

MASIMO CORP
Form 10-Q
November 01, 2007
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 September 29, 2007

OR

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

Commission File Number 001-33642

Masimo Corporation

(Exact Name of Registrant as Specified in its Charter)

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

40 Parker

Irvine, California
(Address of Principal Executive Offices)

33-0368882
(I.R.S. Employer

Identification Number)

92618
(Zip Code)

(949) 297-7000

Edgar Filing: MASIMO CORP - Form 10-Q

(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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer Accelerated Filer Non-accelerated Filer

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 September 29, 2007
Common stock, \$0.001 par value	54,646,932

Table of Contents

MASIMO CORPORATION

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 29, 2007

TABLE OF CONTENTS

PART I. Financial Information

Item 1.	Financial Statements:	
	<u>Condensed Consolidated Balance Sheets as of December 31, 2006 and September 29, 2007 (unaudited)</u>	3
	<u>Condensed Consolidated Statements of Income for the three and nine months ended September 30, 2006 and September 29, 2007 (unaudited)</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2006 and September 29, 2007 (unaudited)</u>	5
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
Item 4.	<u>Controls and Procedures</u>	29
PART II. Other Information		
Item 1.	<u>Legal Proceedings</u>	30
Item 1A.	<u>Risk Factors</u>	31
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	49
Item 6.	<u>Exhibits</u>	49
	<u>Signatures</u>	50

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

(in thousands, except share amounts)

(unaudited)

	December 31, 2006	September 29, 2007
ASSETS		
Current assets		
Cash and cash equivalents	\$ 55,382	\$ 88,557
Accounts receivable, net of allowance for doubtful accounts of \$1,625 and \$1,723 at December 31, 2006 and September 29, 2007, respectively	22,350	27,353
Royalties receivable	1,289	13,125
Inventories	17,135	23,025
Deferred tax assets	18,116	20,402
Other current assets	3,043	4,639
Total current assets	117,315	177,101
Deferred cost of goods sold	21,899	25,233
Property and equipment, net	10,290	10,814
Deferred tax assets	3,163	3,761
Restricted cash	507	511
Intangible assets, net	4,592	4,967
Goodwill	448	448
Other assets	859	1,883
Total assets	\$ 159,073	\$ 224,718
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 10,142	\$ 10,252
Accrued compensation	12,207	10,475
Accrued liabilities	4,655	7,239
Dividends payable	37,533	183
Income taxes payable	1,245	6,114
Deferred revenue	13,880	17,937
Current portion of long-term debt	7,528	11,847
Total current liabilities	87,190	64,047
Deferred revenue	490	625
Long-term debt, less current portion	13,514	22,229
Other liabilities	918	1,137
Total liabilities	102,112	88,038
Commitments and contingencies (Note 12)		
Stockholders' equity		

Edgar Filing: MASIMO CORP - Form 10-Q

Convertible preferred stock, Series A through G; \$0.001 par value, 12,500,000 and 0 shares authorized at December 31, 2006 and September 29, 2007, respectively, 11,537,501 and 0 shares issued and outstanding at December 31, 2006 and September 29, 2007, respectively	88,328	
Preferred stock, \$0.001 par value; 0 and 5,000,000 shares authorized at December 31, 2006 and September 29, 2007, respectively; 0 shares issued and outstanding at December 31, 2006 and September 29, 2007		
Common stock, \$0.001 par value, 23,500,000 and 77,500,000 shares authorized at December 31, 2006 and September 29, 2007, respectively, 16,565,532 and 54,646,932 shares issued and outstanding at December 31, 2006 and September 29, 2007, respectively	17	55
Treasury stock, 114,600 and 156,240 shares at fair market value at December 31, 2006 and September 29, 2007, respectively	(628)	(1,209)
Additional paid-in capital		141,607
Accumulated other comprehensive loss	(317)	(673)
Accumulated deficit	(30,439)	(3,100)
Total stockholders' equity	56,961	136,680
Total liabilities and stockholders' equity	\$ 159,073	\$ 224,718

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

Table of Contents**MASIMO CORPORATION****CONDENSED CONSOLIDATED STATEMENTS OF INCOME****(in thousands, except share information)****(unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 29, 2007	September 30, 2006	September 29, 2007
Revenue:				
Product	\$ 39,755	\$ 51,122	\$ 112,279	\$ 144,513
Royalty and license fee	17,891	13,254	50,447	42,497
Total revenue	57,646	64,376	162,726	187,010
Cost of goods sold	14,704	18,809	45,798	53,630
Gross profit	42,942	45,567	116,928	133,380
Operating expenses:				
Research and development	4,330	6,540	19,267	17,455
Selling, general and administrative	18,281	21,594	69,462	64,575
Patent litigation proceeds			(262,601)	
Antitrust litigation	30	508	103	982
Total operating expenses	22,641	28,642	(173,769)	83,012
Operating income	20,301	16,925	290,697	50,368
Non-operating income (expense):				
Interest income	1,298	726	5,936	1,270
Interest expense	(437)	(719)	(1,413)	(1,831)
Other	134	559	321	770
Total non-operating income	995	566	4,844	209
Income before provision for income taxes	21,296	17,491	295,541	50,577
Provision for income taxes	9,000	6,941	124,626	20,377
Net income	12,296	10,550	170,915	30,200
Preferred stock dividend			(58,571)	
Accretion of preferred stock	(1,956)	(925)	(6,029)	(4,837)
Undistributed income attributable to preferred stockholders	(6,998)	(2,739)	(49,172)	(13,526)
Net income attributable to common stockholders	\$ 3,342	\$ 6,886	\$ 57,143	\$ 11,837
Net income per common share:				
Basic	\$ 0.20	\$ 0.18	\$ 3.46	\$ 0.49
Diluted	\$ 0.16	\$ 0.16	\$ 2.79	\$ 0.40

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		Nine Months Ended	
	September 30, 2006	September 29, 2007	September 30, 2006	September 29, 2007
Cost of goods sold	\$ 49	\$ 56	\$ 2,015	\$ 134
Research and development	73	191	8,491	466
Selling, general and administrative	273	697	21,701	1,992

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

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

	Nine Months Ended	
	September 30, 2006	September 29, 2007
Cash flows from operating activities:		
Net income	\$ 170,915	\$ 30,200
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,654	3,896
Non-cash stock-based compensation	1,062	2,592
Gain on disposal of fixed assets	(13)	
Provision for doubtful accounts	1,077	296
Provision for obsolete inventory	1,156	1,080
Provision for warranty costs	1,042	1,190
Provision for (benefit from) deferred income taxes	3,944	(323)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(7,508)	(5,117)
Increase in royalties receivable		(11,836)
Increase in inventories	(8,574)	(6,858)
Increase in deferred cost of goods sold	(4,367)	(3,301)
Increase in other assets	(3,032)	(2,424)
Increase in accounts payable	7,991	79
Increase (decrease) in accrued compensation	1,251	(1,868)
Decrease in accrued liabilities	(610)	(1,279)
Increase in income taxes payable	17,863	4,819
Increase in deferred revenue	21,980	4,200
Increase (decrease) in other liabilities	149	(401)
Net cash provided by operating activities	206,980	14,945
Cash flows from investing activities:		
Purchases of property and equipment	(3,274)	(3,850)
Increase in intangible assets	(951)	(865)
Cash paid for acquisition	(433)	
Net cash used in investing activities	(4,658)	(4,715)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt		20,075
Repayments on long-term debt	(5,737)	(7,056)
Proceeds from issuance of common stock	14,338	626
Proceeds from initial public offering, net of issuance costs		47,849
Income tax benefit from exercise of stock options	4,188	
Dividends paid	(149,290)	(37,350)
Purchase of treasury stock	(628)	(581)
Net cash provided (used) in financing activities	(137,129)	23,563
Effect of foreign currency exchange rates on cash	19	(618)

Edgar Filing: MASIMO CORP - Form 10-Q

Net increase in cash and cash equivalents	65,212	33,175
Cash and cash equivalents at beginning of period	14,172	55,382
Cash and cash equivalents at end of period	\$ 79,384	\$ 88,557

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 Read-Through Motion and Low Perfusion pulse oximetry to address the primary limitations of conventional pulse oximetry. The Company markets 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. The Company considers both the pulse oximetry device and its consumable sensors and cables to be products as defined in its statements of income. The Company sells to hospitals and the emergency medical services, or EMS, market through its direct sales force and distributors, and markets its circuit boards containing the Company's proprietary algorithm and software architecture to original equipment manufacturer, or OEM, partners.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated balance sheet as of September 29, 2007, the condensed consolidated statements of income for the three and nine months ended September 30, 2006 and September 29, 2007, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2006 and September 29, 2007, and other information disclosed in the related notes are unaudited. The condensed consolidated balance sheet as of December 31, 2006 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 prospectus filed with the Securities and Exchange Commission, or SEC, on August 8, 2007 pursuant to Rule 424(b) of the Securities Act of 1933, as amended, or the Act, in connection with the Company's initial public offering.

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 September 29, 2007, consolidated results of operations for the three and nine months ended September 30, 2006 and September 29, 2007, and consolidated cash flows for the nine months ended September 30, 2006 and September 29, 2007. The results for the three and nine months ended September 29, 2007 are not necessarily indicative of the results to be expected for the year ending December 29, 2007 or for any other interim period or for any future year.

Fiscal Periods

Effective beginning in the first quarter of 2007, the Company changed to a conventional 52/53-week accounting fiscal year. The Company's fiscal year will end on the Saturday closest to December 31, and its fiscal quarters will end on the Saturday closest to the end of each corresponding calendar quarter. As a result, for fiscal 2007, the Company's first, second and third quarters will end on March 31, June 30 and September 29, 2007, respectively, and its fiscal year will end on December 29, 2007. During 2006, the Company followed a calendar year. For fiscal 2006, the first, second and third quarters ended on March 31, June 30 and September 30, 2006, respectively. The change has no impact on the Company's result of operations, financial position or cash flows.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Masimo Corporation, Masimo Laboratories, Inc., and 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.

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.

Table of Contents**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. Estimates are used in several areas including: 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.

Reclassifications

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

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 and the warranty costs for these transactions are expensed as incurred.

Changes in the product warranty accrual for the nine months ended September 30, 2006 and September 29, 2007 were as follows (in thousands):

	Nine Months Ended	
	September 30,	September 29,
	2006	2007
Warranty accrual, beginning of period	\$ 415	\$ 599
Provision for warranty costs	1,042	1,190
Warranty expenditures	(986)	(1,019)
Warranty accrual, end of period	\$ 471	\$ 770

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. 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 they 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 months ended September 29, 2007, the Company calculated net income per share using the two-class method for the first 43 days of the period and the if-converted method for the remaining 48 days of the period. For the nine months ended September 29, 2007, the Company calculated net income per share using the two-class method for the first 224 days of the

Edgar Filing: MASIMO CORP - Form 10-Q

period and the if-converted method for the remaining 48 days of the period. Income was allocated between these periods on a straight-line basis over the number of days of the respective periods. The Company calculated net income per share for the three and nine months ended September 30, 2006 using the two-class method.

