

MASIMO CORP
Form 10-Q
October 29, 2008
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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 27, 2008

OR

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

Commission File Number 001-33642

Masimo Corporation

(Exact Name of Registrant as Specified in its Charter)

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

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

40 Parker
Irvine, California
(Address of Principal Executive Offices)

92618
(Zip Code)

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

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

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

Large Accelerated Filer

Accelerated Filer

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

Smaller Reporting Company

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

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

Class	Number of Shares Outstanding as of September 27, 2008
Common stock, \$0.001 par value	57,013,856

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FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 27, 2008

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

(in thousands, except share amounts)

	December 29, 2007	September 27, 2008 (Unaudited)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 96,733	\$ 122,603
Accounts receivable, net of allowance for doubtful accounts of \$1,370 and \$1,287 at December 29, 2007 and September 27, 2008, respectively	26,970	29,511
Royalties receivable	13,866	11,375
Inventories	23,110	29,261
Prepaid expenses	7,084	7,998
Deferred tax assets	14,334	14,334
Other current assets	1,543	873
Total current assets	183,640	215,955
Deferred cost of goods sold	26,249	27,031
Property and equipment, net	11,164	12,816
Deferred tax assets	5,332	5,332
Intangible assets, net	5,589	7,289
Other assets	3,537	2,809
Total assets	\$ 235,511	\$ 271,232
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	\$ 14,640	\$ 14,510
Accrued compensation	12,409	13,404
Accrued liabilities	6,394	6,105
Deferred revenue	16,827	18,606
Current portion of long-term debt	11,539	548
Total current liabilities	61,809	53,173
Long-term debt, less current portion	19,502	202
Other liabilities	4,134	4,048
Total liabilities	85,445	57,423
Commitments and contingencies		
Stockholders equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized at December 29, 2007 and September 27, 2008; 0 shares issued and outstanding at December 29, 2007 and September 27, 2008		
Common stock, \$0.001 par value, 100,000,000 shares authorized at December 29, 2007 and September 27, 2008; 54,692,232 and 57,013,856 shares issued and outstanding at December 29, 2007 and	55	57

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September 27, 2008, respectively		
Treasury stock, 156,240 shares at December 29, 2007 and September 27, 2008	(1,209)	(1,209)
Additional paid-in capital	143,297	174,245
Accumulated other comprehensive loss	(1,034)	(698)
Retained earnings	8,957	41,414
 Total stockholders' equity	 150,066	 213,809
 Total liabilities and stockholders' equity	 \$ 235,511	 \$ 271,232

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

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MASIMO CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(in thousands, except share information)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 29, 2007	September 27, 2008	September 29, 2007	September 27, 2008
Revenue:				
Product	\$ 51,122	\$ 66,001	\$ 144,513	\$ 187,524
Royalty and license fee	13,254	12,131	42,497	36,484
Total revenue	64,376	78,132	187,010	224,008
Cost of goods sold	18,809	22,393	53,630	64,917
Gross profit	45,567	55,739	133,380	159,091
Operating expenses:				
Research and development	6,540	6,020	17,455	18,298
Selling, general and administrative	21,594	29,167	64,575	89,062
Antitrust litigation	508	46	982	491
Total operating expenses	28,642	35,233	83,012	107,851
Operating income	16,925	20,506	50,368	51,240
Non-operating income (expense):				
Interest income	726	545	1,270	2,129
Interest expense	(719)	(19)	(1,831)	(722)
Other	559	(413)	770	(235)
Total non-operating income (expense)	566	113	209	1,172
Income before provision for income taxes	17,491	20,619	50,577	52,412
Provision for income taxes	6,941	7,554	20,377	19,955
Net income	10,550	13,065	30,200	32,457
Accretion of preferred stock	(925)		(4,837)	
Undistributed income attributable to preferred stockholders	(2,739)		(13,526)	
Net income attributable to common stockholders	\$ 6,886	\$ 13,065	\$ 11,837	\$ 32,457
Net income per common share:				
Basic	\$ 0.18	\$ 0.23	\$ 0.49	\$ 0.58
Diluted	\$ 0.16	\$ 0.22	\$ 0.40	\$ 0.54

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):

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	Three Months Ended		Nine Months Ended	
	September 29, 2007	September 27, 2008	September 29, 2007	September 27, 2008
Cost of goods sold	\$ 56	\$ 55	\$ 134	\$ 159
Research and development	191	608	466	1,627
Selling, general and administrative	\$ 697	\$ 1,328	\$ 1,992	\$ 3,952

