29)	(112)

Edgar Filing: MASIMO CORP - Form 10-Q

Net increase (decrease) in cash and cash equivalents	(95,901)	5,337
Cash and cash equivalents at beginning of period	132,054	146,910
Cash and cash equivalents at end of period	\$ 36,153	\$ 152,247

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

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Description of the Company

Masimo Corporation, or the Company, is a global medical technology company that develops, manufactures and markets noninvasive patient monitoring products that improve patient care. 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 measure multiple blood parameters, including carboxyhemoglobin, methemoglobin, PVI, total hemoglobin and acoustic respiration rate. The Company develops, manufactures and markets a family of patient monitoring solutions which incorporate a monitor or circuit board and sensors, including both proprietary single-patient use and reusable sensors and cables. The Company considers both the pulse oximetry device (monitor or circuit board) and its sensors and cables to be products as defined in its statements of income. 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, or 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 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, or 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 consolidated financial statements. The condensed consolidated balance sheet as of January 2, 2010 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, filed with the Securities and Exchange Commission, or SEC, on February 17, 2010. The results for the three months ended April 3, 2010 are not necessarily indicative of the results to be expected for the year ending January 1, 2011 or for any other interim period or for any future year.

Fiscal Periods

The Company follows a conventional 52/53 week fiscal year. Under a conventional 52/53 week fiscal year, a 52 week year includes four quarters of 13 fiscal weeks while a 53 week fiscal year includes three 13 week quarters and one 14 week quarter. In fiscal 2009, the Company was on a 52 week fiscal calendar in which the Company's first, second and third quarters ended on Saturday, April 4, July 4 and October 3, 2009, respectively, and its fiscal year ended on Saturday, January 2, 2010. Similar to 2009, 2010 is a 52 week fiscal calendar in which the Company's first, second and third quarters will end on Saturday, April 3, July 3 and October 2, 2010, respectively, and its fiscal year will end on Saturday, January 1, 2011.

Principles of Consolidation

The consolidated financial statements include the accounts of Masimo Corporation, Masimo Laboratories, Inc. and SEDLine, Inc. which have been consolidated pursuant to authoritative guidance issued by the Financial Accounting Standards Board, or FASB. In addition, these consolidated financial statements include the accounts of Masimo Corporation's wholly-owned operating subsidiaries, Masimo Americas, Inc., Masimo Europe Ltd., Masimo Japan K.K., Masimo Canada ULC, Masimo Australia Pty. Ltd., Masimo Holdings L.P., Masimo International Sarl, Masimo International Technologies Sarl, Masimo China Medical Technology Co., Ltd., Masimo Hong Kong Limited, Masimo Asia Pacific PTE. Ltd., and Masimo Österreich GmbH. All intercompany accounts and transactions have been eliminated in consolidation.

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)*****Comprehensive Income***

Authoritative accounting guidance establishes requirements for reporting and disclosure of comprehensive income and its components. Comprehensive income includes foreign currency translation adjustments, unrealized gains and losses on available-for-sale securities and other items that have been excluded from net income including noncontrolling interest and reflected in stockholders' equity.

Use of Estimates

The preparation of financial statements in conformity with GAAP 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, distributor channel inventory, royalty revenues, deferred revenue, property tax and uncertain income tax positions. Actual results could differ from those estimates.

Fair Value Measurements

The 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.

The following tables represent the Company's fair value hierarchy for its financial assets and liabilities as of April 3, 2010 and January 2, 2010 (in thousands):

	Fair Value Measurement as of April 3, 2010 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
U.S. Treasuries	\$ 19,996	\$	\$	\$ 19,996
Money Market funds	1,138			1,138
Available-for-sale securities: ⁽¹⁾				
U.S. Treasuries	75,986			75,986

Edgar Filing: MASIMO CORP - Form 10-Q

Total	\$ 97,120	\$	\$	\$ 97,120
-------	-----------	----	----	-----------

(1) Available-for-sale securities are included in short-term investments in the condensed consolidated balance sheet as of April 3, 2010.

	Fair Value Measurement as of January 2, 2010			
	using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
U.S. Treasuries	\$ 118,986	\$	\$	\$ 118,986
Money Market funds	1,691			1,691
Total	\$ 120,677	\$	\$	\$ 120,677

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

As of January 3, 2010, the Company had \$57.0 million of held-to-maturity securities, which consisted of U.S. Treasuries with a maturity between three months and one year at the date of purchase. These amounts were included in short-term investments on the condensed consolidated balance sheet as of January 3, 2010. These held-to-maturity securities were recorded at amortized cost. For purposes of determining any unrecognized gain or loss as of January 3, 2010, the amortized cost was compared to fair value, which approximated \$57.0 million. The fair value was based on quoted market prices in active markets for identical assets, a level 1 input.

In January 2010, the Company adopted a recently issued accounting standard which requires additional disclosure about the amounts of and reasons for significant transfers in and out of level 1 and level 2 fair value measurements. There have been no transfers between level 1 and level 2 inputs during the three months ended April 3, 2010. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring level 2 and level 3 measurements. Since this accounting standard only requires enhanced disclosure, the adoption of this standard did not impact its condensed consolidated financial statements.

Revenue Recognition

The Company follows the current authoritative guidance for software 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: (i) whether an arrangement exists, (ii) how the arrangement consideration should be allocated among the deliverables if there are multiple deliverables, (iii) if fair value can be determined for each deliverable based on vendor specific objective evidence, or VSOE, (iv) when to recognize revenue on the deliverables, and (v) 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 Company's sales under long-term purchase contracts are generally structured such that the Company agrees to provide up-front and at no charge certain monitoring equipment, installation, training and ongoing warranty support in exchange for the hospital's agreement to purchase sensors over the term of the agreement, which ranges from three to six years. The Company does not recognize any revenue when the monitoring and related equipment is delivered to the hospitals and installation and training is complete. The Company recognizes revenue for all of the 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 contract. In the event that the monitoring equipment is delivered over a period of time, revenue under long-term sensor contracts is deferred and recognized on a proportional basis relative to the number of units of the monitoring equipment delivered over time.

In situations where VSOE of fair value does not exist for undelivered elements, the entire contract product revenue and corresponding cost of goods sold are deferred until either the element is delivered, VSOE of fair value is established, or the obligation to deliver the element no longer exists. For the three months ended April 3, 2010, no contract product revenue was deferred and no previously deferred revenue was recognized. For the three months ended April 4, 2009, \$429,000 of contract product revenue was deferred and none of the previously deferred revenue was recognized. Deferred costs associated with this deferred revenue aggregating \$188,000 were deferred in the same 2009 period.

The Company's distributors purchase primarily 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 Company's commitment to its end-user hospital is fulfilled, which occurs when the sensors are sold by the distributor to the end-user hospital. 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 revenues.

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

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

Product Warranty Expense

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 ranges from three to six years. In traditional sales activities, including direct and OEM sales, the Company establishes an accrual for the estimated costs of warranty at the time of revenue recognition. Estimated warranty expenses are recorded as an accrued liability, with a corresponding provision to cost of sales. In long-term sales agreements, revenue related to extended warranty is recognized over the life of the contract, while the product warranty costs related to the long-term sales agreements are expensed as incurred.

Changes in the product warranty accrual for the three months ended April 3, 2010 and April 4, 2009 were as follows (in thousands):

	Three Months Ended	
	April 3, 2010	April 4, 2009
Warranty accrual, beginning of period	\$ 354	\$ 334
Provision for warranty costs	619	495
Warranty expenditures	(575)	(508)
Warranty accrual, end of period	\$ 398	\$ 321

Net Income Per Share

Basic net income per share attributable to Masimo Corporation for the three months ended April 3, 2010 and April 4, 2009, is computed by dividing net income attributable to Masimo Corporation by the weighted average number of shares outstanding during each period. The diluted net income per share attributable to Masimo Corporation for the three months ended April 3, 2010 and April 4, 2009, is computed by dividing the net income attributable to Masimo Corporation 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 April 3, 2010 and April 4, 2009, options to purchase 2,401,800 and 2,461,280, respectively, shares of common stock were not included in the computation of diluted share equivalent because the options' exercise prices were greater than the average market price for the period.

The Company reduced total net income including noncontrolling interests by the amount of net (income) loss attributable to noncontrolling interests for the three months ended April 3, 2010 and April 4, 2009.

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

	Three Months Ended	
	April 3, 2010	April 4, 2009

Edgar Filing: MASIMO CORP - Form 10-Q

Net income attributable to stockholders of Masimo Corporation:		
Net income including noncontrolling interests	\$ 26,164	\$ 13,264
Net (income) loss attributable to the noncontrolling interests	546	(243)
Net income attributable to Masimo Corporation	\$ 26,710	\$ 13,021
Basic net income per share attributable to Masimo Corporation:		
Net income attributable to Masimo Corporation	\$ 26,710	\$ 13,021
Weighted average shares outstanding	58,266,696	57,407,708
Basic net income per share attributable to Masimo Corporation	\$ 0.46	\$ 0.23
Diluted net income per share attributable to Masimo Corporation:		
Weighted average shares outstanding	58,266,696	57,407,708
Diluted share equivalent: stock options	2,197,161	2,759,307
	60,463,857	60,167,015
Diluted net income per share attributable to Masimo Corporation	\$ 0.44	\$ 0.22

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

Dividend Payment

In February 2010, the Company declared a special \$2.00 per share cash dividend, payable on March 31, 2010 to stockholders of record as of the close of business on March 11, 2010. The total dividend payout was \$117.5 million which was made from retained earnings.

Antitrust Litigation Expense (Proceeds)

The Company recorded proceeds from the antitrust litigation and related legal fees on a net basis in the condensed consolidated statement of income under antitrust litigation expense (proceeds).

Intangible Assets

Costs to renew intangibles are capitalized and amortized over the remaining useful life of the intangible. For the three months ended April 3, 2010, total renewal costs capitalized for patents and trademarks were \$112,000 and \$7,000, respectively. As of April 3, 2010, the weighted average number of years until the next renewal is 2 years for patents and 6 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.

New Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update 2009-13, or ASU No. 09-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements*. ASU No. 09-13 modifies the requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. This update shall be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Earlier application as of the beginning of the Company's fiscal year is permitted, provided it has not previously issued financial statements for any period within that year. The Company is currently evaluating what impact this update will have on its condensed consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update 2009-14, or ASU No. 09-14, *Software (Topic 985): Certain Revenue Arrangements That Include Software Elements*. ASU No. 09-14 modifies the software revenue recognition guidance to exclude from its scope tangible products that contain both software and non-software components that function together to deliver a product's essential functionality. ASU No. 09-14 is effective for fiscal years beginning after June 15, 2010 and may be applied retrospectively or prospectively for new or materially modified arrangements. Earlier application as of the beginning of the Company's fiscal year is permitted, provided it has not previously issued financial statements for any period within that year. The Company is currently evaluating what impact this update will have on its condensed consolidated financial statements.

