

MASIMO CORP
Form 10-Q
November 04, 2009
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 October 3, 2009

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

33-0368882
(I.R.S. Employer

Incorporation or Organization)

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

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Edgar Filing: MASIMO CORP - Form 10-Q

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 of each of the issuer's classes of common stock, as of the latest practicable date:

Class	Number of Shares Outstanding as of October 3, 2009
Common stock, \$0.001 par value	57,705,897

Table of Contents

MASIMO CORPORATION
FORM 10-Q FOR THE QUARTER ENDED OCTOBER 3, 2009

TABLE OF CONTENTS

PART I. Financial Information

Item 1.	<u>Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets as of October 3, 2009 (unaudited) and January 3, 2009</u>	3
	<u>Condensed Consolidated Statements of Income for the three and nine months ended October 3, 2009 (unaudited) and September 27, 2008 (unaudited)</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the nine months ended October 3, 2009 (unaudited) and September 27, 2008 (unaudited)</u>	5
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
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>	27
Item 1A.	<u>Risk Factors</u>	27
Item 5.	<u>Other Information</u>	50
Item 6.	<u>Exhibits</u>	50
	<u>Signatures</u>	51

Table of Contents**PART 1. FINANCIAL INFORMATION****Item 1. Financial Statements****MASIMO CORPORATION****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except share amounts)

	October 3, 2009 (Unaudited)	January 3, 2009
ASSETS		
Current assets		
Cash and cash equivalents	\$ 174,686	\$ 146,910
Accounts receivable, net of allowance for doubtful accounts of \$1,950 and \$1,300 at October 3, 2009 and January 3, 2009, respectively	39,222	30,715
Royalties receivable	11,434	11,375
Inventories	31,254	27,400
Prepaid expenses	7,267	4,780
Deferred tax assets	10,511	10,511
Other current assets	793	551
Total current assets	275,167	232,242
Deferred cost of goods sold	27,600	28,431
Property and equipment, net	12,118	12,979
Deferred tax assets	8,817	8,781
Intangible assets, net	7,825	7,410
Other assets	4,462	3,505
Total assets	\$ 335,989	\$ 293,348
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	\$ 13,806	\$ 15,914
Accrued compensation	17,051	15,607
Accrued liabilities	7,168	5,566
Income taxes payable	890	10,862
Deferred revenue	17,314	17,233
Current portion of long-term debt	226	465
Total current liabilities	56,455	65,647
Long-term debt, less current portion	187	157
Other liabilities	8,667	8,046
Total liabilities	65,309	73,850
Commitments and contingencies		
Stockholders equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding at October 3, 2009 and January 3, 2009		
Common stock, \$0.001 par value, 100,000,000 shares authorized; 57,705,897 and 57,326,527 shares issued and outstanding at October 3, 2009 and January 3, 2009, respectively	58	57

Edgar Filing: MASIMO CORP - Form 10-Q

Treasury stock, 156,240 shares at October 3, 2009 and January 3, 2009	(1,209)	(1,209)
Additional paid-in capital	190,832	179,666
Accumulated other comprehensive income (loss)	120	(7)
Retained earnings	80,052	40,884
Total Masimo Corporation stockholders' equity	269,853	219,391
Noncontrolling interest	827	107
Total stockholders' equity	270,680	219,498
Total liabilities and stockholders' equity	\$ 335,989	\$ 293,348

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

Table of Contents

MASIMO CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(in thousands, except share information)

(unaudited)

	Three Months Ended		Nine Months Ended	
	October 3, 2009	September 27, 2008	October 3, 2009	September 27, 2008
Revenue:				
Product	\$ 75,146	\$ 66,125	\$ 219,690	\$ 187,954
Royalty	12,295	12,007	36,812	36,054
Total revenue	87,441	78,132	256,502	224,008
Cost of goods sold	25,198	22,393	73,517	64,917
Gross profit	62,243	55,739	182,985	159,091
Operating expenses:				
Research and development	7,742	6,020	22,761	18,298
Selling, general and administrative	33,476	29,167	99,122	89,062
Antitrust litigation	185	46	228	491
Total operating expenses	41,403	35,233	122,111	107,851
Operating income	20,840	20,506	60,874	51,240
Non-operating income (expense):				
Interest income	48	545	161	2,129
Interest expense	(54)	(19)	(71)	(722)
Other	301	(413)	286	(235)
Total non-operating income (expense)	295	113	376	1,172
Income before provision for income taxes	21,135	20,619	61,250	52,412
Provision for income taxes	7,814	7,554	21,414	19,955
Net income including noncontrolling interest	13,321	13,065	39,836	32,457
Net income attributable to the noncontrolling interest	(266)		(668)	
Net income attributable to Masimo Corporation	\$ 13,055	\$ 13,065	\$ 39,168	\$ 32,457
Net income per share attributable to Masimo Corporation stockholders:				
Basic	\$ 0.23	\$ 0.23	\$ 0.68	\$ 0.58
Diluted	\$ 0.22	\$ 0.22	\$ 0.65	\$ 0.54

The following table presents details of the share based compensation expense that is included in each functional line item in the condensed consolidated statements of income above (in thousands):

Edgar Filing: MASIMO CORP - Form 10-Q

	Three Months Ended		Nine Months Ended	
	October 3, 2009	September 27, 2008	October 3, 2009	September 27, 2008
Cost of goods sold	\$ 102	\$ 55	\$ 273	\$ 159
Research and development	645	608	1,878	1,627
Selling, general and administrative	\$ 1,683	\$ 1,328	\$ 5,752	\$ 3,952

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

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

	Nine Months Ended	
	October 3, 2009	September 27, 2008
Cash flows from operating activities:		
Net income including noncontrolling interest	\$ 39,836	\$ 32,457
Adjustments to reconcile net income including noncontrolling interest to net cash provided by operating activities:		
Depreciation and amortization	4,512	4,226
Share based compensation	7,903	5,738
Loss on disposal of property and equipment	3	
Provision for doubtful accounts	682	20
Provision for obsolete inventory	346	1,175
Provision for warranty costs	1,582	1,085
Income tax benefit from exercise of stock options	1,403	14,488
Excess tax benefit from share based payment arrangements	(185)	(2,449)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(9,377)	(2,428)
(Increase) decrease in royalties receivable	(59)	2,491
Increase in inventories	(4,233)	(7,287)
(Increase) decrease in deferred cost of goods sold	891	(797)
Increase in prepaid expenses	(2,407)	(887)
(Increase) decrease in other assets	(1,165)	1,422
Decrease in accounts payable	(2,124)	(126)
Increase in accrued compensation	1,191	882
Decrease in accrued liabilities	(48)	(1,397)
Increase (decrease) in income taxes payable	(9,781)	2,453
Increase (decrease) in deferred revenue	(99)	1,516
Increase in other liabilities	833	65
Net cash provided by operating activities	29,704	52,647
Cash flows from investing activities:		
Purchases of property and equipment	(2,889)	(5,344)
Increase in intangible assets	(1,100)	(2,195)
Increase in restricted cash	(15)	
Net cash used in investing activities	(4,004)	(7,539)
Cash flows from financing activities:		
Repayments on long-term debt	(268)	(30,310)
Proceeds from issuance of common stock	1,834	8,477
Excess tax benefit from share based payment arrangements	185	2,449
Dividends paid		(13)
Net cash provided by (used in) financing activities	1,751	(19,397)
Effect of foreign currency exchange rates on cash	325	159

Edgar Filing: MASIMO CORP - Form 10-Q

Net increase in cash and cash equivalents	27,776	25,870
Cash and cash equivalents at beginning of period	146,910	96,733
Cash and cash equivalents at end of period	\$ 174,686	\$ 122,603

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 also invented Masimo Rainbow SET which measures multiple blood parameters, including carboxyhemoglobin, methemoglobin, plethysmographic variability index and total hemoglobin. 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 and its sensors and cables to be products as defined in its statements of income. The Company sells to hospitals and the emergency medical services, or EMS, 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 condensed consolidated balance sheet as of October 3, 2009, the condensed consolidated statements of income for the three and nine months ended October 3, 2009 and September 27, 2008, the condensed consolidated statements of cash flows for the nine months ended October 3, 2009 and September 27, 2008, and other information disclosed in the related condensed consolidated notes are unaudited. The condensed consolidated balance sheet as of January 3, 2009 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 March 4, 2009.

The accompanying 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 state fairly the Company's consolidated financial position as of October 3, 2009, consolidated results of operations for the three and nine months ended October 3, 2009 and September 27, 2008, and consolidated cash flows for the nine months ended October 3, 2009 and September 27, 2008. The results for the three and nine months ended October 3, 2009 are not necessarily indicative of the results to be expected for the year ending January 2, 2010 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. The Company's fiscal 2008 was a 53 week fiscal year, in which the first, second and third quarters ended on Saturday, March 29, June 28 and September 27, 2008, respectively. The Company's 2008 fiscal year ended on Saturday, January 3, 2009. The first three quarters were 13 week quarters and the fourth fiscal quarter was a 14 week quarter. In fiscal 2009, the Company is 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 will end on Saturday, January 2, 2010. Each quarter in 2009 will be 13 weeks.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Masimo Corporation and Masimo Laboratories, Inc., which have been consolidated pursuant to Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 810, *Consolidation*, or ASC Topic 810. In addition, these condensed consolidated financial statements include the accounts of Masimo Corporation's

Edgar Filing: MASIMO CORP - Form 10-Q

wholly-owned 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

ASC Topic 220, *Comprehensive Income*, establishes requirements for reporting and disclosure of comprehensive income and its components. Comprehensive income includes foreign currency translation adjustments 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 management 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, property tax and uncertain income tax positions. Actual results could differ from those estimates.

Fair Value Measurements

The Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, which defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. In February 2008, the FASB provided a one year deferral of the effective date for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, effective December 30, 2007, the Company adopted the provisions of ASC Topic 820 with respect to its financial assets and liabilities only. Effective January 4, 2009, the Company adopted the provisions of ASC Topic 820 for non-financial assets and liabilities. The adoption did not have a material impact on the Company's financial position or results of operations.

