

MASIMO CORP  
Form 10-Q  
August 05, 2008  
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 June 28, 2008

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-33642

**Masimo Corporation**

*(Exact Name of Registrant as Specified in its Charter)*

Edgar Filing: MASIMO CORP - Form 10-Q

**Delaware**  
*(State or Other Jurisdiction of  
Incorporation or Organization)*

**33-0368882**  
*(I.R.S. Employer  
Identification Number)*

**40 Parker**

**Irvine, California**  
*(Address of Principal Executive Offices)*

**92618**  
*(Zip Code)*

**(949) 297-7000**  
*(Registrant's Telephone Number, Including Area Code)*

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer  (do not check if a smaller reporting company)

Smaller Reporting Company

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

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 July 26, 2008
Common stock, \$0.001 par value	56,643,524

---

**Table of Contents**

**MASIMO CORPORATION**  
**FORM 10-Q FOR THE QUARTER ENDED JUNE 28, 2008**

**TABLE OF CONTENTS**

**PART I. Financial Information**

Item 1.	<u>Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets as of December 29, 2007 and June 28, 2008 (unaudited)</u>	3
	<u>Condensed Consolidated Statements of Income for the three and six months ended June 30, 2007 and June 28, 2008 (unaudited)</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2007 and June 28, 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>	18
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	26
Item 4(T).	<u>Controls and Procedures</u>	26
<b>PART II. Other Information</b>		
Item 1.	<u>Legal Proceedings</u>	28
Item 1A.	<u>Risk Factors</u>	28
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	47
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	47
Item 6.	<u>Exhibits</u>	48
	<b><u>Signatures</u></b>	49

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

(in thousands, except share amounts)

	December 29, 2007	June 28, 2008 (Unaudited)
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 96,733	\$ 102,903
Accounts receivable, net of allowance for doubtful accounts of \$1,370 and \$1,335 at December 29, 2007 and June 28, 2008, respectively	26,970	29,576
Royalties receivable	13,866	11,375
Inventories	23,110	29,256
Prepaid expenses	7,084	7,079
Deferred tax assets	14,334	14,334
Other current assets	1,543	1,156
Total current assets	183,640	195,679
Deferred cost of goods sold	26,249	27,764
Property and equipment, net	11,164	11,837
Deferred tax assets	5,332	5,332
Restricted cash	513	518
Intangible assets, net	5,589	6,793
Goodwill	448	448
Other assets	2,576	2,539
Total assets	\$ 235,511	\$ 250,910
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities		
Accounts payable	\$ 14,640	\$ 16,810
Accrued compensation	12,409	13,059
Accrued liabilities	6,211	5,135
Dividends payable	183	183
Deferred revenue	16,827	21,946
Current portion of long-term debt	11,539	647
Total current liabilities	61,809	57,780
Deferred revenue	366	336
Long-term debt, less current portion	19,502	285
Other liabilities	3,768	3,837
Total liabilities	85,445	62,238
Commitments and contingencies		
Stockholders equity		

## Edgar Filing: MASIMO CORP - Form 10-Q

Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 29, 2007 and June 28, 2008; 0 shares issued and outstanding at December 29, 2007 and June 28, 2008

Common stock, \$0.001 par value, 100,000,000 shares authorized at December 29, 2007 and June 28, 2008; 54,692,232 and 56,447,961 shares issued and outstanding at December 29, 2007 and June 28, 2008, respectively

	55	56
Treasury stock, 156,240 shares at December 29, 2007 and June 28, 2008	(1,209)	(1,209)
Additional paid-in capital	143,297	162,399
Accumulated other comprehensive loss	(1,034)	(923)
Retained earnings	8,957	28,349
Total stockholders' equity	150,066	188,672
Total liabilities and stockholders' equity	\$ 235,511	\$ 250,910

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		Six Months Ended	
	June 30, 2007	June 28, 2008	June 30, 2007	June 28, 2008
<b>Revenue:</b>				
Product	\$ 47,627	\$ 61,850	\$ 93,391	\$ 121,523
Royalty and license fee	16,053	12,916	29,243	24,353
<b>Total revenue</b>	<b>63,680</b>	<b>74,766</b>	<b>122,634</b>	<b>145,876</b>
Cost of goods sold	17,919	21,403	34,820	42,524
<b>Gross profit</b>	<b>45,761</b>	<b>53,363</b>	<b>87,814</b>	<b>103,352</b>
<b>Operating expenses:</b>				
Research and development	5,460	5,980	10,914	12,278
Selling, general and administrative	21,577	30,366	42,979	59,895
Antitrust litigation	465	277	475	445
<b>Total operating expenses</b>	<b>27,502</b>	<b>36,623</b>	<b>54,368</b>	<b>72,618</b>
<b>Operating income</b>	<b>18,259</b>	<b>16,740</b>	<b>33,446</b>	<b>30,734</b>
<b>Non-operating income (expense):</b>				
Interest income	189	625	544	1,584
Interest expense	(685)	(60)	(1,112)	(703)
Other	170	75	211	178
<b>Total non-operating income (expense)</b>	<b>(326)</b>	<b>640</b>	<b>(357)</b>	<b>1,059</b>
<b>Income before provision for income taxes</b>	<b>17,933</b>	<b>17,380</b>	<b>33,089</b>	<b>31,793</b>
Provision for income taxes	7,377	6,779	13,436	12,401
<b>Net income</b>	<b>10,556</b>	<b>10,601</b>	<b>19,653</b>	<b>19,392</b>
Accretion of preferred stock	(1,956)		(3,913)	
Undistributed income attributable to preferred stockholders	(5,802)		(10,630)	
<b>Net income attributable to common stockholders</b>	<b>\$ 2,798</b>	<b>\$ 10,601</b>	<b>\$ 5,110</b>	<b>\$ 19,392</b>
<b>Net income per common share:</b>				
Basic	\$ 0.17	\$ 0.19	\$ 0.31	\$ 0.35
Diluted	\$ 0.13	\$ 0.18	\$ 0.25	\$ 0.32
<b>Weighted-average number of common shares:</b>				
Basic	16,692,547	56,166,934	16,642,779	55,637,976
Diluted	20,732,014	60,050,622	20,699,111	60,051,325

The following table presents details of the stock 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		Six Months Ended	
	June 30, 2007	June 28, 2008	June 30, 2007	June 28, 2008
Cost of goods sold	\$ 45	\$ 75	\$ 78	\$ 104
Research and development	164	607	275	1,019
Selling, general and administrative	\$ 849	\$ 1,487	\$ 1,295	\$ 2,624

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)**

	<b>Six Months Ended</b>	
	<b>June 30, 2007</b>	<b>June 28, 2008</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 19,653	\$ 19,392
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,596	2,738
Non-cash stock-based compensation	1,648	3,747
Provision for doubtful accounts	126	(19)
Provision for obsolete inventory	752	1,807
Provision for warranty costs	791	675
Benefit from deferred income taxes	(322)	
Income tax benefit from exercise of stock options		8,655
Excess tax benefit from share based payment arrangements		(1,029)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(5,262)	(2,263)
(Increase) decrease in royalties receivable	(13,166)	2,491
Increase in inventories	(6,252)	(7,863)
Increase in deferred cost of goods sold	(3,733)	(1,467)
(Increase) decrease in prepaid expense	(910)	69
(Increase) decrease in other assets	(3,075)	459
Increase in accounts payable	7,687	2,136
Increase (decrease) in accrued compensation	(2,584)	557
Increase (decrease) in accrued liabilities	1,123	(1,852)
Increase in income taxes payable	1,307	1,026
Increase in deferred revenue	4,510	5,029
Increase (decrease) in other liabilities	(269)	37
<b>Net cash provided by operating activities</b>	<b>4,620</b>	<b>34,325</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(2,820)	(3,035)
Increase in intangible assets	(698)	(1,521)
<b>Net cash used in investing activities</b>	<b>(3,518)</b>	<b>(4,556)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of long-term debt	20,075	
Repayments on long-term debt	(4,079)	(30,126)
Proceeds from issuance of common stock	502	5,702
Excess tax benefit from share based payment arrangements		1,029
Dividends paid	(37,171)	
Purchase of treasury stock	(581)	
<b>Net cash used in financing activities</b>	<b>(21,254)</b>	<b>(23,395)</b>
Effect of foreign currency exchange rates on cash	(213)	(204)



Edgar Filing: MASIMO CORP - Form 10-Q

Net increase (decrease) in cash and cash equivalents	(20,365)	6,170
Cash and cash equivalents at beginning of period	55,382	96,733
Cash and cash equivalents at end of period	\$ 35,017	\$ 102,903

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 non-invasive 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 markets a family of non-invasive blood constituent patient monitoring solutions that consists of a monitor or circuit board and their proprietary single-patient use and reusable sensors and cables. Since 2005, the Company has introduced a variety of new non-invasive measurements expanding the capability of the Company's Masimo Rainbow SET platform. 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. The Company considers both the pulse oximetry device and its consumable sensors and cables to be products as defined in its statements of income.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying condensed consolidated balance sheet as of June 28, 2008, the condensed consolidated statements of income for the three and six months ended June 30, 2007 and June 28, 2008, the condensed consolidated statements of cash flows for the six months ended June 30, 2007 and June 28, 2008, and other information disclosed in the related condensed consolidated notes are unaudited. The condensed consolidated balance sheet as of December 29, 2007 was derived from the Company's audited consolidated financial statements at that date. The accompanying 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 Exchange Commission, or SEC, on March 4, 2008.

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 June 28, 2008, consolidated results of operations for the three and six months ended June 30, 2007 and June 28, 2008, and consolidated cash flows for the six months ended June 30, 2007 and June 28, 2008. The results for the three and six months ended June 28, 2008 are not necessarily indicative of the results to be expected for the year ending January 3, 2009 or for any other interim period or for any future year.

***Fiscal Periods***

The Company follows a conventional 52/53 week fiscal year and fiscal 2007 was designated as a 52 week 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. Under the Company's fiscal year policy, each quarter and the year end will end on the Saturday corresponding to either the 13 or 14 week quarter. As a result of the adoption of the 52/53 week convention in fiscal 2007, the Company's first, second and third quarters ended on Saturday, March 31, June 30 and September 29, 2007, respectively, and its fiscal year ended on Saturday, December 29, 2007. In fiscal 2008, the Company is on a 53 week fiscal calendar in which its first and second quarters ended on Saturday, March 29 and June 28, respectively. The Company's third quarter will end on Saturday, September 27, 2008, and its fiscal year will end on Saturday, January 3, 2009. For fiscal 2008, the first three quarters are 13 week quarters and the fourth fiscal quarter is a 14 week quarter.