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

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

	Nine Months Ended	
	September 29, 2007	September 27, 2008
Cash flows from operating activities:		
Net income	\$ 30,200	\$ 32,457
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,896	4,226
Stock-based compensation	2,592	5,738
Provision for doubtful accounts	296	20
Provision for obsolete inventory	1,080	1,175
Provision for warranty costs	1,190	1,085
Benefit from deferred income taxes	(323)	
Income tax benefit from exercise of stock options		14,488
Excess tax benefit from share based payment arrangements		(2,449)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(5,117)	(2,428)
(Increase) decrease in royalties receivable	(11,836)	2,491
Increase in inventories	(6,858)	(7,287)
Increase in deferred cost of goods sold	(3,301)	(797)
Increase in prepaid expenses	(1,179)	(887)
(Increase) decrease in other assets	(1,245)	1,422
Increase (decrease) in accounts payable	79	(126)
Increase (decrease) in accrued compensation	(1,868)	882
Decrease in accrued liabilities	(1,279)	(1,397)
Increase in income taxes payable	4,819	2,453
Increase in deferred revenue	4,200	1,516
Increase (decrease) in other liabilities	(401)	65
Net cash provided by operating activities	14,945	52,647
Cash flows from investing activities:		
Purchases of property and equipment	(3,850)	(5,344)
Increase in intangible assets	(865)	(2,195)
Net cash used in investing activities	(4,715)	(7,539)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	20,075	
Repayments on long-term debt	(7,056)	(30,310)
Proceeds from issuance of common stock	626	8,477
Proceeds from initial public offering, net of issuance costs	47,849	
Excess tax benefit from share based payment arrangements		2,449
Dividends paid	(37,350)	(13)
Purchase of treasury stock	(581)	
Net cash used in financing activities	23,563	(19,397)

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Effect of foreign currency exchange rates on cash	(618)	159
Net increase in cash and cash equivalents	33,175	25,870
Cash and cash equivalents at beginning of period	55,382	96,733
Cash and cash equivalents at end of period	\$ 88,557	\$ 122,603

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

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MASIMO CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. Description of the Company

Masimo Corporation, or the Company, is a global medical technology company that develops, manufactures and markets non-invasive patient monitoring products that improve patient care. The Company invented Masimo Signal Extraction Technology, or Masimo SET, which provides the capabilities of Measure-Through Motion and Low Perfusion pulse oximetry to address the primary limitations of conventional pulse oximetry. The Company markets a family of non-invasive blood constituent patient monitoring solutions that consists of a monitor or circuit board and their proprietary single-patient use and reusable sensors and cables. Since 2005, the Company has introduced a variety of new non-invasive measurements expanding the capability of the Company's Masimo Rainbow SET platform. The Company sells to hospitals and the emergency medical services, or EMS, market through its direct sales force and distributors, and markets its circuit boards containing the Company's proprietary algorithm and software architecture to original equipment manufacturer, or OEM, partners. The Company considers both the pulse oximetry device and its consumable sensors and cables to be products as defined in its statements of income.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated balance sheet as of September 27, 2008, the condensed consolidated statements of income for the three and nine months ended September 29, 2007 and September 27, 2008, the condensed consolidated statements of cash flows for the nine months ended September 29, 2007 and September 27, 2008, and other information disclosed in the related condensed consolidated notes are unaudited. The condensed consolidated balance sheet as of December 29, 2007 was derived from the Company's audited consolidated financial statements at that date. The accompanying financial statements should be read in conjunction with the audited consolidated financial statements and related notes contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2007, filed with the U.S. Securities and Exchange Commission, or SEC, on March 4, 2008.

The accompanying condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the SEC. Certain information and note disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company's consolidated financial position as of September 27, 2008, consolidated results of operations for the three and nine months ended September 29, 2007 and September 27, 2008, and consolidated cash flows for the nine months ended September 29, 2007 and September 27, 2008. The results for the three and nine months ended September 27, 2008 are not necessarily indicative of the results to be expected for the fiscal year ending January 3, 2009 or for any other interim period or for any future year.

Fiscal Periods

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

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Principles of Consolidation

The condensed consolidated financial statements include the accounts of Masimo Corporation and Masimo Laboratories, Inc., which has been consolidated pursuant to FIN 46(R), *Consolidation of Variable Interest Entities an Interpretation of ARB No. 51*. In addition, these condensed consolidated financial statements include the accounts of Masimo Corporation's wholly-owned subsidiaries, Masimo Americas, Inc., Masimo Europe Ltd., Masimo Japan, Masimo Canada ULC and Masimo Australia Pty. Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, establishes requirements for reporting and disclosure of comprehensive income and its components. Comprehensive income includes foreign currency translation adjustments and other items that have been excluded from net income and reflected in stockholders' equity.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates include: determination of accounts receivable allowances, inventory reserves, warranty reserves, rebate reserves, valuation of the Company's 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.

Fair Value Measurements

Effective December 30, 2007, the Company adopted Statement of Financial Accounting Standard No. 157, or SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. In February 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, effective December 30, 2007, the Company adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only.

SFAS 157 describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1 - Quoted prices in active markets for *identical* assets or liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for *similar* assets or liabilities; quoted prices in markets that are not active; or other inputs that can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The estimated fair values of the Company's financial instruments, which include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, income taxes payable and long-term debt, approximate their carrying values due to their short maturities and because the weighted average borrowing rate of the long-term debt approximates the current market rates for similar borrowings. These items are classified as either Level 1 or Level 2 inputs. Cash equivalents consist of highly liquid investments, with a maturity of three months or less at the

date of purchase, including U.S. Treasury bills and money market funds.