ASC Topic 820 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, which are the following:

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.

Also, the Company follows ASC Topic 825, *Financial Instruments*, which allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for specified financial assets and liabilities on a contract-by-contract basis. The Company did not elect the fair value option under this statement as to specific assets or liabilities.

The estimated fair values of the Company's financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, income taxes payable and long-term debt, approximate their carrying values due to their short maturities and because the weighted average borrowing rate of the long-term debt approximates the current market rates for similar borrowings. Cash equivalents consist of highly liquid investments, with maturities of three months or less at the date of purchase, including U.S. Treasury bills and money market funds.

Edgar Filing: MASIMO CORP - Form 10-Q

The Company records U.S. Treasury bills at cost and continues to carry those amounts at cost, which approximates fair value. The cost and fair value of the U.S. Treasury bills as of October 3, 2009, excluding accrued interest, were both \$164.4 million, as compared to a cost and fair value of \$125.5 million as of January 3, 2009. The fair value is based on quoted market prices in active markets for identical assets.

The Company records money market funds at cost and continues to carry those amounts at cost, which equals fair value. The fair value is based on quoted market prices in active markets for identical assets. As of October 3, 2009 and January 3, 2009, the cost and fair value of the Company's money market funds was equal to \$1.2 million and \$13.6 million, respectively.

Reclassifications

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

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

Revenue Recognition and Deferred Revenue

The Company recognizes revenue pursuant to the requirements of ASC Topic 985-605, *Software Revenue Recognition*, and other authoritative accounting guidance.

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 situations where VSOE of fair value does not exist for undelivered elements, the contract product revenue and corresponding cost of goods sold are deferred until either the element is delivered or VSOE of fair value is established. For the three and nine months ended October 3, 2009, \$306,000 and \$1.2 million, respectively, of contract product revenue was deferred. During the three and nine months ended October 3, 2009, \$3.4 million of previously deferred revenue was recognized, related to the expiration of requirements under two agreements to deliver elements for which VSOE of fair value was not established. Deferred costs associated with this revenue aggregating \$1.5 million were expensed in the same 2009 periods. For the three and nine months ended September 27, 2008, \$672,000 and \$3.1 million, respectively, of contract product revenue was deferred. During the three and nine months ended September 27, 2008, \$2.6 million of previously deferred revenue was recognized, including \$1.9 million related to an agreement in which VSOE of fair value was established as a result of a contract amendment providing the Company the option to substitute a deliverable for which VSOE of fair value was established in place of a deliverable for which VSOE of fair value was not established and \$683,000 related to the collection of cash for sales which had been deferred due to uncertainty over collectability. Deferred costs associated with this revenue aggregating \$852,000 were expensed in the same 2008 periods. Pursuant to the Company's revenue recognition policy, it expects to continue to defer revenue and the related costs of goods sold, and recognize previously deferred revenue in future periods as required under applicable accounting guidance.

The Company's distributors purchase primarily sensor products which they then resell to hospitals that are typically fulfilling their purchase obligation to the Company under the end-user hospital's 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 and an increase to deferred revenues.

The Company also earns revenue from the sale of integrated circuit boards that use the Company's software technology and royalty fees for allowing others the right to use the Company's technology in their products. The royalty revenue 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 end-user hospital contracts, revenue related to extended warranty is recognized over the life of the contract, while the product warranty costs related to the end-user hospital contracts are expensed as incurred.

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

Changes in the product warranty accrual for the nine months ended October 3, 2009 and September 27, 2008 were as follows (in thousands):

	Nine Months Ended	
	October 3, 2009	September 27, 2008
Warranty accrual, beginning of period	\$ 334	\$ 649
Provision for warranty costs	1,582	1,085
Warranty expenditures	(1,623)	(1,380)
Warranty accrual, end of period	\$ 293	\$ 354

Net Income Per Share

In accordance with ASC Topic 260, *Earnings Per Share*, basic net income per share attributable to Masimo Corporation for the three and nine months ended October 3, 2009 and September 27, 2008, 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 and nine months ended October 3, 2009 and September 27, 2008, 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 and nine months ended October 3, 2009, options to purchase 2,693,230 and 2,584,730, 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. For the three and nine months ended September 27, 2008, options to purchase 447,400 and 623,300, 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.

Pursuant to ASC Topic 810, the Company reduced total net income including noncontrolling interest by the amount of net income attributable to noncontrolling interests for the three and nine months ended October 3, 2009. During the three and nine months ended September 27, 2008, the Company recaptured net income earned by the noncontrolling interest and applied it against accumulated losses of the noncontrolling interest. The net income attributable to the noncontrolling interest for the three and nine months ended September 27, 2008, was \$0 since such net income was fully applied against the accumulated losses of the noncontrolling interest.

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		Nine Months Ended	
	October 3, 2009	September 27, 2008	October 3, 2009	September 27, 2008
Net income attributable to stockholders of Masimo Corporation:				
Net income including noncontrolling interest	\$ 13,321	\$ 13,065	\$ 39,836	\$ 32,457
Net income attributable to the noncontrolling interest	(266)		(668)	

Edgar Filing: MASIMO CORP - Form 10-Q

Net income attributable to Masimo Corporation	\$ 13,055	\$ 13,065	\$ 39,168	\$ 32,457
Basic net income per share attributable to Masimo Corporation:				
Net income attributable to Masimo Corporation	\$ 13,055	\$ 13,065	\$ 39,168	\$ 32,457
Weighted average shares outstanding	57,665,932	56,774,983	57,541,982	56,016,978
Basic net income per share attributable to Masimo Corporation	\$ 0.23	\$ 0.23	\$ 0.68	\$ 0.58
Diluted net income per share attributable to Masimo Corporation:				
Weighted average shares outstanding	57,665,932	56,774,983	57,541,982	56,016,978
Diluted share equivalent: stock options	2,491,256	3,601,755	2,585,219	4,159,815
	60,157,188	60,376,738	60,127,201	60,176,793
Diluted net income per share attributable to Masimo Corporation	\$ 0.22	\$ 0.22	\$ 0.65	\$ 0.54

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

In June 2009, the FASB issued Statement of Financial Accounting Standard No. 167, or SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)*. SFAS No. 167 eliminates the exceptions to consolidating qualifying special-purpose entities, contains new criteria for determining the primary beneficiary and increases the frequency of required reassessments to determine whether a company is the primary beneficiary of a variable interest entity. SFAS No. 167 also requires enhanced disclosure that will provide users of financial statements with more transparent information about an enterprise's involvement in a variable interest entity. SFAS No. 167 is effective for fiscal periods beginning after November 15, 2009. The Company does not expect the adoption of this statement to have a material impact on its condensed consolidated financial statements.

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, if any, 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, if any, this update will have on its condensed consolidated financial statements.

3. Comprehensive Income

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

	Three Months Ended		Nine Months Ended	
	October 3, 2009	September 27, 2008	October 3, 2009	September 27, 2008
Net income including noncontrolling interest	\$ 13,321	\$ 13,065	\$ 39,836	\$ 32,457
Other comprehensive income:				
Foreign currency translation gain	363	225	127	336
Total comprehensive income including noncontrolling interest	13,684	13,290	39,963	32,793
Net income attributable to the noncontrolling interest	(266)		(668)	
Other comprehensive income attributable to noncontrolling interest				
Comprehensive income attributable to Masimo Corporation	\$ 13,418	\$ 13,290	\$ 39,295	\$ 32,793

4. Masimo Laboratories, Inc.

Masimo Laboratories, Inc., or Masimo Labs, is an independent entity spun off from the Company to its stockholders in 1998. Joe E. 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 E. 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 had paid Masimo Labs \$7.5 million in option fees and 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 will provide to Masimo Labs going forward.

The Cross-Licensing Agreement requires the Company to pay certain royalties on products incorporating the licensed Rainbow technology. Beginning in 2009, for hospital contracts where the Company places equipment and enters into a sensor contract, it 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 royalty is up to 10% of the Rainbow royalty base, which will include handhelds, tabletop and multi-parameter devices. The Company is also subject to certain specific annual minimum aggregate royalty payments. These minimum aggregate royalty payments were \$1.0 million and \$3.0 million for the three and nine months ended October 3, 2009, respectively, and \$875,000 and \$2.6 million for the three and nine months ended September 27, 2008, 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 from \$4.0 million to \$10.0 million for 2009, and from \$5.0 million to \$15.0 million per year 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 and nine months ended October 3, 2009, these expenses totaled \$887,000 and \$1.2 million, respectively.

The condensed consolidated balance sheets include a noncontrolling equity interest in Masimo Labs of \$827,000 and \$107,000 as of October 3, 2009 and January 3, 2009, 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 \$4.0 million and \$3.6 million as of October 3, 2009 and January 3, 2009, respectively, related to Masimo Labs. Of the total assets for both periods presented, \$1.8 million was for deferred tax assets. Also, as of October 3, 2009 and January 3, 2009, \$1.5 million and \$1.1 million, respectively, were for intangible assets of Masimo Labs. The condensed consolidated balance sheets include total liabilities, net of intercompany eliminations, of \$888,000 and \$397,000 as of October 3, 2009 and January 3, 2009, respectively, related to Masimo Labs. Upon consolidation, \$3.6 million and \$3.0 million of receivables due from Masimo Corporation as of October 3, 2009 and January 3, 2009, respectively, were eliminated. Also upon consolidation, \$6.1 million and \$6.4 million of deferred revenue related to technology licensed to Masimo Corporation as of October 3, 2009 and January 3, 2009, 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.

Pursuant to ASC Topic 810, 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 defined under ASC Topic 810, 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 in accordance with ASC

Edgar Filing: MASIMO CORP - Form 10-Q

Topic 810, 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.

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

For the foreseeable future, the Company anticipates that it will continue to consolidate Masimo Labs pursuant to the guidance set forth in ASC Topic 810; however, in the event that Masimo Labs secures additional external financing, is no longer financially dependent upon the Company or meets other criteria as discussed in ASC Topic 810, the Company may discontinue consolidating Masimo Labs.