***Principles of Consolidation***

The condensed consolidated financial statements include the accounts of Masimo Corporation and Masimo Laboratories, Inc., which has been consolidated pursuant to FIN 46(R), *Consolidation of Variable Interest Entities: an Interpretation of ARB No. 51*. In addition, these condensed

## Edgar Filing: MASIMO CORP - Form 10-Q

consolidated financial statements include the accounts of Masimo Corporation's wholly-owned subsidiaries, Masimo Americas, Inc., Masimo Europe Ltd., Masimo Japan, Masimo Canada ULC and Masimo Australia Pty. Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

---

## **Table of Contents**

### ***Comprehensive Income***

SFAS No. 130, *Reporting 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 and reflected in stockholders' equity.

### ***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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, sales return reserves, warranty reserves, rebate reserves, valuation of the Company's common stock, stock options, distributor channel inventory, royalty revenues, property tax and income tax contingencies. Actual results could differ from those estimates.

### ***Fair Value Measurements***

Effective December 30, 2007, the Company adopted Statement of Financial Accounting Standard No. 157, or SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. In February 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 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 has adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only.

The statement 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.

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.

As of June 28, 2008, \$97.9 million of the Company's total \$102.9 million of cash and cash equivalents are held in money market accounts measured at fair value on a recurring basis. These accounts consist of highly liquid investments that are readily convertible into known amounts of cash and have an original maturity of three months or less when acquired. In accordance with SFAS 157, and based on the fair value hierarchy described above, these financial assets are valued on Level 1 inputs.

Effective December 30, 2007, the Company adopted SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159. SFAS 159 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 to specific assets or liabilities.

### ***Reclassifications***

## Edgar Filing: MASIMO CORP - Form 10-Q

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

**Table of Contents*****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.

Changes in the product warranty accrual for the six months ended June 30, 2007 and June 28, 2008 were as follows (in thousands):

	Six Months Ended	
	June 30, 2007	June 28, 2008
Warranty accrual, beginning of period	\$ 599	\$ 649
Provision for warranty costs	791	675
Warranty expenditures	(814)	(905)
Warranty accrual, end of period	\$ 576	\$ 419

***Net Income Per Common Share***

Basic net income per common share is computed by dividing net income attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. For the three and six months ended June 30, 2007, net income attributable to common stockholders is calculated using the two-class method under Emerging Issues Task Force, or EITF, Issue No. 03-6, *Participating Securities and the Two-Class Method under FASB Statement No. 128*. EITF No. 03-6 establishes standards regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder of such securities to participate in dividends and earnings of the Company. Pursuant to EITF 03-6, the two-class method of computing basic earnings per share is required when an entity has participating securities. Dividends must be calculated for the participating security on undistributed earnings and are a reduction in the net income attributable to common shareholders. The Company's previously outstanding Series A through G preferred stock were participating securities as these securities had the right to dividends should dividends be declared on common stock. Assumed dividends on undistributed earnings are allocated as if the entire net income were distributed and are based on the relationship of the weighted average number of common shares outstanding and the weighted average number of common shares outstanding if the preferred stock were converted into common stock.

Upon closing of the Company's initial public offering on August 13, 2007, all of the outstanding convertible preferred shares were converted into common shares. Therefore, subsequent to this stock conversion the Company uses the if-converted method under SFAS No. 128, *Earnings Per Share* to calculate earnings per share. Accordingly, for the three and six months ended June 28, 2008, the Company calculated net income per share using the if-converted method for the entire period while the two-class method was used for the three and six months ended June 30, 2007.

Diluted net income per common share is computed by dividing the net income attributable to common stockholders for the period by the weighted average number of common and potential common shares outstanding during the period, if the effect of potential common shares is dilutive. Potential common shares include incremental shares of common stock issuable upon the exercise of stock options.

**Table of Contents**

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

	Three Months Ended		Six Months Ended	
	June 30, 2007	June 28, 2008	June 30, 2007	June 28, 2008
<b>Numerator:</b>				
Net income as reported	\$ 10,556	\$ 10,601	\$ 19,653	\$ 19,392
Accretion of preferred stock	(1,956)		(3,913)	
Undistributed income attributable to preferred stockholders	(5,802)		(10,630)	
<b>Net income attributable to common stockholders</b>	<b>\$ 2,798</b>	<b>\$ 10,601</b>	<b>\$ 5,110</b>	<b>\$ 19,392</b>
<b>Denominator:</b>				
Weighted average common shares outstanding number of shares used in per share calculation Basic	16,692,547	56,166,934	16,642,779	55,637,976
Options to purchase common stock	4,039,467	3,883,688	4,056,332	4,413,349
<b>Weighted average number of shares used in per common share calculation Diluted</b>	<b>20,732,014</b>	<b>60,050,622</b>	<b>20,699,111</b>	<b>60,051,325</b>
<b>Net income per common share:</b>				
Basic	\$ 0.17	\$ 0.19	\$ 0.31	\$ 0.35
Diluted	\$ 0.13	\$ 0.18	\$ 0.25	\$ 0.32

**Stock Based Compensation**

The Company accounts for stock based compensation in accordance with the provisions of SFAS No. 123(R), *Share Based Payment*, which require companies to expense the estimated fair value of employee stock options and similar awards based on the fair value of the award on the date of grant. The cost is recognized over the period during which an employee is required to provide services in exchange for the award, which is usually the vesting period.

The Company adopted SFAS No. 123(R) using the prospective transition method that applies to awards granted, modified or canceled subsequent to the date of adoption of January 1, 2006. As a result, options granted prior to the adoption continue to be accounted for using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* unless such options are modified, repurchased or cancelled. In accordance with EITF Issue No. 00-15, *Classification in the Statement of Cash Flows of the Income Tax Benefit Received by a Company upon Exercise of a Nonqualified Employee Stock Option*, which was nullified by SFAS No. 123(R) except for companies that continue to account for awards under Opinion No. 25, the cash flows related to the reduction of income taxes paid as a result of the deduction triggered by employee exercise of stock options granted or modified prior to the adoption of SFAS No. 123(R) will continue to be presented as an operating cash flow.

**New Accounting Pronouncements**

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141(R), or SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) provides greater consistency in the accounting and financial reporting of business combinations. It requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. If the Company consummates any acquisitions after December 2008, the purchase accounting treatment could result in a material difference from current accounting treatment.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, or SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of this statement to have a

material impact on its consolidated financial statements.



**Table of Contents**

In March 2008, the FASB issued Statement of Financial Accounting Standards No. 161, or SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities – an amendment of FASB Statement No. 133*. SFAS No. 161 enhances the disclosure requirements for derivative instruments and hedging activities and thereby is designed to improve the transparency of financial reporting. SFAS No. 161 is effective for fiscal years beginning after November 15, 2008. The Company does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

In May 2008, the FASB issued Statement of Financial Accounting Standard No. 162, or SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles. SFAS No. 162 will become effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not expect the adoption of this statement to have a material effect on its consolidated financial statements.

**3. Comprehensive Income**

The Company's total comprehensive income is as follows (in thousands):

	Three Months Ended		Six Months Ended	
	June 30, 2007	June 28, 2008	June 30, 2007	June 28, 2008
Net income	\$ 10,556	\$ 10,601	\$ 19,653	\$ 19,392
Other comprehensive income (loss):				
Foreign currency translation adjustments	(304)	(311)	(308)	111
Comprehensive income	\$ 10,252	\$ 10,290	\$ 19,345	\$ 19,503

**4. Masimo Laboratories, Inc.**

Masimo Laboratories, Inc., or Masimo Labs, is an independent entity spun off from the Company to the Company's stockholders in 1998. The Company is a party to a cross-licensing agreement with Masimo Labs, which was amended and restated effective January 1, 2007, or the Cross-Licensing Agreement, that governs each party's rights to certain of the intellectual property held by the two companies.

Pursuant to FASB Interpretation No. 46(R), *Consolidation of Variable Interest Entities – an Interpretation of ARB No. 51*, or FIN 46(R), Masimo Labs is consolidated within the Company's financial statements for all periods presented. Accordingly, all royalties, option and license fees and other charges between the Company and Masimo Labs have been eliminated in these consolidated financial statements.

For the foreseeable future, the Company anticipates that it will continue to consolidate Masimo Labs pursuant to the guidance set forth in FIN 46(R); however, the Company may discontinue consolidating Masimo Labs in the event it is permitted under FIN 46(R).

**5. Related Party Transactions**

As of December 29, 2007 and June 28, 2008, the Company had amounts due from employees of \$598,000 and \$231,000, respectively. As of December 29, 2007 and June 28, 2008, these amounts are classified in other current assets and other assets in the accompanying condensed consolidated balance sheet.

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, since 1997. The Company has paid Saba Software \$19,000 and \$48,000 during the six months ended June 30, 2007 and June 28, 2008, respectively, for various software products and services.

**6. Royalties Receivable**

The royalty receivable of \$13.9 million as of December 29, 2007 represents the amount received in February 2008, for the three months ended December 29, 2007. The royalty receivable of \$11.4 million as of June 28, 2008 represents the Company's estimated amount due for the three months ended June 28, 2008. Pursuant to the settlement agreement with Nellcor Puritan Bennett, Inc. (currently Covidien Ltd., or Covidien), the royalties are paid to the Company based on 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 quarter.

**Table of Contents****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):

	December 29, 2007	June 28, 2008
Raw materials	\$ 13,173	\$ 18,532
Work in-process	1,956	2,599
Finished goods	7,981	8,125
Total	\$ 23,110	\$ 29,256

**8. Long-Term Debt**

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

	December 29, 2007	June 28, 2008
Total debt	\$ 30,771	\$ 676
Less current portion of long-term debt	(11,477)	(580)
Long-term portion	\$ 19,294	\$ 96

As of December 29, 2007 and June 28, 2008, the Company had two arrangements and one arrangement, respectively, which allow for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements. These agreements provided for an equipment line whereby some 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 financial statements 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. Both financing arrangements are non-recourse to the Company. In the event the hospital was 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. To date, no hospitals have defaulted under this program.

At December 29, 2007 and June 28, 2008, the carrying value of the equipment collateralizing the borrowings was \$3.4 million and \$175,000, respectively. During the six months ended June 28, 2008, the Company repaid \$26.7 million, or the entire amount owed, on one of these arrangements, and \$168,000 in prepayment fees which are included in other non-operating income (expense). As of June 28, 2008, principal and interest payments under the remaining financing agreement were \$85,000 per month based on an average interest rate of 7.1% per year.