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)****3. Comprehensive Income**

The Company's total comprehensive income attributable to Masimo Corporation is as follows (in thousands):

	Three Months Ended	
	April 3, 2010	April 4, 2009
Net income including noncontrolling interests	\$ 26,164	\$ 13,264
Other comprehensive income:		
Foreign currency translation gain (loss)	64	(491)
Total comprehensive income before noncontrolling interests	26,228	12,773
Net (income) loss attributable to the noncontrolling interests	546	(243)
Other comprehensive income attributable to noncontrolling interests		
Comprehensive income attributable to Masimo Corporation	\$ 26,774	\$ 12,530

4. Variable Interest Entities (VIEs)

Effective January 1, 2010, the Company adopted a newly issued accounting standard which provides guidance for the consolidation of VIEs and requires an enterprise to determine whether its variable interest gives it a controlling financial interest in a VIE. This amended consolidation guidance for VIEs replaces the existing *quantitative* approach for identifying which enterprise should consolidate a VIE, with a *qualitative* approach. The Company's adoption of this standard did not change its initial assessment and it will continue to consolidate both Masimo Labs and SEDLine. 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.

The changes in noncontrolling interest for the consolidated VIEs from January 2, 2010 to April 3, 2010 are as follows (in thousands):

	Amount
Noncontrolling interests, as of January 2, 2010	\$ 974
Increase in additional paid-in capital of noncontrolling interest	17
Net loss attributable to noncontrolling interests	(546)
Other comprehensive income attributable to noncontrolling interests	
Noncontrolling interests, as of April 3, 2010	\$ 445

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

Masimo Laboratories, Inc.

Edgar Filing: MASIMO CORP - Form 10-Q

Masimo Laboratories, Inc., or Masimo Labs, 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, or Board, are also members of the board of directors of Masimo Labs. Joe Kiani, the Company's Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs. The Company is a party to a Cross-Licensing Agreement with Masimo Labs, which was most recently amended and restated effective January 1, 2007, that governs each party's rights to certain intellectual property held by the two companies.

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

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

The Company exclusively licenses from Masimo Labs the right to make and distribute products in the professional medical caregiver markets, or the Masimo Market, that utilize Rainbow technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation, and total hemoglobin, which includes hematocrit. To date, the Company has developed and commercially released devices that measure carbon monoxide, methemoglobin and total hemoglobin using licensed Rainbow technology. The Company also has the option to obtain the exclusive license to make and distribute products that utilize Rainbow technology for the measurement of other non-vital signs parameters, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver.

From May 1998 through May 2009, Masimo Labs contracted the services of the Company's employees for the development of Rainbow technology. The Company paid Masimo Labs for the option to market and develop products based on Masimo Labs technology in defined markets. Through December 2005, the Company paid Masimo Labs \$7.5 million in option fees. Nearly all these option fees were used by Masimo Labs to repay the Company for the services that the Company had provided to Masimo Labs. In addition, through September 2009, the Company exercised its options to three licenses, for \$2.5 million each, for the right to market products based on the new carbon monoxide, methemoglobin and total hemoglobin parameter technologies developed by Masimo Labs. Effective as of January 1, 2007, the Company entered into a Services Agreement with Masimo Labs to govern the general and administrative services the Company provides to Masimo Labs.

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

The Company is also subject to certain specific annual minimum aggregate royalty payments. These minimum aggregate royalty payments were \$1.25 million and \$1.0 million for the three months ended April 3, 2010 and April 4, 2009, respectively. In addition, in connection with a change in control, as defined in the Cross-Licensing Agreement, the minimum aggregate annual royalties for all licensed Rainbow parameters payable to Masimo Labs will increase to \$15.0 million per year for 2010 and thereafter and up to \$2.0 million per year for other Rainbow parameters.

In order to accelerate the product development of Masimo's total hemoglobin spot check measurement device, in February 2009, the Masimo Board of Directors agreed to fund additional Masimo Labs' engineering expenses. Specifically, these expenses included third party engineering materials and supplies expense as well as 50% of total Masimo Labs' engineering and engineering related payroll expenses from April 2009 until completion of the product development efforts. During the three months ended April 3, 2010, these expenses totaled \$756,000.

The condensed consolidated balance sheets include a noncontrolling interest in Masimo Labs of \$1.2 million and \$974,000 as of April 3, 2010 and January 2, 2010, respectively, which represents the value of common stock, additional paid in capital and retained earnings of Masimo Labs, which is not available to Masimo Corporation. In addition, the condensed consolidated balance sheets include, net of intercompany eliminations, total assets of \$4.5 million and \$4.9 million as of April 3, 2010 and January 2, 2010, respectively, related to Masimo Labs. Of the total assets as of April 3, 2010 and January 2, 2010, \$1.9 million and \$1.9 million, respectively, were for intangible assets of Masimo Labs. Also, for both periods presented, \$1.6 million was for deferred tax assets. The condensed consolidated balance sheets include total liabilities, net of intercompany eliminations, of \$927,000 and \$1.5 million as of April 3, 2010 and January 2, 2010, respectively, related to Masimo Labs. Upon consolidation, \$3.3 million of receivables due from Masimo Corporation as of both April 3, 2010 and January 2, 2010, was eliminated. Also upon consolidation, \$5.9 million and \$6.0 million of deferred revenue related to technology licensed to Masimo Corporation as of April 3, 2010 and January 2, 2010, respectively, were eliminated. Masimo Corporation has not been required to collateralize any of Masimo Labs' obligations, and creditors of Masimo Labs have no recourse to the general credit of Masimo Corporation.

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

Pursuant to authoritative accounting guidance, Masimo Labs is consolidated within the Company's financial statements for all periods presented. The Company was required to consolidate since it was deemed to be the primary beneficiary of Masimo Labs' activities. This determination was based on the obligation to absorb the expected losses, as well as exercising significant influence over the operations and decision making of Masimo Labs. Accordingly, all inter-company royalties, option and license fees and other charges between the Company and Masimo Labs 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 Masimo Labs have not been eliminated and are included as research and development expense in the Company's condensed consolidated statements of income.

SEDLine, Inc.

SEDLine, Inc., or SEDLine, a privately held entity that was formed in the fourth quarter of 2009, is a company with the mission to expand the scope and applications for neuromonitoring. This entity manufactures and sells brain function monitoring devices to hospitals. The Company made loans to SEDLine totaling \$3.0 million during 2009. These loans, which are secured by the assets of SEDLine, bear an initial interest rate of 7% and may be converted into equity upon certain events. These loans, if converted to equity, would entitle the Company to a 39% ownership in SEDLine. However, as of April 3, 2010, the Company had 0% ownership of SEDLine and therefore 100% of SEDLine's net loss was allocated to deficit noncontrolling interest. Pursuant to an investment agreement with SEDLine, the Company is obligated to provide additional loans of up to \$1.5 million subject to SEDLine achieving certain product development milestones. Concurrent with the investment agreement, the Company and SEDLine entered into a merger agreement, whereby the Company may acquire SEDLine at certain pre-determined valuations. Also, in December 2009, the Company purchased two patents from SEDLine for \$500,000. Pursuant to authoritative accounting guidance, it was determined that the Company is the primary beneficiary of SEDLine and therefore is required to consolidate SEDLine's financial statements within the Company's financial statements.

The condensed consolidated balance sheets include a deficit noncontrolling interest in SEDLine of \$760,000 and \$0 as of April 3, 2010 and January 2, 2010, respectively, which represents the retained deficit of SEDLine, which is not available to Masimo Corporation. In addition, the condensed consolidated balance sheets include, net of intercompany eliminations, total assets of \$2.5 million and \$3.0 million as of April 3, 2010 and January 2, 2010, respectively, related to SEDLine. Of the total assets as of April 3, 2010 and January 2, 2010, \$969,000 and \$1.7 million, respectively, was for cash and cash equivalents. Also, \$709,000 and \$627,000 was for inventory of SEDLine as of April 3, 2010 and January 2, 2010, respectively. The condensed consolidated balance sheets include total liabilities, net of intercompany eliminations, of \$162,000 and \$0 as of April 3, 2010 and January 2, 2010, respectively, related to SEDLine. Also, SEDLine had \$3.1 million and \$3.0 million of notes payable, including interest, to Masimo Corporation, which was eliminated upon consolidation, as of April 3, 2010 and January 2, 2010, respectively. Masimo Corporation has not been required to collateralize any of SEDLine's obligations, and creditors of SEDLine have no recourse to the general credit of Masimo Corporation.

5. Related Party Transactions

As of April 3, 2010 and January 2, 2010, the Company had amounts due from employees of \$236,000 and \$242,000, respectively, which are classified in other assets in the accompanying condensed consolidated balance sheets.

Since 1997, the Company's Chief Executive Officer has been a member of the board of directors of Saba Software, Inc., a human capital development and management solutions provider. The Company paid Saba Software \$0 and \$15,000 during the three months ended April 3, 2010 and April 4, 2009, respectively, for various software products and services.

The Company's Chief Executive Officer is also the Chairman of the Masimo Foundation for Ethics, Innovation and Competition in Healthcare, or Masimo Foundation, a non-profit organization which was founded to benefit worldwide healthcare. For the three months ended April 3, 2010, the Company contributed a total of \$10.3 million to the Masimo Foundation, which has been recorded within selling, general and administrative expenses in the condensed consolidated statements of income.

6. Cash, Cash Equivalents and Short-Term Investments

Edgar Filing: MASIMO CORP - Form 10-Q

As of April 3, 2010, the Company's cash balance was \$15.0 million, comprised of checking and savings accounts. Additionally, the Company had cash equivalents of \$21.1 million, consisting of \$20.0 million of U.S. Treasury bills with a maturity of three months or less at the date of purchase, and \$1.1 million of money market funds.

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

As of January 2, 2010, the Company's cash balance was \$11.4 million, comprised of checking and savings accounts. Additionally, the Company had cash equivalents of \$120.7 million, consisting of \$119.0 million of U.S. Treasury bills with a maturity of three months or less at the date of purchase, and \$1.7 million of money market funds.

Short-term investments at January 2, 2010 and April 3, 2010, consist of U.S. Treasury bills with a maturity between three months and one year at the date of purchase.

As of January 2, 2010, short-term investments of \$57.0 million were classified as held-to-maturity and recorded at amortized cost, which approximated fair value. Gross unrecognized gains or losses as of January 2, 2010 were de minimis.

In March 2010, the Company received \$27.0 million from the sale of specific short-term investments classified as held-to-maturity, prior to their maturity date. The proceeds were used to pay a portion of the special dividend declared in February 2010. The carrying value of these short-term investments sold was their amortized cost basis of approximately \$27.0 million and the realized loss on the sale of these short-term investments was de minimis. The remaining short-term investments with a carrying value of \$30.0 million were reclassified as available-for-sale, but were redeemed at their maturity dates, which were prior to April 3, 2010.

As of April 3, 2010, short-term investments of \$76.0 million are classified as available-for-sale. These available-for-sale short-term investments are recorded at fair value. For the three months ended April 3, 2010, the unrealized gain or loss on these investments was de minimis. Accordingly, the amortized cost basis of these investments is \$76.0 million.

7. Royalties Receivable

The royalty receivable of \$12.0 million as of April 3, 2010, represents the Company's estimated amount due for the three months ended April 3, 2010. Pursuant to the settlement agreement 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 following quarter, when the Company receives the Covidien royalty report, which is generally 60 days after the end of each of Covidien's fiscal quarters.

8. 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):

	April 3, 2010	January 2, 2010
Raw materials	\$ 20,663	\$ 18,259
Work in-process	3,781	3,949
Finished goods	9,255	9,351
Total	\$ 33,699	\$ 31,559

9. Capital Lease Obligations

Capital lease obligations, classified as long-term debt, consist of the following not including interest expense (in thousands):

	April 3, 2010	January 2, 2010
Capital lease obligations	\$ 216	\$ 231
Less current portion of capital lease obligations	(61)	(60)
Long-term portion	\$ 155	\$ 171

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

The Company currently has six capital leases related to office equipment. These leases have interest rates ranging from 5.2% to 8.8% per year and mature on various dates from March 2011 through May 2014. As of April 3, 2010, the total future remaining interest cost under all capital leases was \$17,000.