The changes in noncontrolling interest for Masimo Labs from January 3, 2009 to October 3, 2009 are as follows (in thousands):

	Amount
Balance at January 3, 2009	\$ 107
Increase in Additional paid-in capital of noncontrolling interest	52
Net income attributable to noncontrolling interest	668
Other comprehensive income attributable to noncontrolling interest	
Balance at October 3, 2009	\$ 827

5. Related Party Transactions

As of both October 3, 2009 and January 3, 2009, the Company had amounts due from employees of \$239,000 which is 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 \$16,000 and \$81,000 during the nine months ended October 3, 2009 and September 27, 2008, respectively, for various software products and services.

6. Royalties Receivable

The royalty receivable of \$11.4 million as of October 3, 2009, represents the Company's estimated amount due for the three months ended October 3, 2009. 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.

7. 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):

October 3, 2009	January 3, 2009
--------------------	--------------------

Edgar Filing: MASIMO CORP - Form 10-Q

Raw materials	\$ 19,946	\$ 17,678
Work in-process	2,601	2,001
Finished goods	8,707	7,721
Total	\$ 31,254	\$ 27,400

8. Long-Term Debt and Capital Lease Obligations

Long-term debt, excluding capital leases noted below, consists of the following (in thousands):

	October 3, 2009	January 3, 2009
Total debt	\$ 167	\$ 395
Less current portion of long-term debt	(167)	(395)
Long-term portion	\$	\$

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

As of October 3, 2009, the Company had one arrangement, which allows for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements. This agreement provides for an equipment line whereby draws are collateralized by (i) equipment and (ii) either a future revenue stream associated with the long-term sensor purchase agreement or a defined repayment schedule associated with the long-term sensor purchase agreement. The related equipment securing these borrowings is recorded on the Company's condensed consolidated balance sheets as deferred cost of goods sold and is depreciated on a straight-line basis over the life of the sensor contract to which they are related. The financing arrangement is non-recourse to the Company. In the event the hospital is unable to continue performing under the terms of the long-term sensor agreement, the Company would be required to write-down the remaining deferred cost of goods sold and the related financing obligation reflected in long-term debt. As of October 3, 2009, no hospitals have defaulted under this program. As of October 3, 2009, principal and interest payments under the remaining financing agreement were \$41,000 per month based on an average interest rate of 7.0% per year.

Capital lease obligations consist of the following, not including interest expense (in thousands):

	October 3, 2009	January 3, 2009
Capital lease obligations	\$ 246	\$ 227
Less current portion of capital lease obligations	(59)	(70)
Long-term portion	\$ 187	\$ 157

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 October 3, 2009, the total future remaining interest cost under all capital leases was \$23,000.

9. 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 stock option plans, including the 2004 Plan. 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 Company's share reserve of the 2007 Plan on January 4, 2009. These additional shares represented 3% of the Company's total shares outstanding as of the close of business on January 3, 2009.

Edgar Filing: MASIMO CORP - Form 10-Q

The number and weighted average exercise price of options issued and outstanding under all stock option plans, at exercise prices ranging between \$1.67 and \$41.51 per share, are as follows:

	Nine Months Ended October 3, 2009	
	Shares	Average Exercise Price
Options outstanding, beginning of period	7,329,474	\$ 15.97
Granted	1,438,000	\$ 24.91
Canceled	(186,840)	\$ 23.65
Exercised	(379,370)	\$ 4.83
Options outstanding, end of period	8,201,264	\$ 17.88
Options exercisable, end of period	3,417,260	\$ 9.89
Options available for grant, end of period	4,222,134	

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

(unaudited)

The weighted-average fair value of options granted was \$11.67 for the nine months ended October 3, 2009.

The Company applies the provisions of ASC Topic 718, *Compensation - Stock Compensation*. The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions used for grants:

	Three Months Ended		Nine Months Ended	
	October 3, 2009	September 27, 2008	October 3, 2009	September 27, 2008
Risk-free interest rate	2.2% to 2.8%	2.8% to 3.7%	1.2% to 3.1%	2.5% to 3.8%
Expected term	5.3 years	6.5 years	5.3 years	6.5 years
Estimated volatility	42.7% to 46.1%	36.6%	42.7% to 55.1%	36.6% to 37.1%
Expected dividends	0%	0%	0%	0%

In accordance with ASC Topic 718, the Company recorded share based compensation expense of \$2.4 million and \$7.9 million during the three and nine months ended October 3, 2009, respectively, and \$2.0 million and \$5.7 million during the three and nine months ended September 27, 2008, 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 October 3, 2009 was \$82.6 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 October 3, 2009 was \$58.9 million. The aggregate intrinsic value of options exercised during the three and nine months ended October 3, 2009 was \$1.9 million and \$8.0 million, respectively. 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 October 3, 2009 was \$50.5 million related to unvested options granted after January 1, 2006. The weighted average remaining contractual term of options outstanding as of October 3, 2009 was 6.4 years. The weighted average remaining contractual term of options exercisable as of October 3, 2009 was 4.9 years.

10. Commitments and Contingencies**Leases**

The Company leases its facilities in North America, Europe and Asia under operating lease agreements expiring at various dates through 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. As of October 3, 2009 and January 3, 2009, rent expense accrued in excess of the amount paid aggregated \$124,000 and \$282,000, 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 October 3, 2009		
	Operating Leases	Capital Leases	Total
2009 (balance of year)	\$ 778	\$ 18	\$ 796
2010	2,473	72	2,545
2011	2,117	57	2,174
2012	2,230	53	2,283

Edgar Filing: MASIMO CORP - Form 10-Q

2013	2,200	49	2,249
Thereafter	1,488	20	1,508
Total	\$ 11,286	\$ 269	\$ 11,555

Rental expense related to operating leases was \$881,000 and \$2.6 million for the three and nine months ended October 3, 2009, respectively, and was \$842,000 and \$2.5 million for the three and nine months ended September 27, 2008, 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. The Company contributed \$302,000 and \$877,000 to the Plan for the three and nine months ended October 3, 2009, respectively, and \$260,000 and \$791,000 to the Plan for the three and nine months ended September 27, 2008, respectively.

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

Employment and Severance Agreement

As of October 3, 2009, the Company had an employment agreement with one of its key employees that provides for an aggregate annual base salary of \$686,400 plus other benefits, with annual increases at the discretion of the Compensation Committee of the Board of Directors. 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.

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 four 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, fifty percent 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 \$26.3 million of purchase commitments as of October 3, 2009, all of which is expected to be purchased within one year. These purchase commitments were made for certain inventory items to secure better pricing and to ensure the Company will have raw materials when necessary.

Concentrations of Risk

The Company is exposed to credit loss for the amount of cash deposits with financial institutions in excess of federally insured limits. As of October 3, 2009, the Company had \$9.1 million of bank balances of which \$800,000 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 October 3, 2009, the Company had \$164.4 million in U.S. Treasury bills which are insured 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 and nine months ended October 3, 2009, revenue from the sale of the Company's pulse oximetry products to U.S. hospitals that are members of GPOs amounted to \$39.8 million and \$121.1 million, respectively. In the three and nine months ended September 27, 2008, revenue from sales to U.S. hospitals that are members of GPOs was \$35.4 million and \$99.1 million, respectively.

Edgar Filing: MASIMO CORP - Form 10-Q

For the three and nine months ended October 3, 2009, one customer represented 13.2% and 13.3% of the total revenue, respectively. For the three and nine months ended September 27, 2008, one customer represented 10.3% and 11.7% 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.

Table of Contents

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

As of October 3, 2009 and January 3, 2009, one customer represented 7% and 10%, respectively, of the accounts receivable balance. Also, as of October 3, 2009, one customer represented 6% of accounts receivable, and as of January 3, 2009, another customer represented 7% of accounts receivable.

Litigation

In May 2002, the Company filed a lawsuit against Tyco Healthcare, parent company of Nellcor, in the United States 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.

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 filed its opening brief on December 17, 2007 with the United States Court of Appeals for the 9th Circuit. On December 27, 2007, the Consumer Federation of America and Medical Device Manufacturers Association filed an Amicus brief supporting the Company. Tyco filed its opposition and appeal brief on March 3, 2008 and a group of law professors filed an Amicus brief supporting Tyco on March 10, 2008. The Company filed its response and reply brief on May 19, 2008. The Consumer Federation of America and Medical Device Manufacturers Association filed an additional Amicus brief in support of the Company on May 29, 2008. Tyco filed its second appeal brief on July 17, 2008. The Company is seeking 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 is also asking the appellate court to increase the amount of damages awarded by the trial court. Oral argument took place on December 8, 2008. Even if the Company is ultimately awarded damages in this litigation, the amount will be subject to a 50% legal fee contingency agreement, in which case the Company would receive 50% of the net (of costs) proceeds from the award. Even though most of the legal expenses to date have been on a contingency basis, the Company has incurred and expects to incur expenses related to the appellate work, which will be reported as operating expense within the Company's statements of income.

The Company believes the jury verdict it received in the Tyco Healthcare antitrust litigation has been important in its efforts to increase its market share among certain large hospital systems and GPOs that were formerly closed as a result of Tyco Healthcare's anti-competitive conduct. However, the lawsuit has been and will continue to be a diversion of management's attention from the implementation of the Company's business strategy.

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 United States 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 a previous suit by the Company 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. The Company believes that it has good and substantial defenses to the antitrust and patent infringement claims asserted by Philips.

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,

Edgar Filing: MASIMO CORP - Form 10-Q

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. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

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

From time to time, the Company may be involved in 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 legal proceedings which, individually or in the aggregate, would have a material adverse effect on its consolidated financial position, results of operations or cash flows.

11. Segment Information and Enterprise Reporting

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

	Three Months Ended				Nine Months Ended			
	October 3, 2009		September 27, 2008		October 3, 2009		September 27, 2008	
Geographic Area by Destination								
North and South America	\$ 59,156	78.7%	\$ 51,605	78.0%	\$ 170,904	77.8%	\$ 144,796	77.0%
Europe, Middle East and Africa	8,858	11.8	9,215	14.0	28,731	13.1	27,816	14.8
Asia and Australia	7,132	9.5	5,305	8.0	20,055	9.1	15,342	8.2
Total product revenues	\$ 75,146	100%	\$ 66,125	100%	\$ 219,690	100%	\$ 187,954	100%

Sales to customers located in the United States were \$57.4 million and \$165.8 million for the three and nine months ended October 3, 2009, respectively, and \$50.1 million and \$140.2 million for the three and nine months ended September 27, 2008, respectively.