The Company currently has seven 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 December 2009 through April 2013. As of June 28, 2008, the total future remaining interest was \$31,000. Not including this interest expense, the capital lease obligations consist of the following (in thousands):

	December 29, 2007	June 28, 2008
Capital lease obligations	\$ 270	\$ 256

Edgar Filing: MASIMO CORP - Form 10-Q

Less current portion of capital lease obligations	(62)	(67)
Long-term portion	\$ 208	\$ 189

**Table of Contents****9. Cash Dividends**

In March 2006, the Company declared a cash dividend of \$3.365 per share, in the aggregate amount of \$171.8 million, to holders of the Company's common and preferred stock, assuming the conversion of all outstanding shares of preferred stock into an aggregate of 34,612,503 shares of common stock. During the year ended December 31, 2006, \$171.4 million of this dividend declared had been paid.

In December 2006, the Company declared an additional cash dividend of \$0.725 per share, in the aggregate amount of \$37.1 million to holders of the Company's common and preferred stock, assuming the conversion of all outstanding shares of preferred stock into common stock. Of the total cash dividends declared in both March and December 2006, the Company paid in aggregate \$37.2 million in the first six months of 2007 and \$180,000 in the third quarter of 2007. No dividends were declared or paid in the fourth quarter of 2007, or the first or second quarters of 2008. The total outstanding dividends payable balance as of December 29, 2007 and June 28, 2008 was \$183,000.

**10. Stock 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 are reserved for future issuance, 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. In addition, the 2007 Plan includes an evergreen provision which automatically increases the number of shares reserved for issuance on the first day of each fiscal year by 3% of the shares outstanding on last day of the preceding fiscal year. However, on February 7, 2008, the Company's Board of Directors amended the Company's 2007 Plan to decrease the number of shares reserved under the plan by 1,640,748 shares of common stock, the exact amount automatically added to the share reserve effective December 30, 2007, pursuant to the evergreen provision.

The options granted under the 2007 Plan generally vest annually over five years using the straight-line method, unless otherwise provided, and expire ten years from the date of grant. The number and weighted average exercise price of options issued and outstanding under all stock option plans, at exercise prices ranging between \$1.33 and \$41.18 per share, are as follows:

	<b>Six Months Ended June 28, 2008</b>	
	<b>Shares</b>	<b>Average Exercise Price</b>
Options outstanding, beginning of period	8,321,191	\$ 7.53
Granted	1,671,650	\$ 31.00
Canceled	(635,122)	\$ 17.33
Exercised	(1,755,729)	\$ 3.25
Options outstanding, end of period	7,601,990	\$ 12.86
Options exercisable, end of period	3,087,562	\$ 4.80
Options available for grant, end of period	4,359,548	

The weighted-average fair value of options granted was \$13.19 for the six months ended June 28, 2008.

**Table of Contents**

The Company applies the provisions of Staff Accounting Bulletin, or SAB, No. 107 *Share-Based Payment* and SAB No. 110, *Share-Based Payment* in its application of SFAS No. 123(R), *Share-Based Payment*. 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		Six Months Ended	
	June 30, 2007	June 28, 2008	June 30, 2007	June 28, 2008
Risk-free interest rate	4.6%	3.2%	4.6%	3.2%
Expected term	6.5 years	6.5 years	6.5 years	6.5 years
Estimated volatility	39.9%	37.1%	40.1%	36.7%
Expected dividends	0%	0%	0%	0%

In accordance with SFAS 123(R), the Company recorded stock-based compensation expense of \$774,000 and \$1.2 million during the three and six months ended June 30, 2007, respectively, and \$2.2 million and \$3.7 million during the three and six months ended June 28, 2008, respectively.

The aggregate intrinsic value of options outstanding as of June 28, 2008 was \$167.9 million. The aggregate intrinsic value of options exercisable as of June 28, 2008 was \$92.8 million. The aggregate intrinsic value of options exercised during the three months ended June 28, 2008 was \$16.5 million. The aggregate intrinsic value is calculated as the difference between the market value of the Company's common stock on the date of exercise or the respective period end, as appropriate, and the exercise price of the options. The unrecognized stock based compensation as of June 28, 2008 was \$38.9 million related to unvested options granted after January 1, 2006. The weighted average remaining contractual term of options outstanding as of June 28, 2008 was 7.2 years. The weighted average remaining contractual term of options exercisable as of June 28, 2008 was 5.4 years. The total fair value on the respective vesting dates of all options vesting during the three months ended June 28, 2008 was \$14.3 million.

In February 2007, the Company repurchased 11,640 shares of common stock at an average price of \$13.56 per share totaling \$158,000 from a former employee. The difference between the repurchase price and the original option exercise price totaled \$134,000 and was recorded as operating expense during the three months ended March 31, 2007. In May 2007, the Company repurchased another 30,000 shares of common stock at an average price of \$14.09 per share, totaling \$423,000, from another former employee. The difference between the repurchase price and the original option exercise price totaled \$283,000 and was recorded as operating expense during the three months ended June 30, 2007. All these shares were recorded in treasury stock and are available for reissue. Since these events occurred prior to the Company's initial public offering, no public announcement regarding stock repurchase was made.

**11. Commitments and Contingencies****Leases**

The Company leases its facilities in North America, Europe and Asia under operating lease agreements expiring at various dates through August 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 December 29, 2007 and June 28, 2008, rent expense accrued in excess of the amount paid aggregated \$625,000 and \$470,000, 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 June 28, 2008		
	Operating Leases	Capital Leases	Total
2008 (balance of year)	\$ 1,592	\$ 40	\$ 1,632
2009	2,528	81	2,609
2010	965	70	1,035

Edgar Filing: MASIMO CORP - Form 10-Q

2011	525	56	581
2012	512	40	552
Thereafter	815		815
Total	\$ 6,937	\$ 287	\$ 7,224

---

## **Table of Contents**

Rental expense related to operating leases was \$476,000 and \$1.0 million for the three and six months ended June 30, 2007, respectively, and was \$856,000 and \$1.7 million for the three and six months ended June 28, 2008, respectively.

### ***Employee Benefit 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 \$235,000 and \$459,000 to the Plan for the three and six months ended June 30, 2007, respectively, and \$277,000 and \$577,000 to the Plan for the three and six months ended June 28, 2008, respectively.

### ***Employment Agreements***

As of June 28, 2008, the Company had an employment agreement with one of its key employees that provides for an aggregate annual base salary of \$660,000, plus other benefits, with annual increases at the discretion of the Board of Directors. The agreement with the Company also provides for an annual bonus based on the Company's attainment of certain objectives and goals. The agreement automatically renews on a daily basis and terminates three years from the date either party gives notice of termination to the other party.

As of June 28, 2008, the Company had an additional employment agreement with one of its key employees, which provides for an annual base salary of EUR 150,000 (approximately \$236,000). The agreement also contemplates an annual bonus based on the attainment of certain revenue, gross margin and operating income milestones. The agreement also contains a non-compete provision. If the Company enforces this provision following the employee's termination of employment, the employee would be entitled to receive a lump sum payment equal to 50% of his annual base salary as of the date of his termination, which shall be paid in equal installments over the term of the non-competition period.

### ***Severance Agreements***

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. Under the Agreements, the 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.

### ***Purchase Commitments***

Pursuant to contractual obligations with vendors, the Company had \$21.7 and \$16.7 million of purchase commitments as of December 29, 2007 and June 28, 2008, respectively. These purchase commitments were made for certain inventory items to secure better pricing and to ensure the Company will have materials on hand to meet anticipated demands for inventory.

### ***Concentrations of Risk***

The Company is exposed to credit loss for the amount of cash deposits with financial institutions in excess of federally insured limits. The Company invests its excess cash deposits in money market accounts with major financial institutions. The amount of bank balances in excess of Federal Deposit Insurance Corporation limits was \$102.5 million as of June 28, 2008.

While the Company and its contract manufacturers rely on sole source suppliers for certain components and contract manufacturing services, management believes that 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. There can be no assurance that a shortage or stoppage of shipments of the materials or components or services 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 six months ended June 30, 2007, revenue from the sale of the Company's pulse oximetry products to U.S. hospitals that are members of GPOs amounted to \$26.7 million and \$48.5 million, respectively. In the three and six months ended June 28, 2008, revenue from sales to U.S. hospitals that are members of GPOs was \$33.0 million and \$63.7 million, respectively.



## Edgar Filing: MASIMO CORP - Form 10-Q

For the three months ended June 30, 2007, no customers represented over 10% of the Company's total revenue. For the six months ended June 30, 2007, one customer represented 11.0% of the total revenue. For the three and six months ended June 28, 2008, one customer represented 11.7% and 12.5% of the total revenue, respectively.

---

**Table of Contents**

Two customers represented 8.4% and 5.3% of accounts receivable at December 29, 2007, and 7.5% and 5.5% of accounts receivable at June 28, 2008.

***Litigation***

In May 2002, the Company filed a lawsuit against Tyco Healthcare (currently Covidien), 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, market share-based compliance pricing contracts and co-marketing agreements with patient monitoring companies were unlawful restraints of trade and exclusionary dealing arrangements and, as a result, violated federal antitrust laws. The jury awarded the Company \$140 million in damages. Under the antitrust laws, if the jury verdict is sustained in whole or in part, all damages are trebled. 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. As a result, the Company may not receive any damages in this lawsuit. The District Court held an evidentiary hearing in October 2006 to re-try the damages. On January 25, 2007, the District Court issued a preliminary ruling which did not set damages, but resolved some issues of dispute about damages, and ordered another evidentiary hearing on issues still undecided by the District Court. The District Court held this evidentiary hearing in March 2007. On July 2, 2007, the District Court entered its final judgment awarding the Company damages which were trebled 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 have 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 9<sup>th</sup> Circuit. On December 27, 2007, the Consumer Federation of America and Medical Device Manufacturers Association filed an Amicus brief supporting Masimo. 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. 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 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. See Risk Factors for a description of the risks related to the Company's litigation against Tyco Healthcare.

On July 24, 2007, Shaklee Corporation filed suit against the Company in the United States District Court, Central District of California, alleging that the Company's pulse oximeters incorporate patented calibration methods that are licensed to Shaklee. NIR Diagnostics, Inc., the original licensee of the patents, was originally named as a defendant, but then agreed to become a plaintiff. Shaklee and NIR are seeking an injunction and damages against the Company. The Company's management believes that its devices do not infringe either of the cited patents and intends to vigorously defend against these claims. The Company believes that the claims asserted by Shaklee and NIR will not materially affect the Company's business, financial conditions or future operating results. However, in the event a preliminary or permanent injunction were granted, the Company would be unable to sell products found to infringe the cited patents, which would cause a reduction in the Company's revenues, a decline in income and a loss of customer goodwill for an unknown period of time. Additionally, the Company could be ordered to pay royalties on past sales of the Company's products found to infringe the cited patents and, to the extent the Company continued to sell such products, the Company could be required to continue paying royalties to Shaklee and NIR. Although the Company believes that these claims are without merit, no assurance can be given with respect to the ultimate outcome for any such claim or litigation. At this time, the Company is not able to accurately estimate the potential financial impact of an injunction and/or damages against the Company.