Table of Contents

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. The Company's potentially dilutive shares have not been included in the computation of diluted net loss per common share for periods in which the result would be anti-dilutive. Such potentially dilutive shares are excluded since the effect would be to reduce the net loss per common share. No potentially dilutive shares have been excluded for the three months ended September 30, 2006 and September 29, 2007 or the nine months ended September 30, 2006 and September 29, 2007.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 29, 2007	September 30, 2006	September 29, 2007
Net income attributable to common stockholders:				
Net income - two class method (1)	\$ 12,296	\$ 4,985	\$ 170,915	\$ 24,871
Preferred stock dividend			(58,571)	
Accretion of preferred stock	(1,956)	(925)	(6,029)	(4,837)
Income attributable to preferred stockholders	(6,998)	(2,739)	(49,172)	(13,526)
Net income attributable to common stockholders	\$ 3,342	\$ 1,321	\$ 57,143	\$ 6,508
Basic net income per common share:				
Weighted average common shares outstanding two class method	16,528,305	16,704,285	16,519,364	16,654,586
Basic earnings per share for period during which two classes of equity securities were outstanding	\$ 0.20	\$ 0.08	\$ 3.46	\$ 0.39
Net income for period during which single class of equity securities was outstanding (1)	N/A	\$ 5,565	N/A	\$ 5,329
Weighted average common shares outstanding single class (2)	N/A	54,630,610	N/A	54,630,610
Basic net income per share for period during which single class of equity securities were outstanding	N/A	\$ 0.10	N/A	\$ 0.10
Basic net income per common share	\$ 0.20	\$ 0.18	\$ 3.46	\$ 0.49
Diluted net income per common share:				
Weighted average common shares outstanding two class method	16,528,305	16,704,285	16,519,364	16,654,586
Diluted common share equivalent: stock options	3,880,363	4,221,224	3,950,765	4,078,314
	20,408,668	20,925,509	20,470,129	20,732,900
Diluted earnings per share for period during which two classes of equity securities were outstanding	\$ 0.16	\$ 0.06	\$ 2.79	\$ 0.31
Net income for period during which single class of equity securities was outstanding (1)	N/A	\$ 5,565	N/A	\$ 5,329
Weighted average common shares outstanding single class (2)	N/A	54,630,610	N/A	54,630,610
Diluted common share equivalent: stock options	N/A	4,747,848	N/A	4,747,848

Edgar Filing: MASIMO CORP - Form 10-Q

N/A 59,378,458 N/A 59,378,458

Diluted net income per share for period during which single class of equity securities were outstanding	N/A	\$ 0.10	N/A	\$ 0.09
---	-----	---------	-----	---------

Diluted net income per common share	\$ 0.16	\$ 0.16	\$ 2.79	\$ 0.40
--	----------------	----------------	----------------	----------------

Table of Contents

- (1) Net income for the three months ended September 29, 2007 was allocated between the periods during which two classes of equity securities were outstanding and during which a single class of equity securities was outstanding based on the respective number of days. The convertible preferred stock was converted into common stock on August 13, 2007, the closing date of the Company's initial public offering. For the three months ended September 29, 2007, two classes of equity securities were outstanding for 43 days and a single class of equity securities was outstanding for 48 days, or 47.3% and 52.7% of the total days in the reporting period, respectively. For the nine months ended September 29, 2007, two classes of equity securities were outstanding for 224 days and a single class of equity securities was outstanding for 48 days, or 82.4% and 17.6% of the total days in the reporting period, respectively.
- (2) Weighted average shares outstanding used to compute basic net income per share after conversion of convertible preferred stock; one class of common shares was outstanding for the period from August 13, 2007 to September 29, 2007.

Stock Based Compensation

On January 1, 2006, the Company adopted 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. Prior periods were not revised for comparative purposes, and existing options continue to be accounted for in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, unless such options are modified, repurchased or canceled after the adoption date. Prior to January 1, 2006, the Company accounted for employee stock options using the intrinsic value method and using the minimum value method for its pro forma disclosures under SFAS No. 123, *Accounting for Stock Based Compensation*. As a result, options granted prior to the adoption of SFAS No. 123(R) will continue to be accounted for using the intrinsic value method in accordance with APB No. 25 unless such options are modified, repurchased or cancelled.

New Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Management does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment to FASB Statement No. 115*. SFAS No. 159 permits entities to choose to measure financial instruments and certain other items at fair value at specified election dates. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings. Most of the provisions of SFAS No. 159 apply only to entities that elect the fair value option. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. Management does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

3. Stockholders Equity
2007 Stock Incentive Plan

In May 2007 and June 2007, the Company's board of directors and stockholders, respectively, approved an amendment to the Company's 2007 Stock Incentive Plan to (i) reserve for issuance an aggregate of 3,000,000 shares of common stock and (ii) provide that the shares reserved for issuance will be automatically increased annually on January 1st of each year, beginning in 2008, by 3% of the aggregate number of shares of common stock outstanding on December 31st of the immediately preceding year. The 2007 Stock Incentive Plan became effective in connection with the Company's initial public offering on August 7, 2007.

Initial Public Offering

Edgar Filing: MASIMO CORP - Form 10-Q

On August 13, 2007, the Company completed its 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 the Company at the initial closing and 1,787,494 shares sold by the Company pursuant to the underwriters' full exercise of their over-allotment option, at an issue price of \$17.00 per share. The Company 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 estimated 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 common stock.

Table of Contents

The condensed consolidated financial statements as of and for the periods ended September 29, 2007, including share and per share amounts, include the effects of the offering since it was completed prior to September 29, 2007.

4. Comprehensive Income

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

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 29, 2007	September 30, 2006	September 29, 2007
Net income	\$ 12,296	\$ 10,550	\$ 170,915	\$ 30,200
Other comprehensive income:				
Foreign currency translation gain (loss)	(78)	(48)	33	(356)
Comprehensive income	\$ 12,218	\$ 10,502	\$ 170,948	\$ 29,844

5. 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 recently amended and restated effective January 1, 2007, or the Cross-Licensing Agreement, that governs each party's rights to certain of the intellectual property held by the two companies.

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, as soon as it is possible, such as in the event that Masimo Labs secures additional external financing and/or expands its customer base or is no longer financially dependent upon the Company and the Company is no longer the primary beneficiary of Masimo Labs activities, the Company may discontinue consolidating Masimo Labs.

6. Related Party Transactions

Two of the Company's stockholders are customers of the Company. Sales to these two customers for the three months ended September 30, 2006 and September 29, 2007 were \$5.0 million and \$4.9 million, respectively, and for the nine months ended September 30, 2006 and September 29, 2007 were \$14.2 million and \$15.3 million, respectively. At December 31, 2006 and September 29, 2007, aggregate accounts receivable from these two customers were \$2.9 million and \$3.0 million, respectively. During the year ended December 31, 2006, the Company declared dividends totaling \$10.3 million to these two stockholders, of which \$8.5 million was paid in March 2006 and \$1.8 million was paid in February 2007. No dividends were declared in the nine months ended September 29, 2007.

The Company purchased certain inventory from one of the stockholders referred to in the preceding paragraph. Total purchases from this stockholder for the three months ended September 30, 2006 and September 29, 2007 were \$739,000 and \$386,000, respectively, and for the nine months ended September 30, 2006 and September 29, 2007 were \$2.0 million and \$2.2 million, respectively. At December 31, 2006 and September 29, 2007, aggregate accounts payable to this related party were \$84,000 and \$116,000, respectively.

The Company made payments of \$2.7 million and \$2.6 million for the nine months ended September 30, 2006 and September 29, 2007, respectively, to a stockholder for legal services. At December 31, 2006 and September 29, 2007, payables to this stockholder were \$517,000 and \$518,000, respectively. The Company declared dividends of \$513,000 to this stockholder during the year ended December 31, 2006, of which \$423,000 was paid in March 2006 and \$90,000 was paid in February 2007. No dividends were declared in the nine months ended September 29, 2007.

Edgar Filing: MASIMO CORP - Form 10-Q

The Company also has amounts outstanding under a term loan with one of the Company's stockholders. At December 31, 2006 and September 29, 2007, the amounts outstanding on this term loan were \$316,000 and \$31,000, respectively. Interest expense under this term loan for the three months ended September 30, 2006 and September 29, 2007 was \$12,000 and \$1,000, respectively, and for the nine months ended September 30, 2006 and September 29, 2007 was \$54,000 and \$9,000, respectively.

Table of Contents

As of December 31, 2006 and September 29, 2007, the Company had amounts due from employees of \$439,000 and \$603,000, respectively. Loans outstanding to officers of the Company as of December 31, 2006 and September 29, 2007 were \$4,000 and \$0, respectively. As of December 31, 2006 and September 29, 2007, 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 \$13,000 and \$22,000 during the nine months ended September 30, 2006 and September 29, 2007, respectively, for various software products and services.

In the first quarter of 2006, the Company made \$12.0 million in loans to certain of its directors and executive officers and \$1.6 million in loans to employees in connection with their exercise of stock options. Each loan bore interest at a rate of 4.34%, which was equivalent to the adjusted applicable federal short term rate as of December 31, 2005. Each loan was evidenced by a promissory note and secured by shares of the Company's common stock acquired in connection with the loan and other personal guarantees. All of the loans plus accrued interest aggregating \$75,000 were repaid in full in March 2006. As a result of exercising stock options with non-recourse loans, dividends paid in the first quarter of 2006 of \$21.7 million on the related shares of common stock were recorded as stock compensation expense, pursuant to EITF Issue No. 95-16 *Accounting for Stock Compensation Arrangements with Employer Loan Features Under APB 25*.

7. Royalties Receivable

In September 2005, the U.S. Federal Court of Appeals ruled that Mallinckrodt, Inc., now part of Covidien Ltd. (formerly Tyco Healthcare), and one of its subsidiaries, Nellcor Puritan Bennett, Inc., infringed the Company's patents and ordered the lower court to enjoin Nellcor infringing products. On January 17, 2006, the Company settled all existing patent litigation with Nellcor. Under terms of the agreement, Nellcor agreed to stop selling its infringing products and to pay the Company \$263.0 million for damages through January 2006. In addition, in exchange for the Company's covenant not to sue Nellcor on future sales of its new products, Nellcor agreed to pay the Company royalties on its total U.S. pulse oximetry revenue at least through March 14, 2011.