10. Share-Based Compensation

In April 2004, the Company adopted the 2004 Incentive Stock Option, Nonqualified Stock Option, and Restricted Stock Purchase Plan, or the 2004 Plan, which initially provided for the issuance of options to purchase up to 3,000,000 shares of the Company's common stock, plus any shares available under the prior year stock option plans, including shares that become available due to forfeitures at prices not less than the fair market value of the Company's common stock on the date the option is granted, as determined by the Board. 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. The Board approved increases in the number of shares available for grant under the 2004 Plan to 4,500,000 shares on February 6, 2006, 6,000,000 shares on November 1, 2006 and 7,500,000 shares on May 24, 2007.

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, 3,000,000 shares of common stock were initially reserved for future issuance, plus shares available under the prior year equity incentive plans, including shares that become available under the 2007 Plan due to forfeitures at prices not less than the fair market value of the Company's common stock on the date the option is granted. 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 forfeited under the 2007 Plan and the Company's other option plans are automatically added to the share reserve of the 2007 Plan. Pursuant to the evergreen provision contained in the 2007 Plan, an additional 1,719,796 shares of common stock were added to the share reserve of the 2007 Plan on January 4, 2009, which represented 3% of the Company's total shares outstanding as of the close of business on January 3, 2009. In addition, pursuant to the evergreen provision, 1,736,294 shares of common stock were added to the share reserve of the 2007 Plan on January 3, 2010, which represented 3% of the Company's total shares outstanding as of January 1, 2010.

The number and weighted average exercise price of options issued and outstanding under all stock option plans, at exercise prices ranging between \$2.75 and \$41.51 per share, are as follows:

	Three Months Ended April 3, 2010	
	Shares	Average Exercise Price
Options outstanding, beginning of period	8,125,871	\$ 18.21
Granted	573,125	\$ 27.37
Canceled	(195,590)	\$ 24.09
Expired	(30,000)	\$ 1.83
Exercised	(883,381)	\$ 6.06
Options outstanding, end of period	7,590,025	\$ 20.23
Options exercisable, end of period	3,092,306	\$ 13.92
Options available for grant, end of period	5,512,733	

The weighted-average fair value of options granted was \$11.00 for the three months ended April 3, 2010.

Edgar Filing: MASIMO CORP - Form 10-Q

The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended	
	April 3, 2010	April 4, 2009
Risk-free interest rate	2.5% to 2.8%	1.3% to 1.9%
Expected term	5.5 years	5.29 years
Estimated volatility	37.5% to 39.9%	52.3% to 55.1%
Expected dividends	0%	0%

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)**

In accordance with authoritative accounting pronouncements, the Company recorded share-based compensation expense of \$2.8 million and \$2.6 million during the three months ended April 3, 2010 and April 4, 2009, 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 April 3, 2010 was \$60.7 million. The aggregate intrinsic value of options exercisable, with an exercise price less than the closing price of the Company's common stock, as of April 3, 2010 was \$43.2 million. The aggregate intrinsic value of options exercised during the three months ended April 3, 2010 was \$19.3 million. The aggregate intrinsic value is calculated as the difference 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 April 3, 2010 was \$51.7 million related to unvested options granted after January 1, 2006. The weighted average remaining contractual term of options outstanding as of April 3, 2010 was 6.4 years. The weighted average remaining contractual term of options exercisable as of April 3, 2010 was 5.0 years.

11. Commitments and Contingencies**Leases**

The Company leases its facilities in North America, Europe and Asia under operating lease agreements expiring at various dates through September 2014. Certain facilities leases contain pre-determined price escalations. 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 \$650,000 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 April 3, 2010 and January 2, 2010, rent expense accrued in excess of the amount paid aggregated \$105,000 and \$100,000, respectively, and is classified in other liabilities. The Company also leases automobiles in Europe and Japan that are classified as operating leases and expire at various dates through October 2010.

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):

	As of April 3, 2010		
	Operating Leases	Capital Leases	Total
2010 (balance of year)	\$ 2,209	\$ 54	\$ 2,263
2011	2,710	57	2,767
2012	2,661	53	2,714
2013	2,591	49	2,640
2014	1,883	20	1,903
Thereafter			
Total	\$ 12,054	\$ 233	\$ 12,287

Rental expense related to operating leases was \$927,000 and \$862,000 for the three months ended April 3, 2010 and April 4, 2009, respectively.

Employee Retirement Savings Plan

In fiscal year 1996, the Company adopted the Masimo Retirement Savings Plan, or the Plan, which is a 401(k) plan covering all of the Company's full-time U.S. employees who meet certain eligibility requirements. The Company contributes to the Plan on a discretionary basis.

Edgar Filing: MASIMO CORP - Form 10-Q

The Company contributed \$254,000 and \$267,000 to the Plan for the three months ended April 3, 2010 and April 4, 2009, respectively, all in the form of matching contributions.

Employment and Severance Agreement

As of April 3, 2010, the Company had an employment agreement with one of its key employees that provides for an aggregate annual base salary of \$706,992 plus other benefits, with annual increases at the discretion of the Compensation Committee of the Board. The agreement with the Company, which was restated effective July 14, 2009, also provides for an annual bonus based on the Company's attainment of certain objectives and goals. The agreement had an initial term of three years, with automatic 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.

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

On January 11, 2008, the Company entered into a severance plan participation agreement with three 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 was amended effective December 31, 2008. Under 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 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.

On February 18, 2009, the Company entered into a limited severance plan participation agreement with three of its executive officers. The limited participation agreements, or Limited Agreements, are governed by the terms and conditions of the Severance Plan. Under the Limited Agreements, 50% of the executive officer's unvested and outstanding stock options will immediately vest if he is terminated by the Company upon a change in control 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 \$31.7 million of purchase commitments as of April 3, 2010, of which at least \$31.2 million is expected to be purchased within one year. The remaining \$500,000 may be purchased within the next one to two years. The Company does not have any purchase commitments for more than two years. 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. As of April 3, 2010, the Company had \$15.0 million of bank balances, of which \$8.1 million was covered by the Federal Deposit Insurance Corporation limit. The Company invests its excess cash deposits in U.S. Treasury bills and money market accounts with major financial institutions. As of April 3, 2010, the Company had \$96.0 million, including cash equivalents and short-term investments, in U.S. Treasury bills which are 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 excess 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 Group Purchasing Organizations, or GPOs. Many existing and potential customers for the Company's products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. During the three months ended April 3, 2010 and April 4, 2009, revenue from the sale of the Company's pulse oximetry products to U.S. hospitals that are members of GPOs amounted to \$43.8 million and \$41.3 million, respectively.

For the three months ended April 3, 2010 and April 4, 2009, one customer represented 13% and 17% of the total revenue, respectively. For all periods, this particular customer was a distributor, which takes and fulfills orders from the Company's direct customers, many of whom have signed long-term sensor agreements with the Company. In the event this distributor was unable to fulfill these orders, the orders would be redirected to other distributors or fulfilled directly by the Company.

As of April 3, 2010, two customers represented 7% and 6% of the accounts receivable balance. As of January 2, 2010, two customers each represented 6% of the accounts receivable balance.

Litigation

In May 2002, the Company filed a lawsuit against Tyco Healthcare, parent company of Nellcor, in the U.S. District Court for the Central District of California, alleging damage to the Company's business as a result of the anti-competitive business practices of Tyco Healthcare. Specifically, the Company alleges that it had incurred damages as a result of a series of illegal exclusionary and anti-competitive acts by Tyco Healthcare that were designed to maintain its monopoly in the pulse oximetry market in violation of federal antitrust laws.

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

In March 2005, a jury found that Tyco Healthcare's use of sole-source contracts, product bundling and market share-based compliance pricing contracts, among other conduct, violated the federal antitrust laws and awarded damages on that basis. Tyco Healthcare filed post-trial motions requesting that the District Court either override the jury decision or grant a new trial. In March 2006, the District Court upheld a portion of the jury verdict and vacated the remaining verdict. In addition, the District Court vacated the jury's damages award and granted Tyco Healthcare a new trial on damages. After a retrial of damages to the court, on July 2, 2007, the District Court entered its final judgment awarding the Company damages which were trebled as is mandatory under federal antitrust law to \$43.5 million and denying the Company's request for a permanent injunction with respect to Tyco Healthcare's business practices found to be anti-competitive. The Company and Tyco Healthcare each filed a notice of appeal from the judgment. The Company sought reinstatement of the jury's verdict on bundling and an affirmation of the liability findings concerning sole-source and market share-based compliance contracts. The Company also asked the appellate court to increase the amount of damages awarded by the trial court.

On October 28, 2009, the Ninth Circuit Court of Appeals affirmed the district court's decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its Nellcor pulse oximetry products. On January 11, 2010, the Company completed negotiations to resolve the merits of its antitrust litigation with Covidien, following the Ninth Circuit Court of Appeals October 2009 affirmation of a Federal District Court decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products. The judgment against Covidien for the antitrust violations was for \$43.5 million; however, the total payment, after reimbursement for legal fees, costs, and interest was \$59.0 million. In January 2010, the Company received a total of \$30.1 million which represented the portion of the total payment from Covidien less the amount paid to the law firm that handled the trial for the Company.

On February 3, 2009, the Company 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 Philips patient monitors. The suit was brought in the U.S. District Court for the District of Delaware. Two patents at issue in this suit, related to the Company's measure-through-motion technology, were successfully enforced in its previous suit against Nellcor. On June 15, 2009, Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH 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 their patent misuse defense, as well as stayed the discovery phase on those claims pending trial in the patent case. 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 April 24, 2009, the Company sent a letter to Hygia Health Services, Inc., or Hygia, demanding that Hygia cease and desist from reprocessing used Masimo sensors. In response to that cease and desist letter, on May 5, 2009, Hygia filed a Declaratory Judgment action against the Company in the District Court for the Northern District of Alabama, Southern Division. On May 28, 2009, the Company filed its counterclaims, alleging patent and trademark infringement, unfair competition, false designation of origin and injury to business reputation. On June 24, 2009, Hygia filed its reply to the Company's counterclaims, denying the allegations, and has alleged that the Company's patents are unenforceable. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does 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.

Table of Contents**MASIMO CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(unaudited)****12. 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 non-invasive 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 interests. In addition, the Company's assets are primarily located in the U.S. and are not allocated to any specific region. 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.

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):

Geographic Area by Destination	Three Months Ended			
	April 3, 2010		April 4, 2009	
North and South America	\$ 64,898	75.6%	\$ 58,856	79.0%
Europe, Middle East and Africa	12,198	14.2	9,433	13.0
Asia and Australia	8,770	10.2	6,208	8.0
Total product revenue	\$ 85,866	100%	\$ 74,497	100%

Sales to customers located in the U.S. were \$60.9 million and \$57.2 million for the three months ended April 3, 2010 and April 4, 2009, respectively.

13. Income Taxes

As of April 3, 2010, the balance of the gross unrecognized tax benefit was \$8.4 million, of which \$7.2 million (net of federal benefit on state taxes), if recognized, would affect the effective tax rate. As of January 2, 2010, the balance of the gross unrecognized tax benefit was \$8.1 million, of which \$6.9 million (net of federal benefit on state taxes), if recognized, would affect the 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 decrease up to \$2.0 million in the next 12 months due to the expiration of statutes of limitation.