On February 19, 2008, the Company filed a lawsuit against Respironics, Inc. for breach of contract, breach of the covenant of good faith and fair dealing, and interference with prospective economic advantage, based on a January 16, 2006, contract between Respironics and the Company. On April 7, 2008, Respironics filed a demurrer seeking to dismiss the lawsuit on the grounds that the Company's complaint fails to state sufficient facts to constitute valid claims. The court subsequently denied Respironics' demurrer. 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**

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.

**Voluntary Recall**

On July 31, 2007, the Company initiated a voluntary recall of its Rad-9 pulse oximeter, a standalone bedside pulse oximeter product, sales of which represented less than 0.2% and 0.3% of the Company's product revenue in the three and six months ended June 28, 2008, respectively. In accordance with its original design and similar to other pulse oximeter devices, the Rad-9 gives a visual alarm if there is a sensor fault; under other circumstances, the Rad-9 gives both a visual and audio alarm. In late 2006, the Company sent notice to owners of the Rad-9 that a free upgrade was available to add an audio alarm to the Rad-9 when a sensor fault is detected. Although the Company received notification from the U.S. Food and Drug Administration, or FDA, that recall of its Rad-9 was not mandatory, the Company decided to voluntarily recall the Rad-9 and implement this upgrade. The Company does not believe that a non-upgraded Rad-9 poses a significant risk to health or would cause serious injury or death. The Company decided to voluntarily recall the Rad-9 because it believes it has the possibility of improving the care of patients. This decision follows a customer report that an elderly patient, who may have damaged her pulse oximeter sensor, had died after removing her tracheostomy tube. Based on what is currently known, the Rad-9 appears to have been operating in accordance with its specifications. The Company had originally estimated that the total costs resulting from this voluntary recall would be approximately \$300,000, although this was an estimate and the actual costs could differ. The Company incurred this charge in the quarter ended September 29, 2007. As of June 28, 2008, the Company had incurred actual upgrade costs of approximately \$262,000 and expected to incur an additional \$30,000 for units not yet upgraded, which has been accrued for at June 28, 2008. Any future recall could result in a diversion of management resources, substantial cost and negative publicity, all of which could adversely affect the Company's business, financial condition and results of operations.

**12. Segment Information and Enterprise Reporting**

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

Geographic Area by Destination	Three Months Ended				Six Months Ended			
	June 30, 2007		June 28, 2008		June 30, 2007		June 28, 2008	
North and South America	\$ 36,425	76.5%	\$ 47,013	76.0%	\$ 72,205	77.3%	\$ 93,020	76.5%
Europe, Middle East and Africa	7,220	15.1	9,533	15.4	13,722	14.7	18,565	15.3
Asia and Australia	3,982	8.4	5,304	8.6	7,464	8.0	9,938	8.2
Total product revenues	\$ 47,627	100%	\$ 61,850	100%	\$ 93,391	100%	\$ 121,523	100%

Sales to customers located in the United States were \$35.6 million and \$70.2 million for the three and six months ended June 30, 2007, respectively, and \$45.3 million and \$90.0 million for the three and six months ended June 28, 2008, respectively.

**13. Income Taxes**

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109*, or FIN 48, which became effective on January 1, 2007. FIN 48 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be

## Edgar Filing: MASIMO CORP - Form 10-Q

recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The adoption of FIN 48 on January 1, 2007 resulted in an increase to the Company's accumulated deficit of \$618,000. As of June 28, 2008, the balance of the gross unrecognized tax benefit was \$3.4 million, of

**Table of Contents**

which \$2.3 million (net of federal benefit on state taxes), if recognized, would affect the effective tax rate. The remaining balance relates to timing differences, of which the ultimate deductibility is highly certain, but there is uncertainty about the timing of such deductibility. It is reasonably possible that the amount of unrecognized tax benefits will decrease in the next 12 months by \$197,000 primarily related to certain timing differences.

Interest and penalties related to unrecognized tax benefits are recognized in income tax expense. For the three and six months ending June 28, 2008, the Company had accrued \$58,000 and \$127,000 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 existence of net operating loss carryforwards, all years since 1994 are open for examination by major taxing authorities.

The provision for income taxes was \$7.4 million and \$13.4 million, or an effective tax rate of 41.1% and 40.6% for the three and six months ended June 30, 2007, respectively. The provision for income taxes was \$6.8 million and \$12.4 million, or an effective tax rate of 39.0% and 39.0% for the three and six months ended June 28, 2008, respectively. The effective tax rate differs from the statutory U.S. federal income tax rate of 35.0% primarily due to state taxes and permanent differences between pre-tax income for financial reporting purposes and taxable income.

**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 that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially 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; 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 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 Form 10-Q and in our other SEC filings, including our Annual Report on Form 10-K, which we filed with the SEC on March 4, 2008. 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 after the date of such statements.*

**Overview**

We are a global medical technology company that develops, manufactures and markets non-invasive patient monitoring products that improve patient care. We invented 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 non-invasive 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 significantly addressed many of the previous technology limitations. The benefits of Masimo SET have been validated in over 100 independent clinical and laboratory studies.

We market a family of patient monitoring solutions which incorporate a monitor or circuit board and consumables, including both proprietary single-patient use and reusable sensors and cables. In addition, we offer a remote-alarm/monitoring solution, software and other accessories. Although our Masimo SET platform is only operable with our proprietary sensors, our sensors have the capability to work with certain competitor pulse oximeters through the use of our adapter cables. In 2005, we launched our Masimo Rainbow SET Pulse CO-Oximetry platform utilizing licensed Rainbow technology from Masimo Laboratories, Inc., or Masimo Labs, which enables the non-invasive measurement of not only arterial blood oxygen saturation level and pulse rate, but also carboxyhemoglobin, or carbon monoxide levels in the blood, and in 2006 methemoglobin saturation levels in the blood. Most recently, in May 2008, we received clearance from the FDA for SpHb, our non-invasive measurement of total hemoglobin levels in the blood. We have applied for FDA clearance of our Single Patient Adhesive Rainbow SpHb sensors. We have not started commercial shipments of SpHb. We intend to sell SpHb on a limited basis to select customers beginning in the second half of 2008. Along with the release of our Masimo Rainbow SET Pulse CO-Oximetry products, we have developed multi-wavelength sensors that have the ability to monitor multiple measurements with a single sensor.

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 (ARM). 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, Pulse Co-Oximeters and circuit boards generates recurring sales of our consumables, 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 estimate that our worldwide installed base was approximately 515,000 units as of June 28, 2008, up from 424,000 units as of June 30, 2007. We estimate our installed base to be the number of bedside pulse oximeters and circuit boards that we have shipped in the past seven years.



## **Table of Contents**

We currently manufacture bedside and handheld pulse oximeters, a full line of single-patient use and reusable sensors and patient cables. We use third-party contract manufacturers for some of our products and components that can be more efficiently manufactured by these parties, primarily circuit boards, cables and plastics for instrument housings. We perform incoming inspection, final assembly and testing of any products or subassemblies manufactured by third-party contract manufacturers to assure quality control.

### **Masimo Laboratories**

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 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 and methemoglobin 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 FASB Interpretation No. 46(R), *Consolidation of Variable Interest Entities - an Interpretation of ARB No. 51*, or FIN 46(R), 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 consolidated financial statements. For the foreseeable future, we anticipate that we will continue to consolidate Masimo Labs pursuant to the guidance set forth in FIN 46(R); however, we may discontinue consolidating Masimo Labs in the event it is permitted under FIN 46(R).

### **Results of Operations**

The following tables provide a comparison of our earnings per share calculated under Emerging Issues Task Force Issue No. 03-6, *Participating Securities and the Two-Class Method under FASB Statement No. 128*, or EITF 03-6, and SFAS No. 128 *Earnings per Share*, or SFAS 128, in accordance with GAAP and the non-GAAP if-converted method based solely upon SFAS No. 128. The non-GAAP if-converted method assumes conversion of all shares of our preferred stock into common stock as of December 31, 2006.

Upon closing of the Company's initial public offering on August 13, 2007, all of the outstanding convertible preferred shares were converted into common shares. Therefore, subsequent to this stock conversion the Company uses the if-converted method under SFAS No. 128 to calculate earnings per share.



**Table of Contents**

We believe that the following non-GAAP earnings per share information for the three and six months ended June 30, 2007 is relevant and useful information that can be used by analysts, investors and other interested parties to assess our performance on a comparable basis to the three and six months ended June 28, 2008 and future reported earnings per share. Accordingly, we are disclosing this information to permit additional analysis of our performance (in thousands, except share data):

	2007				2008	
	As Reported		Non-GAAP		As Reported	
	Three months ended June 30, 2007 (unaudited)	Six months ended June 30, 2007 (unaudited)	Three months ended June 30, 2007 (unaudited)	Six months ended June 30, 2007 (unaudited)	Three months ended June 28, 2008 (unaudited)	Six months ended June 28, 2008 (unaudited)
<b>Numerator:</b>						
Net income as reported	\$ 10,556	\$ 19,653	\$ 10,556	\$ 19,653	\$ 10,601	\$ 19,392
Accretion of preferred stock	(1,956)	(3,913)				
Undistributed income attributable to preferred stockholders	(5,802)	(10,630)				
<b>Net income attributable to common stockholders</b>	<b>\$ 2,798</b>	<b>\$ 5,110</b>	<b>\$ 10,556</b>	<b>\$ 19,653</b>	<b>\$ 10,601</b>	<b>\$ 19,392</b>
<b>Denominator:</b>						
Weighted average common shares outstanding number of shares used in per share calculation Basic	16,692,547	16,642,779				
Options to purchase common stock	4,039,467	4,056,332				
<b>Weighted average number of shares used in per common share calculation Diluted</b>	<b>20,732,014</b>	<b>20,699,111</b>				
Weighted average common shares outstanding			16,692,547	16,642,779		
Weighted average preferred shares outstanding			34,612,503	34,612,503		
Number of shares used in per share calculation Basic			51,305,050	51,255,282	56,166,934	55,637,976
Options to purchase common stock			4,039,467	4,056,332	3,883,688	4,413,349
<b>Weighted average number of shares used in per share calculation Diluted</b>			<b>55,344,517</b>	<b>55,311,614</b>	<b>60,050,622</b>	<b>60,051,325</b>
<b>Net income per share:</b>						
Basic	\$ 0.17	\$ 0.31	\$ 0.21	\$ 0.38	\$ 0.19	\$ 0.35
Diluted	\$ 0.13	\$ 0.25	\$ 0.19	\$ 0.36	\$ 0.18	\$ 0.32