In January 2006, Nellcor estimated their 2006 sales and made an advance royalty payment to the Company of \$67.5 million related to the settlement agreement. Based on actual sales information provided by Nellcor, the Company's total 2006 Nellcor royalties were \$68.8 million. As a result, the Company recorded a receivable from Nellcor at December 31, 2006 for the additional \$1.3 million due for 2006. The royalty receivable of \$13.1 million as of September 29, 2007 represents the Company's estimated amount due for the three months ended September 29, 2007. Pursuant to the settlement agreement, the Nellcor royalties are paid to the Company based on sales of Nellcor 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 Nellcor's sales for each quarter. Any adjustments to the quarterly estimate are recorded prospectively in the following quarter, when the Company receives the Nellcor royalty report, which is generally 60 days after the end of each quarter.

8. Inventories

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

	December 31, 2006	September 29, 2007
Raw materials	\$ 11,055	\$ 14,312
Work in-process	1,615	1,792
Finished goods	4,465	6,921
Total	\$ 17,135	\$ 23,025

Edgar Filing: MASIMO CORP - Form 10-Q

Finished goods inventory held by distributors was \$1.5 million and \$1.8 million as of December 31, 2006 and September 29, 2007, respectively, and is included in the table above.

Table of Contents**9. Long-Term Debt**

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

	December 31,	September 29,
	2006	2007
Financing arrangements	\$ 20,485	\$ 33,828
Term loan with preferred stockholder	316	31
Capital lease agreements	241	217
Total debt	21,042	34,076
Less current portion of long-term debt	(7,528)	(11,847)
Long-term portion	\$ 13,514	\$ 22,229

The Company has established various credit facilities with third-party medical equipment financing companies.

The Company has two arrangements which allow for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements. These agreements provide 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. During the nine months ended September 29, 2007, the Company borrowed \$20.1 million under these facilities. As of September 29, 2007, principal and interest payments under these financing agreements were \$1.2 million per month based on an average interest rate of 7.7% per year. At December 31, 2006 and September 29, 2007, the carrying value of the equipment collateralizing these borrowings was \$5.6 million and \$3.9 million, respectively. As of September 29, 2007, the amount available for additional borrowing under the terms of the agreements was \$19.9 million. Unless otherwise extended, the agreements will expire on December 31, 2007.

In June 2001, the Company entered into a Master Selective Business Security Agreement, or the Master Agreement, with one of the Company's stockholders allowing the Company to borrow up to a maximum of \$5.0 million. The Master Agreement consisted of an equipment line whereby all draws are collateralized by equipment placed at hospitals under long-term sensor purchase agreements. Each draw is converted into a five-year note with interest and principal paid on a monthly basis. The interest rate on each note is based on 475 basis points over the U.S. Treasury Rate on the date of the borrowing. The most recent draw was in December 2002 and there are no additional borrowings available under this Master Agreement. As of December 31, 2006 and September 29, 2007, the Company had \$316,000 and \$31,000, respectively, outstanding under this borrowing at an average interest rate of 7.9%. At December 31, 2006 and September 29, 2007, the carrying value of the equipment collateralizing these borrowings was \$198,000 and \$65,000, respectively.

Future maturities of long-term debt for each of the years ending December 31st are as follows (in thousands):

	As of
	September 29, 2007
2007 (balance of year)	\$ 3,385
2008	11,528
2009	9,417
2010	7,405
2011	2,341

Total

\$ 34,076

10. Cash Dividends and Special Bonus Payments

In March 2006, the Company declared a cash dividend of \$3.365 per share, in the aggregate amount of approximately \$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. Of this amount, \$21.7 million relates to dividend payments made to stockholders who exercised stock options by delivering a promissory note for the full exercise price. In accordance with Emerging Issues Task Force, or EITF, 95-16, the \$21.7 million in cash dividends have been classified as compensation expense in the accompanying consolidated financial statements, under cost of goods sold, research and

Table of Contents

development and selling, general and administrative expenses. In December 2006, the Company declared additional cash dividends of \$0.468 per share and \$0.257 per share, in the aggregate amount of approximately \$37.1 million, to holders of the Company's common and preferred stock assuming conversion into common stock. In March 2006 and December 2006, the Company also recorded special bonus charges in the aggregate amount of approximately \$9.7 million and \$2.0 million, respectively, to employees and directors who held vested stock options as of March 1, 2006. These cash dividends and special bonus payments were made from the after-tax proceeds that the Company received from the Company's patent infringement lawsuit against Nellcor and interest earned thereon.

The following table identifies, from December 31, 2005 through September 29, 2007, the activity in dividends payable and convertible preferred stock resulting from the accretion, dividends declared and dividends paid during this period (in thousands).

	Dividends Payable	Convertible Preferred Stock
Balance as of December 31, 2005	\$	\$ (143,959)
Accretion of redemption value on convertible preferred stock		(7,985)
Dividends declared:		
Reclassification of cumulative dividends accreted to dividends payable	(63,616)	63,616
Common shares securing the outstanding non recourse notes	(21,673)	
Dividends declared in excess of (i) amounts previously accreted to holders of preferred stock and (ii) amount included in stock compensation expense	(123,620)	
Total dividends declared	(208,909)	63,616
Dividends paid in 2006	171,376	
Balance as of December 31, 2006	(37,533)	(88,328)
Accretion of redemption value on convertible preferred stock		(6,029)
Dividends paid in 2007	37,350	
Conversion of preferred stock into common shares upon completion of initial public offering		94,357
Balance as of September 29, 2007	\$ (183)	\$

11. 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. 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 number and weighted average exercise price of options issued and outstanding under all stock option plans, at exercise prices ranging between \$1.33 and \$16.00 per share, are as follows:

Table of Contents

	Nine Months Ended September 29, 2007	
	Shares	Average Exercise Price
Options outstanding, beginning of period	7,691,388	\$ 4.95
Granted	1,217,900	\$ 15.05
Canceled	(530,070)	\$ 7.21
Exercised	(223,043)	\$ 2.86
Options outstanding, end of period	8,156,175	\$ 6.37
Options exercisable, end of period	3,875,599	\$ 3.27
Options available for grant, end of period	5,606,392	

The weighted-average fair value of options granted was \$7.21 for the nine months ended September 29, 2007.

In March 2005, the SEC issued Staff Accounting Bulletin, or SAB, No. 107, *Share-Based Payment*, relating to SFAS No. 123(R). The Company has applied the provisions of SAB No. 107 in the adoption of SFAS No. 123(R).

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

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 29, 2007	September 30, 2006	September 29, 2007
Risk-free interest rate	4.9%	4.8%	4.8%	4.7%
Expected term	6.5 years	6.5 years	6.5 years	6.5 years
Estimated volatility	47.6%	38.1%	47.9%	39.3%
Expected dividends	0%	0%	0%	0%

As a result of adopting SFAS 123(R), the Company recorded stock-based compensation of \$395,000 and \$711,000 during the three and nine months ended September 30, 2006, respectively, and \$944,000 and \$2.2 million during the three and nine months ended September 29, 2007, respectively.

The aggregate intrinsic value of options outstanding as of September 29, 2007 was \$157.3 million. The aggregate intrinsic value of options exercisable as of September 29, 2007 was \$86.8 million. The aggregate intrinsic value of options exercised during the three and nine months ended September 29, 2007 was \$826,000 and \$2.9 million, respectively. The aggregate intrinsic value is calculated as the difference between the market value of the Company's common stock on the date of exercise or the respective period end, as appropriate, and the exercise price of the options. The unrecognized stock based compensation as of September 29, 2007 was \$16.9 million related to unvested options granted after January 1, 2006. The weighted average remaining contractual term of options outstanding as of September 29, 2007 was 6.7 years. The weighted average remaining contractual term of options exercisable as of September 29, 2007 was 4.9 years. The total fair value on the respective vesting dates of all options vesting during the nine months ended September 29, 2007 was \$18.0 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. In May 2007, the Company repurchased 30,000 shares of common stock at an average price of \$14.09 per share, totaling \$423,000, from another former employee. Since these events occurred prior to the Company's initial public offering, no public announcement regarding stock repurchase was made.

12. Commitments and Contingencies**Leases**

The Company leases its facilities in North America, Europe and Asia under operating lease agreements expiring at various dates through December 2011. 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 31, 2006 and September 29, 2007, rent expense accrued in excess of the amount paid

Edgar Filing: MASIMO CORP - Form 10-Q

aggregated \$873,000 and \$672,000, 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 July 2011.

Table of Contents

Future minimum lease payments under operating and capital leases for each of the years ending December 31 are as follows (in thousands):

	As of September 29, 2007		
	Operating Leases	Capital Leases	Total
2007 (balance of year)	\$ 587	\$ 17	\$ 604
2008	2,210	70	2,280
2009	1,541	70	1,611
2010	426	60	486
2011	175	25	200
Total	\$ 4,939	\$ 242	\$ 5,181

Rental expense related to operating leases for the three months ended September 30, 2006 and September 29, 2007 were \$436,000 and \$560,000, respectively, and for the nine months ended September 30, 2006 and September 29, 2007 were \$1.1 million and \$1.6 million, respectively. Included in the capital lease obligation as of September 29, 2007 was interest aggregating \$25,000.

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 \$299,000 and \$710,000 to the Plan for the nine months ended September 30, 2006 and September 29, 2007, respectively.

Employment Agreements

As of September 29, 2007, 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 has an initial term of three years, with automatic renewal, unless either the Company or the executive notifies the other party of non-renewal of the agreement.

As of September 29, 2007, the Company had an additional employment agreement with one of its key employees, which provides for an annual base salary of EUR 144,200 (approximately \$195,000). The agreement also contemplates an annual bonus based on the attainment of certain revenue, profit and gross margin 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.

Purchase Commitments

Pursuant to contractual obligations with vendors, the Company had \$17.2 million of purchase commitments as of September 29, 2007. 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 government securities and money market accounts with major financial institutions. The amount of bank balances in excess of Federal Deposit Insurance Corporation limits was \$88.3 million as of September 29, 2007.

While the Company and its contract manufacturers rely on sole source suppliers for certain components, steps have been taken to minimize the impact of a shortage or stoppage of shipments, such as maintaining excess inventory and designing products that may be easily modified to use a different component. There can be no assurance that a shortage or stoppage of shipments of the materials or components that the Company purchases will not result in a delay in production, or adversely affect the Company's business.

Table of Contents

The Company's ability to sell its products to U.S. hospitals depends in part on its relationships with Group Purchasing Organizations, or GPOs. Many existing and potential customers for the Company's products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. During the three months ended September 30, 2006 and September 29, 2007, revenue from the sale of the Company's pulse oximetry products related to GPOs amounted to \$16.8 million and \$24.4 million, respectively. In the nine months ended September 30, 2006 and September 29, 2007, revenue from sales related to GPOs was \$45.8 million and \$72.9 million, respectively.