12. Income Taxes

As of October 3, 2009, the balance of the gross unrecognized tax benefit, classified in other long-term liabilities, was \$8.0 million, of which \$6.8 million (net of federal benefit on state taxes), if recognized, would affect the effective tax rate. As of January 3, 2009, the balance of the gross unrecognized tax benefit was \$7.3 million, of which \$6.1 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 will decrease in the next 12 months by \$30,000 primarily related to certain state tax issues.

Interest and penalties related to unrecognized tax benefits are recognized in income tax expense. For the three and nine months ending October 3, 2009, the Company expensed \$83,000 and \$239,000 respectively, for interest. For the three and nine months ended September 27, 2008, the Company expensed \$68,000 and \$195,000, 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.

Edgar Filing: MASIMO CORP - Form 10-Q

The provision for income taxes was \$7.8 million and \$21.4 million, or an effective tax rate of 37.0% and 35.0%, for the three and nine months ended October 3, 2009, respectively. The provision for income taxes was \$7.6 million and \$20.0 million, or an effective tax rate of 36.6% and 38.1%, for the three and nine months ended September 27, 2008, 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

MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(unaudited)

13. Subsequent Events

Pursuant to ASC Topic 855, *Subsequent Events*, the Company evaluated all events or transactions that occurred after October 3, 2009 up through November 3, 2009, the date the Company issued these financial statements.

On November 2, 2009, the Company announced that the Ninth Circuit Court of Appeals has affirmed the 2006 Federal District Court decision that Tyco Healthcare, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its Nellcor pulse oximetry products. The 2006 decision found that Tyco had unlawfully maintained monopoly power in violation of Section 2 of the Sherman Act, and that Tyco's sole-source agreements and market-share based compliance pricing contracts were unlawful restraints of trade in violation of Section 1 of the Sherman Act and unlawful exclusionary dealing arrangements in violation of Section 3 of the Clayton Act. The Ninth Circuit also held that above-cost bundling discounts when combined with sole-source or market-share-based pricing can be anticompetitive when such practices involve a significant portion of the market.

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 3, 2009, which we filed with the SEC on March 4, 2009. 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-alarm/monitoring solutions, such as the Masimo Patient SafetyNet. 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 platform utilizing licensed Rainbow technology, which we believe includes the first devices cleared by the U.S. Food and Drug Administration, or FDA, to noninvasively measure select noninvasive blood parameters that previously required invasive procedures. In 2005, we launched carboxyhemoglobin, allowing measurement of carbon monoxide levels in the blood. In 2006, we launched methemoglobin, allowing for the measurement of a dangerous condition known as methemoglobinemia, which occurs as a reaction to some common drugs used in hospitals and in out patient procedures. In 2007, we launched Plethysmographic Variability Index, or PVI. Independent clinical studies have demonstrated that PVI can predict fluid responsiveness in surgical and intensive care patients. In 2009, we initiated a full market release of total hemoglobin, our most recent Rainbow measurement.

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 emergency medical services, or EMS, 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 United States, 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

Table of Contents

Rainbow SET Pulse CO-Oximetry, we have established a small sales force to concentrate on the EMS market. Over the past year, we have expanded our sales and marketing staffing levels. We supplement our direct sales with sales through our distributors. During this period, direct and distributor sales have increased to \$177.0 million, or 80.6%, of product revenue for the nine months ended October 3, 2009, from \$145.0 million, or 77.2%, of product revenue for nine months ended September 27, 2008. We expect the percentage of our revenue from direct and distributor sales to continue to increase over the long term as we expand our worldwide direct sales force.

We are continuing the research and development of products for the non-invasive measurement of other measurements based on the Masimo Rainbow SET platform. Included in this development are products for acoustic respiratory monitoring, or ARM. We expect to begin our limited market release of ARM in the first half of 2010 and commercial launch in the second half of 2010. Although we plan to continue to research, innovate and develop new technologies and products, we are unable to predict which potential measurements can be achieved, the time and cost to complete development and ultimately whether we will have any additional measurements approved by the FDA or other regulatory agencies.

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 621,000 units as of October 3, 2009, up from 540,000 units as of September 27, 2008. We estimate our installed base to be the number of pulse oximeters and pulse oximeter circuit boards that we have shipped in the past seven years. In the event we increase this assessment period beyond seven years in the future, our estimated installed base may increase materially. 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.

Masimo Laboratories

Masimo Laboratories, Inc., or Masimo Labs, is an independent entity spun off from us to our stockholders in 1998. We are a party to a cross-licensing agreement with Masimo Labs, which was most recently amended and restated effective January 1, 2007, or the Cross-Licensing Agreement, that governs each party's rights to certain of the 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 measurements and to develop and sell devices incorporating Masimo SET for monitoring non-vital signs measurements in any product market in which a product is intended to be used by a patient or pharmacist rather than a professional medical caregiver, which we refer to as the Labs Market. 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.

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 measurements, including blood glucose, in product markets where the product is intended to be used by a professional medical caregiver.

Pursuant to Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 810, *Consolidation*, or ASC Topic 810, Masimo Labs is consolidated within our financial statements for all periods presented. Accordingly, all royalties, option and license fees and other charges between us and Masimo Labs have been eliminated in the consolidation. For the foreseeable future, we anticipate that we will continue to consolidate Masimo Labs pursuant to the guidance set forth in ASC Topic 810; however, in the event that Masimo Labs secures additional external financing, is no longer financially dependent upon us or meets other criteria as discussed in ASC Topic 810, we may discontinue consolidating Masimo Labs.

Table of Contents**Results of Operations**

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

	Three months ended				Nine months ended			
	October 3, 2009	% of Revenue	September 27, 2008	% of Revenue	October 3, 2009	% of Revenue	September 27, 2008	% of Revenue
Revenue:								
Product	\$ 75,146	85.9%	\$ 66,125	84.6%	\$ 219,690	85.6%	\$ 187,954	83.9%
Royalty	12,295	14.1	12,007	15.4	36,812	14.4	36,054	16.1
Total revenue	87,441	100.0	78,132	100.0	256,502	100.0	224,008	100.0
Cost of goods sold	25,198	28.8	22,393	28.7	73,517	28.7	64,917	29.0
Gross profit	62,243	71.2	55,739	71.3	182,985	71.3	159,091	71.0
Operating expenses:								
Research and development	7,742	8.9	6,020	7.7	22,761	8.9	18,298	8.2
Selling, general and administrative	33,476	38.3	29,167	37.3	99,122	38.6	89,062	39.8
Antitrust litigation	185	0.2	46	0.1	228	0.1	491	0.2
Total operating expenses	41,403	47.4	35,233	45.1	122,111	47.8	107,851	48.2
Operating income	20,840	23.8	20,506	26.2	60,874	23.7	51,240	22.8
Non-operating income (expense):								
Interest income	48	0.1	545	0.7	161	0.1	2,129	1.0
Interest expense	(54)	(0.1)	(19)	(0.5)	(71)	(0.1)	(722)	(0.3)
Other	301	0.3	(413)	(0.5)	286	0.1	(235)	(0.1)
Total non-operating income (expense)	295	0.3	113	0.2	376	0.2	1,172	0.6
Income before provision for income taxes	21,135	24.2	20,619	26.4	61,250	23.9	52,412	23.4
Provision for income taxes	7,814	8.9	7,554	9.7	21,414	8.3	19,955	8.9
Net income including noncontrolling interest	13,321	15.3	13,065	16.7	39,836	15.6	32,457	14.5
Net income attributable to the noncontrolling interest	(266)	(0.3)			(668)	(0.3)		
Net income attributable to Masimo Corporation	\$ 13,055	15.0%	\$ 13,065	16.7%	\$ 39,168	15.3%	\$ 32,457	14.5%

Comparison of the Three Months ended October 3, 2009 to the Three Months ended September 27, 2008

Revenue. Total revenue increased \$9.3 million, or 11.9%, to \$87.4 million for the three months ended October 3, 2009 from \$78.1 million for the three months ended September 27, 2008.

Product revenues increased \$9.0 million, or 13.6%, to \$75.1 million in the three months ended October 3, 2009 from \$66.1 million for the three months ended September 27, 2008. 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 621,000 units at October 3, 2009 up from an estimated 540,000 units at September 27, 2008. Contributing to the increase in our product revenue was our Rainbow technology product revenues which increased \$3.0

Edgar Filing: MASIMO CORP - Form 10-Q

million, or 98.0%, to \$6.0 million in the three months ended October 3, 2009, from \$3.0 million in the three months ended September 27, 2008. Revenue generated through our direct and distribution sales channels increased \$8.1 million, or 15.6%, to \$60.1 million for the three months ended October 3, 2009 compared to \$52.0 million for the three months ended September 27, 2008. During the three months ended October 3, 2009, revenues from our OEM channel increased \$900,000, or 6.4%, to \$15.0 million from \$14.1 million in the three months ended September 27, 2008. During the three months ended October 3, 2009, \$3.4 million of previously deferred revenue was recognized, related to the expiration of requirements under two agreements to deliver elements for which VSOE of fair value was not established. During the three months ended September 27, 2008, \$2.6 million of previously deferred revenue was recognized, including \$1.9 million related to an agreement in which VSOE of fair value was established for an undelivered element as a result of a contract amendment and \$683,000 related to the collection of cash for excess sensor sales which had been deferred due to uncertainty over collectability.