Interest and penalties related to unrecognized tax benefits are recognized in income tax expense. For the three months ended April 3, 2010 and April 4, 2009, the Company expensed \$100,000 and \$73,000 respectively, for interest.

The Company conducts business in multiple jurisdictions, and as a result, one or more of the Company's subsidiaries files income tax returns in the U.S. federal, various state, local and foreign jurisdictions. Due to the generation of net operating loss carryforwards, all years since 1994 are open for examination by major taxing authorities.

The provision for income taxes was \$14.3 million and \$6.5 million, or an effective tax rate of 35.3% and 33.0%, for the three months ended April 3, 2010 and April 4, 2009, respectively. The effective tax rate differs from the statutory U.S. federal income tax rate of 35% primarily due to state taxes, permanent differences between pre-tax income for financial reporting purposes and taxable income, research related tax credits and anticipated income in jurisdictions in which the Company does business with lower effective tax rates.

Table of Contents**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 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, and similar expressions or variations. These 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 Form 10-Q and in our other Securities and Exchange Commission, or SEC, filings including our Annual Report on Form 10-K for the fiscal year ended January 2, 2010, which we filed with the SEC on February 17, 2010. 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.

Overview

We are a global medical technology company that develops, manufactures and markets noninvasive patient monitoring products that improve patient care. We 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. Pulse oximetry is the noninvasive measurement of the oxygen saturation level of arterial blood, or the blood that delivers oxygen to the body's tissues, and pulse rate. Conventional pulse oximetry is subject to technological limitations that reduce its effectiveness and the quality of patient care. In particular, when using conventional pulse oximetry, arterial blood signal recognition can be distorted by motion artifact, or patient movement, and low perfusion, or low arterial blood flow. Low perfusion can also cause the failure of the conventional pulse oximeter to obtain an accurate measurement. Conventional pulse oximetry readings can also be impacted by bright light and electrical interference from the presence of electrical surgical equipment. Published independent research shows that over 70% of the alarms were false outside the operating room using conventional pulse oximetry. Our Masimo SET platform has addressed many of the previous technology limitations. The benefits of Masimo SET have been validated in over 100 independent clinical and laboratory studies.

We develop, manufacture and market a family of noninvasive blood constituent patient monitoring solutions that consists of a monitor or circuit board and our proprietary single-patient use and reusable sensors and cables. In addition, we offer remote-monitoring and clinician notification solutions. Although our Masimo SET platform is only operable with our proprietary sensors, our sensors have the capability to work with certain competitor pulse oximeters through the use of our adapter cables. In 2005, we launched our Masimo Rainbow SET Pulse CO-Oximetry platform utilizing licensed Rainbow technology from Masimo Labs, which enables the noninvasive and continuous measurement of not only arterial blood oxygen saturation level and pulse rate, but also carboxyhemoglobin, or carbon monoxide levels in the blood, methemoglobin (2006) saturation levels in the blood and total hemoglobin (2008), or the oxygen-carrying component of red blood cells. In 2007, we launched PVI, which is a measurement that quantifies changes in the plethysmographic waveform over the respiration cycle. Along with the release of our Masimo Rainbow SET Pulse CO-Oximetry products, we have developed multi-wavelength sensors that have the ability to monitor multiple parameters with a single sensor. In November 2009, we received U.S. Food and Drug Administration, or the FDA, clearance for Rainbow Acoustic Monitoring for continuous and noninvasive monitoring of respiration rate, or RRA, which is the number of breaths per minute. In December 2009, we announced initial market release of the parameter and expect to continue limited market release activities throughout the first half of 2010 and we are planning for full commercial launch in the second half of 2010.

We have focused on building our U.S. and international sales and marketing infrastructure to market our products to end-users, such as hospitals, and to original equipment manufacturer, or OEM, partners for incorporation into their patient-monitoring products. We market our pulse oximetry products to hospitals and the alternate care market through our direct sales force, and market our circuit boards to our OEM partners. Today, the primary focus of our hospital sales force is to facilitate the conversion of hospitals to our Masimo SET or Masimo Rainbow SET products. In the U.S., we typically enter into long-term sales contracts with hospitals, pursuant to which we ship and install our pulse oximeters at no cost to the hospital in exchange for a commitment to purchase a minimum number of sensors from us over a specified period of time. With the introduction of Masimo Rainbow SET Pulse CO-Oximetry, we have established a small sales force to concentrate on the alternate care market. Over the past year, we have expanded our sales and marketing staffing levels. We supplement our direct sales with sales through our distributors who, within the U.S., function as inventory or fulfillment houses for our hospital customers. Direct and distributor sales have increased to \$68.0 million, or 79.2%, of product revenue for the three months ended April 3, 2010, from \$59.5 million, or 79.8%, of product revenue for three months ended April 4, 2009. We expect our revenue from direct and distributor sales to continue to increase over the long term.

as we expand our worldwide direct sales force.

Table of Contents

The building of our installed base of pulse oximeters and pulse oximeter circuit boards generates recurring sales of our sensors, primarily single-patient use sensors. A user of one of our pulse oximeters or our OEMs pulse oximeters can obtain the benefit of the Masimo SET or Masimo Rainbow SET only by using our proprietary sensors that are designed for our system. We currently estimate that our worldwide installed base was 757,000 units, based on an estimated 10 year field life assumption, as of April 3, 2010, up from 651,000 units as of April 4, 2009. We estimate our installed base to be the number of pulse oximeters and pulse oximeter circuit boards that we have shipped in the past 10 years. We expect our worldwide installed base to continue to increase as we expand our market share and expand the pulse oximetry market to other patient care settings.

Antitrust Litigation Proceeds

On January 11, 2010, we completed negotiations to resolve the merits of our antitrust litigation with Covidien and, as a result, we retained \$30.1 million from a payment from Covidien following the Ninth Circuit Court of Appeals October 2009 affirmation of a Federal District Court decision that Tyco Healthcare, now Covidien violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products. The judgment against Covidien for the antitrust violations was for \$43.5 million; however, the total payment, after reimbursement for legal fees, costs, and interest was \$59.0 million. The portion of the total payment from Covidien that was not retained by us was paid to the law firm that handled the trial for us.

Of the \$30.1 million retained, we intend to spend approximately \$15.0 million on one-time marketing initiatives, including the establishment of the Masimo Foundation, expanded clinical research and other direct marketing related activities focused on expanding market awareness of our new products. As of April 3, 2010, we have spent a total of \$10.9 million, including \$10.3 million to establish and fund the Masimo Foundation and \$675,000 for various one-time grants and marketing activities.

Dividend Payment

Over the past year, our Board has evaluated a variety of options to return capital to shareholders, including acquisition opportunities and a stock buy-back program before concluding that a special dividend was the best and most direct way to reward shareholders for their continued investment and confidence in Masimo. Therefore, in February 2010, we declared a special \$2.00 per share cash dividend, payable on March 31, 2010 to stockholders of record as of the close of business on March 11, 2010. The total dividend payout was \$117.5 million.

We previously paid special dividends to shareholders in 2006 and 2007 totaling \$4.09 per share related to the 2006 intellectual property patent suit settlement agreement with a competitor. While there can be no guarantees of future dividends, our Board remains committed to enhancing shareholder value based on their consideration of various factors, including our operating results, financial condition and anticipated capital requirements. This special dividend represented only a portion of our cash reserves, which the Board believes is sufficient to cover operational needs, and to fund continued research and development investments and strategic initiatives.

Masimo Laboratories, Inc.

Masimo Laboratories, Inc., or Masimo Labs, 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 Masimo Labs. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs. We are a party to a cross-licensing agreement with Masimo Labs, which was 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.

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

Table of Contents

We exclusively license from Masimo Labs the right to make and distribute products in the professional medical caregiver markets, or the Masimo Market, that utilize Rainbow technology for the measurement of carbon monoxide, methemoglobin, fractional arterial oxygen saturation and total hemoglobin, which includes hematocrit. To date, we have developed and commercially released devices that measure carbon monoxide, methemoglobin and total hemoglobin using licensed Rainbow technology. We also have the option to obtain the exclusive license to make and distribute products that utilize Rainbow technology for the measurement of other non-vital signs parameters, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver.

In order to accelerate the product development of our total hemoglobin spot check measurement device, in February 2009, we agreed to fund additional Masimo Labs engineering expenses. Specifically, these expenses included third party engineering materials and supplies expense as well as 50% of total Masimo Labs engineering and engineering related payroll expenses from April 2009 until completion of the product development efforts. During the three months ended April 3, 2010, these expenses totaled \$756,000. For additional discussion of Masimo Labs, see note 4 to the condensed consolidated financial statements.

SEDLine, Inc.

SEDLine, Inc., or SEDLine, a privately held entity that was formed in December 2009, is a company with the mission to expand the scope and applications for neuromonitoring. SEDLine manufactures and sells brain function monitoring devices to hospitals. We made loans to SEDLine totaling \$3.0 million during 2009. These loans, which are secured by the assets of SEDLine, bear an initial interest rate of 7% and may be converted into equity upon certain events. These loans, if converted to equity, would entitle us to a 39% ownership in SEDLine. However, as of April 3, 2010, we had 0% ownership of SEDLine and therefore 100% of SEDLine's net loss was considered noncontrolling interest to us. Pursuant to an investment agreement with SEDLine, we are obligated to provide additional loans up to \$1.5 million subject to SEDLine achieving certain product development milestones. Concurrent with the investment agreement, we entered into a merger agreement with SEDLine, whereby we may acquire SEDLine at certain pre-determined valuations. Also, in December 2009, we purchased two patents from SEDLine for \$500,000. Pursuant to authoritative accounting guidance, it was determined that we are the primary beneficiary of SEDLine for 2009 and therefore are required to consolidate SEDLine's financial statements within our financial statements. We have not been required to collateralize any of SEDLine's obligations, and creditors of SEDLine have no recourse to our general credit. For additional discussion of SEDLine, see note 4 to the condensed consolidated financial statements.

For the foreseeable future, we anticipate that we will continue to consolidate both of our Variable Interest Entities, Masimo Labs and SEDLine, pursuant to the current authoritative accounting guidance; however, in the event that Masimo Labs or SEDLine is no longer considered a VIE or in the event that we are no longer the primary beneficiary of Masimo Labs or Sedline, we may discontinue consolidating the entity.

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).

	April 3, 2010	Three months ended % of Revenue	April 4, 2009	% of Revenue
Revenue:				
Product	\$ 85,866	86.9%	\$ 74,497	87.1%
Royalty	12,899	13.1	10,995	12.9
Total revenue	98,765	100.0	85,492	100.0
Cost of goods sold	29,228	29.6	24,745	28.9
Gross profit	69,537	70.4	60,747	71.1
Operating expenses:				
Research and development	9,410	9.5	7,767	9.1
Selling, general and administrative	49,311	49.9	32,880	38.5
Antitrust litigation expense (proceeds)	(29,968)	(30.3)	14	
Total operating expenses	28,753	29.1	40,661	47.6

Edgar Filing: MASIMO CORP - Form 10-Q

Operating income	40,784	41.3	20,086	23.5
Non-operating expense	(347)	(0.4)	(287)	(0.3)
Income before provision for income taxes	40,437	40.9	19,799	23.2
Provision for income taxes	14,273	14.5	6,535	7.6
Net income including noncontrolling interests	26,164	26.4	13,264	15.6
Net (income) loss attributable to the noncontrolling interests	546	0.6	(243)	(0.3)
Net income attributable to Masimo Corporation	\$ 26,710	27.0%	\$ 13,021	15.3%

Table of Contents***Comparison of the Three Months ended April 3, 2010 to the Three Months ended April 4, 2009***

Revenue. Total revenue increased \$13.3 million, or 15.5%, to \$98.8 million for the three months ended April 3, 2010 from \$85.5 million for the three months ended April 4, 2009.