For the year ended December 31, 2006, no individual customer represented over 10% of the Company's total revenue. For the nine months ended September 29, 2007, one customer represented 10.6% of the Company's total revenue. There were no other customers that represented over 10% of the total revenue.

Two customers represented 10% and 6% of accounts receivable at December 31, 2006. Two customers represented 14% and 8% of accounts receivable at September 29, 2007.

Litigation

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

In March 2005, a jury found that Tyco Healthcare's use of sole-source contracts, product bundling, 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. 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 a separate line item within the Company's statements of income. For the three and nine months ended September 29, 2007, the Company incurred \$508,000 and \$982,000, respectively, related to this appellate work.

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. Shaklee is 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 will not materially affect the Company's business, financial conditions or future operating results. In the event a preliminary or permanent injunction were granted, however, 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. Although the Company believes that these claims are without merit, no assurance can be given with respect to the ultimate outcome for any

Table of Contents

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 October 1, 2007, the Company filed a lawsuit in the United States District Court, Central District of California, against Gregory Jay and P2Lethlogics, LLC, seeking a declaratory judgment that the Company's pulse oximeters do not infringe a patent of Gregory Jay and/or P2Lethlogics. Dr. Jay had made allegations that a new parameter of Masimo, Pleth Variability Index, offered as an option in Masimo's pulse oximeters, infringes these patents. On October 17, 2007, P2Lethlogics, LLC, filed a lawsuit in the United States District Court, District of Massachusetts, alleging that the Company's products, including but not limited to, the Company's Rainbow pulse oximeters infringe the same patent. Gregory Jay and P2Lethlogics have moved to dismiss the California case on the grounds of lack of personal jurisdiction over Gregory Jay and P2Lethlogics. The Company's management believes that its devices do not infringe the cited patent and the Company intends to vigorously defend against these claims. The Company believes that the claims asserted in this action will not materially affect the Company's business, financial conditions or future operating results. In the event a preliminary or permanent injunction were granted, however, 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 if 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. 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 this litigation against the Company.

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 determined to initiate a voluntary recall of its Rad-9 pulse oximeter, a standalone bedside pulse oximeter product, sales of which represented less than 0.6% and 0.4% of the Company's product revenue in 2006 and the nine months ended September 29, 2007, 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 notices 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. The Company has now determined to voluntarily recall the Rad-9 to implement this upgrade. The Company does not believe that a non-upgraded Rad-9 poses a significant risk to health. 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 estimates that the total costs resulting from this voluntary recall will be approximately \$300,000 and, as previously disclosed, has recorded this charge in the quarter ended September 29, 2007. 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.

13. 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.

Table of Contents

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				Nine Months Ended			
	September 30, 2006		September 29, 2007		September 30, 2006		September 29, 2007	
North and South America	\$ 32,016	80.5%	\$ 40,964	80.2%	\$ 89,264	79.5%	\$ 113,167	78.3%
Europe, Middle East and Africa	4,584	11.6	6,309	12.3	14,102	12.5	20,029	13.9
Asia and Australia	3,155	7.9	3,849	7.5	8,913	8.0	11,317	7.8
Total product revenues	\$ 39,755	100%	\$ 51,122	100%	\$ 112,279	100%	\$ 144,513	100%

Sales to customers located in the United States were \$31.3 million and \$40.5 million for the three months ended September 30, 2006 and September 29, 2007, respectively, and \$87.2 million and \$110.7 million for the nine months ended September 30, 2006 and September 29, 2007, respectively.

14. 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 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 January 1, 2007 and September 29, 2007, the balance of the gross unrecognized tax benefit was \$3.6 million and \$2.8 million, respectively, of which \$599,000 (net of federal benefit on state taxes) and \$710,000 (net of federal benefit on state taxes), respectively, if recognized, would affect the effective tax rate. In both periods, 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. The FIN 48 liability balance may change as the timing of some deductions becomes less uncertain.

It is expected that the amount of unrecognized tax benefits may change in the next 12 months if the timing of deductibility changes; however, quantification of such change cannot be estimated at this time. The Company recognizes penalties and interest related to unrecognized tax benefits in income tax expense. Interest and penalties are immaterial as of the date of adoption and are included in unrecognized tax benefits.

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 inception in 1989 are open for examination by major taxing authorities.

The provision for income taxes was \$9.0 million and \$6.9 million, or an effective tax rate of 42.3% and 39.7% for the three months ended September 30, 2006 and September 29, 2007, respectively. The provision for income taxes was \$124.6 million and \$20.4 million, or an effective tax rate of 42.2% and 40.3% for the nine months ended September 30, 2006 and September 29, 2007, respectively. The effective tax rate differs from the statutory U.S. federal income tax rate of 35% 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 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 Securities and Exchange Commission filings, including our final prospectus, which we filed with the SEC on August 8, 2007 pursuant to Rule 424(b) of the Act in connection with our initial public offering. 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 Signal Extraction Technology, or Masimo SET, which provides the capabilities of read-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 methemoglobin saturation levels in the blood. Along with the release of our Masimo Rainbow SET Pulse CO-Oximetry products, we have developed multi-wavelength sensors that have the ability to monitor multiple parameters with a single sensor.

We are continuing the research and development of products for the non-invasive measurement of other parameters based on the Masimo Rainbow SET platform. Included in this development are products for the non-invasive measurement of hemoglobin (SpHb) and 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 parameters can be achieved, the time and cost to complete development, and ultimately whether we will have any additional parameters approved by the FDA or other regulatory agencies.

The building of our installed base of pulse 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 448,000 units as of September 29, 2007, up from 353,000 units as of September 30, 2006. We estimate our installed base to be the number of 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 recently amended and restated effective January 1, 2007, or the Cross-Licensing Agreement, that governs each party's rights to certain of the intellectual property held by the two companies.

Under the Cross-Licensing Agreement, we granted Masimo Labs an exclusive, perpetual and worldwide license, with sublicense rights to use all Masimo SET owned by us, including all improvements on this technology, for the measurement of non-vital signs parameters and to develop and sell devices incorporating Masimo SET for monitoring non-vital signs parameters in any product market in which a product is intended to be used by a patient or pharmacist rather than a professional medical caregiver, 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 parameters, 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 consolidation. 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, in the event that Masimo Labs secures additional external financing and/or expands its customer base or is no longer financially dependent upon us and we are no longer the primary beneficiary of Masimo Labs' activities, we may discontinue consolidating Masimo Labs.

Revenue and Expense Components

The following is a description of the primary components of our revenue and expenses:

Revenue. Our product revenue consists primarily of sales of consumables, including sensors and cables, circuit boards and pulse oximeters. We sell our consumables and circuit boards to our OEM partners and, pursuant to our OEM agreements, typically recognize revenue upon shipment. We also sell consumables and pulse oximeters directly through our sales force and, based on individual contracts, typically recognize revenue upon shipment. Sales to our distributors are recognized upon the sell-through of our products by our distributors, rather than upon shipment. In the United States, we have long-term contracts with hospitals under which we typically ship and install our pulse oximeters at hospitals at no cost to the hospital in exchange for commitments by the hospital to purchase a minimum number of sensors from us over a specified period of time. In these cases, we do not recognize any revenue at the time the equipment is installed at the hospital. Rather, pursuant to our revenue recognition policy, we recognize revenue as we ship sensors in accordance with the contract.

Our royalty revenue consists primarily of royalties associated with our January 2006 patent infringement settlement with Nellcor. Pursuant to the settlement agreement, we will receive quarterly royalty payments based on the amount of Nellcor's U.S. pulse oximetry revenues. A predetermined royalty rate will be applied against the amount of Nellcor's U.S. oximetry sales and this will determine the amount of royalties we will be paid. Under terms of the agreement, the royalty rates decline from 20% in 2006 to either 12% or 15% in 2007 and then to either 10% or 13% in each year throughout the remainder of the settlement agreement. The royalty rate paid is dependant on whether Nellcor is able to remove certain infringing technology from its products. The Company recognizes royalty revenue based on the royalty rate per the settlement agreement multiplied by its estimate of Nellcor's sales for each quarter. Any adjustments to the quarterly estimate are recorded prospectively in the following quarter, when the Company receives the Nellcor royalty report, 60 days after the end of each quarter.

Cost of Goods Sold. We manufacture a substantial majority of the products that we sell. Our cost of goods sold includes material and component costs, direct labor and other direct and indirect manufacturing overhead costs. We recognize cost of

Table of Contents

goods sold when we recognize revenue for the transaction. For equipment placed with a customer pursuant to a long-term sales contract, we capitalize the cost of the equipment shipped as deferred cost of goods sold and amortize the cost to cost of goods sold on a straight-line basis over the term of the contract. In addition, pursuant to our Cross-Licensing Agreement, we are required to pay certain royalties to Masimo Labs on products incorporating the licensed Rainbow technology. However, pursuant to FIN 46(R), these royalties are eliminated in these condensed consolidated financial statements.

Research and Development. Our research and development expenses consist primarily of costs associated with the design, development, enhancement and testing of new and existing products. These expenses include personnel costs, the cost of materials, supplies and services and an allocation of facility and overhead costs. Through December 31, 2006, an aggregate of \$10.5 million of our historical research and development expenses were Masimo Labs research and development expenses. Since Masimo Labs is consolidated within our financial statements pursuant to FIN 46(R), these research and development expenses are not eliminated and therefore are included in these consolidated financial statements.

Selling, General and Administrative. Selling, general and administrative expenses consist primarily of salaries, promotional, training, trade show, professional fees, facility costs and travel and entertainment expenses.

Patent Litigation Proceeds. Patent litigation proceeds, which we report separately from selling, general and administrative expenses, consist of external legal costs exclusively related to our patent infringement lawsuit against Nellcor offset by the proceeds received from our patent infringement lawsuit, which we settled in January 2006.

Antitrust Litigation. Antitrust litigation expense which we report separately from selling, general and administrative expense, consists of external legal costs exclusively related to our antitrust lawsuit against Tyco Healthcare (currently Covidien).

Non-Operating Income. Non-operating income is comprised of interest income from our cash and cash equivalents and interest expense on our debt and term loans. Other expense typically consists of gains or losses on sales of fixed assets and foreign currency transactions.

Provision for Income Taxes. Provision for income taxes is comprised of federal, state, local and foreign taxes based on income.