Table of Contents

Our royalty revenue increased \$288,000 to \$12.3 million in the three months ended October 3, 2009 from \$12.0 million in the three months ended September 27, 2008. For the three months ended October 3, 2009 and September 27, 2008, our reported Covidien royalties were 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 \$2.8 million to \$25.2 million in the three months ended October 3, 2009 from \$22.4 million in the three months ended September 27, 2008. Our total gross margin decreased to 71.2% for the three months ended October 3, 2009 from 71.3% for the three months ended September 27, 2008. Excluding royalties, product gross margin increased by 0.4% to 66.5% for the three months ended October 3, 2009, from 66.1% for the three months ended September 27, 2008. This increase was primarily due to increased sales of Rainbow related products and manufacturing efficiencies related to higher production volumes. We incurred \$1.0 million and \$875,000 in Masimo Labs' royalty expenses for the three months ended October 3, 2009 and September 27, 2008, respectively, which, in accordance with ASC Topic 810, 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 65.1% and 64.8% for the three months ended October 3, 2009 and September 27, 2008, respectively.

Research and Development. Research and development expenses increased \$1.7 million, or 28.6%, to \$7.7 million for the three months ended October 3, 2009, from \$6.0 million for the three months ended September 27, 2008. The increase is due to additional engineering supplies of \$587,000 for clinical trials research related to new product development during the three months ended October 3, 2009 compared to September 27, 2008. In addition, payroll and payroll related costs increased by \$407,000 due to increased research and development staffing levels. Also contributing to the increase was a credit of \$400,000 related to capitalized software development costs recorded during the three months ended September 27, 2008, compared to \$0 during the three months ended October 3, 2009. Share based compensation expense related to ASC Topic 718, *Compensation - Stock Compensation*, which is included in payroll and payroll related costs, was \$645,000 and \$608,000 for the three months ended October 3, 2009 and September 27, 2008, respectively. Included in these total research and development expenses are \$62,000 and \$727,000 of engineering expenses incurred by Masimo Labs for the three months ended October 3, 2009 and September 27, 2008, respectively. Masimo Labs engineering expenses were lower for the three months ended October 3, 2009 due to additional production work being performed by Masimo Labs and reimbursed by Masimo Corporation.

Selling, General and Administrative. Selling, general and administrative expenses increased \$4.3 million, or 14.8% to \$33.5 million for the three months ended October 3, 2009 from \$29.2 million in the three months ended September 27, 2008. The increase was primarily due to a \$3.8 million increase in payroll and payroll related costs consistent with an increase in staffing levels. Share based compensation expense related to ASC Topic 718 which is included in payroll and payroll related costs, was \$1.7 million and \$1.3 million for the three months ended October 3, 2009 and September 27, 2008, respectively. Included in these total selling, general and administrative expenses are \$380,000 and \$293,000 of direct expenses incurred by Masimo Labs for the three months ended October 3, 2009 and September 27, 2008, respectively.

Non-Operating Income (expense). Non-operating income was \$295,000 for the three months ended October 3, 2009, compared to \$113,000 for the three months ended September 27, 2008. This increase in income was primarily due to foreign exchange gains of \$743,000 which was offset by a decline in interest income of \$497,000, resulting from the significant decline in year over year interest rates, which, in turn, has lowered our interest income. Changes in foreign exchange rates, primarily due to the weakening of the U.S. dollar as compared to the Euro and Japanese yen during the quarter ended October 3, 2009 resulted in a currency transaction and translation gain of \$290,000, as compared to a currency loss of \$453,000 during the three months ended September 27, 2008.

Provision for Income Taxes. Our provision for income taxes was \$7.8 million for the three months ended October 3, 2009, compared to \$7.6 million for the three months ended September 27, 2008. Our effective tax rate increased to 37.0% for the three months ended October 3, 2009, compared to 36.6% for the three months ended September 27, 2008. This increase in the effective tax rate was due to the change in anticipated income in jurisdictions in which we do business with lower effective rates and was partially offset by research related tax credits. 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.

Comparison of the Nine Months ended October 3, 2009 to the Nine Months ended September 27, 2008

Revenue. Total revenue increased \$32.5 million, or 14.5%, to \$256.5 million for the nine months ended October 3, 2009 from \$224.0 million for the nine months ended September 27, 2008.

Table of Contents

Product revenues increased \$31.7 million, or 16.9%, to \$219.7 million in the nine months ended October 3, 2009 from \$188.0 million for the nine months ended September 27, 2008. 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 621,000 units at October 3, 2009 up from an estimated 540,000 units at September 27, 2008. Contributing to the increase in our product revenue was our Rainbow technology product revenues which increased \$5.0 million, or 57.8%, to \$13.7 million in the nine months ended October 3, 2009, from \$8.7 million in the nine months ended September 27, 2008. Revenue generated through our direct and distribution sales channels increased \$31.9 million, or 22.1%, to \$177.0 million for the nine months ended October 3, 2009 compared to \$145.1 million for the nine months ended September 27, 2008. During the nine months ended October 3, 2009 revenues from our OEM channel decreased \$258,000, or 0.6%, to \$42.7 million from \$42.9 million in the nine months ended September 27, 2008. During the nine months ended October 3, 2009, \$3.4 million of previously deferred revenue was recognized, related to the expiration of requirements under two agreements to deliver elements for which VSOE of fair value was not established. During the nine months ended September 27, 2008, \$2.6 million of previously deferred revenue was recognized, including \$1.9 million related to an agreement in which VSOE of fair value was established for an undelivered element as a result of a contract amendment and \$683,000 related to the collection of cash for excess sensor sales which had been deferred due to uncertainty over collectability.

Our royalty revenue increased \$758,000, to \$36.8 million in the nine months ended October 3, 2009 from \$36.1 million in the nine months ended September 27, 2008. For the nine months ended October 3, 2009 and September 27, 2008, our reported Covidien royalties were 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 \$8.6 million to \$73.5 million in the nine months ended October 3, 2009 from \$64.9 million in the nine months ended September 27, 2008. Our total gross margin increased 0.3% to 71.3% for the nine months ended October 3, 2009 from 71.0% for the nine months ended September 27, 2008. Excluding royalties, product gross margin increased 1.0% to 66.5% for the nine months ended October 3, 2009 from 65.5% for the nine months ended September 27, 2008. This increase was due to greater sensor sales, increased sales of Rainbow related products and manufacturing efficiencies related to higher production volumes. We incurred \$3.0 million and \$2.6 million in Masimo Labs royalty expenses for the nine months ended October 3, 2009 and September 27, 2008, respectively, which, in accordance with ASC Topic 810, 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 65.2% and 64.1% for the nine months ended October 3, 2009 and September 27, 2008, respectively.

Research and Development. Research and development expenses increased \$4.5 million, or 24.4%, to \$22.8 million for the nine months ended October 3, 2009, from \$18.3 million for the nine months ended September 27, 2008. The increase was primarily due to increased payroll and payroll related costs of \$1.3 million, associated with increased research and development staffing levels. In addition, expenses for additional engineering supplies and clinical trials research related to new product development increased \$1.3 million for the nine months ended October 3, 2009 compared to September 27, 2008. Also, contributing to the year over year increase was a credit of \$844,000 related to capitalized software development costs recorded during the nine months ended September 27, 2008, compared to \$0 during the nine months ended October 3, 2009. Share based compensation expense related to ASC Topic 718, which is included in payroll and payroll related costs, was \$1.9 million and \$1.6 million for the nine months ended October 3, 2009 and September 27, 2008, respectively. Included in these total research and development expenses are \$1.5 million and \$1.7 million of engineering expenses incurred by Masimo Labs for the nine months ended October 3, 2009 and September 27, 2008, respectively. Masimo Labs engineering expenses were lower for the nine months ended October 3, 2009 due to additional production work performed by Masimo Labs and reimbursed by Masimo Corporation.

Selling, General and Administrative. Selling, general and administrative expenses increased \$10.0 million, or 11.3%, to \$99.1 million for the nine months ended October 3, 2009 from \$89.1 million in the nine months ended September 27, 2008. The increase was primarily due to a \$10.3 million increase in payroll and payroll related costs consistent with an increase in staffing levels. In addition, expense related to distribution of new product samples increased \$1.5 million during the nine months ended October 3, 2009. These increases were offset by a decrease in tradeshow expenses of \$1.0 million due to a reduction in the number of tradeshows attended during the nine months ended October 3, 2009 as compared to the nine months ended September 27, 2008. Share based compensation expense related to ASC Topic 718 which is included in payroll and payroll related costs, was \$5.8 million and \$4.0 million for the nine months ended October 3, 2009 and September 27, 2008, respectively. Included in these total selling, general and administrative expenses are \$740,000 and \$883,000 of direct expenses incurred by Masimo Labs for the nine months ended October 3, 2009 and September 27, 2008, respectively.

Non-Operating Income (expense). Non-operating income was \$376,000 for the nine months ended October 3, 2009, compared to \$1.2 million for the nine months ended September 27, 2008. This decrease in income was primarily due to the decline in interest income of \$2.0 million resulting from the significant decline in year over year interest rates which, in turn, has lowered our interest income. This

Table of Contents

income decline was partially offset by a decrease in interest expense of \$651,000, resulting from repayments of long-term debt balances during March 2008 and a foreign exchange gain of \$421,000. Changes in foreign exchange rates, primarily due to the weakening of the U.S. dollar as compared to the Euro and Japanese yen during the nine months ended October 3, 2009 resulted in a currency transaction and translation gain of \$227,000, as compared to a currency loss of \$194,000 during the nine months ended September 27, 2008.

Provision for Income Taxes. Our provision for income taxes was \$21.4 million for the nine months ended October 3, 2009, compared to \$20.0 million for the nine months ended September 27, 2008. Our effective tax rate decreased to 35.0% for the nine months ended October 3, 2009, compared to 38.1% for the nine months ended September 27, 2008. This decrease in the effective tax rate was due primarily to the increase in anticipated income in jurisdictions in which we do business with lower effective rates and research related tax credits. 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.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the sale of equity securities. Through October 3, 2009, we raised \$81.7 million through seven preferred stock private equity financings, \$47.8 million from our August 2007 initial public offering and \$28.4 million from the exercise of stock options.