Product revenues increased \$11.4 million, or 15.3%, to \$85.9 million in the three months ended April 3, 2010 from \$74.5 million in the three months ended April 4, 2009. This increase was primarily due to higher consumable sales resulting from an increase in our installed base of circuit boards and pulse oximeters which we estimate totaled 757,000 units at April 3, 2010 up from 651,000 units at April 4, 2009, based on an estimated 10 year field life assumption. Revenue generated through our direct and distribution sales channels increased to \$68.0 million, up 14.4%, for the three months ended April 3, 2010, compared to \$59.5 million for the three months ended April 4, 2009. During the three months ended April 3, 2010 revenues from our OEM channel increased to \$17.8 million, up 18.7%, from \$15.0 million in the three months ended April 4, 2009. Contributing to the increase in our product revenue was an increase in our Rainbow technology product revenues which rose 71% to \$5.3 million in the three months ended April 3, 2010, from \$3.1 million in the three months ended April 4, 2009.

Our royalty revenue increased \$1.9 million to \$12.9 million in the three months ended April 3, 2010 from \$11.0 million in the three months ended April 4, 2009. For the three months ended April 3, 2010 and April 4, 2009, our reported Covidien royalties are based upon an estimate of Covidien's U.S. pulse oximeter sales for that period and the contractual royalty rate as prescribed by the 2006 settlement agreement.

Cost of Goods Sold. Cost of goods sold increased \$4.5 million, or 18.1% to \$29.2 million in the three months ended April 3, 2010 from \$24.7 million in the three months ended April 4, 2009. Our total gross margin decreased to 70.4% for the three months ended April 3, 2010 from 71.1% for the three months ended April 4, 2009. Excluding royalties, the product gross profit margins decreased by 0.8% to 66.0% for the three months ended April 3, 2010 from 66.8% for the three months ended April 4, 2009. This decrease in margin was primarily due to lower manufacturing absorption levels resulting from start up training costs associated with our transition of manufacturing processes to Mexico, a change in product mix towards a higher volume of monitor and board revenues, as well as selected inventory charge-offs related to product transition activity. We incurred \$1.3 million and \$1.0 million in Masimo Labs' royalty expenses for the three months ended April 3, 2010 and April 4, 2009, respectively, which have been eliminated in our condensed consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 64.5% and 65.4% for the three months ended April 3, 2010 and April 4, 2009, respectively.

Research and Development. Research and development expenses increased \$1.6 million, or 21.2%, to \$9.4 million for the three months ended April 3, 2010, from \$7.8 million for the three months ended April 4, 2009. The increase was primarily due to additional engineering supplies and new project costs of \$772,000 for clinical trials research related to new product development during the three months ended April 3, 2010, compared to April 4, 2009. In addition, payroll and payroll related costs increased by \$477,000 due to the increased research and development staffing levels. Included in these total research and development expenses are \$771,000 and \$685,000 of engineering expenses incurred in total by our variable interest entities, for the three months ended April 3, 2010 and April 4, 2009, respectively.

Selling, General and Administrative. Selling, general and administrative expenses increased \$16.4 million, or 50.0%, to \$49.3 million for the three months ended April 3, 2010 from \$32.9 million for the three months ended April 4, 2009. The increase was primarily due to \$10.9 million of one-time expenses, comprised of a \$10.3 million contribution to establish the Masimo Foundation, various charitable and research related donations of \$509,000 and other marketing initiatives of \$107,000. The \$10.3 million gift to the Masimo Foundation represents a portion of the \$30.1 million payment we received in January 2010, following the Ninth Circuit Court of Appeals' October 2009 affirmation of a Federal District Court judgment in our favor that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products. Excluding the impact of these one-time expenses, total selling, general and administrative expenses increased \$5.5 million, or 16.7%, to \$38.4 million for the three months ended April 3, 2010. This increase was due primarily to increased payroll and payroll related costs of \$4.1 million associated with increased staffing levels, and increased legal fees of \$750,000 during the three months ended April 3, 2010, compared to the same prior year period. Included in these total selling, general and administrative expenses are \$934,000 and \$81,000 of direct expenses incurred in total by our variable interest entities, for the three months ended April 3, 2010 and April 4, 2009, respectively.

Table of Contents

Antitrust litigation expenses (proceeds). Antitrust litigation proceeds were \$30.0 million for the three months ended April 3, 2010, as compared to expenses of \$14,000 for the three months ended April 4, 2009. The change was due to retaining \$30.1 million from a payment from Covidien in January 2010, upon completion of negotiations to resolve the merits of the antitrust litigation with Covidien. This resolution followed the Ninth Circuit Court of Appeals October 2009 affirmance of a Federal District Court decision that Tyco Healthcare, now Covidien violated the antitrust laws through anticompetitive business practices related to the sale of its pulse oximetry products.

Non-Operating expense. Non-operating expense, net was \$347,000 for the three months ended April 3, 2010, as compared to \$287,000 for the three months ended April 4, 2009. This net expense increase of \$60,000 was due to a reduction in interest income, as a result of a decline in interest rates for the three months ended April 3, 2010 as compared to the three months ended April 4, 2009.

Provision for Income Taxes. Our provision for income taxes was \$14.3 million for the three months ended April 3, 2010, compared to \$6.5 million for the three months ended April 4, 2009. Our effective tax rate increased to 35.3% for the three months ended April 3, 2010, compared to 33.0% for the three months ended April 4, 2009. Excluding Masimo Labs and SEDLine, our effective tax rate increased to 34.6% for the three months ended April 3, 2010, from 33.2% for the three months ended April 4, 2009. This increase in the effective tax rate excluding Masimo Labs and SEDLine was due primarily to the suspension of the federal research and experiment credit and the change in mix of income in jurisdictions in which we do business. Our future effective income tax rate will depend on various factors, including profits (losses) before taxes, changes to tax law and the geographic composition of pre-tax income.

Net income (loss) attributable to the noncontrolling interests. Net loss attributable to the noncontrolling interests was \$546,000 for the three months ended April 3, 2010, as compared to net income of \$243,000 for the three months ended April 4, 2009. This net change of \$789,000 was primarily due to the addition of SEDLine's \$760,000 loss for the three months ended April 3, 2010, as compared to \$0 for the three months ended April 4, 2009. Also, Masimo Labs had income of \$214,000 for the three months ended April 3, 2010, as compared to \$243,000 for the same prior year period. For both periods presented, we did not absorb any of the income or loss of SEDLine or Masimo Labs in the calculation of our net income attributable to Masimo Corporation.

Liquidity and Capital Resources

As of April 3, 2010, we had cash and short-term investments of \$112.1 million, of which \$96.0 million was invested in U.S. Treasury bills, \$1.1 million was in money market accounts with major financial institutions and \$15.0 million was in checking accounts and certificates of deposit. We carry cash equivalents at cost which approximates fair value.

The cash and short-term investment balance declined to \$112.1 million as of April 3, 2010, from \$189.0 million as of January 2, 2010, primarily due to the dividend payment of \$117.5 million in March 2010, offset by \$30.1 million of antitrust litigation proceeds. During the three months ended April 3, 2010, we have received \$12.4 million from Covidien for royalties related to their sales. We expect to continue to receive a royalty based on Covidien's pulse oximetry products sales in the U.S., through the term of the royalty agreement and at least through March 14, 2011. The royalty rate is currently 13%, but may decline to 10%, subject to Covidien's ability to develop new products or technologies that avoid some of our current patent coverage as negotiated in our settlement agreement with Covidien. Should Covidien discontinue paying the royalty payment after March 14, 2011, our royalty revenue will decline to zero, which would have a material impact on our cash flow from operations and condensed consolidated financial statements.

Cash Flows from Operating Activities. Cash provided by operating activities was \$36.1 million in the three months ended April 3, 2010. The source of cash consists primarily of net income including noncontrolling interests of \$26.2 million and an increase in income taxes payable of \$11.4 million as a result of higher income during the three months ended April 3, 2010. Additionally, deferred revenue increased \$4.4 million, accounts payable increased \$4.3 million and non-cash share-based compensation was \$2.8 million, all due to continued growth of our business. These sources of cash were partially offset by an increase in accounts receivable of \$7.4 million resulting from higher sales, a decrease in accrued compensation of \$2.6 million as a result of accrued bonus payouts in the first quarter of 2010, and an increase in inventory of \$2.4 million to meet increased demand for our products.

Table of Contents

Cash provided by operating activities was \$5.7 million in the three months ended April 4, 2009. The source of cash consists primarily of net income including noncontrolling interest of \$13.3 million, non-cash share-based compensation of \$2.6 million, and an increase in deferred revenue of \$2.7 million due to the continued growth of our business. These sources of cash were partially offset by a net decrease in income tax liability of \$6.1 million, resulting from the combination of our \$14.9 million payment for our tax charge related to the implementation of a new international business organization and structure, offset by our first quarter of 2009 tax provision accrual. In addition, uses of cash included an increase in accounts receivable of \$5.5 million due to the growth of our business, an increase in inventory of \$2.6 million to meet the increasing demand for our products, and a decrease in accrued compensation of \$2.3 million related to the payment of certain year end obligations, including management and employee bonuses.

Cash Flows from Investing Activities. Cash used in investing activities for the three months ended April 3, 2010 was \$21.1 million consisting of purchases of short-term investments of \$76.0 million, offset by sales and maturities of short-term investments of \$57.0 million, due to our investment strategy of obtaining higher interest rates while preserving capital. Additionally, we used \$1.9 million of cash to purchase property and equipment to support our manufacturing operations. Cash used in investing activities for the three months ended April 4, 2009 was \$995,000 consisting primarily of \$676,000 of property and equipment purchases related primarily to assets to support our manufacturing operations and \$340,000 for the increase in intangible assets related to capitalized patent related expenses.

Cash Flows from Financing Activities. Cash used in financing activities for the three months ended April 3, 2010 was \$110.8 million, primarily due to \$117.5 million of dividend payments, offset by \$5.4 million of proceeds from the issuance of common stock associated with the exercise of stock options. Cash provided by financing activities for the three months ended April 4, 2009 was \$725,000. This total net cash flow was primarily due to \$739,000 of proceeds from the issuance of common stock.

Future Liquidity Needs. 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 international operations including manufacturing, sales, marketing and other areas of necessary infrastructure growth. Our focus on international expansion will also require both continuing and incremental investments in facilities and infrastructure in the Americas, Europe and Asia. We also anticipate possible uses of cash for the acquisition of technologies or the acquisition of technology companies. The amount and timing of our actual investing activities will vary significantly depending on numerous factors, such as the progress of our product development efforts, our timetable for international sales operations and manufacturing expansion and both domestic and international regulatory requirements. Despite these capital investment requirements, we anticipate that our existing cash and cash equivalents will be sufficient to meet our working capital requirements, capital expenditures and operations for at least the next 12 months. In addition, we remain committed to our previously announced programs to intensify marketing and clinical research efforts this year using funds awarded from a recent legal decision.