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 Financial Accounting Standards Board No. 128 *Earnings per Share*, or FASB 128, in accordance with GAAP and the non-GAAP if converted method based upon FASB 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 the closing of our initial public offering on August 13, 2007, all outstanding shares of our prior Series A through Series G convertible preferred stock were converted into an aggregate of 34,612,503 shares of common stock. Therefore, effective August 13, 2007, we transitioned from computing earnings per share from the two class method in accordance with EITF 03-6 to the if converted method in accordance with FASB 128. Net income for the three and nine months ended September 29, 2007 was allocated between the periods during which two classes of equity securities were outstanding and during which a single class of equity securities was outstanding based on the respective number of days. For the three months ended September 29, 2007, two classes of equity securities were outstanding for 43 days and a single class of equity securities was outstanding for 48 days, or 47.3% and 52.7% of the total days in the three month reporting period, respectively. For the nine months ended September 29, 2007, two classes of equity securities were outstanding for 224 days and a single class of equity securities was outstanding for 48 days, or 82.4% and 17.6% of the total days in the nine month reporting period, respectively.

We believe that the following non-GAAP earnings per share information 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 future reported earnings per share. Accordingly, we are disclosing this information to permit additional analysis of our performance (in thousands, except share data):

Table of Contents

	As Reported		Pro forma	
	Three months	Nine months	Three months	Nine months
	ended September 29, 2007 (unaudited)	ended September 29, 2007 (unaudited)	ended September 29, 2007 (unaudited)	ended September 29, 2007 (unaudited)
Net income attributable to common stockholders:				
Net income - two class method (1)	\$ 4,985	\$ 24,871		
Accretion of preferred stock	(925)	(4,837)		
Income attributable to preferred stockholders	(2,739)	(13,526)		
Net income attributable to common stockholders	\$ 1,321	\$ 6,508		
Basic net income per common share:				
Weighted average common shares outstanding two class method	16,704,285	16,654,586		
Basic earnings per share for period during which two classes of equity securities were outstanding	\$ 0.08	\$ 0.39		
Net income for period during which single class of equity securities was outstanding (1)	\$ 5,565	\$ 5,329	\$ 10,550	\$ 30,200
Weighted average common shares outstanding single class (2)	54,630,610	54,630,610	53,064,738	51,860,652
Basic net income per share for period during which single class of equity securities were outstanding	\$ 0.10	\$ 0.10		
Basic net income per common share	\$ 0.18	\$ 0.49	\$ 0.20	\$ 0.58
Diluted net income per common share:				
Weighted average common shares outstanding two class method	16,704,285	16,654,586		
Diluted common share equivalent: stock options	4,221,224	4,078,314		
	20,925,509	20,732,900		
Diluted earnings per share for period during which two classes of equity securities were outstanding	\$ 0.06	\$ 0.31		
Net income for period during which single class of equity securities was outstanding (1)	\$ 5,565	\$ 5,329	\$ 10,550	\$ 30,200
Weighted average common shares outstanding single class (2)	54,630,610	54,630,610	53,064,738	51,860,652
Diluted common share equivalent: stock options	4,747,848	4,747,848	4,527,282	4,231,074
	59,378,458	59,378,458	57,592,020	56,091,726
Diluted net income per share for period during which single class of equity securities were outstanding	\$ 0.10	\$ 0.09		
Diluted net income per common share	\$ 0.16	\$ 0.40	\$ 0.18	\$ 0.54

(1)

Edgar Filing: MASIMO CORP - Form 10-Q

Net income for the three months ended September 29, 2007 was allocated between the periods during which two classes of equity securities were outstanding and during which a single class of equity securities was outstanding based on the respective number of days. The convertible preferred stock was converted into common stock on August 13, 2007, the closing date of the Company's initial public offering. For the three months ended September 29, 2007, two classes of equity securities were outstanding for 43 days and a single class of equity securities was outstanding for 48 days, or 47.3% and 52.7% of the total days in the reporting period, respectively. For the nine months ended September 29, 2007, two classes of equity securities were outstanding for 224 days and a single class of equity securities was outstanding for 48 days, or 82.4% and 17.6% of the total days in the reporting period, respectively.

- (2) Weighted average shares outstanding used to compute basic net income per share after conversion of convertible preferred stock; one class of common shares was outstanding for the period from August 13, 2007 to September 29, 2007.

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. The patent litigation proceeds and the royalty received from Nellcor in the first three months of 2006 have significantly affected our revenues, results of operations and financial position for the periods presented. Accordingly, our results of operations for the nine months ended September 29, 2007 are difficult to compare to our results of operations for the nine months ended September 30, 2006 (in thousands, except percentages).

	Three months ended				Nine months ended			
	September 30, 2006	% of Revenue	September 29, 2007	% of Revenue	September 30, 2006	% of Revenue	September 29, 2007	% of Revenue
Revenue:								
Product	\$ 39,755	69.0%	\$ 51,122	79.4%	\$ 112,279	69.0%	\$ 144,513	77.3%
Royalty and license fee	17,891	31.0	13,254	20.6	50,447	31.0	42,497	22.7
Total revenue	57,646	100.0	64,376	100.0	162,726	100.0	187,010	100.0
Cost of goods sold	14,704	25.5	18,809	29.2	45,798	28.1	53,630	28.7
Gross profit	42,942	74.5	45,567	70.8	116,928	71.9	133,380	71.3
Operating expenses:								
Research and development	4,330	7.5	6,540	10.2	19,267	11.8	17,455	9.3
Selling, general and administrative	18,281	31.7	21,594	33.5	69,462	42.7	64,575	34.5
Patent litigation proceeds					(262,601)	(161.4)		
Antitrust litigation	30	0.1	508	0.8	103	0.1	982	0.5
Total operating expenses	22,641	39.3	28,642	44.5	(173,769)	(106.8)	83,012	44.3
Operating income	20,301	35.2	16,925	26.3	290,697	178.6	50,368	26.9
Non-operating income (expense):								
Interest income	1,298	2.3	726	1.1	5,936	3.6	1,270	0.7
Interest expense	(437)	(0.8)	(719)	(1.1)	(1,413)	(0.9)	(1,831)	(1.0)
Other	134	0.2	559	0.9	321	0.2	770	0.4
Total non-operating income	995	1.7	566	0.9	4,844	2.9	209	0.1
Income before provision for income taxes	21,296	36.9	17,491	27.2	295,541	181.6	50,577	27.0
Provision for income taxes	9,000	15.6	6,941	10.8	124,626	76.6	20,377	10.9
Net income	12,296	21.3	10,550	16.4	170,915	105.0	30,200	16.1
Preferred stock dividend					(58,571)	(36.0)		
Accretion of preferred stock	(1,956)	(3.4)	(925)	(1.4)	(6,029)	(3.7)	(4,837)	(2.6)
Undistributed income attributable to preferred stockholders	(6,998)	(12.1)	(2,739)	(4.3)	(49,172)	(30.2)	(13,526)	(7.2)
Net income attributable to common stockholders	\$ 3,342	5.8%	\$ 6,886	10.7%	\$ 57,143	35.1%	\$ 11,837	6.3%

Table of Contents***Comparison of the Three Months ended September 29, 2007 to the Three Months ended September 30, 2006***

Revenue. Total revenue increased \$6.8 million, or 11.7%, to \$64.4 million for the three months ended September 29, 2007 from \$57.6 million for the three months ended September 30, 2006.

Product revenues increased \$11.4 million, or 28.6%, to \$51.1 million in the three months ended September 29, 2007 from \$39.8 million for the three months ended September 30, 2006. 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 448,000 units at September 29, 2007 up from 353,000 units at September 30, 2006. Revenue generated through our direct and distribution sales channels increased \$8.5 million, or 31.5%, to \$35.7 million for the three months ended September 29, 2007 compared to \$27.2 million for the three months ended September 30, 2006. During the three months ended September 29, 2007 revenues from our OEM channel increased \$2.8 million, or 22.5%, to \$15.4 million from \$12.6 million in the prior year period ended September 30, 2006. Contributing to the increase in our direct and distribution sales channel revenue was our Rainbow technology product revenues which increased 10%, or approximately \$51,000, to \$1.4 million in the three months ended September 29, 2007, from \$1.2 million in the three months ended September 30, 2006.

Our royalty and license fee revenue decreased \$4.6 million, to \$13.3 million in the three months ended September 29, 2007 from \$17.9 million in the three months ended September 30, 2006, primarily due to a lower royalty rate associated with our 2006 settlement agreement with Nellcor. For the three months ended September 30, 2006, our reported Nellcor royalties are based upon Nellcor's actual reported U.S. pulse oximeter sales for that period. For the three months ended September 29, 2007, our reported Nellcor royalties are based upon an estimate of Nellcor's U.S. pulse oximeter sales for that period and the contractual royalty rate as prescribed by the 2006 settlement agreement.

Cost of Goods Sold. Cost of goods sold increased 27.9% to \$18.8 million in the three months ended September 29, 2007 from \$14.7 million in the three months ended September 30, 2006. Our gross margin decreased to 70.8% for the three months ended September 29, 2007 from 74.5% for the three months ended September 30, 2006. This decline in gross margin was due to the \$4.6 million decrease in Nellcor royalty revenues. Excluding the royalty revenues in both 2007 and 2006, the gross margin would have increased by 0.2%, to 63.2% from 63.0%. This increase was primarily related to an increased percentage of revenues from our consumables which in general have a higher margin than our other products. During the three months ended September 29, 2007, we also recorded a \$300,000 charge for the voluntary recall of Rad-9 monitors (see Note 12 of the Notes to the Condensed Consolidated Financial Statements).

Research and Development. Research and development expenses increased 51.0% to \$6.5 million for the three months ended September 29, 2007, from \$4.3 million for the three months ended September 30, 2006. Research and development expenses increased \$2.2 million, of which \$1.4 million was due to increased payroll and payroll related costs associated with increased research and development staffing levels which rose to 130 at September 29, 2007 from 98 at September 30, 2006. Additional increased spending was attributable to higher project supplies expense by \$540,000 in the three months ended September 29, 2007. Included in total research and development expenses are \$464,000 and \$919,000 of engineering expenses incurred by Masimo Labs for the three months ended September 29, 2007 and September 30, 2006, respectively.

Selling, General and Administrative. Selling, general and administrative expenses increased \$3.3 million, or 18.1% to \$21.6 million for the three months ended September 29, 2007 from \$18.3 million in the three months ended September 30, 2006. The increase was primarily due to a \$3.1 million increase in payroll and payroll related costs, consistent with an increase in staffing to 349, which included 105 sales staff, at September 29, 2007 from 281, which included 86 sales staff, at September 30, 2006.

Antitrust Litigation. Litigation expense resulting from our antitrust lawsuit against Tyco Healthcare (currently Covidien) increased to \$508,000 for the three months ended September 29, 2007 from \$30,000 for the three months ended September 30, 2006. This increase was due to additional expense related to the new appeals process which began in the first quarter of 2007.

Non-Operating Income. Non-operating income was \$566,000 for the three months ended September 29, 2007, compared to \$1.0 million for the three months ended September 30, 2006. This decline was primarily due to a decrease in interest income of \$572,000, resulting from lower cash balances during the three months ended September 29, 2007 as compared to the three months ended September 30, 2006.