As of October 3, 2009, we had cash and cash equivalents of \$174.7 million, of which \$164.4 million was invested in U.S. Treasury bills, \$1.2 million was in money market accounts with major financial institutions and \$9.1 million was in checking accounts and certificates of deposit. These U.S. Treasury bills are classified as cash equivalents since they are highly liquid investments, with a maturity of three months or less at the date of purchase. We carry cash equivalents at cost which approximates fair value.

During the nine months ended October 3, 2009, we have received \$36.8 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 United States, 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.

Cash Flows from Operating Activities. Cash provided by operating activities was \$29.7 million in the nine months ended October 3, 2009. The source of cash consists primarily of net income including noncontrolling interest of \$39.8 million, non-cash share based compensation of \$7.9 million, and depreciation and amortization expense of \$4.5 million. These sources of cash were partially offset by a net decrease in income tax liability of \$9.8 million, resulting primarily from tax payments of \$30.6 million, offset by our tax provision accrual of \$21.4 million, during the nine months ended October 3, 2009. In addition, uses of cash included an increase in accounts receivable of \$9.4 million due to both timing of collections and growth of our business and an increase in inventory of \$4.2 million to meet the increasing demand for our products

Cash provided by operating activities was \$52.6 million in the nine months ended September 27, 2008. The source of cash consists primarily of net income of \$32.5 million, a net tax benefit of \$14.5 million relating to employee stock option exercises for options granted prior to the adoption of ASC Topic 718, and stock based compensation expense of \$5.7 million resulting from options granted under ASC Topic 718. Also, depreciation and amortization expense was \$4.2 million, royalties receivable decreased \$2.5 million due to a lower royalty rate per our agreement with Covidien and income taxes payable increased \$2.5 million resulting from higher taxable income. These increases were offset partially by an increase in inventory of \$7.3 million to meet the increasing demand for our products and the introduction of new products, an excess tax benefit from share based payments of \$2.4 million and an increase in accounts receivable of \$2.4 million due to the growth of our business.

Cash Flows from Investing Activities. Cash used in investing activities for the nine months ended October 3, 2009 was \$4.0 million consisting primarily of \$2.9 million of property and equipment purchases related primarily to assets to support our manufacturing operations and \$1.1 for the increase in intangible assets related to capitalized patent related expenses. Cash used in investing activities for the nine months ended September 27, 2008 was \$7.5 million consisting of \$5.3 million of property and equipment purchases related primarily to assets to support our manufacturing operations and \$2.2 million for the increase in intangible assets related to capitalized patent and capitalized software development.

Cash Flows from Financing Activities. Cash provided by financing activities for the nine months ended October 3, 2009 was \$1.8 million, primarily due to proceeds from stock option exercises. Cash used by financing activities for the nine months ended September 27, 2008 was \$19.4 million. This use was primarily the result of our decision in March 2008 to repay \$26.7 million in long-term debt related to the financing of equipment placed at hospitals. In total, we repaid \$30.3 million of long term debt in the nine month period ended September 27, 2008. These total debt repayments were partially offset by \$8.5 million of proceeds from stock option exercises and by \$2.4 million of excess tax benefit

from share based payment arrangements.

Table of Contents

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.

Current Financing Arrangements. As of October 3, 2009, we had one financing arrangement with an outstanding balance of \$167,000. The total monthly principal and interest payment under this financing agreement was \$41,000 based on an average interest rate of 7.0%. There are no additional amounts available for future borrowing under this remaining arrangement. As of October 3, 2009, we had capital leases related to office equipment with an outstanding balance of \$246,000 and total remaining interest of \$23,000.

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 allowances, inventory reserves, warranty reserves, rebate reserves, valuation of our stock options, distributor channel inventory, royalty revenues, 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.

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 filed with the SEC on March 4, 2009. There have been no material changes in any of our accounting policies since January 3, 2009.

New Accounting Pronouncements

In June 2009, the FASB issued Statement of Financial Accounting Standard No. 167, or SFAS No. 167, *Amendments to FASB Interpretation No. 46(R)*. SFAS No. 167 eliminates the exceptions to consolidating qualifying special-purpose entities, contains new criteria for determining the primary beneficiary and increases the frequency of required reassessments to determine whether a company is the primary beneficiary of a variable interest entity. SFAS No. 167 also requires enhanced disclosure that will provide users of financial statements with more transparent information about an enterprise's involvement in a variable interest entity. SFAS No. 167 is effective for fiscal periods beginning after November 15, 2009. We do not expect the adoption of this statement to have a material impact on our condensed consolidated financial statements.

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.

Table of Contents

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, if any, 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, if any, 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 to interest expense is limited to our outstanding financing 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 change in interest rates along the entire interest rate yield curve could significantly affect the fair value of our interest-sensitive financial instruments at October 3, 2009. However, we hold our U.S. Treasury bill investments until their maturity, thereby reducing the risk of loss of principal balance due to interest rate increases.

Foreign Currency Exchange Rate Risk

A majority of our assets and liabilities are maintained in the United States in U.S. dollars and a majority of our sales and expenditures are transacted in U.S. dollars. However, certain of our foreign subsidiaries transact in their respective country's local currency, which is also their functional currency. As a result, revenues and expenses of these foreign subsidiaries when converted into U.S. dollars can vary depending on average monthly exchange rates during a respective period. Intercompany transactions of certain of our foreign subsidiaries with Masimo Corporation are denominated in U.S. dollars and are considered foreign currency denominated transactions by the subsidiary. In addition, any other transactions between us or one of our subsidiaries and a third party, denominated in a currency different from the functional currency, is 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.

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 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.

Table of Contents

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 affect 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 October 3, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are involved in legal proceedings in the ordinary course of business. During the three months ended October 3, 2009, there were no material developments to the proceedings described in our Annual Report on Form 10-K for the fiscal year ended January 3, 2009, and our Quarterly Reports on Form 10-Q for the quarters ended April 4, 2009 and July 4, 2009.

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 Quarterly Report on Form 10-Q filed with the SEC on August 5, 2009, 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 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 reflect substantive changes from the risk factors included in our Quarterly Report on Form 10-Q filed with the SEC on August 5, 2009.*

Table of Contents

Risks Related to Our Business

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 provide 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.

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 United States 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 be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. 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 original equipment manufacturer, or 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 United States. 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. 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;

Table of Contents

be expensive and time consuming to defend;

result in us being required to pay significant damages to third parties;

force us to cease making or selling products that incorporate the challenged intellectual property;

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

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

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

divert the attention of our management and other key employees;

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

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

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

We believe competitors may currently be violating and may in the future violate our intellectual property rights, and we may bring additional litigation to protect and enforce our intellectual property rights, which may result in substantial expense and may divert 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 Nellcor was infringing some of our pulse oximetry signal processing patents. 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. 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.

Both Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GmbH are associated with Philips Medical Systems, an OEM partner of ours. We cannot be certain that we will have the required financial resources to pursue this and other litigation or otherwise to protect these rights in the future. In addition, any future litigation could result in significant additional costs and further divert the

Edgar Filing: MASIMO CORP - Form 10-Q

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.

*** 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.**

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. Given that all 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

Table of Contents

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 effectiveness of our products;

sales price of our products;

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

perceived advantages of our products over competing products; and

introduction and acceptance of competing products or technologies;

In March 2008, we introduced our most recent Rainbow parameter, total hemoglobin. In May 2008, we received FDA clearance to begin to market this new parameter. In September 2008, we began our limited market release of the product 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. While we are enthusiastic about the product's long-term market potential, we cannot determine how quickly or successfully the product will be received within its initial targeted market. As with any new technology, there are significant barriers to market adoption and we cannot be assured that the marketplace will respond favorably to this new technology and product.

We expect to begin our limited market release of ARM in the first half of 2010 and commercial launch in the second half of 2010. As with our total hemoglobin release, we expect to initially provide this new measurement to the market in a limited market release to allow us to evaluate the product's performance in the field. While we believe that we should be able to achieve this market timing, there can be no assurances of this timing or obtaining the regulatory approvals still required. Also, while we expect this product will have an important role within the hospital general floor environment, there can be no assurance that this product will be successful within this initial target market. As with any new technology, there are significant barriers to market adoption and we cannot be assured that the marketplace will respond favorably to this new technology and product.

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.

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. 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.

Edgar Filing: MASIMO CORP - Form 10-Q

From our inception through October 3, 2009, we initiated four voluntary recalls of our products, none of which was material. 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.

Table of Contents

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

Recently, the credit markets and the financial services industry have been experiencing 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 United States 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.

Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments and such losses have historically been within our expectations and the allowances we have established, we cannot guarantee that we will continue to experience the same loss 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 uncertainties related to the economy or 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 including but not limited to, their ability to obtain the necessary access to capital as well as lower overall hospital census for paying patients and the impact of that lower census on hospital budgets. Also, recent budget proposal and health care reform discussions have created additional levels of uncertainty regarding hospital spending.

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 which could be impacted by hospital budget reductions. To the extent that the current economic uncertainty and budgetary reductions cause our potential customers to reduce, delay or cancel new capital equipment purchases or sensor purchase agreements, our ability to generate revenues could be impacted. Also, while our long term sensor agreements provide for minimum annual sensor purchases, if hospital census levels fall, the volume of sensors purchased by our customers could decline and, as a result, negatively impact our ability to generate revenues.

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 customer's 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 in an attempt to reduce their overall operating costs.

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

Edgar Filing: MASIMO CORP - Form 10-Q

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

Table of Contents

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 signs measurements consist of body fluid constituents other than vital signs 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 emergency medical services, or EMS, 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.

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.

*** 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 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, in accordance with ASC Topic 810, we are required to consolidate Masimo Labs within our financial statements. Accordingly, the royalties that we owe to Masimo Labs are eliminated in our condensed consolidated financial statements presented within this Quarterly Report on Form 10-Q and the gross profit margins reported in our consolidated financial results do not include the royalty expense that we pay to Masimo Labs. Also in accordance with ASC Topic 810, we are obligated to include, and have

Table of Contents

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. As a result of this requirement to consolidate, we report within our public filings, both our reported gross profit, engineering expense and administrative expenses as if we were not required to consolidate. To date, the amount of royalty expense has approximated the amount of engineering and administrative expense and therefore, the net impact to our condensed 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 condensed 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.