**Table of Contents**

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				Six months ended			
	June 30, 2007	% of Revenue	June 28, 2008	% of Revenue	June 30, 2007	% of Revenue	June 28, 2008	% of Revenue
<b>Revenue:</b>								
Product	\$ 47,627	74.8%	\$ 61,850	82.7%	\$ 93,391	76.2%	\$ 121,523	83.3%
Royalty and license fee	16,053	25.2	12,916	17.3	29,243	23.8	24,353	16.7
Total revenue	63,680	100.0	74,766	100.0	122,634	100.0	145,876	100.0
Cost of goods sold	17,919	28.1	21,403	28.6	34,820	28.4	42,524	29.2
Gross profit	45,761	71.9	53,363	71.4	87,814	71.6	103,352	70.8
<b>Operating expenses:</b>								
Research and development	5,460	8.6	5,980	8.0	10,914	8.9	12,278	8.4
Selling, general and administrative	21,577	33.9	30,366	40.6	42,979	35.0	59,895	41.1
Antitrust litigation	465	0.7	277	0.4	475	0.4	445	0.3
Total operating expenses	27,502	43.2	36,623	49.0	54,368	44.3	72,618	49.8
Operating income	18,259	28.7	16,740	22.4	33,446	27.3	30,734	21.0
<b>Non-operating income (expense):</b>								
Interest income	189	0.3	625	0.8	544	0.4	1,584	1.1
Interest expense	(685)	(1.1)	(60)	(0.1)	(1,112)	(0.9)	(703)	(0.5)
Other	170	0.3	75	0.1	211	0.2	178	0.1
Total non-operating income (expense)	(326)	(0.5)	640	0.8	(357)	(0.3)	1,059	0.7
Income before provision for income taxes	17,933	28.2	17,380	23.2	33,089	27.0	31,793	21.8
Provision for income taxes	7,377	11.6	6,779	9.1	13,436	11.0	12,401	8.5
Net income	10,556	16.6	10,601	14.1	19,653	16.0	19,392	13.3
Accretion of preferred stock	(1,956)	(3.1)			(3,913)	(3.2)		
Undistributed income attributable to preferred stockholders	(5,802)	(9.1)			(10,630)	(8.6)		
Net income attributable to common stockholders	\$ 2,798	4.4%	\$ 10,601	14.1%	\$ 5,110	4.2%	\$ 19,392	13.3%

**Comparison of the Three Months ended June 28, 2008 to the Three Months ended June 30, 2007**

*Revenue.* Total revenue increased \$11.1 million, or 17.4%, to \$74.8 million for the three months ended June 28, 2008 from \$63.7 million for the three months ended June 30, 2007.

Product revenues increased \$14.2 million, or 29.9%, to \$61.8 million in the three months ended June 28, 2008 from \$47.6 million for the three months ended June 30, 2007. This increase was primarily due to higher consumable sales resulting from an increase in our installed base of circuit boards and pulse oximeters which totaled 515,000 units at June 28, 2008 up from 424,000 units at June 30, 2007. Revenue generated through our direct and distribution sales channels increased \$15.2 million, or 46.2%, to \$48.0 million for the three months ended June 28, 2008 compared to \$32.8 million for the three months ended June 30, 2007. During the three months ended June 28, 2008 revenues from our OEM channel decreased \$1.0 million, or 6.3%, to \$13.8 million from \$14.8 million in the three months ended June 30, 2007. Contributing to the increase in our direct and distribution sales channel revenue was our Rainbow technology product revenues which increased 40.2%, or approximately \$800,000, to \$2.9 million in the three months ended June 28, 2008, from \$2.1 million in the three months ended June 30, 2007.



**Table of Contents**

Our royalty and license fee revenue decreased \$3.2 million, to \$12.9 million in the three months ended June 28, 2008 from \$16.1 million in the three months ended June 30, 2007, primarily due to a lower royalty rate associated with our 2006 settlement agreement with Tyco Healthcare (currently Covidien). For the three months ended June 30, 2007, our reported Covidien royalties were based upon Covidien's actual reported U.S. pulse oximeter sales for that period. For the three months ended June 28, 2008, our reported Covidien royalties are based upon an estimate of Covidien's U.S. pulse oximeter sales for that period and the contractual royalty rate as prescribed by the 2006 settlement agreement. Any adjustments to the quarterly estimate are recorded prospectively in the following quarter, when we receive the Covidien royalty report, which is generally 60 days after the end of each quarter.

*Cost of Goods Sold.* Cost of goods sold increased 19.4% to \$21.4 million in the three months ended June 28, 2008 from \$17.9 million in the three months ended June 30, 2007. Total gross profit margin decreased to 71.4% for the three months ended June 28, 2008 from 71.9% for the three months ended June 30, 2007. This decline in total gross margin was due to the impact of the \$3.2 million year over year decline in Covidien royalty revenues which have no related cost of goods sold. In the three months ended June 28, 2008, product gross profit margin rose to 65.4% from 62.4% in the comparable prior year period due to greater sensor sales, increased sales of Rainbow related products and manufacturing efficiencies related to higher production volumes. We incurred \$875,000 and \$789,000 in Masimo Lab's royalty expenses for the three months ended June 28, 2008 and June 30, 2007, respectively, which, in accordance with FIN 46(R), have been eliminated in our condensed consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 64.0% and 60.7% for the three months ended June 28, 2008 and June 30, 2007, respectively.

*Research and Development.* Research and development expenses increased 9.5% to \$6.0 million for the three months ended June 28, 2008, from \$5.5 million for the three months ended June 30, 2007. The increase was primarily due to increased staffing and related stock based compensation during the three months ended June 28, 2008. We also incurred \$465,000 and \$379,000, respectively, of Masimo Lab's engineering expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

*Selling, General and Administrative.* Selling, general and administrative expenses increased \$8.8 million, or 40.7% to \$30.4 million for the three months ended June 28, 2008 from \$21.6 million in the three months ended June 30, 2007. The increase was primarily due to a \$4.1 million increase in payroll and payroll related costs, including stock based compensation, consistent with an increase in staffing from 328 at June 30, 2007 to 393 at June 28, 2008. In addition to the increased staffing levels, professional fees increased \$1.7 million due to a combination of higher patent litigation expense and increased tax, audit and other professional fees associated with the cost of being a public company. Also, sales related travel increased \$1.4 million due to additional sales representatives and tradeshow marketing expense increased by \$540,000 due to an increase in the number of tradeshows attended. For the three months ended June 28, 2008 and June 30, 2007, we also incurred a net \$395,000 and \$180,000, respectively, of Masimo Lab's administrative expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

*Non-Operating Income (expense).* Non-operating income was \$640,000 for the three months ended June 28, 2008, compared to \$326,000 of expense for the three months ended June 30, 2007. This change was primarily due to a decrease in interest expense of \$625,000 resulting from repayments of long term debt balances during March 2008. In addition, interest income increased \$436,000 resulting from higher cash balances during the three months ended June 28, 2008 as compared to the three months ended June 30, 2007.

*Provision for Income Taxes.* Our provision for income taxes was \$6.8 million, or an effective tax rate of 39.0%, for the three months ended June 28, 2008 compared to \$7.4 million, or an effective tax rate of 41.1%, for the three months ended June 30, 2007. This decrease in the provision was primarily due to a decrease in our taxable income for the three months ended June 28, 2008 as compared to the three months ended June 30, 2007. The decrease in the effective tax rate was due to foreign income not being taxed and research and development credits benefited. The effective tax rate differs from the statutory U.S. federal income tax rate of 35.0% primarily due to state taxes, and permanent differences between pre-tax income for financial reporting purposes and taxable income.

***Comparison of the Six Months ended June 28, 2008 to the Six Months ended June 30, 2007***

*Revenue.* Total revenue increased \$23.3 million, or 19.0%, to \$145.9 million for the six months ended June 28, 2008 from \$122.6 million for the six months ended June 30, 2007.

Product revenues increased \$28.1 million, or 30.1%, to \$121.5 million in the six months ended June 28, 2008 from \$93.4 million for the six months ended June 30, 2007. This increase was primarily due to higher consumable sales resulting from an increase in our installed base of circuit boards and pulse oximeters which totaled 515,000 units at June 28, 2008 up from 424,000 units at June 30, 2007. Revenue generated through our direct and distribution sales channels increased \$26.9 million,



**Table of Contents**

or 40.6%, to \$93.0 million for the six months ended June 28, 2008 compared to \$66.2 million for the six months ended June 30, 2007. During the six months ended June 28, 2008 revenues from our OEM channel increased \$1.3 million, or 4.7%, to \$28.5 million from \$27.2 million in the six months ended June 30, 2007. Contributing to the increase in our direct and distribution sales channel revenue was our Rainbow technology product revenues which increased 65.2%, or approximately \$2.2 million, to \$5.6 million in the six months ended June 28, 2008, from \$3.4 million in the six months ended June 30, 2007.

Our royalty and license fee revenue decreased \$4.8 million, to \$24.4 million in the six months ended June 28, 2008 from \$29.2 million in the six months ended June 30, 2007, primarily due to a lower royalty rate associated with our 2006 settlement agreement with Covidien. For the six months ended June 30, 2007, our reported Covidien royalties were based upon Covidien's actual reported U.S. pulse oximeter sales for that period. For the six months ended June 28, 2008, our reported Covidien royalties are the combination of an estimate of Covidien's U.S. pulse oximeter sales for the three months ended June 28, 2008 at the contractual royalty rate as prescribed by the 2006 settlement agreement and actual royalties for the three months ended March 29, 2008.

*Cost of Goods Sold.* Cost of goods sold increased 22.1% to \$42.5 million in the six months ended June 28, 2008 from \$34.8 million in the six months ended June 30, 2007. Total gross profit margin decreased to 70.8% for the six months ended June 28, 2008 from 71.6% for the six months ended June 30, 2007. This decline in total gross margin was due to the impact of the \$4.9 million year over year decline in Covidien royalty revenues which have no related cost of goods sold. In the six months ended June 28, 2008, product gross profit margin rose to 65.0% from 62.7% in the comparable prior year period due to greater sensor sales, increased sales of Rainbow related products and manufacturing efficiencies related to higher production volumes. We incurred \$1.8 million and \$1.6 million in Masimo Lab's royalty expenses for the six months ended June 28, 2008 and June 30, 2007, respectively, which, in accordance with FIN 46(R), 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 63.6% and 61.0% for the six months ended June 28, 2008 and June 30, 2007, respectively.