Provision for Income Taxes. Our provision for income taxes was \$6.9 million, or an effective tax rate of 39.7%, for the three months ended September 29, 2007, compared to \$9.0 million or an effective tax rate of 42.3%, for the three months ended September 30, 2006. This decrease in the provision was primarily due to a decrease in our taxable income for the three months ended September 29, 2007 as compared to the three months ended September 30, 2006. The effective tax rate differs

Table of Contents

from the statutory U.S. federal income tax rate of 35% primarily due to state taxes, and permanent differences between pre-tax income for financial reporting purposes and taxable income.

Comparison of the Nine Months ended September 29, 2007 to the Nine Months ended September 30, 2006

Revenue. Total revenue increased \$24.3 million, or 14.9%, to \$187.0 million for the nine months ended September 29, 2007 from \$162.7 million for the nine months ended September 30, 2006.

Product revenues increased \$32.2 million, or 28.7%, to \$144.5 million in the nine months ended September 29, 2007 from \$112.3 million for the nine months ended September 30, 2006. 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 448,000 units at September 29, 2007 from 353,000 units at September 30, 2006. Revenue generated through our direct and distribution sales channels increased \$26.2 million, or 34.5%, to \$101.9 million compared to \$75.7 million for the nine months ended September 30, 2006. During the nine months ended September 29, 2007, revenues from our OEM channel increased \$6.1 million, or 16.6%, to \$42.6 million from \$36.5 million for the nine months ended September 30, 2006. Contributing to the increase in our direct and distribution sales channel revenue was Rainbow technology product revenues which increased 103%, or \$2.2 million, to \$4.5 million in the nine months ended September 29, 2007 from \$2.2 million in the nine months ended September 30, 2006.

Our royalty and license fee revenue decreased \$7.9 million, to \$42.5 million in the nine months ended September 29, 2007 from \$50.4 million in the nine months ended September 30, 2006, primarily due to a lower royalty rate associated with our 2006 settlement agreement with Nellcor.

Cost of Goods Sold. Cost of goods sold increased 17.1% to \$53.6 million in the nine months ended September 29, 2007 from \$45.8 million in the nine months ended September 30, 2006. Our gross margin decreased to 71.3% for the nine months ended September 29, 2007 from 71.9% for the nine months ended September 30, 2006. This decline in gross margin was due to the \$7.9 million decrease in Nellcor royalty revenue. Product gross margin increased to 62.9% in the nine months ended September 29, 2007 from 59.2% in the nine months ended September 30, 2006. This increase was related to a prior year stock-based compensation change of \$1.8 million and an increase in sales of higher margin products. During the nine months ended September 29, 2007, we also recorded a \$300,000 charge for the voluntary recall of Rad-9 monitors (see Note 12 of the Notes to the Condensed Consolidated Financial Statements).

Research and Development. Research and development expenses decreased 9.4% to \$17.5 million for the nine months ended September 29, 2007 from \$19.3 million for the nine months ended September 30, 2006. The expense for the nine months ended September 30, 2006 included a stock-based compensation charge of \$8.3 million associated with the prior period dividend and special bonus payments. Excluding that prior period charge, research and development expenses during these comparable nine month periods increased \$6.5 million primarily due to increased payroll and payroll related costs of \$4.8 million associated with increased research and development staffing levels which rose to 130 at September 29, 2007 from 98 at September 30, 2006. In addition, higher spending was attributable to increased project supplies expense by \$966,000 in the nine months ended September 29, 2007. Included in total research and development expenses are \$1.1 million and \$2.5 million of engineering expenses incurred by Masimo Labs for the nine months ended September 29, 2007 and September 30, 2006, respectively.

Selling, General and Administrative. Selling, general and administrative expenses decreased 7.0% to \$64.6 million for the nine months ended September 29, 2007, from \$69.5 million in the nine months ended September 30, 2006, which included a \$21.3 million charge in stock-based compensation associated with the dividend and special bonus payments. Excluding that charge, selling, general and administrative expenses increased a total of \$16.4 million, from the nine months ended September 30, 2006 to the nine months ended September 29, 2007. This increase was primarily due to a \$8.6 million increase in payroll and payroll related costs associated with an increase in total staffing to 349, which included 105 sales staff, at September 29, 2007 from 281, which included 86 sales staff, at September 30, 2006. Additional increased spending was attributable to \$3.4 million in higher marketing related expenses, including trade show costs, customer training and product samples, as well as a \$1.5 million increase in professional and other service fees and \$790,000 in GPO fees.

Patent Litigation Proceeds. Litigation proceeds from our patent infringement lawsuit against Nellcor decreased to \$0 for the nine months ended September 29, 2007, from \$262.6 million for the nine months ended September 30, 2006. This decrease was due to the one-time patent litigation settlement in January 2006 and related proceeds of \$263.0 million less current and related legal fees.

Antitrust Litigation. Litigation expense resulting from our antitrust lawsuit against Tyco Healthcare (currently Covidien) increased to \$982,000 for the nine months ended September 29, 2007 from \$103,000 for the nine months ended September

Table of Contents

30, 2006. This increase was due to additional expense related to the new appeals process which began in the first quarter of 2007.

Non-Operating Income. Non-operating income was \$209,000 for the nine months ended September 29, 2007, compared to \$4.8 million for the nine months ended September 30, 2006. This change was primarily due to the decrease in interest income of \$4.7 million, resulting from lower cash balances during the nine months ended September 29, 2007, as compared to the nine months ended September 30, 2006.

Provision for Income Taxes. Our provision for income taxes was \$20.4 million, or an effective tax rate of 40.3%, for the nine months ended September 29, 2007, compared to \$124.6 million, or an effective tax rate of 42.2%, for the nine months ended September 30, 2006. This decrease in the provision was primarily due to a non-deductible dividend payment which was made during the nine months ended September 30, 2006. The effective tax rate differs from the statutory U.S. federal income tax rate of 35% primarily due to state taxes, and permanent differences between pre-tax income for financial reporting purposes and taxable income.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the sale of equity securities. Through September 29, 2007, we raised \$81.7 million through seven preferred stock private equity financings, approximately \$47.8 million from our August 2007 initial public offering and \$16.7 million from the exercise of stock options for a total of \$146.2 million. As of September 29, 2007, we had cash and cash equivalents of \$88.6 million.

Under the terms of our patent litigation settlement with Nellcor, Nellcor 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 Nellcor's products for the remainder of 2006. In total, we received \$330.5 million in cash from Nellcor 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 for 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 Nellcor and interest earned thereon. In the future, we do not intend to distribute any royalties received from Nellcor under the settlement agreement to our stockholders or our option holders.

Cash Flows from Operating Activities. Cash provided by operating activities was \$14.9 million in the nine months ended September 29, 2007. The source of cash consists primarily of net income of \$30.2 million, an increase in income taxes payable of \$4.8 million and depreciation and amortization expense of \$3.9 million. Deferred revenue increased \$4.2 million due to increases in customer rebates and inventory in the distribution channel as a result of the continued growth of our business. This increase was offset partially by increases in royalties receivable of \$11.8 million due to the Nellcor settlement agreement, an increase in inventory of \$6.9 million to meet the increased demand for our products, an increase in accounts receivable of \$5.1 million due to the growth of our business, and an increase in deferred cost of goods sold of \$3.3 million due to the increase in equipment placed at hospitals under long term sensor purchase agreements.

Cash provided by operating activities was \$207.0 million in the nine months ended September 30, 2006. This consists primarily of net income of \$170.9 million, resulting primarily from the patent litigation settlement in 2006. In addition, deferred revenue increased by \$22.0 million and income taxes payable increased by \$17.9 million, also as a result of the patent litigation settlement. During the nine months ended September 30, 2006, accounts payable increased by \$8.0 million due to growth in our business and deferred income taxes increased by \$3.9 million. These sources of cash were offset by uses of cash including an increase in inventories of \$8.6 million to meet the increased demand for our products, an increase in accounts receivable of \$7.5 million due to growth in our business and timing of receipts, and an increase in deferred cost of goods sold of \$4.4 million due to the increase in equipment placed at hospitals under long term sensor purchase agreements.

Cash Flows from Investing Activities. Cash used in investing activities for the nine months ended September 29, 2007 was \$4.7 million consisting of \$3.8 million of property and equipment purchases and \$865,000 for the increase in intangible assets necessary to support the growth of our business.

Cash used in investing activities for the nine months ended September 30, 2006 was \$4.7 million consisting primarily of \$3.3 million of property and equipment purchases and \$951,000 for the increase in intangible assets necessary to support the growth of our business.

Cash Flows from Financing Activities. Cash provided by financing activities for the nine months ended September 29, 2007 was \$23.6 million. This primarily consists of \$47.8 million of proceeds from the initial public offering and \$20.1 million of additional long term debt, offset by \$37.3 million of dividends paid and repayment of long term debt of \$7.1 million.

Table of Contents

Cash used in financing activities for the nine months ended September 30, 2006 was \$137.1 million. This primarily consists of dividends paid of \$149.3 million and repayment of long term debt of \$5.7 million, offset by \$14.3 million of proceeds from common stock issuances in connection with the exercise of stock options and \$4.2 million of income tax benefit from exercise of stock options.

Future Liquidity Needs. In the future, in addition to funding our working capital requirements, we anticipate our primary use of cash to be the equipment that we provide to hospitals under our long-term sensor purchase agreements. We anticipate additional capital purchases related to expanding our worldwide 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, Japan and Asia. The amount and timing of our actual investing activities will vary significantly depending on numerous factors, such as the progress of our product development efforts, our timetable for international sales and marketing expansion and both domestic and international regulatory requirements. Despite these capital investment requirements, we anticipate that our existing cash and cash equivalents, including the proceeds we received from our recently completed initial public offering, will be sufficient to meet our working capital requirements, capital expenditures, and operations for at least the next 12 months.

Current Financing Arrangements. As of September 29, 2007, we had various arrangements that allow for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements. During the nine months ended September 29, 2007 and September 30, 2006, we borrowed a total of \$20.1 million and \$0, respectively, under these facilities. As of September 29, 2007 and December 31, 2006, we had outstanding under these financing agreements \$33.8 million and \$20.5 million, respectively. As of September 29, 2007, principal and interest payments under these financing agreements were \$1.2 million per month based on an average interest rate of 7.7%, and \$15.8 million of the outstanding debt was collateralized by \$3.9 million of equipment, net of amortization. As of September 29, 2007, the amount available for additional borrowing under the terms of the agreements was \$19.9 million. Unless otherwise extended, the agreements will expire on December 31, 2007.