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 financial condition and results of operations.

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 E. 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 will increase to up to \$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.

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 October 3, 2009, a number of stockholders of Masimo Labs continued to own shares of our common stock. Joe E. 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

Table of Contents

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 may not maintain our recent profitability and we may experience significant fluctuations in our quarterly results in the future.

We incurred net losses attributable to common stockholders in each year from our inception through 2004. We expect our expenses to increase as we continue to expand our research and development and sales and marketing activities. As a result, if we are unable to maintain or increase our revenue, we may incur net losses in the future.

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 group purchasing organizations, or GPOs;

delays in hospital conversions to our products;

declines in hospital patient census;

our legal expenses, particularly those related to litigation matters;

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;

product recalls; and

high levels of returns and repairs.

Edgar Filing: MASIMO CORP - Form 10-Q

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. To respond to these and other factors, we may need to make business decisions that could result in our failure to meet financial expectations. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. Most of our expenses, including our employee compensation, inventory and debt repayment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenue for a particular period were 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, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance. In future quarters, our operating results may be below the expectations of securities analysts or investors.

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 elect not, and they have no contractual obligation, to do so in the near future 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. Our success will depend in part upon whether our OEM partners devote sufficient resources to the promotion of products that incorporate these technologies. These products may represent a relatively small percentage of business for some of our OEM partners and therefore they may have less incentive to promote these products rather than other products that do not incorporate these technologies; the desire and ability of our OEMs to commit these resources could be negatively impacted by the current

Table of Contents

turbulent and volatile economic turmoil. In addition, some of our OEM partners offer products that compete with ours. Therefore, we cannot guarantee that our OEM partners will vigorously promote products incorporating Masimo SET and licensed Rainbow technology, or at all. If any of our OEM partners were to be acquired, we cannot assure you that an acquiring company would devote sufficient resources to promote products that incorporate technology we own or license.

*** 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 and nine months ended October 3, 2009, one of our customers represented 13.2% and 13.3%, respectively, of our total revenue.

*** 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 harm 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.**

In fiscal 2008, our royalties from the Covidien settlement totaled \$47.5 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 fiscal 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, there is a significant financial risk to our total revenues, gross margins, operating income and earnings per share if we are unable to generate sufficient revenues and gross margins to offset either the impact of declining royalty rates on sales of Covidien's pulse oximetry products in the United States.

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 with 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 choose to discontinue abiding by the terms of the current settlement and continuing 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.

*** 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 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. In the three and nine months ended October 3, 2009, shipments of our pulse oximetry products to customers that are members of GPOs were \$39.8 million and \$121.1 million, respectively. 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.

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 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. In addition, we may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business. Furthermore, one or more of our competitors may develop products that are substantially equivalent to our FDA-cleared products, or those of our 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 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. One company, Covidien, currently holds a substantial share of the pulse oximetry market. Our revenue and profit are significantly smaller than our primary competitors. A number of the companies in the pulse oximetry market 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.

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.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

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. Defending against these claims could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research and development or sales personnel could limit our ability to sell our existing products and develop new products and technologies, which could adversely affect our business, financial condition and results of operations.

Table of Contents

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 currently have product liability insurance that we believe to be adequate, but we cannot be certain that it 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.

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

Each medical device that we wish to market in the United States 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 approval of a product is granted, the 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 usually takes from four to six months, although it can take longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain and generally takes from one to three years or even longer.

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 revoked 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. In that case, our ability to upgrade our products in a timely fashion could be limited. The withdrawal of existing 510(k) clearances or the inability to obtain new ones on a timely basis, or at all, could severely harm our business, financial condition and results of operations.

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 United States. 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 the Quality Systems Regulations, 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 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;

finances and civil penalties;

unanticipated expenditures to address or defend such actions;

delays in clearing or approving, or refusal to clear or approve, our products;

Table of Contents

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;

operating restrictions;

injunctions; and

criminal prosecution.

If any of these actions were to occur, it would harm our reputation and adversely affect our business, financial condition and results of operations. Furthermore, our key component suppliers may not currently be, or may not continue to be, in compliance with applicable regulatory requirements.

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

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

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.

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

Edgar Filing: MASIMO CORP - Form 10-Q

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 unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, 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

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.

The Food and Drug Administration Amendments Act of 2007, or the Amendments, requires, among other things, that the FDA propose and ultimately implement regulations that will require manufacturers to label medical devices with unique identifiers unless a waiver is received from the FDA. Once implemented, compliance with those regulations may require us to take additional steps in the manufacture of our products and labeling. These steps may require additional resources and could be costly. In addition, the Amendments will require us to, among other things, pay annual establishment registration fees to the FDA for each of our FDA-registered facilities.

If we are unable to increase our sales, marketing and distribution capabilities or maintain or establish arrangements with third parties to sell, market, manufacture 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 United States 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;

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;

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 United States and internationally. Our sales force will be competing with the experienced and well-funded sales and marketing operations of our competitors. Increasing our direct sales capabilities will be expensive and time consuming. 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 and sell our approved products in the United States and internationally. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue could be lower than if we directly marketed and sold 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, manufacturing and distribution capabilities, independently or with others, we may not be able to generate sufficient product revenue to be profitable.

We anticipate and plan for significant growth, which we may not be able to effectively manage.

Both domestically and internationally, we expect to rapidly expand our operations and our research and development, product development, sales, marketing and administrative organizations. This growth and activity will likely result in new and increased responsibilities for management and place a significant strain upon our operating and financial systems and resources. To accommodate our expected growth and compete effectively, we will be required to improve our current infrastructure, including information systems, as well as create additional processes, procedures and controls and expand, train, motivate and manage our work force. In addition, our anticipated growth may strain our ability to manufacture an increasingly large supply of our products. Manufacturing facilities often experience difficulties in scaling up production, including problems with production yields and quality control and assurance.

Table of Contents

We cannot be certain that our personnel, infrastructure, financial systems, processes, procedures, asset management, facilities and controls will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products and meet market demand, and would materially and adversely affect our business, financial condition and results of operations.

We manufacture our products at two locations. 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 our Irvine, California facility is 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. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance 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 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, including but not limited to outbreaks of Avian and Swine flu. 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 in our manufacturing capacity 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, therefore, may adversely affect our revenue, gross margins and results of operations. Any disruption or delay at our manufacturing facilities 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.

In the future, we may choose to add new manufacturing capabilities in either our existing facilities or in new facilities throughout the world. If we expand our worldwide manufacturing locations, there can be no assurance that this expansion will occur without implementation difficulties, or at all, or that such expansion will ultimately lower our overall cost of production.

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 E. 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. In some specific situations, officers who signed a severance agreement, have agreed to provide the company up to six months of notice in the event they elect to terminate their employment 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.

Table of Contents

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.

In order to expand our products and technology platform, 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:

difficulties in integrating any acquired companies, personnel, products and other assets into our existing business;

delays in realizing the benefits of the acquired company, products or other assets;

diversion of our management's time and attention from other business concerns;

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

higher costs of integration than we anticipated; 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.

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 soliciting, receiving, offering or providing 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services, as well as imposed certain

Edgar Filing: MASIMO CORP - Form 10-Q

requirements relating to the privacy, security and transmission of individually identifiable health information; and

state laws analogous to each of the above federal laws, such as 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 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

Table of Contents

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 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 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.

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

We derive a portion of our net sales from international operations. In the three and nine months ended October 3, 2009, 23.6% and 24.5%, 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 and sales activities.

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;

Edgar Filing: MASIMO CORP - Form 10-Q

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;

possible failure to comply with anti-bribery laws such as the FCPA and similar anti-bribery laws in other jurisdictions;

political instability and actual or anticipated military or political conflicts;

Table of Contents

longer payment cycles; and

difficulties in enforcing or defending intellectual property rights.

We cannot assure you that one or more of these factors will not harm our business. Any material decrease in our international sales would adversely affect our business, financial condition and results of operations.

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

In the fourth quarter of 2008, we implemented a new 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.

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 United States dollar weakens against these currencies, the dollar value of the foreign-currency denominated expense increases, and when the dollar strengthens against these currencies, the dollar value of the foreign-currency denominated expense decreases. Changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations. Our primary foreign currency exchange rate exposures are with the Euro, the Japanese yen, 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.

Our international operations could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions.

The FCPA 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 United States 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 results of business, financial condition and results of operations.

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

Sales of our products depend in part on the reimbursement and coverage policies of governmental and private health care payers. The ability of our health care provider customers, including hospitals, to obtain adequate coverage and reimbursement for our products, or 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.

Table of Contents

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.

*** 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 if certain types of health care reform programs are adopted in our key markets and other administration and legislative proposals are enacted into law.**

Recently, President Obama and members of Congress have proposed significant reforms to the U.S. health care system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. health care reform. The Obama administration's fiscal year 2010 budget included proposals to limit Medicare payments, reduce drug spending and increase taxes. In addition, members of Congress have proposed a single-payer health care system, a government health insurance option to compete with private plans and other expanded public health care measures.

Most recently, in September 2009, the Chairman of the U.S. Senate Finance Committee released a draft of the committee's health care reform bill, a bill which included an excise tax on all medical devices, requiring the medical device industry to contribute \$4 billion to health care reform each year for a period of 10 years. Various health care reform proposals have also emerged at the state level. We cannot predict what health care initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, if the excise tax contained in the proposed legislation from the U.S. Senate Finance Committee is enacted into law, our operating expenses resulting from such an excise tax and results of operations would be materially and adversely affected.

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.

Changes in the health care industry in the United States and elsewhere could adversely affect the demand for our products as well as the way in which we conduct our business. Significantly, the new administration and Congressional and state leaders have expressed a strong desire to reform the U.S. health care system. Included in this reform could be laws that narrow Medicare coverage or reduce reimbursement levels for health care services or items provided by physicians and hospitals. 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 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.

Edgar Filing: MASIMO CORP - Form 10-Q

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

Table of Contents

elections in the United States. 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 United States, 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 United States. 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 United States are not obtained, sales of our products outside of the United States may be adversely affected.