*Research and Development.* Research and development expenses increased 12.5% to \$12.3 million for the six months ended June 28, 2008, from \$10.9 million for the six months ended June 30, 2007. The increase was primarily due to increased payroll and payroll related costs of \$1.5 million and increased stock based compensation expense. We also incurred \$943,000 and \$638,000, respectively, of Masimo Lab's engineering expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

*Selling, General and Administrative.* Selling, general and administrative expenses increased \$16.9 million, or 39.4% to \$59.9 million for the six months ended June 28, 2008 from \$43.0 million in the six months ended June 30, 2007. The increase was primarily due to a \$8.2 million increase in payroll and payroll related costs, including stock based compensation, consistent with an increase in staffing from 328 at June 30, 2007 to 393 at June 28, 2008. In addition to the increased staffing levels, professional fees increased \$2.9 million due to a combination of higher patent litigation expense and increased tax, audit and other professional fees associated with the cost of being a public company. Also, sales related travel increased \$1.7 million due to additional sales representatives, tradeshow marketing expense increased by \$1.5 million due to an increase in the number of tradeshows attended and occupancy costs increased \$1.1 million due to an increase in rent and property taxes. We also incurred a net \$590,000 and \$279,000, respectively, of Masimo Lab's administrative expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

*Non-Operating Income (expense).* Non-operating income was \$1.1 million for the six months ended June 28, 2008, compared to \$357,000 of expense for the six months ended June 30, 2007. This change was primarily due to an increase in interest income of \$1.0 million resulting from higher cash balances during the six months ended June 28, 2008 as compared to the six months ended June 30, 2007. In addition, interest expense decreased by \$409,000 resulting from repayments of long term debt balances in March 2008.

*Provision for Income Taxes.* Our provision for income taxes was \$12.4 million, or an effective tax rate of 39.0%, for the six months ended June 28, 2008 compared to \$13.4 million or an effective tax rate of 40.6%, for the six months ended June 30, 2007. This decrease in the provision was primarily due to a decrease in our taxable income for the six months ended June 28, 2008 as compared to the six months ended June 30, 2007. The decrease in the effective tax rate was due to foreign income not being taxed and research and development credits benefited. The effective tax rate differs from the statutory U.S. federal income tax rate of 35.0% primarily due to state taxes, and permanent differences between pre-tax income for financial reporting purposes and taxable income.

---

## Table of Contents

### **Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through the sale of equity securities. Through June 28, 2008, we have raised \$81.7 million through seven preferred stock private equity financings, approximately \$47.8 million from our August 2007 initial public offering and \$22.6 million from the exercise of stock options, of which \$6.0 million was from exercises after our initial public offering. As of June 28, 2008, we had cash and cash equivalents of \$102.9 million. We invest our excess cash deposits in money market accounts with major financial institutions.

Under the terms of our patent litigation settlement with Covidien in January 2006, Covidien paid us \$263.0 million for damages incurred through January 2006 and made an advance royalty payment to us of \$67.5 million related to sales of Covidien's products for the remainder of 2006. In total, we received \$330.5 million in cash from Covidien through December 2006. In March 2006 and December 2006, we declared dividends in the aggregate amount of approximately \$208.9 million to holders of our stock, of which \$10.8 million was to related parties. In addition, in March 2006 and March 2007, we made special bonus payments in the aggregate amount of approximately \$11.7 million to our employees and directors who held vested stock options as of March 1, 2006. The majority of these cash dividends and special bonus payments were made from the after-tax proceeds that we received from our settlement with Covidien and interest earned thereon. In the future, we do not intend to distribute any royalties received from Covidien under the settlement agreement to our stockholders or our option holders.

*Cash Flows from Operating Activities.* Cash provided by operating activities was \$34.3 million in the six months ended June 28, 2008. The source of cash consists primarily of net income of \$19.4 million, an increase in deferred revenue of \$5.0 million due to the continued growth of our business, a net tax benefit of \$7.6 million relating to employee stock option exercises and stock based compensation expense of \$3.7 million resulting from options granted under FASB 123(R). Also, depreciation and amortization expense was \$2.7 million, royalties receivable decreased \$2.5 million due to a lower royalty rate per our agreement with Covidien and accounts payable increased \$2.1 million resulting from continued growth of our business. These increases were offset partially by an increase in inventory of \$7.9 million to meet the increasing demand for our products and the introduction of new products and an increase in accounts receivable of \$2.3 million due to the growth of our business.

In the six months ended June 30, 2007, cash provided by operating activities was \$4.6 million. This consisted primarily of net income of \$19.7 million, an increase in accounts payable of \$7.7 million due to growth in our business and timing of payments, and deferred revenue increase of \$4.5 million as a result of the continued growth in our business. These sources of cash were offset by uses of cash including an increase in royalties receivable of \$13.2 million, which were prepaid in 2006 in accordance with the Covidien settlement agreement and an increase in inventory of \$6.3 million due to increasing demand for our products and the introduction of new products. In addition, accounts receivable increased by \$5.3 million due to growth in our business and timing of cash collections, deferred cost of goods sold increased \$3.7 million due to the increase in equipment placed at hospitals under long term sensor purchase agreements and accrued compensation decreased by \$2.6 million due to the timing of bonus and commission payments.

*Cash Flows from Investing Activities.* Cash used in investing activities for the six months ended June 28, 2008 was \$4.6 million consisting of \$3.1 million of property and equipment purchases related primarily to assets to support our manufacturing operations and \$1.5 million for the increase in intangible assets related to capitalized patent related expenses.

Cash used in investing activities for the six months ended June 30, 2007 was \$3.5 million consisting of \$2.8 million of property and equipment purchases related to our manufacturing activities and \$698,000 for the increase in intangible assets related to the capitalization of patent related expenses.

*Cash Flows from Financing Activities.* Cash used by financing activities for the six months ended June 28, 2008 was \$23.4 million. This use was primarily the result of our decision in March 2008 to repay approximately \$26.7 million in long term debt related to the financing of equipment placed at hospitals. In total, we repaid \$30.1 million of long term debt in the six month period ended June 28, 2008. These total debt repayments were partially offset by \$5.7 million of proceeds from stock option exercises.

Cash used in financing activities for the six months ended June 30, 2007 was \$21.3 million. This use of cash was primarily related to the payment of \$37.2 million in dividends and the repayment of long term debt of \$4.1 million. Partially offsetting this net use of cash was \$20.1 million of proceeds from borrowings related to equipment financing.

*Future Liquidity Needs.* 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 manufacturing capability as well as additional investments in productivity enhancing tools. Our focus on international expansion will also require additional investments in facilities and infrastructure in North and South America, Europe and Asia. The amount and timing of our

## Edgar Filing: MASIMO CORP - Form 10-Q

actual investing activities will vary significantly depending on numerous factors, such as the progress of our product development efforts, our timetable for international sales and marketing 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.



## **Table of Contents**

*Current Financing Arrangements.* As of December 29, 2007, we had two long term borrowings that allowed for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements. In March 2008, we repaid \$26.7 million, or the entire then outstanding balance, on one of the arrangements. This is a non-recurring event and is not expected to occur in the future. In addition, the Company paid \$168,000 in prepayment fees which are included in other non-operating income (expense). Therefore, as of June 28, 2008, we had only one remaining financing arrangement with an outstanding balance of \$676,000. As of June 28, 2008, principal and interest payments under this remaining financing agreement are \$85,000 per month based on an average interest rate of 7.1%.

### **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 had 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 consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these 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 consolidated financial statements, as well as revenue and expenses during the reporting periods. 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 could therefore 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, 2008. There have been no material changes in any of our accounting policies since December 29, 2007.

### **New Accounting Pronouncements**

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141(R), or SFAS No. 141(R), *Business Combinations*. SFAS No.141(R) provides greater consistency in the accounting and financial reporting of business combinations. It requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. If we consummate any acquisitions after December 2008, the purchase accounting treatment could result in a material difference from current accounting treatment.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, or SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS No.160 is effective for fiscal years beginning after December 15, 2008. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

In March 2008, the FASB issued Statement of Financial Accounting Standards No. 161, or SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133*. This Statement enhances the disclosure requirements for derivative instruments and hedging activities, and thereby is designed to improve the transparency of financial reporting. SFAS No.161 is effective for fiscal years beginning after November 15, 2008. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

---

**Table of Contents**

In May 2008, the FASB issued Statement of Financial Accounting Standard No. 162, or SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles. SFAS No. 162 will become effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not expect the adoption of this Statement to have a material effect on our 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 outstanding debt instruments. Our risk associated with fluctuation to interest expense is limited to our outstanding term loans and 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 enhance the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest-sensitive financial instruments at June 28, 2008. Declines in interest rates over time will, however, reduce our interest income and expense while increases in interest rates will increase our interest income and expense.

***Foreign Currency Exchange Rate Risk***

A majority of our assets and liabilities are maintained in the United States in U.S. dollars and our sales and expenditures are transacted in U.S. dollars. The expenses and capital spending of our foreign entities are transacted in the respective country's local currency and are subject to foreign exchange rate risk. In particular, we are exposed to foreign currency risk related to our international operations, including foreign denominated intercompany receivables and payables. Our foreign currency transactions are translated into U.S. dollars at prevailing rates and gains or losses resulting from foreign currency transactions are included in current period income or loss as incurred. Our foreign entities balance sheets are translated in U.S. dollars at the month end spot rates and the statements of income and cash flows using the average exchange rate for the periods and any foreign exchange gain or loss is included in equity as a component of accumulated other comprehensive income (loss). Historically, we have not engaged in foreign currency hedging transactions. We estimate that a 10% change in the ending foreign exchange rates would not have resulted in a material change to our net income during the six months ended June 28, 2008. As our foreign operations continue to grow, our exposure to foreign currency risk may become more significant.

***Inflation Risk***

We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the periods presented but we can not be certain if it will have a material adverse effect in the future.

**Item 4(T). 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.



**Table of Contents**

As required by SEC Rule 13a-15(b), 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 Form 10-Q. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective.