In June 2001, we entered into a Master Selective Business Security Agreement, or Master Agreement, with one of our stockholders allowing us to borrow up to a maximum of \$5.0 million. The Master Agreement consisted of an equipment line whereby all draws are collateralized by equipment placed at hospitals under long-term sensor purchase agreements. Each draw was converted into a five-year note with interest and principal paid on a monthly basis. The interest rate on each note is based on 475 basis points over the U.S. Treasury Rate on the date of the borrowing. The most recent draw was in December 2002 and there are no additional borrowings available under this Master Agreement. As of December 31, 2006 and September 29, 2007, we had \$316,000 and \$31,000, respectively, outstanding under the Master Agreement at an average interest rate of 7.9%. At September 29, 2007, the carrying value of the equipment collateralizing these borrowings was \$65,000, net of amortization.

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 Policies and Estimates* section of the *Management's Discussion and Analysis of Financial Condition and Results of Operations* section contained in our Prospectus dated August 7, 2007, as filed with the SEC. There have been no material changes in any of our accounting policies since December 31, 2006.

Table of Contents

New Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment to FASB Statement No. 115*. SFAS No. 159 permits entities to choose to measure financial instruments and certain other items at fair value at specified election dates. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings. Most of the provisions of SFAS No. 159 apply only to entities that elect the fair value option. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We do not expect the adoption of this statement to have a material impact 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 various 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 ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest-sensitive financial instruments at September 29, 2007. 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 nine months ended September 29, 2007. 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, and we do not anticipate that it will have a material adverse effect in the future.

Table of Contents

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by 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 report. 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 our most recent fiscal quarter 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 October 1, 2007, we filed a lawsuit in the United States District Court, Central District of California, against Gregory Jay and P2Lethlogics, LLC, seeking a declaratory judgment that our pulse oximeters do not infringe a patent of Gregory Jay and/or P2Lethlogics. Dr. Jay had made allegations that a new parameter of ours, Pleth Variability Index, offered as an option in our pulse oximeters, infringes these patents. On October 17, 2007, P2Lethlogics, LLC, filed a lawsuit in the United States District Court, District of Massachusetts, alleging that our products, including but not limited to, our Rainbow pulse oximeters infringe the same patent. Gregory Jay and P2Lethlogics have moved to dismiss the California case on the grounds of lack of personal jurisdiction over Gregory Jay and P2Lethlogics. Our management believes that our devices do not infringe the cited patent and we intend to vigorously defend against these claims. We believe that the claims asserted in this action will not materially affect our business, financial conditions or future operating results. In the event a preliminary or permanent injunction were granted, however, we would be unable to sell products found to infringe the cited patents, which would cause a reduction in our revenues, a decline in income and a loss of customer goodwill for an unknown period of time. Additionally, we could be ordered to pay royalties on past sales of our products if found to infringe the cited patents and, to the extent we continued to sell such products, we could be required to continue paying royalties. Although we believe 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, we are not able to accurately estimate the potential financial impact of this litigation against us.

From time to time, we are involved in legal proceedings in the ordinary course of business. Other than the proceeding described above and the proceedings set forth in our quarterly report on Form 10-Q for the quarter ended June 30, 2007, we are not currently involved in any material legal proceedings.

Table of Contents

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 on September 20, 2007, 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 previously filed quarterly report on Form 10-Q.*

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 Signal Extraction Technology, or 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 to be 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 U.S. Patent and Trademark Office, or PTO, may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO. These proceedings could result in adverse decisions as to the claims included in our patents.

Our issued and licensed patents and those that may be issued or licensed in the future may 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. Although we have taken steps to protect our intellectual property and technology, there is no assurance that competitors will not be able to design around our patents. We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology with confidentiality agreements and intellectual property assignment agreements with our employees, or OEM partners, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Our common law trademarks provide less protection than our registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

Table of Contents

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 product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. 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 as yet a matter of public knowledge, 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, 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;

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

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

divert the attention of our management; and

result in our customers or potential customers deferring or limiting their purchase or use of the affected products until the litigation is resolved.

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 proprietary 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 the implementation of our business strategy.

Edgar Filing: MASIMO CORP - Form 10-Q

We believe that the success of our business depends, in significant part, on obtaining patent protection for our products and technology, defending our patents once obtained 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 Nellcor was infringing certain of our pulse oximetry signal processing patents. We believe that other competitors of ours, including some of our OEM partners, may be infringing at least one of our patents. Our failure to pursue any potential claim could result in the loss of our proprietary rights and harm our position in the marketplace. Therefore, we may be forced to pursue litigation to enforce our rights. 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, including 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

Table of Contents

quantities sufficient for us to be 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 over competing products;

introduction and acceptance of competing products or technologies; and

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

In order for any of these products to be accepted, we must prove that they are effective and commercially beneficial. Even if customers accept these products, this acceptance may not translate into 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 could be limited, which could adversely affect our business, financial condition and results of operations.

Our products are subject to reporting requirements and may be subject to recalls, which could be expensive, damage our reputation and result in a diversion of management resources. *

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 similar governmental bodies in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of manufacturing or labeling errors or design defects. Any voluntary or government mandated recall may divert management attention and financial resources and harm our reputation with customers. Any recall involving one of our products could also harm the reputation of the product and us and would be particularly harmful to our business and financial results.

We may recall our products, either voluntarily or involuntarily, if any prove or are perceived to be defective. 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 September 29, 2007, we initiated three voluntary recalls of our products, none of which was material.

On July 31, 2007, we determined to initiate a voluntary recall of our Rad-9 pulse oximeter, a standalone bedside pulse oximeter product, sales of which represented less than 0.6% and 0.4% of our product revenue in 2006 and the nine months ended September 29, 2007, 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, we 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. We have now determined 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. 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 estimate that the total costs resulting from this voluntary recall will be approximately \$300,000, 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 products that incorporate Masimo SET or Rainbow technology is limited.

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

Edgar Filing: MASIMO CORP - Form 10-Q

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 parameters and to develop and sell devices incorporating Masimo SET for monitoring non-vital signs parameters in any product market in which a product is intended to be used by a patient or pharmacist rather than by a professional medical caregiver, which we refer to as the Labs Market, and

Table of Contents

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

Non-vital signs parameters consist of body fluid constituents other than vital signs parameters, 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 parameters 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 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 revenue and impair our growth.

We will be required to pay Masimo Labs for the right to use certain improvements to Masimo SET that we develop.

Under the Cross-Licensing Agreement, when we develop improvements to Masimo SET for the non-invasive measurement of non-vital signs parameters, 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 parameters, 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 parameter 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 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 may not be able to commercialize our products incorporating licensed Rainbow technology cost-effectively or successfully.

It costs us more to make products that incorporate Rainbow technology than products without Rainbow technology due to increased production costs in addition to the royalties that we must pay to Masimo Labs. In order to successfully commercialize these products, 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 to be profitable, which could adversely affect our business, financial condition and results of operations.

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

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-parameter 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

Table of Contents

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 parameters 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.

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, which, as defined in the Cross-Licensing Agreement, includes the resignation or termination of Joe E. Kiani from his position of Chief Executive Officer of either Masimo or Masimo Labs, 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. 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 parameters 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 parameters. Also, if the surviving or acquiring entity ceases to use Masimo as a company name and trademark following a change in control, all rights to the Masimo trademark will automatically be assigned to Masimo Labs. This could delay or discourage transactions involving an actual or potential change in control of us, including transactions in which our stockholders might otherwise receive a premium for their shares over then current prices. In addition, our requirement to assign all future improvements for non-vital signs to Masimo Labs could impede a change in control.

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

Masimo Labs has conducted the 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 parameters, 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.

As of September 29, 2007, our stockholders owned approximately 99.9% of the outstanding shares of capital stock of Masimo Labs. 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 technology and products;

Table of Contents

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, such as employee compensation, inventory and debt repayment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenue for a particular period were below our expectations, we would not be able to proportionately reduce our operating expenses for that period. Any revenue shortfall would have a disproportionately negative effect on our operating results for the period.

Due to these and other factors, we believe that quarter-to-quarter comparisons of our operating results may not be meaningful. You should not rely on our results for any one quarter as an indication of our future performance. In future quarters, our operating results may be below the expectations of securities analysts or investors.

We depend on our OEM partners for a portion of our revenue. If they do not devote sufficient resources to the promotion of products that use Masimo SET and licensed Rainbow technology, our business would be harmed.

We are, and will continue to be, dependent upon our OEM partners for a portion of our revenue through their marketing, selling and distribution of certain of their products that incorporate Masimo SET and licensed Rainbow technology. Although we expect that our OEM partners will accept and actively market, sell and distribute products that incorporate licensed Rainbow technology, they may elect not 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 year ended December 31, 2006, we did not have any customers who accounted for over 10.0% of our total revenues and for the nine months ended September 29, 2007, one customer represented 10.6% of our total revenues. However, we have a concentration of OEM, distribution and direct customers. If, for any reason, we were to lose our ability to sell to a specific group or class of customers, we would experience a significant reduction in revenues. This would, in turn, 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.

Table of Contents

Our royalty agreement with Nellcor provides for a declining royalty rate schedule over the term of the settlement agreement which, if not offset by other revenues and sources of income, could significantly harm our total sales and operating results.

In fiscal 2006, our royalties from the Nellcor settlement totaled \$68.8 million. 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 agreement will have a significant impact on our revenues, gross margins and operating income. Under terms of the agreement, we earn royalties on Nellcor'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 in 2007 will decline to either 12% or 15% depending on Nellcor's ability to re-design their products in a manner that would avoid some of our patent coverage in the settlement agreement. In 2008 and through the term of the royalty agreement, at least through March 14, 2011, the royalty rates will decline to either 10% or 13%, also subject to Nellcor's ability to develop new products that avoid the current patent coverage as negotiated in the settlement agreement. As a result of these declining royalty rates in 2007 and beyond, 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 Nellcor's U.S. pulse oximetry products.

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, affiliated hospitals and other members may be less likely to purchase our products, and if the 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. 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 2006 and for the nine months ended September 29, 2007, revenue from the sale of our pulse oximetry products related to GPOs amounted to \$66.6 million and \$72.9 million, respectively. We do not have any contracts expiring in 2007. In the future, if we are unable to keep our relationships and develop new relationships with GPOs, our competitive position would likely suffer.

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 parameters, 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 in particular, Nellcor, a subsidiary of Tyco Healthcare, 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, as well as worldwide distribution channels that are more effective than ours. Competition could result in price reductions, fewer orders, reduced gross margins and loss of market share.