Current Financing Arrangements. As of April 3, 2010, we had capital leases related to office equipment with an outstanding balance of \$216,000 and total remaining interest of \$17,000. We had no other debt obligations.

Dividend Payment. In February 2010, we declared a special \$2.00 per share cash dividend, payable on March 31, 2010 to stockholders of record as of the close of business on March 11, 2010. The total dividend payout was \$117.5 million. This special dividend represents only a portion of our cash reserves, which our Board believes is sufficient to cover operational needs, and fund continued research and development investments and strategic initiatives.

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.

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, or GAAP. The preparation of these condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as revenue and expenses during the reporting periods. Significant estimates include: determination of accounts receivable

Edgar Filing: MASIMO CORP - Form 10-Q

allowances, inventory reserves, warranty reserves, rebate reserves, valuation of our stock options, distributor channel inventory, royalty revenues, deferred revenue, property tax and uncertain income tax positions. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results therefore could differ materially from those estimates under different assumptions or conditions.

Table of Contents

For a description of our critical accounting policies and estimates, please refer to the *Critical Accounting Estimates* section of the *Management's Discussion and Analysis of Financial Condition and Results of Operations* section contained in our Annual Report on Form 10-K for the year ended January 2, 2010 filed with the SEC on February 17, 2010. There have been no material changes in any of our accounting policies since January 2, 2010.

New Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update 2009-13, or ASU No. 09-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements*. ASU No. 09-13 modifies the requirements that must be met for an entity to recognize revenue from the sale of a delivered item that is part of a multiple-element arrangement when other items have not yet been delivered. This update shall be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Earlier application as of the beginning of our fiscal year is permitted, provided we have not previously issued financial statements for any period within that year. We are currently evaluating what impact this update will have on our condensed consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update 2009-14, or ASU No. 09-14, *Software (Topic 985): Certain Revenue Arrangements That Include Software Elements*. ASU No. 09-14 modifies the software revenue recognition guidance to exclude from its scope tangible products that contain both software and non-software components that function together to deliver a product's essential functionality. ASU No. 09-14 is effective for fiscal years beginning after June 15, 2010 and may be applied retrospectively or prospectively for new or materially modified arrangements. Earlier application as of the beginning of our fiscal year is permitted, provided we have not previously issued financial statements for any period within that year. We are currently evaluating what impact this update will have on our condensed consolidated financial statements.

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 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 fluctuation in interest expense is limited to our outstanding capital lease arrangements, which have fixed interest rates. 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 drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest-sensitive financial instruments at April 3, 2010. 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. We transact with foreign customers in currencies other than the U.S. dollar. These foreign currency revenues, when converted into U.S. dollars, can vary depending on average exchange rates during a respective period. In addition, we are exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of income as incurred. Certain of our foreign sales support subsidiaries transact in their respective country's local currency, which is also their functional currency. As a result, expenses of these foreign subsidiaries when converted into U.S. dollars can vary depending on average monthly exchange rates during a respective period. Certain intercompany transactions may give rise to realized and unrealized foreign currency gains or losses. These foreign currency gains or losses are included in our statements of income as incurred. In addition, any other transactions between us or our subsidiaries and a third party, denominated in a currency different from the functional currency, are a foreign currency transaction. Realized and unrealized foreign currency gains or losses on these transactions are included in our statements of income as incurred and are converted to U.S. dollars at average exchange rates for a respective period.

Table of Contents

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 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 (loss).

Our primary foreign currency exchange rate exposures are with the Euro, the Japanese yen, the Canadian dollar, the British pound and the Australian dollar against the U.S. dollar. 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 an immediate 10% change in foreign currency exchange rates could have a material effect on our future operating results or cash flows, depending on which foreign currency exchange rates change and depending on the directional change (either a strengthening or weakening against the U.S. dollar). As our foreign operations continue to grow, our exposure to foreign currency exchange rate risk may become more significant.

Inflation Risk

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

Item 4. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure 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) 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.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended April 3, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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 related to Philips FAST pulse oximetry technology and certain Philips patient monitors. The suit was brought in the U.S. District Court for the District of Delaware. Two patents at issue in this suit, related to our measure-through motion technology, were successfully enforced in our previous suit against Nellcor. On June 15, 2009, Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH 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 their patent misuse defense, as well as stayed the discovery phase on those claims pending trial in the patent case. Philips has objected to this decision. 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 it does prevail.

From time to time, we are involved in legal proceedings in the ordinary course of business. Other than the proceeding described above and in our Annual Report on Form 10-K for the year ended January 2, 2010, we are not currently involved in any material legal proceedings.

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 with the SEC on February 17, 2010, together with the other information contained in this Quarterly Report on Form 10-Q. We believe the risks described below are the risks that are material to us as of the date this Quarterly Report on Form 10-Q is initially filed with the SEC. If any of the following risks comes to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you could lose all or part of your investment or interest.

We have marked with an asterisk () those risk factors below that include a substantive change from the risk factors included in our Annual Report on Form 10-K filed with the SEC on February 17, 2010.*

Risks Related to Our Revenues

We currently derive substantially all of our revenue from our Masimo 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. 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, 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. 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.

Edgar Filing: MASIMO CORP - Form 10-Q

Our products that have been 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. Our first product incorporating licensed Rainbow technology was made commercially available in September 2005. In September 2008, we began our limited market release of total hemoglobin, and focused on obtaining data and clinical feedback on the performance of the product in the hospital. In the first quarter of 2009, we commercially launched our total hemoglobin product for continuous and noninvasive monitoring in the hospital. We also have begun our limited market release of Rainbow Acoustic Monitoring and we expect to do full commercial launch in the second half of 2010. As with our total hemoglobin release, we have initially provided this new measurement to the market in a limited market release to allow us to evaluate the product's performance in the field. However, there can be no assurances of when we will roll it out fully.

Table of Contents

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 and effectiveness of our products and their sales prices;

reimbursement available through Centers for Medicare and Medicaid Services, or CMS, programs for using our products; and

introduction and acceptance of competing products or technologies;

In order for any of our products to be accepted in the marketplace, we must demonstrate that they are effective and commercially beneficial. Even if customers accept these products, this acceptance may not result in sales if our competitors develop similar products that our customers prefer over ours. 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.

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 Masimo Labs, which may impair our growth and adversely affect our financial condition and results of operations.

In May 1998, we created a newly-formed entity, Masimo Laboratories, Inc., or Masimo Labs, 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 Masimo Labs, which has been amended several times, most recently in an Amended and Restated Cross-Licensing Agreement, effective January 1, 2007, or the Cross-Licensing Agreement. Under the Cross-Licensing Agreement, we granted Masimo Labs:

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 measurement 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 by a professional medical caregiver, which we refer to as the Labs Market, and

a non-exclusive, perpetual and worldwide license, with sublicense rights, to use all Masimo SET for measurement of vital signs in the Labs 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, total hemoglobin and bilirubin.

Under the Cross-Licensing Agreement, we are only permitted to sell devices utilizing Masimo SET for the measurement of non-vital signs measurements 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 market, 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 Masimo Labs the right to make and distribute products in the Masimo Market that utilize Rainbow technology for the measurement of only carbon monoxide, methemoglobin, fractional arterial oxygen saturation and total hemoglobin, which includes hematocrit. As a result, the opportunity to expand the market for our products incorporating Rainbow technology is limited, which could limit our ability to maintain or increase our revenue and impair our growth.

Table of Contents

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.

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 acoustic 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.

We depend on our 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 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, or at all. The failure of our OEM partners to successfully market, sell or distribute products incorporating these technologies, the termination of OEM agreements, the loss of OEM partners or the inability to enter into future OEM partnership agreements would have a material adverse effect on our business, financial condition and results of operations.

*** If we fail to maintain 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 group purchasing organizations, or 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 the contractual arrangement. For the three months ended April 3, 2010 and April 4, 2009, shipments of our pulse oximetry products to customers that are members of GPOs represented, were \$43.8 million and \$41.3 million, respectively, of our revenue from sales to U.S. hospitals. Our failure to renew our contracts with GPOs may cause us to lose market share and could have a material adverse effect on our 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.

If we are unable to increase our sales, marketing and distribution capabilities or maintain or establish arrangements with third parties to sell, market and distribute our pulse oximetry and Rainbow technology products, our business, financial condition and results of operations could be adversely affected.

We have limited sales and marketing experience both in the U.S. and internationally and may not be successful in developing and implementing our business strategy. In addition, we currently have a small sales organization compared to many of our competitors. To increase our commercial capabilities, we need to:

increase our sales and marketing forces;

Edgar Filing: MASIMO CORP - Form 10-Q

continue to maintain domestic and international OEM partners;

ensure that distributors and OEM partners provide the technical and educational support customers need to use products incorporating Masimo SET and Rainbow technology successfully;

Table of Contents

promote monitoring systems using Masimo SET and Rainbow technology so that sales of those systems and our sensors increase;
and

be prepared to provide services, as necessary, to geographically dispersed users of monitoring systems using Masimo SET and Rainbow technology.

Failure to accomplish any of these requirements could have a material adverse effect on our business, financial condition and results of operations.

We currently plan to increase the size of our direct sales force to further market our products in the U.S. and internationally. Increasing our direct sales capabilities will be expensive and time consuming and we may not be able to further develop this capacity on a timely basis or at all. If we are unable to expand our sales and marketing capabilities, we will need to continue to contract with third parties to market, sell and distribute our approved products in the U.S. and internationally, which could cause our product revenue to be lower than if we directly marketed, sold and distributed our products. Furthermore, to the extent that we enter into co-promotion or other sales and marketing arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we are unable to maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate sufficient product revenue to be profitable.

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.

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.

Recent deterioration in the credit markets and the financial services industry may negatively impact our business, results of operations, financial condition and liquidity.

Since 2008, the credit markets and the financial services industry have experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. While the ultimate outcome of these events cannot be predicted, they may have a material adverse effect on our liquidity, financial condition and results of operations if our customers' ability to borrow money from their existing lenders, or to obtain credit from other sources to purchase our products under long term sensor agreements, were to be impaired. This credit market deterioration could affect our ability to acquire new customers for our products. In addition, the recent economic crisis could also adversely impact our suppliers' ability to provide us with materials and components, either of which may negatively impact our ability to meet our customers' requirements and grow our business.

Edgar Filing: MASIMO CORP - Form 10-Q

We cannot guarantee that we will continue to experience the same collection rates that we have in the past, especially given the recent deterioration of the credit markets worldwide. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in our receivable collections and additional allowances may be required. These additional allowances could materially and adversely affect our financial results.

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

As a result of the current worldwide economic environment, 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.

Table of Contents

In addition to the overall economic environment, there are specific portions of our business, such as our OEM customers, who, due to their capital equipment sales model, could be impacted by the ongoing economic environment and the resulting constraints on hospital budgets. These hospital budget constraints could cause our OEMs more difficulty in selling their large, relatively high priced multi-parameter 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 total hemoglobin are sold with upfront license fees and more complex, and therefore, more expensive sensors could be impacted by hospital budget reductions.

The difficult economic environment and its impact on hospital budgets could also have other implications to our business, financial condition and results of operations. As an example, despite our agreements and our customers' acknowledged preference for disposable single patient adhesive sensors due to performance and risk of contamination, our customers that are worried about finances could take desperate measures such as switching from disposable sensors to reusable sensors. In addition, our customers could also begin purchasing third party recycled sensors, rather than our new sensors, in an attempt to reduce their overall operating costs.