***Changes in Internal Control Over Financial Reporting***

There has been no change in our internal control over financial reporting during the quarter ended June 28, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

On February 19, 2008, we filed a lawsuit against Respironics, Inc. for breach of contract, breach of the covenant of good faith and fair dealing, and interference with prospective economic advantage, based on a January 16, 2006, contract between Respironics and us. On April 7, 2008, Respironics filed a demurrer seeking to dismiss the lawsuit on the grounds that our complaint fails to state sufficient facts to constitute valid claims. The court subsequently denied Respironics' demurrer. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

From time to time, we are involved in legal proceedings in the ordinary course of business. Other than the proceedings described above and in our Annual Report on Form 10-K for the year ended December 29, 2007, we are not currently involved in any material legal proceedings.

**Item 1A. Risk Factors**

*Before you decide to invest or maintain an interest in our common stock, you should consider carefully the risks described below, which have been updated since the filing of our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 1, 2008, in their entirety, 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 of this Quarterly Report on Form 10-Q. If any of the following risks comes to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.*

*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 May 1, 2008.*

**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, more accurate or reliable, 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 products, 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 keep 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.

## Edgar Filing: MASIMO CORP - Form 10-Q

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

---

**Table of Contents**

competitors will not be able to design around our patents. We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology with confidentiality agreements and intellectual property assignment agreements with our employees, our OEM partners, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Our common law trademarks provide less protection than our registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the 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. Prior to launching major new products in our key markets, we normally evaluate existing intellectual property rights. However, 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;

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 and product candidates;

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;

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 a product's continued life in the market even after it has 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 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., now a part of Covidien Ltd. (formerly Tyco Healthcare), and one of its subsidiaries, Nellcor Puritan Bennett, Inc., in which we claimed that Covidien was infringing some of our pulse oximetry signal processing patents. We believe that other competitors of ours, including some of our OEM partners, may be infringing at least one of our



---

**Table of Contents**

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. We cannot be certain that we will have the required financial resources to pursue litigation or otherwise to protect these rights in the future. In addition, any future litigation could result in the diversion of management's attention from 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. Accordingly, we do not know to what degree the market will accept these products, if at all. Even if our customers recognize the benefits of our products, we cannot assure you that our customers will purchase them in quantities sufficient for us to be profitable or successful. We will need to invest in significant sales and marketing resources to achieve market acceptance of these products with no assurance of success. The degree of market acceptance of these products will depend on a number of factors, including:

perceived effectiveness of our products;

cost of our products;

perceived advantages of our products over competing products;

introduction and acceptance of competing products or technologies; and

obtaining the required domestic and international regulatory approvals for our product candidates under development.

In order for any of our products to be accepted, we must prove 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. 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 a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.**

Under the FDA medical device reporting regulations, or MDR, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product 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 bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. We may experience events that may require reporting to the FDA pursuant to the MDR regulations. Any adverse event involving our products could result in future voluntary corrective actions, including recalls or customer notifications, or agency action, including inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation, business operations and financial results.

**\*\*Our products have been, and may in the future be, subject to product recalls that could harm our reputation, business operations and financial results.**

After a device is placed on the market, numerous regulatory requirements apply, including medical device reporting regulations that require us to report to the FDA or similar governmental bodies in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA and

## Edgar Filing: MASIMO CORP - Form 10-Q

similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design 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. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. 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. 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. We may initiate certain voluntary recalls involving our products in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If we determine that a recall does not require notification of the FDA, the FDA may disagree with our determination and require us to report the recall to the FDA.

---

## **Table of Contents**

Much of our growth may come from the introduction and sale of new products, which may result in a greater frequency of recalls. From our inception through June 28, 2008, we initiated three 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.

Of the three recalls that we have implemented, one remains open, the recall of our Rad-9 pulse oximeters, a standalone bedside pulse oximeter product, sales of which represented less than 0.3% and 0.3% of our product revenue in the six months ended June 30, 2007 and June 28, 2008, respectively. On July 31, 2007, we determined to initiate a voluntary recall of that product. In accordance with its original design and similar to other pulse oximeter devices, the Rad-9 gives a visual alarm if there is a sensor fault and under other circumstances, the Rad-9 gives both a visual and audio alarm. In late 2006, we sent notice to owners of our Rad-9 pulse oximeter that a free upgrade was available to add an audio alarm to the Rad-9 when a sensor fault is detected. We decided to voluntarily recall the Rad-9 to implement this upgrade. We do not believe that a non-upgraded Rad-9 poses a significant risk to health or would cause serious injury or death. We decided to voluntarily recall the Rad-9 because we believe it has the possibility of improving the care of patients. This decision follows a customer report that an elderly patient, who may have damaged her pulse oximeter sensor, had died after removing her tracheostomy tube. Based on what is currently known, the Rad-9 appears to have been operating in accordance with its specifications. We submitted an MDR to the FDA for this event on August 3, 2007. As of June 28, 2008, we estimate that the remaining total costs resulting from this voluntary recall will be approximately \$30,000, although this is an estimate and the actual cost may differ. Any future recall could result in a diversion of management resources, substantial cost and negative publicity, all of which could adversely affect our business, financial condition and results of operations.

**Our ability to commercialize new products, new or improved technologies and additional applications for Masimo SET and our right to use Rainbow technology are each limited to certain markets by our Cross-Licensing Agreement with Masimo Labs, which may impair our growth and adversely affect our financial condition and results of operations.**

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

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

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

Non-vital 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.



---

## **Table of Contents**

### **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 non-invasive 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 may not be able to develop comparable technology or license similar technology on commercially favorable terms or at all, and 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.**

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 hand-held, 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 revenues 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.

While the payment of royalties for enabled Rainbow measurements should not have a negative impact on our overall margins, the minimum annual royalties will have a negative impact to the extent that we do not generate sufficient Rainbow product revenues to offset the minimum royalties owed to Masimo Labs. In addition, the requirement for us to provide Masimo Labs with up to 10% of our board and sensor production at our manufactured cost will, if requested by Masimo Labs, have a negative impact on our gross margins.

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

It is 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

## Edgar Filing: MASIMO CORP - Form 10-Q

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.

---

**Table of Contents**

**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 research and development of Rainbow technology. Although we expect Masimo Labs to continue its research and development activities related to Rainbow technology and specific non-invasive monitoring measurements, including blood glucose and total hemoglobin, no assurance can be given 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 June 28, 2008, a number of stockholders of Masimo Labs continued to own shares of our common stock. In addition, Joe E. Kiani and Jack Lasersohn, members of our board of directors, are also members of the board of directors of Masimo Labs. Joe E. Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs. Due to the interrelated nature of Masimo Labs with us, conflicts of interest will arise with respect to transactions involving business dealings between us and Masimo Labs, potential acquisitions of businesses or products, development of products and technology, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Masimo Labs. We cannot assure you that any conflict of interest will be resolved in our favor, or that with respect to our transactions with Masimo Labs we will negotiate terms that are as favorable to us as if such transactions were with an unaffiliated third party.

**Our operating results are volatile and difficult to predict and, prior to 2005, we had a history of net losses. We may experience significant fluctuations in our quarterly results and we may not maintain our recent profitability in the future.**

We incurred net losses attributable to common stockholders in each year from our inception through 2004. Our net losses attributable to common stockholders were approximately \$8.6 million, \$15.4 million and \$12.3 million in 2002, 2003 and 2004, respectively. We expect our expenses to increase as we 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 and negative cash flows in the future.

Our operating results have fluctuated in the past and are likely to fluctuate significantly 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;

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.

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 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.



---

## **Table of Contents**

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 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. 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. 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.**

For the three and six months ended June 28, 2008, one customer represented 11.7% and 12.5%, respectively, of our total revenues. 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 revenues. This would adversely impact our operating results because we may not be able to react quickly enough to reduce our operating expenses. Also, we cannot assure you that we will retain our current customers or groups of customers or that we will be able to attract and retain additional customers.

**\*\*Our royalty agreement with Covidien provides for a declining royalty rate schedule over the term of the settlement agreement which could significantly harm our total sales and operating results.**

In the three and six months ended June 28, 2008, our royalties from the Covidien settlement totaled \$12.7 million and \$24.0 million, respectively. Because these royalty payments do not carry any significant cost, they result in significant improvements to our reported gross profit and operating income levels. As a result, any decline in royalties that we earn under this settlement agreement will have a significant impact on our revenues, gross margins and operating income. Under the 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 rates for 2007 declined to 15%. In 2008 and through the term of the royalty agreement, 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 of these declining royalty rates since 2006, there is a significant financial risk to our operating income if we are unable to generate sufficient revenues and gross margins to offset the impact of declining royalty rates on sales of Covidien's pulse oximetry products in the United States.

**\*\*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 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. If we are not one of the providers selected by a GPO, the GPO's affiliated hospitals and other members may be less likely 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 precluded from making sales to members of the GPO for the duration of the contractual arrangement. In addition, our failure to renew 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 the three and six months ended June 28, 2008, revenue from the sale of our pulse oximetry products related to GPOs amounted to \$33.0 million and \$63.7 million, respectively. In the future, if we are unable to keep our relationships and 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 techniques developed by others, we could lose revenue opportunities and customers, and our ability to achieve growth 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 revenues 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 reputations with our target customers, relationships with GPO's, as well as 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 non-invasive 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 non-invasive 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 non-invasive 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 those that may arise from misuse, including but not limited to unauthorized off-label use, which is use of a device in a manner outside the 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 future 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, could adversely affect our business, financial condition and results of operations. Any product liability claims could require significant cost and management resources and may subject us to significant damages. 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 PMA approval, 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 approval 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.

Most recently, in May 2008, we received clearance from the FDA for SpHb, our non-invasive measurement of total hemoglobin levels in the blood. We have applied for FDA clearance of our Single Patient Adhesive Rainbow SpHb sensors.

### **The failure of our OEM partners to obtain FDA clearances or approvals for products that incorporate our products or 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 system regulation, or QSR, which covers the methods and documentation of the design, testing, production, 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:

Edgar Filing: MASIMO CORP - Form 10-Q

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 can involve 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 approval is 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 cleared by the FDA. Use of a device outside its cleared or approved indications is known as off-label use. Physicians may use our products off-label because the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. Although we may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. We must have adequate substantiation for our product performance claims. If the

## Edgar Filing: MASIMO CORP - Form 10-Q

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 seek 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 the 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 disagree and 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 adversely affect our ability to sell our products profitably.**

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 a medical device. 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.

In 2007, the Food and Drug Administration Amendments Act of 2007, or the Amendments, were enacted. The Amendment 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 success, 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.



**If we are unable to manufacture an adequate supply of our products, we could lose customers and our revenue and growth could be limited.**

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. If we cannot scale our manufacturing operations appropriately, maintain control over expenses or otherwise adapt to anticipated growth, or if we have underestimated our future growth, we may not have the capability to satisfy market demand, which would have an adverse effect on our business, financial condition and results of operations.