Table of Contents

Reliance on clinical studies is an important means of demonstrating the effectiveness of products in our industry. We are aware of a number of clinical and laboratory studies with results that are less favorable to the Masimo SET platform than those contained in the over 100 independent clinical and laboratory studies that validate our technology. We believe that these studies either (i) lack independence because they were funded by competing companies evaluated in the studies or were conducted by employees of such companies, or (ii) lack objectivity because of the absence of clinical procedures and protocols required to ensure objective and accurate results. If subsequent independent studies validate these studies or these studies are otherwise shown to be accurate, 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 patient monitoring solutions, and if we are unable to obtain these components on a timely basis, we will not be able to deliver our 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 patient monitoring solutions. We may experience delays in production of our products if we fail to identify alternate vendors, 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 employees have disclosed, or that we have used, trade secrets or other proprietary information of their 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, which could adversely affect our business, financial condition and results of operations.

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 or malfunction of, or design flaws 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 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, by filing a 510(k) pre-market notification, or PMA approval, by filing a PMA application, from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act. 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 the Masimo SET or licensed Rainbow technology. The FDA's 510(k) clearance process usually takes from four to twelve months, although it can last 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 if safety or effectiveness problems develop with our devices. 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

Table of Contents

would require a new 510(k) clearance. 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. If so, 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.

The failure of our OEM partners to obtain FDA clearances or approvals 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:

issuance of public warning letters;

a shut-down or interruption of our manufacturing operations;

withdrawal or suspension of clearance or approval by the FDA or other regulatory bodies;

product recall, detention or seizure;

fines and civil penalties;

unanticipated expenditures;

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 countries and can involve additional testing, and the time required to obtain approval 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 countries, 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 would 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

Table of Contents

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 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. Although we may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. We must have adequate substantiation for our product performance claims. If the FDA determines that we or our OEM partners have promoted our products for off-label use, or have made false or misleading or inadequately substantiated promotional claims, we could be subject to fines, injunctions or other significant penalties or restrictions.

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 force;

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, in turn, sales of our consumable products increase; and

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

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 is 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.

Edgar Filing: MASIMO CORP - Form 10-Q

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.

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

Table of Contents

personnel and place 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, our anticipated growth may be impaired and our business, financial condition and results of operations would be adversely affected.

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

We have relied, to date, 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. In the event that one of our facilities was affected by a disaster, we would be forced to rely on third-party manufacturers if we could not shift production to another 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 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 their employment at any time without notice and without cause or good 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;

Edgar Filing: MASIMO CORP - Form 10-Q

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

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

higher costs of integration than we anticipated; and

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

Table of Contents

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, nor 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 new 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 liabilities related to certain hazardous materials used in our operations.

Our manufacturing processes involve the use, generation and disposal of certain hazardous materials and wastes, including silicone adhesives, solder and solder paste, sealants, epoxies and various solvents such as methyl ethyl ketone, acetone and isopropyl alcohol. As such, 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, thereby increasing

Edgar Filing: MASIMO CORP - Form 10-Q

our manufacturing costs. In our research and manufacturing activities, we use materials that are hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury 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

Table of Contents

to prevail or settle the action. Similarly, if the physicians or other providers or entities with which we do business are found to be non-compliant with 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 conditions and results of operations. *

We derive a portion of our net sales from operations in international markets. In 2005, 2006 and the nine months ended September 29, 2007, 19.2%, 22.6% and 23.4%, 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:

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.

We are subject to fluctuations in 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. Accordingly, if the U.S. dollar strengthens against international currencies, our U.S. dollar payments from such distributors, if any, will decrease.

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.

Table of Contents

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

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 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, has 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 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), parent company of Nellcor, in the United States District Court for the Central District of California, alleging damage to our business as a result of the anti-competitive business practices of Tyco Healthcare in connection with its pulse oximetry brand in violation of federal antitrust laws. Specifically, we alleged that we had incurred damages as a result of a series of illegal exclusionary and anti-competitive acts by Tyco Healthcare that were designed to maintain its monopoly in the pulse oximetry market.

In March 2005, a jury found that Tyco Healthcare's use of sole-source contracts, product bundling, 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 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

Edgar Filing: MASIMO CORP - Form 10-Q

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. Even if

Table of Contents

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 the award.

We believe that Nellcor 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 Nellcor pulse oximeters for most of their pulse oximetry needs. Co-marketing agreements also provide significant impediments to competition in that Nellcor pays large patient monitoring companies to integrate Nellcor 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 issue additional securities in the future, including shares, debt or equity-linked debt, which may depress our stock price.

Our issuance of additional securities could:

cause substantial dilution of the percentage ownership of our stockholders 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.

We do not intend to seek stockholder approval for any such acquisition or security issuance unless required by applicable law or regulation or the terms of existing securities. If these securities are issued, such issuances may cause the trading price of our stock to decline.

We may require additional capital in the future, which may not be available on favorable terms, if at all.

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 equity or debt financing, if available at all, may be on terms that are not favorable to us. Equity financings could result in dilution to our stockholders, and the securities issued in future financings may have rights, preferences and privileges that are senior to those of our common stock. 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, 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 Exchange Act and Section 404 of the Sarbanes-Oxley Act, 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 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 and restrict our ability to access financing. In addition, we are required under applicable law and regulations to integrate 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

Edgar Filing: MASIMO CORP - Form 10-Q

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 in 2007. 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 December 31, 2008. If we fail to achieve and maintain the adequacy of our internal control and do not address the deficiencies identified by our auditors, we may not be

Table of Contents

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.

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. You may not be able to resell your shares at or above the initial public offering price 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:

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 Securities and Exchange Commission, or SEC;

strategic actions by us or our competitors, such as acquisitions or restructurings;

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

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

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

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

our inability to raise additional capital as needed;

concern as to the efficacy of our products;

changes in financial markets or general economic conditions;

sales of 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.

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

As of September 29, 2007, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 20.4% of our outstanding common stock. As a result, these stockholders, subject to any fiduciary duties owed to our other stockholders under Delaware law, 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 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.

If there are substantial sales of our common stock, our stock price could decline. *

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that these sales may occur, the market price of our common stock could decline. As of September 29, 2007, we had approximately 54,646,932 shares of common stock outstanding. Of these, 14,922,279 shares were freely tradable as of that date and 69,300

Table of Contents

shares became eligible for sale in the public market beginning on November 6, 2007 without restriction or further registration under the federal securities laws, unless held by our affiliates. Taking into consideration the effect of lock-up agreements entered into by our stockholders with the underwriters of our initial public offering, the remaining 39,655,353 shares will be available for sale pursuant to Rules 144 and 701, and the volume, manner of sale and other limitations under these rules, as follows:

39,578,503 shares of common stock will be eligible for sale in the public market beginning on February 4, 2008, unless the lock-up period is otherwise extended pursuant to its terms; and

the remaining 57,000 shares of common stock will be eligible for sale in the public market at various times thereafter. Piper Jaffray & Co. may waive the restrictions set forth in the lock-up agreements in their sole discretion at any time.

Existing stockholders holding an aggregate of 30,112,503 shares of common stock have rights with respect to the registration of these shares of common stock with the SEC. If we register their shares of common stock following the expiration of the lock-up agreements, they can immediately sell those shares in the public market.

We intend to register 3,000,000 shares of our common stock reserved under our 2007 Stock Incentive Plan and up to approximately 10,805,217 shares of common stock that are authorized for issuance under our other stock incentive plans. As of September 29, 2007, 8,156,175 shares were subject to outstanding options, of which 3,875,599 options were vested and exercisable as of that date. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above and restrictions on our affiliates.

Our corporate documents and Delaware law contain provisions that could discourage, delay or prevent a change in control of our company. *

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 approximately one third of the directors coming up for reelection each year. A staggered board will make it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

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

In addition, our board of directors has adopted a form of stockholder rights plan. We expect our pricing committee to implement the stockholder rights plan in the near future. The stockholder rights plan will grant all of our stockholders other than the acquiring person the right to purchase common stock at a price of \$136.00 per share 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. 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.

We have never operated as a public company. As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, we will be 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 will require that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act will require that we maintain effective disclosure

Edgar Filing: MASIMO CORP - Form 10-Q

controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures

Table of Contents

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 Global Market, 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, results of operations and cash flows.

We will be exposed to risks relating to evaluations of 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 the NASDAQ Global Market. 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 the NASDAQ Global Market. 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, therefore, 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. Therefore, you should not expect to receive dividend income from shares of our common stock.

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.

Table of Contents

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

(a) Sales of Unregistered Securities

During the three months ended September 29, 2007, we issued and sold 42,650 shares of our common stock that were not registered under the Act to our employees upon the exercise of options for aggregate cash consideration of \$136,258. These securities were issued in reliance upon the exemption from registration provided under Section 4(2) of the Act or Rule 701 promulgated under the Act. During the same period, we granted options to our employees to purchase 224,000 shares of common stock at a weighted average exercise price of \$16.00 per share. These options were granted prior to our initial public offering in reliance upon the exemption from registration provided under Section 4(2) of the Act or Rule 701 promulgated under the Act. The recipients of securities in each transaction represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution and appropriate legends were affixed to the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us.

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

Our initial public offering of our common stock, par value \$0.001, was effected through a Registration Statement on Form S-1 (File No. 333-142171) that was declared effective by the SEC on August 7, 2007. The Registration Statement covered the offer and sale by us of 3,287,494 shares of our common stock, which we sold to the public on August 13, 2007 at a price of \$17.00 per share. Our initial public offering commenced on April 17, 2007 and terminated following the sale of all of the securities registered under the Registration Statement. Our initial public offering resulted in aggregate proceeds to us of approximately \$47.8 million, net of underwriting discounts and commissions of approximately \$3.9 million and offering expenses of approximately \$4.2 million, through a syndicate of underwriters managed by Piper Jaffray & Co., Deutsche Bank Securities Inc., Citigroup Global Markets Inc., Cowen and Company, LLC and Thomas Weisel Partners LLC. We did not receive any proceeds from the sale of shares in the initial public offering by selling stockholders.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or person owning ten percent or more of any class of our equity securities or to any other affiliates. All offering expenses were paid directly to others.

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, investment-grade interest-bearing securities or guaranteed obligations of the U.S. government. 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 Act.

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: November 1, 2007

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

Date: November 1, 2007

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	(1) Amended and Restated Certificate of Incorporation (Exhibit 3.2)
3.2	(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 Company and certain of its stockholders (Exhibit 4.2)
10.1 +	(1) Form of Indemnity Agreement between the Company and its officers and directors (Exhibit 10.1)
10.2 +	(1) Employment Agreement, dated July 19, 2007, between the Company and Joe E. Kiani (Exhibit 10.2)
10.3 +	(1) 2007 Stock Incentive Plan, effective August 7, 2007, and forms of agreements related thereto (Exhibit 10.33)
10.4 +	(1) 2007 Severance Protection Plan, effective July 19, 2007 (Exhibit 10.42)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certifications of Chief Executive Officer and 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 with the SEC on April 17, 2007. The number given in parenthesis indicates the corresponding exhibit number in such Form S-1.
+	Indicates management contract or compensatory plan.