Our ongoing antitrust litigation against Tyco Healthcare (currently Covidien) could result in significant additional costs and further divert the attention of our management and key personnel from our business operations.

In May 2002, we filed a lawsuit against Tyco Healthcare, parent company of Nellcor, in the United States District Court for the Central District of California, alleging damage to our business as a result of the anti-competitive business practices of Tyco Healthcare in connection with its Nellcor pulse oximetry brand in violation of federal antitrust laws. Specifically, we alleged that we 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 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, on July 2, 2007, the District Court entered its final judgment, awarding us damages which were trebled as is mandatory under federal antitrust law to \$43.5 million and denying our request for a permanent injunction with respect to the Tyco Healthcare business practices found to be anti-competitive. We and Tyco Healthcare each filed a notice of appeal from the judgment.

We filed our opening brief on December 17, 2007 with the United States Court of Appeals for the 9th Circuit. On December 27, 2007, the Consumer Federation of America and the Medical Device Manufacturers Association filed an Amicus brief supporting us. Tyco filed its opposition and appeal brief on March 3, 2008. A group of law professors filed an Amicus brief supporting Tyco on March 10, 2008. We filed our response and reply brief on May 19, 2008. The Consumer Federation of America and the Medical Device Manufacturers Association filed an additional Amicus brief in support of us on May 29, 2008. Tyco filed its second appeal brief on July 17, 2008. We are seeking reinstatement of the jury's verdict on bundling and an affirmance of the liability findings concerning sole-source and market share-based compliance contracts. We are also asking the appellate court to increase the amount of damages awarded by the trial court. Oral argument took place on December 8, 2008. Even if we are ultimately awarded damages in this litigation, the amount will be subject to a 50% legal fee contingency agreement, in which case we would receive 50% of the net (of costs) proceeds from any award.

On November 2, 2009, we announced that the Ninth Circuit Court of Appeals has affirmed the 2006 Federal District Court decision that Tyco, now Covidien, violated the antitrust laws through anticompetitive business practices related to the sale of its Nellcor pulse oximetry products. The 2006 decision found that Tyco had unlawfully maintained monopoly power and that Tyco's sole-source agreements and market-share based compliance pricing contracts were unlawful restraints of trade and unlawful exclusionary dealing arrangements. The Ninth Circuit also held that above-cost bundling discounts when combined with sole-source or market-share-based pricing can be anticompetitive when such practices involve a significant portion of the market.

We believe that Covidien continues to enter into sole-source contracts, product bundling agreements and market share-based agreements. In bundling agreements, the customer is able to obtain discounts on unrelated products when they purchase Covidien pulse oximeters for most of their pulse oximetry needs. Co-marketing agreements also provide significant impediments to competition in that Covidien pays large patient monitoring companies to integrate Covidien pulse oximetry products into their products.

Continued litigation could result in substantial costs and diversion of resources that would harm our business. In addition, there can be no assurance that we will receive any cash award or any equitable relief from the litigation.

Table of Contents

We may require additional capital in the future, which may not be available on favorable terms, if at all. To raise capital, we may issue additional securities, including shares, debt or equity-linked debt, which may dilute our existing stockholders and depress our stock price.

To the extent that our existing capital is insufficient to meet our requirements and cover any losses, we will need to raise additional funds through financings or borrowings or curtail our growth and reduce our assets. Any issuance of equity securities or convertible debt or other equity-linked securities to raise financing could:

cause substantial dilution of the percentage ownership of our security holders at the time of the issuance;

cause substantial dilution of our earnings per share;

subject us to the risks associated with increased leverage, including a reduction in our ability to obtain financing or an increase in the cost of any financing we obtain;

subject us to restrictive covenants that could limit our flexibility in conducting future business activities; and

adversely affect the prevailing market price for our outstanding securities.

Securities issued in future financings may have rights, preferences and privileges that are senior to those of our common stock. These rights, preferences and privileges may include, among others, dividend rights, conversion rights, voting rights and liquidation rights. As a result, the rights of holders of our common stock will be subject to, and could be adversely affected by, the rights of holders of any preferred stock or other senior securities that may be issued in the future. We do not intend to seek stockholder approval for any such security issuance unless required by applicable law or regulation or the terms of existing securities.

In addition, any financing may not be on terms that are favorable to us, if at all. If our need for capital arises because of significant losses, the occurrence of these losses may make it more difficult for us to raise the necessary capital. If we cannot raise funds on acceptable terms, if and when needed, or if the funds are not available to us, we may not be able to develop or enhance our products or technologies, take advantage of future opportunities, grow our business or respond to competitive pressures or unanticipated requirements.

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, or Nasdaq, 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. We have dedicated, and we expect to continue to dedicate, significant management, financial and other resources in connection with maintaining compliance with Section 404 based on the standards adopted by the Public Company Accounting Oversight Board. These efforts include reviewing our existing internal control structure and performing system and process evaluation and testing (and any necessary remediation). As a result of these ongoing activities, we may either hire or outsource additional personnel to expand and strengthen our finance function. In addition, 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.

Edgar Filing: MASIMO CORP - Form 10-Q

We cannot provide any assurance that we will be able to successfully maintain the certification requirements of Section 404 or that our independent registered public accounting firm will be able to provide the attestation report required under the regulations. If we fail to maintain the adequacy of our internal control 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. Our failure to maintain the requirements of Section 404 may subject us to investigations by regulatory authorities, including the SEC or Nasdaq, and sanctions. As a result, our 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 common stock, and adversely affect investors confidence in our company and our ability to access capital markets for financing.

Table of Contents

Changes to existing accounting pronouncements or taxation rules or practices may affect how we conduct our business and affect our reported results of operations.

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.

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.

Risks Related to Our Common Stock

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

There has been significant volatility in the market price and trading volume of equity securities, which is unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our common stock. From July 5, 2009 to October 3, 2009, our closing stock price ranged from \$22.13 to \$28.44. 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 common 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 common stock market price, many of which we cannot control, 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;

Edgar Filing: MASIMO CORP - Form 10-Q

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

changes in stock market analyst recommendations or earnings estimates regarding our common 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.

Table of Contents

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

As of October 3, 2009, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned 12.7% of our outstanding common 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 common 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.

*** 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 October 3, 2009, an aggregate of 12,423,398 shares of our common stock were reserved for future issuance under our three equity incentive plans, 8,201,264 of which were subject to options outstanding as of that date at a weighted average exercise price of \$17.88 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 common stock, including those by our insiders, may cause our stock price to decline.**

As of October 3, 2009, there were 57,705,897 shares of our common stock outstanding. A significant portion of our shares of common stock outstanding prior to our initial public offering, or IPO, that were not sold by selling stockholders in the offering became eligible for sale in the public market on February 4, 2008 upon expiration of lock-up agreements entered into in connection with our IPO, although as of October 3, 2009, 5,867,195 of these shares were held by directors, executive officers and other affiliates. Shares held by these affiliates are subject to volume limitations on resale under Rule 144 promulgated by the SEC under the Securities Act, or Rule 144. In addition, a large portion of our outstanding shares are held by 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 common stock or the perception that substantial resales may be made, could significantly reduce the market price of our common stock. Moreover, the holders of 236,766 shares of common stock at October 3, 2009 have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold or to include these shares in registration statements that we may file for ourselves or other stockholders from time to time.

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 common 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 common 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 common 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

Table of Contents

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, our board of directors has 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 common 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 common 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 common stock.

We will continue to incur significant increased costs as a result of operating as a public company, and our management and key employees will be required to devote substantial time to new regulations and compliance initiatives.

Prior to August 2007, we operated as a private concern. As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The reporting requirements of the Exchange Act and the Sarbanes-Oxley Act may place a strain on our people, systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition and results of operations.

We do not intend to declare cash dividends on our stock, and any return on investment may be limited to the value of our stock.

We currently intend to retain all future earnings for the operation and expansion of our business and do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends on our common 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.

Securities analysts may not cover our common stock or may issue negative reports, which may have a negative impact on the market price of our common stock.

Securities analysts may elect not to provide research coverage of our common stock. If securities analysts do not cover our common stock, the lack of research coverage may cause the market price of our common stock to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about our business or the pulse oximetry market. If one or more of the analysts who elects to cover us downgrades our stock, our stock price could decline rapidly. If one or more of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, recently adopted rules mandated by the Sarbanes-Oxley Act, and a global settlement reached in 2003 between the SEC, other regulatory agencies and a number of investment banks, has led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms are required to contract with independent financial analysts for their stock research. As long as we have a smaller market capitalization, it may be difficult for us to attract independent financial analysts who will cover our common stock, which could have a negative effect on the market price of our common stock.

Table of Contents

Item 5. Other Information

We entered into two new lease agreements with Northwestern Mutual Life Insurance Company, or Northwestern Mutual Life. The first lease agreement, effective November 1, 2009, amended and restated a prior lease agreement with Northwestern Mutual Life for 70,200 square feet of space and was entered into to extend the term of the lease. The second lease agreement, effective August 1, 2009, added 32,100 additional square feet of property adjacent to the current facility. In addition, we entered into an amendment to a lease agreement, dated April 30, 2009, with Northwestern Mutual Life covering 50,200 square feet of space to extend the term of the lease and to reduce our rent obligation under the lease agreement.

In total, the three leases cover 152,500 square feet of space in Irvine, California, for our corporate headquarters, product manufacturing, research and development, warehousing and distribution operations. All three lease agreements expire in September 2014.

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: November 3, 2009

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

Date: November 3, 2009

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)
10.1	Lease Agreement, relating the premises at 40 Parker, effective as of November 1, 2009, between the Company and Northwestern Mutual Life Insurance Company
10.2	Lease Agreement, relating the premises at 60 Parker, effective as of August 1, 2009, between the Company and Northwestern Mutual Life Insurance Company
10.3	Amendment No. 1 to Lease Agreement, relating the premises at 50 Parker, dated April 30, 2009, between the Company and Northwestern Mutual Life Insurance Company
31.1	Certification of Joe E. 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	Certification of Joe E. 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. Confidential treatment has been requested with respect to certain provisions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.