---

## **Table of Contents**

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

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 personnel 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 information systems, create additional procedures and controls and expand, train, motivate and manage our work force. We also may need to expand our manufacturing resources.

We cannot be certain that our personnel, systems, procedures, 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 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 another one of our manufacturing facilities. 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. 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. 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. Each of our officers may terminate his employment at any time without notice for any reason. We carry key person life insurance on only Mr. Kiani, who is also the Chief Executive Officer of Masimo Labs. Mr. Kiani devotes substantially all of his time to us.

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

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 and products into our existing business;

delays in realizing the benefits of the acquired company or products;

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;

---

**Table of Contents**

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 such 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 that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as imposed certain 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, certain of these arrangements may not meet the Federal Anti-Kickback Law's safe harbor requirements, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws.

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

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

## Edgar Filing: MASIMO CORP - Form 10-Q

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 or may be exposed to materials that are hazardous

---

**Table of Contents**

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. Similarly, if the physicians or other providers or entities with which we do business are found to violate applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

**\*\*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 operations in international markets. In 2006, 2007 and the six months ended June 28, 2008, 22.6%, 23.6% and 25.9%, 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;

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;

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 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 distribution agreements may provide for payments in a foreign currency. 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. Accordingly, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations. We currently do not hedge against our foreign currency risks.

---

## **Table of Contents**

### **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 revenues 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 and, therefore, could have a material adverse effect on our business.

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

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.**

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. Additionally, there have been, and we expect there will continue to be, federal, state or local legislative and regulatory changes and proposals to change the health care system, which could affect our business. For instance, the Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicare and Medicaid programs, determined that, beginning in 2007, certain uses of pulse oximetry monitoring are eligible for separate Medicare payment in the hospital outpatient setting and are no longer bundled into payments for other services. The result of this change could be an increase in Medicare payments to hospitals for use of our products. However, each year CMS examines the reimbursement rates for both the inpatient and outpatient settings and could either increase or decrease the reimbursement rate for procedures utilizing our products. In addition, as a result of the focus on health care reform in connection with the 2008 presidential election, there is risk that Congress may implement changes in laws and regulations governing health care service providers, including measures to control costs or reductions in reimbursement levels. Overall, 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, as a result, our revenues to decline.

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 (currently Covidien), 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.



## Edgar Filing: MASIMO CORP - Form 10-Q

In March 2005, a jury found that Tyco Healthcare's use of sole-source contracts, product bundling, market share-based compliance pricing contracts and co-marketing agreements with OEM patient monitoring companies were unlawful restraints of trade and exclusionary dealing arrangements and, as a result, violated federal antitrust laws. The jury awarded us \$140.0 million in damages. 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

---

**Table of Contents**

verdict. In addition, the District Court vacated the jury's damages award and granted Tyco Healthcare a new trial on damages. The District Court held an evidentiary hearing in October 2006 to re-try the damages. On January 25, 2007, the District Court issued a preliminary ruling which did not set damages, but resolved some issues of dispute about damages, and ordered another evidentiary hearing on issues still undecided by the District Court. The District Court held this evidentiary hearing in March 2007. On July 2, 2007, the District Court entered its final judgment, awarding us damages which were trebled 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 have 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 9<sup>th</sup> Circuit. On December 27, 2007, the Consumer Federation of America and 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 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. 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.

We believe that Covidien continues to enter into sole-source contracts, product bundling agreements, market share-based agreements, and co-marketing 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.

**\*\*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, 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 achieve and maintain adequate internal controls over financial reporting, our business, results of operations and financial condition and investors' confidence in us could be materially affected.**

As a public company, we are required to comply with the periodic reporting obligations of the Securities Exchange Act of 1934, or Exchange Act, including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits

---

## **Table of Contents**

and restrict our ability to access financing. In addition, we are required under applicable law and regulations to evaluate and provide a management report of our systems of internal controls over financial reporting. We plan to evaluate our existing internal controls with respect to the standards adopted by the Public Company Accounting Oversight Board. During the course of our evaluation, 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.

We expect to dedicate significant management, financial and other resources in connection with our compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in and after 2008. We expect these efforts to include a review of our existing internal control structure. As a result of this review, we may either hire or outsource additional personnel to expand and strengthen our finance function. We cannot be certain at this time that we will be able to comply with all of our reporting obligations and successfully complete the certification and attestation requirements of Section 404 of the Sarbanes-Oxley Act by the time that we are required to file our annual report on Form 10-K for the year ending January 3, 2009. If we fail to achieve and maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls 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. As a result, our failure to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act 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 and negatively impact the trading price of our common stock.

### **\*\*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.

### **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 March 31, 2008 to June 28, 2008, our closing stock price ranged from \$25.06 to \$35.00. 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 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;

## Edgar Filing: MASIMO CORP - Form 10-Q

new laws or regulations or new interpretations of existing laws or regulations applicable to our business;

changes in accounting standards, policies, guidance, interpretations or principles;

changes in our growth rates or our competitors' growth rates;

developments regarding our patents or proprietary rights or those of our competitors;

our inability to raise additional capital as needed;

concern as to the efficacy of our products;

changes in financial markets or general economic conditions;

sales of common stock by us or members of our management team; and

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

---

**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 June 28, 2008, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 14.5% of our outstanding common stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, the stockholders will be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant 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 June 28, 2008, an aggregate of 11,961,538 shares of our common stock were reserved for future issuance under our three equity incentive plans, 7,601,990 of which were subject to options outstanding as of that date at a weighted average exercise price of \$12.86 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 June 28, 2008, there were 56,447,961 shares of our common stock outstanding, including 3,287,494 shares sold by us and 10,416,626 shares sold by our selling stockholders in our initial public offering, or IPO, in August 2007. A significant portion of our shares of common stock outstanding prior to our IPO that were not sold by selling stockholders 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 June 28, 2008, 7,232,129 of these shares were held by directors, executive officers and other affiliates and subject to volume limitations under Rule 144 as of that date. A large portion of our outstanding shares are held by a small number of persons and investment funds. Resales by these stockholders of a substantial number of shares, announcements of the proposed resales 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 2,447,129 shares of common stock at June 28, 2008 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.

Certain of our directors and executive officers have entered into Rule 10b5-1 trading plans pursuant to which they have sold and will continue to sell shares of our common stock. Generally, these sales require public filings. Actual or potential sales by these insiders, including those under a pre-arranged Rule 10b5-1 trading plans, could be viewed negatively by the market and adversely affect the market price of our common stock.

In December 2007, we registered an aggregate of 11,218,285 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 and impede our ability to raise future capital.

**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 common stock.**

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



---

## **Table of Contents**

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 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 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. In addition, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. These requirements 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 controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls 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 The Nasdaq Stock Market, LLC, or 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 will be exposed to risks relating to evaluations of internal controls required by Section 404 of the Sarbanes-Oxley Act.**

We will be evaluating our internal controls systems to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 by our compliance deadlines, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations because there is presently no precedent available by which to measure compliance adequacy. If we are unable to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, including the SEC or Nasdaq. This type of action could adversely affect our financial results or investors' confidence in our company and our ability to access capital markets, and could cause our stock price to decline. In addition, the controls and procedures that we will implement may not comply with all of the relevant rules and regulations of the SEC and Nasdaq. If we fail to develop and maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner.

### **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.



---

**Table of Contents**

**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 that will cover our common stock, which could have a negative effect on the market price of our stock.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

*(b) Use of Proceeds from Public Offering of Common Stock*

On August 13, 2007, we completed our initial public offering, or IPO, of common stock in which a total of 13,704,120 shares were sold, comprised of 10,416,626 shares sold by selling stockholders, 1,500,000 shares sold by us at the initial closing and 1,787,494 shares sold by us pursuant to the underwriters' full exercise of their over-allotment option, at a price of \$17.00 per share. We raised a total of \$55.9 million in gross proceeds from the IPO, or approximately \$47.8 million in net proceeds after deducting underwriting discounts and commissions of \$3.9 million and other offering costs of approximately \$4.2 million. Upon the closing of the IPO, all shares of convertible preferred stock outstanding automatically converted into an aggregate of 34,612,503 shares of our common stock.

We anticipate that we will use the net proceeds from our initial public offering for the placement of equipment at hospitals under long-term sensor purchase agreements, capital expenditures and sales and marketing activities, research and development activities and working capital and general corporate purposes. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. We have invested the net proceeds from our initial public offering in short-term, money market securities. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus filed with the SEC on August 8, 2007 pursuant to Rule 424(b) under the Securities Act of 1933.

**Item 4. Submission of Matters to a Vote of Security Holders**

We held our 2007 Annual Meeting of Stockholders, or the Annual Meeting, on June 5, 2008 at our corporate headquarters located at 40 Parker, Irvine, California 92618. At the Annual Meeting, our stockholders:

1. Elected two Class I directors to hold office until the 2011 Annual Meeting of Stockholders or until their successors are duly elected and qualified; and
2. Ratified the appointment of Grant Thornton, LLP to serve as our independent registered public accounting firm for our fiscal year ending January 3, 2009.

At the Annual Meeting, the stockholders voted as follows:

1. Election of Directors

Edgar Filing: MASIMO CORP - Form 10-Q

<b>Directors</b>	<b>Votes For</b>	<b>Votes Withheld</b>
Steven J. Barker, M.D., Ph.D.	40,100,902	11,303,919
Sanford Fitch	40,157,046	11,247,775

2. Ratification of the appointment of Grant Thornton LLP to serve as our independent registered public accounting firm for our fiscal year ending January 3, 2009.

Votes For:	51,237,510
Votes Against:	152,937
Abstentions:	14,374

**Table of Contents**

**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.

Date: August 5, 2008

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

Date: August 5, 2008

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

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

<b>Number</b>	<b>Description of Document</b>
2.1 (1)	Asset Purchase Agreement, dated December 21, 2005, between the Registrant, 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 (1)	Amended and Restated Bylaws (Exhibit 3.4)
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 (3)	Masimo Retirement Savings Plan. (Exhibit 4.7)
10.1 (4)++	Lease Agreement, effective as of September 1, 2007, by and among Industrias Asociadas Maquiladoras, S.A. de C.V., Industrial Vallera de Mexicali, S.A. de C.V. and the Company, as guarantor. (Exhibit 10.1)
31.1	Certification of Joe E. Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Mark P. de Raad, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.
(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 exhibits 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.
(4)	Incorporated by reference to the exhibit to the Company's Current Report on Form 8-K, filed on June 5, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
++	Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

## Edgar Filing: MASIMO CORP - Form 10-Q

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 SEC upon request.