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

We also 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, we would 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 that we will be able to attract and retain additional customers in the future. For the three months ended April 3, 2010 and April 4, 2009, one of our customers represented 13% and 17%, respectively, of our total revenue. The loss of this customer could have a material adverse effect on our financial condition and results of operations.

Medical device reproprocessors that reprocess our single-use sensors and then resell them to hospitals at a cost lower than our new sensors, may adversely affect our business, financial condition and results of operations.

Certain medical device reproprocessors have been collecting our used single-use sensors from hospitals and then reprocessing, repackaging and reselling those sensors to hospitals at a price lower than our new sensors. These reprocessed sensors may lead to confusion with our authorized products, reduce our revenue and harm our customer relationships. In addition, this may increase time and expense spent investigating and addressing performance issues with the reprocessed sensors, and enforcing our proprietary rights and contracts against the reproprocessors.

*** Our royalty agreement with Covidien provides for a royalty rate schedule that could decline over the term of the settlement agreement. In addition, Covidien has the option to stop paying on March 14, 2011, which could significantly reduce our royalty revenue, total revenues and operating results due to not only the loss of royalties, but to the potential legal fees associated with a potential lawsuit resulting from Covidien's continued patent infringement of our technology.**

During the three months ended April 3, 2010, our royalties from the Covidien settlement totaled \$12.9 million. 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, any decline in 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. Under the current settlement agreement, we earn royalties on Covidien's total U.S.-based pulse oximetry sales. The royalty rate in 2006 was nearly 20% if averaged over the entire year. The royalty rate for 2007 declined to 15%. In 2008, 2009 and through the remaining term of the settlement agreement, which will continue at least through March 14, 2011, the royalty rate is 13%, but may decline to 10%, subject to Covidien's ability to develop new products that avoid some of our current patent coverage as negotiated in the settlement agreement. As a result, our total revenues, gross margins, operating income and earnings per share could be significantly reduced as compared to prior periods if we are unable to generate sufficient revenues and gross margins to offset either the impact of declining royalty rates or declining sales of Covidien's pulse oximetry products in the U.S.

The current royalty agreement provides Covidien with the option to stop paying the royalty on March 14, 2011. In exchange for this royalty payment, we have provided Covidien the ability to ship its patent infringing product with our covenant not to sue Covidien as long as they are abiding by the terms of the agreement. Should Covidien decide to discontinue abiding by the terms of the current settlement agreement, including paying us the required royalty payment, then our royalty payments could decline to zero which would have a material impact on our royalty revenue, total revenues, gross margins, operating income and earnings per share. In addition, if Covidien chooses to discontinue abiding by the terms of the current settlement and to continue to ship its pulse oximetry technology, then it is likely that we would file a new patent infringement lawsuit against Covidien resulting in higher legal expenses which would increase our operating expenses thereby adversely impacting our business, financial condition and results of operations.

Table of Contents

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, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect our technology. 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, or 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. These proceedings could result in adverse decisions as to the claims included in our patents. Our issued and licensed patents and those that may be issued or licensed in the future may expire, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Some Masimo patents related to our Masimo SET algorithm technology begin to expire in March 2011. Additionally, upon expiration of our issued or licensed patents, we may lose some of our rights to exclude others from making, using, selling or importing products using the technology based on the expired patents. We also must rely on contractual rights with the third parties that license technology to us to protect our rights in the technology licensed to us. There is no assurance that competitors will not be able to design around our patents. We also 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. Our common law trademarks provide less protection than our registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

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

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

Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage in the marketplace. Whether a technology or product infringes a patent involves complex legal and factual issues and is often difficult to determine. 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;

Edgar Filing: MASIMO CORP - Form 10-Q

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;

Table of Contents

require us to redesign, reengineer or rebrand our products, product candidates and technologies;

require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property on terms that may not be favorable or acceptable to us;

require us to indemnify third parties pursuant to contracts in which we have agreed to provide indemnification for intellectual property infringement claims;

divert the attention of our management and other key employees;

result in our customers or potential customers deferring or limiting their purchase or use of the affected products impacted by the claims until the claims are resolved; and

otherwise have a material adverse effect on our business, financial condition and results of operations.

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

We believe competitors may currently be violating and may in the future violate our intellectual property rights, and we may bring additional litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert 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. On February 3, 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 Philips patient monitors. Two patents at issue in this suit, related to our measure-through-motion technology, were successfully enforced in a previous suit by us against Nellcor. On June 15, 2009, Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH 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 their patent misuse defense, as well as stayed the discovery phase on those claims pending trial in the patent case. Philips has objected to this decision. Both Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH are associated with Philips Medical Systems, an OEM partner of ours.

We believe that other competitors of ours, including some of our OEM partners, may be infringing at least one of our patents. Our failure to pursue any potential claim could result in the loss of our proprietary rights and harm our position in the marketplace. Therefore, we may be forced to pursue litigation to enforce our rights. Our ongoing and future litigation could result in significant additional costs and further divert the attention of our management and key personnel from our business operations and the implementation of our business strategy and may not be adequate to protect our intellectual property rights.

Risks Related to Our Regulatory Environment

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

Edgar Filing: MASIMO CORP - Form 10-Q

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, or pre-market approval, or 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 assure you 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 year 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 has informally modified its 510(k) review protocol and process. Specifically, it appears that the FDA's medical device product reviews currently require applicants to provide much more information and data than in prior periods, the FDA is not consistently relying upon prior precedents leading 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 12 months, which has delayed the 510(k) clearance process for our products and uses over this period compared to prior periods. In addition, in September 2009, the FDA commissioned the Institute of Medicine to study the premarket notification program used to review and clear certain medical devices marketed in the U.S. It is believed that this study may result in formal changes to the FDA's 510(k) clearance review and approval processes which could potentially lengthen the review process of any future application of ours even further.

Table of Contents

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 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 assure you 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. In particular, we and our suppliers are required to comply with FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, component suppliers control, quality assurance, labeling, 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. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, discovery of previously unknown problems with our products (including unanticipated adverse events or adverse events of unanticipated severity or frequency), manufacturing problems, or failure to comply with regulatory requirements, or failure to adequately respond to any FDA observations concerning these issues, 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; and

operating restrictions.

Furthermore, our key component suppliers may not currently be, or may not continue to be, in compliance with applicable regulatory requirements. 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.

Table of Contents

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.

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. We have made modifications to our devices in the past and we may make additional modifications in the future, some of which we may believe do not or will not require additional clearances or approvals. 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 changes could make it more difficult for us to maintain or attain approval to develop and commercialize our products and technologies.

If our products cause or contribute to a death or serious injury, 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, or MDR, 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 occurred involving devices produced or sold by the manufacturer.

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 April 3, 2010, we initiated four voluntary recalls of our products, none of which was material to our operating results. Each of these recalls was reported to the FDA within the appropriate regulatory timeframes. Because of our dependence upon patient and physician perceptions, any negative publicity associated with these 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.

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. We must have adequate substantiation for our product performance claims. 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 result in significant fines or penalties under other

Edgar Filing: MASIMO CORP - Form 10-Q

statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, we would be subject to extensive fines and penalties and 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.

Table of Contents

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 and health information privacy and security 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);

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 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;

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 health information.

We have certain arrangements with hospitals that may be affected by these 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.

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.

We are required to comply with federal and state laws governing the transmission, security and privacy of individually identifiable health information that we may obtain or have access to in connection with manufacture and sale of our products. We may be required to make costly system modifications to comply with the 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 HITECH.

Table of Contents

Numerous other federal and state laws protect the confidentiality of patient information 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.

State and federal human subject protection laws apply to our receipt of individually identifiable health information 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.

*** 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 recently enacted 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. Significantly, President Obama recently signed health care reform legislation into law that will require most individuals to have health insurance, establish new regulations on health plans, and create insurance pooling mechanisms and other expanded public health care measures. This legislation also will reduce Medicare spending on services provided by hospitals and other providers and, after December 31, 2012, impose a 2.3% tax on the sale of a taxable medical device by the manufacturer, producer or importer. Our operating expenses resulting from this excise tax and results of operations will be materially and adversely affected if we are unable to pass the excise tax onto our customers.

Many details of the recently enacted health care reform legislation will be addressed in the implementing regulations. 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.

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.

Furthermore, many private payors look to Medicare's coverage and reimbursement policies in setting their coverage policies and reimbursement amounts such that federal reforms could influence the private sector as well. Finally, many states also may attempt to reform their Medicaid programs such that either coverage for certain items or services may be narrowed or reimbursement for them could be reduced. These health care reforms may adversely affect our business.

Consistent with or in addition to Congressional or state reforms, the Centers for Medicare and Medicaid Services, or 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.

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. Such changes are particular possibilities in light of the 2008 elections in the U.S. There may be heightened scrutiny by federal and state regulators and legislators of the FDA's device approval process, the agency's efforts to assure the safety of marketed devices, and physician payments and promotional activities by manufacturers. 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.

Further, our success in international markets also depends 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.

Table of Contents

Risks Related to Our Business and Operations

Masimo Labs has conducted most of the research and development of Rainbow technology and we are dependent upon Masimo Labs to develop improvements to Rainbow technology.

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

We will experience conflicts of interest with Masimo Labs with respect to business opportunities and other matters.

Prior to our initial public offering in August 2007, our stockholders owned approximately 99% of the outstanding shares of capital stock of Masimo Labs and we believe that as of January 2, 2010, a number of stockholders of Masimo Labs continued to own shares of our stock. Joe Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs. Jack Lasersohn, another member of our board of directors, also serves on the board of directors of Masimo Labs. Due to the interrelated nature of Masimo Labs with us, conflicts of interest will arise with respect to transactions involving business dealings between us and Masimo Labs, 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 Masimo Labs. We cannot assure you that any conflict of interest will be resolved in our favor, or that with respect to our transactions with Masimo Labs we will negotiate terms that are as favorable to us as if such transactions were with an unaffiliated third party.

We will be required to pay Masimo Labs 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 measurement of non-vital signs measurements, we would be required to assign these developments to Masimo Labs and then license the technology back from Masimo Labs in consideration for a license fee and royalty obligations to Masimo Labs. Therefore, any improvement to this technology would be treated as if it had been developed exclusively by Masimo Labs. In addition, we will not be reimbursed by Masimo Labs 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 measurement of non-vital signs measurements, which could adversely affect our business, financial condition and results of operations.

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

The Cross-Licensing Agreement requires us to pay Masimo Labs a royalty for all products that we sell which include their proprietary Rainbow technology. This includes handheld, table-top and multi-measurement products that incorporate licensed Rainbow technology. Beginning in 2009, for hospital contracts where we place equipment and enter into a sensor contract, we will pay a royalty to Masimo Labs on the total sensor contract revenue based on the ratio of Rainbow enabled devices to total devices. The agreement also requires that we provide to Masimo Labs, 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 Masimo Labs specific annual minimum royalty payments.

Currently, we are required to consolidate Masimo Labs within our financial statements. Accordingly, the royalties that we owe to Masimo Labs are eliminated in our consolidated financial statements presented within this Annual Report on Form 10-K 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 Masimo Labs. We are also obligated to include, and have included, Masimo Labs' engineering and administrative expenses in our reported engineering and administrative expenses. If our financial statements were not consolidated with Masimo Labs, 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 and therefore, the net impact to our consolidated financial statements has not been significant. However, in the future, depending upon the success of Rainbow products and the royalties earned by Masimo Labs on those revenues, it is possible that the royalty expense will grow at a rate higher than the growth of engineering and administrative expenses. In the event the net impact on our consolidated results is material, we will reflect the amount of Masimo Labs income through our consolidated statement of income as an element of noncontrolling interest income. As a result, despite the current requirement to consolidate, any profit in our consolidated financial results that is attributable to Masimo Labs will be separately identified.

Table of Contents

Despite describing and reflecting this Masimo Labs consolidation requirement within our financial statements, failure to understand or appreciate the significance of our consolidation of Masimo Labs 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 Masimo Labs grants a license to Rainbow technology to a third party, our business would be materially and adversely affected.

Masimo Labs owns all of the proprietary rights to Rainbow technology developed with our proprietary Masimo SET for products intended to be used in the Labs 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, Masimo Labs 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 Masimo Labs or competitors who obtain a license to Rainbow technology from Masimo Labs would be able to offer related products.

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

It is generally more expensive for us to make products that incorporate Rainbow technology than products that do not due to increased production costs and the royalties that we must pay to Masimo Labs. In order to successfully commercialize products incorporating Rainbow technology, we must be able to pass these higher costs on to the market. We cannot assure you that we will be able to sell products incorporating Rainbow technology at a price the market is willing to accept. If we cannot commercialize our products incorporating licensed Rainbow technology successfully, we may not be able to generate sufficient product revenue from these products to be profitable, which could adversely affect our business, financial condition and results of operations.

Rights provided to Masimo Labs in the Cross-Licensing Agreement may impede a change in control of our company.

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 Masimo Labs for use in blood glucose monitoring. 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 Masimo Labs. Additionally, our per product royalties payable to Masimo Labs will become subject to specified minimums, and the minimum aggregate annual royalties for all licensed Rainbow measurements payable to Masimo Labs is \$15.0 million for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, total 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 Masimo Labs. 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 Masimo Labs could impede a change in control of our company.

We may experience significant fluctuations in our quarterly results in the future and we may not maintain our recent 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;

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;

Table of Contents

changes in our product or customer mix;

unanticipated delays or problems in the introduction of new products, including delays in obtaining clearance or approval from the FDA; and

high levels of returns and repairs.

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.

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 or the adoption of new rules may adversely affect our reported financial results or the way we conduct our business.

We face competition from other companies, many of which have substantially greater resources than we do and may be able to develop products perceived as more effective or easier to use than ours or are more readily accepted, or offer their products at lower prices than we can, which could adversely affect our business, financial condition and results of operations.

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. Our revenue and profit are significantly smaller than our primary competitors. A number of our competitors have substantially greater capital resources, larger customer bases, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours, and have established stronger reputations with our target customers and built relationships with GPOs and worldwide distribution channels that are more effective than ours. 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. Reliance on clinical studies is an important means of demonstrating the effectiveness of products in our industry. If clinical studies supporting our competitors' products are perceived to be accurate and reliable, market acceptance and sales of our products could be adversely impacted and we could lose market share to our competitors.

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. We carry key person life insurance on only Mr. Kiani, who is also the Chief Executive Officer of Masimo Labs. Mr. Kiani devotes most of his time to us.

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 four 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:

Edgar Filing: MASIMO CORP - Form 10-Q

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;

Table of Contents

limited or no direct prior experience in new markets or countries we may enter;

higher costs of integration than we anticipated; and

difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions.

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.

Our international business structure may not result in expected operational benefits.

In the fourth quarter of 2008, we implemented an international business structure designed to better serve and support our growing international business. By centralizing our international operations, including sales management, marketing, customer support, planning, logistics and administrative functions, we believe we will be able to develop a more efficient and scalable international organization capable of being even more responsive to the business needs of our international customers all under one centralized management structure. We commenced the implementation of an international business structure to align our operations with the business needs of our non-U.S. customers and we believe that we may, in the long run, also benefit from certain operational benefits and achieve a lower overall tax rate. However, there can be no assurance that our efforts will produce any anticipated operational benefits or provide an overall lower tax rate. Realization of the expected benefits will depend on a number of factors, including our future business results and profitability, the effectiveness and timing of our implementation of our international business structure, changes in U.S. or international tax law and the geographic composition of our pre-tax income. Legislative action may be taken by the U.S. Congress which, if ultimately enacted, could adversely affect our effective tax rate and/or require us to take further action, at potentially significant expense, to seek to preserve our effective tax rate. We cannot predict the outcome of any specific legislative proposals. However, if proposals were enacted that had a negative effect on our international business structure, we could be subjected to increased taxation and/or potentially significant expense.

*** 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. During the three months ended April 3, 2010 and April 4, 2009, 29.0% and 23.3%, 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;

Table of Contents

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;

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. Accordingly, our operating results are subject to fluctuations in foreign currency exchange rates. When the U.S. dollar weakens against these currencies, the dollar value of foreign-currency denominated revenue and expense increases, and when the dollar strengthens against these currencies, the dollar value of foreign-currency denominated revenue and expense decreases. We are exposed to foreign currency risk on outstanding foreign currency denominated receivables and payables. Changes in exchange rates may adversely affect our results of operations. Our primary foreign currency exchange rate exposures are with the Euro, the Japanese yen, the British pound, the Canadian dollar and the Australian dollar against the U.S. dollar.

We currently do not hedge against our foreign currency exchange rate risks and therefore believe our exposure to these risks may be higher than if we entered into hedging transactions, including forward exchange contracts or similar instruments. If we decide in the future to enter into forward foreign exchange contracts to attempt to reduce the risk related to foreign currency exchange rates, 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, these types of contracts may themselves cause financial harm to us and have inherent levels of counterparty risk over which we would have no control.

*** We manufacture our products at two locations and any disruption in these manufacturing facilities could adversely affect our business, financial condition and results of operations.**

To date, we have relied on our manufacturing facilities in Irvine, California and Mexicali, Mexico. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since both our Irvine, California and Mexicali, Mexico 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 organizations, 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 facility. 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, we may incur additional

Edgar Filing: MASIMO CORP - Form 10-Q

costs and we may experience a disruption in the supply of our products until those facilities are available. 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 could 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, and 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.

Table of Contents

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 or that the prices we pay for these materials or components will not increase. 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 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 the requirements of Section 404 on a timely basis 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.

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, or malfunction of, or design flaws or manufacturing defects in, our products or the use of our products with incompatible components or systems. Any losses that we may suffer from product liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our technology and products, together with the corresponding diversion of the attention of our key employees, may subject us to significant damages and could adversely affect our business, financial condition and results of operations. We cannot be certain that our product liability insurance will be sufficient to cover any or all damages or claims. 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.

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.

Future environmental laws may significantly affect our operations because, for instance, our manufacturing processes may be required to be altered, which may increase our manufacturing costs. 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, including to our employees, or contamination from these

Edgar Filing: MASIMO CORP - Form 10-Q

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.

Table of Contents

Risks Related to Our Stock

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

There has been significant volatility in the market price and trading volume of equity securities, which is often unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our stock. From January 3, 2010 to April 3, 2010, our closing stock price ranged from \$25.73 to \$29.76. 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.

Some specific factors, in addition to the other risk factors identified above, that may have a significant effect on our stock market price, many of which we cannot control. 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;

our inability to raise additional capital as needed;

concern as to the efficacy of our products;

changes in financial markets or general economic conditions;

sales of stock by us or members of our management team, our Board of Directors or certain institutional stockholders; and

Edgar Filing: MASIMO CORP - Form 10-Q

changes in stock market analyst recommendations or earnings estimates regarding our stock, other comparable companies or our industry generally.

In particular, the current decline of the financial markets and related factors beyond our control, including the credit and mortgage crisis in both the U.S. and worldwide, may cause our stock price to decline rapidly and unexpectedly.

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

As of April 3, 2010, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned 12.1% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, the 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 us or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our stock. In addition, these stockholders, some of whom have representatives sitting on our board of directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes in control of us, 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.

Table of Contents

*** 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 April 3, 2010, an aggregate of 13,102,758 shares of our stock were reserved for future issuance under our three equity incentive plans, 7,590,025 of which were subject to options outstanding as of that date at a weighted average exercise price of \$20.23 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.

Future resales of our stock, including those by our insiders, may cause our stock price to decline.

A large portion of our outstanding shares are held by directors, executive officers and a small number of investment funds. Resale by these stockholders of a substantial number of shares, announcements of the 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.

In March 2009, we registered an aggregate of 4,657,660 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 the anti-takeover provisions of the 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. An interested stockholder means, generally, 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 the stockholder rights plan if any person becomes the beneficial owner of 15% or more of the outstanding shares of 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 to not declare cash dividends on our stock, or may elect to only pay dividends on an infrequent or irregular basis, and any return on your investment may be limited to the value of our stock.

Our board of directors 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 of directors 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 of directors declares any dividends, there is no assurance with respect

to the amount, timing or frequency of any such dividends.

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.

Table of Contents

SIGNATURES

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

MASIMO CORPORATION

Date: May 4, 2010

By: */s/* JOE KIANI
Joe Kiani
Chief Executive Officer and Chairman

Date: May 4, 2010

By: */s/* MARK P. DE RAAD
Mark P. de Raad
Executive Vice President and Chief Financial Officer

Table of Contents**EXHIBIT INDEX****Exhibit**

Number	Description of Document
2.1	(1) Asset Purchase Agreement, dated December 21, 2005, between the Company, Masimo Canada ULC and Andromed Inc. (Exhibit 2.1)
2.1(a)	(1) List briefly identifying the contents of schedules omitted from Exhibit 2.1 (Exhibit 2.1(a))
3.1	(1) Amended and Restated Certificate of Incorporation (Exhibit 3.2)
3.2	(2) Certificate of Designation of Series A Junior Participating Preferred Stock (Exhibit 3.1)
3.3	(3) Amended and Restated Bylaws adopted on October 9, 2008 (Exhibit 3.1)
4.1	(1) Form of Common Stock Certificate (Exhibit 4.1)
4.2	(1) Fifth Amended and Restated Registration Rights Agreement made and entered into as of September 14, 1999 between the Registrant and certain of its stockholders (Exhibit 4.2)
4.3	(2) Rights Agreement, dated November 9, 2007, between the Company and Computershare Trust Company, N.A., as Rights Agent (Exhibit 4.1)
4.4	(4) Masimo Retirement Savings Plan. (Exhibit 4.7)
31.1	Certification of Joe Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
31.2	Certification of Mark P. de Raad, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended
32.1	Certification of Joe Kiani, Chief Executive Officer, and Mark P. de Raad, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended
(1)	Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (No. 333-142171) originally filed on April 17, 2007. The number given in parentheses indicates the corresponding exhibit number in such Form S-1, as amended.
(2)	Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on November 9, 2007. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
(3)	Incorporated by reference to the exhibit to the Company's Current Report on Form 8-K filed on October 10, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
(4)	Incorporated by reference to the exhibit to the Company's Registration Statement on Form S-8 filed on February 11, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form S-8. Pursuant to Item 601(b)(2) of Regulation S-K, the schedules to this agreement have been omitted. A list identifying the contents of the omitted schedules is included as Exhibit 2.1(a). The Company agrees to furnish supplementally a copy of any omitted schedule to the Securities and Exchange Commission upon request.