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Effective December 30, 2007, the Company adopted SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159. SFAS 159 allows an entity the irrevocable option to elect fair value for the initial and subsequent measurement for specified financial assets and liabilities on a contract-by-contract basis. The Company did not elect the fair value option under this statement as to specific assets or liabilities. Therefore, through September 27, 2008, the Company has not recognized the net change in fair value of their U.S. Treasury bills.

The Company records U.S. Treasury bills at cost and continues to carry those amounts at cost, which approximates, but does not equal fair value. The fair value of the U.S. Treasury bills at September 27, 2008, excluding accrued interest, was \$103.9 million as compared to a cost of \$103.8 million. The fair value is based on quoted market prices in active markets for identical assets, level 1 input.

The Company records money market funds at cost and continues to carry those amounts at cost which equals fair value. The fair value is based on quoted market prices in active markets for identical assets, level 1 input. As of September 27, 2008, the cost and fair value of our money market funds was equal to \$11.9 million.

Revenue Recognition and Deferred Revenue

The Company recognizes revenue pursuant to the requirements of American Institute of Certified Public Accountants, or AICPA, Statement of Position, or SOP, 97-2, *Software Revenue Recognition*, as amended by SOP 98-9, *Software Revenue Recognition, With Respect to Certain Transactions*, Financial Accounting Standards Board, or FASB, Emerging Issues Task Force, or EITF, Issue No. 03-5, *Applicability of AICPA Statement of Position 97-2 to Non-Software Deliverables in an Arrangement Containing More-Than-Incidental Software*, and other authoritative accounting guidance.

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

The Company's sales under long-term purchase contracts are generally structured such that the Company agrees to provide up-front and at no charge certain monitoring equipment, installation, training and ongoing warranty support in exchange for the hospital's agreement to purchase sensors over the term of the agreement, which ranges from three to six years. The Company does not recognize any revenue when the monitoring and related equipment is delivered to the hospitals and installation and training is complete. The Company recognizes revenue for all of the delivered elements, on a pro-rata basis, as the sensors are delivered under the long-term purchase commitment. The cost of the monitoring equipment initially placed at the hospitals is deferred and amortized to cost of goods sold over the life of the underlying long-term sensor contract.

In situations where VSOE does not exist for undelivered elements, the contract product revenue and corresponding cost of goods sold are deferred until either the element is delivered or VSOE is established. For the three and nine months ended September 29, 2007, \$888,000 and \$3.5 million, respectively, of contract product revenue was deferred. During the three and nine months ended September 29, 2007, \$2.0 million of previously deferred revenue was recognized related to the delivery of an upgrade which occurred during the third quarter of 2007. Deferred costs associated with this revenue aggregating \$718,000 were expensed in the same 2007 periods. For the three and nine months ended September 27, 2008, \$672,000 and \$3.1 million, respectively, of contract product revenue was deferred. During the three and nine months ended September 27, 2008, \$2.6 million of previously deferred revenue was recognized, including \$1.9 million related to an agreement in which VSOE was established as a result of a contract amendment providing the Company the option to substitute a deliverable with VSOE in place of a deliverable with no VSOE and \$683,000 related to the collection of cash for sales which had been deferred due to uncertainty over collectability. Deferred costs associated with this revenue aggregating \$852,000 were expensed in the same 2008 periods. Pursuant to the Company's revenue recognition policy, it expects to continue to defer revenue and the related costs of goods sold, and recognize previously deferred revenue in future periods as required under applicable accounting guidance.

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The Company's distributors purchase primarily sensor products which they then resell to hospitals that are typically fulfilling their purchase obligation to the Company under the end-user hospital's long-term sensor purchase commitments. Upon shipment to the distributor, revenue is deferred until the Company's commitment to their end user consumer is fulfilled, which occurs when the sensors are sold by the distributor to the end-user hospital. The Company also provides certain end-user hospitals with the ability to purchase sensors under rebate programs. Under these programs, the end-user hospitals may earn rebates based on their purchasing activity. The Company estimates and provides allowances for these programs at the time of sale as a reduction to revenues and an increase to deferred revenues.

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

Changes in the product warranty accrual for the nine months ended September 29, 2007 and September 27, 2008 were as follows (in thousands):

	Nine Months Ended	
	September 29, 2007	September 27, 2008
Warranty accrual, beginning of period	\$ 599	\$ 649
Provision for warranty costs	1,190	1,085
Warranty expenditures	(1,019)	(1,380)
Warranty accrual, end of period	\$ 770	\$ 354

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 stockholders. The Company's previously outstanding Series A through G preferred stock were participating securities because 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 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 27, 2008 using the if-converted method for the entire periods.

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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.

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 29, 2007	September 27, 2008	September 29, 2007	September 27, 2008
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	\$ 13,065	\$ 5,329	\$ 32,457
Weighted average common shares outstanding single class (2)	54,630,610	56,774,983	54,630,610	56,016,978
Basic net income per share for period during which single class of equity securities was outstanding	\$ 0.10	\$ 0.23	\$ 0.10	\$ 0.58
Basic net income per common share	\$ 0.18	\$ 0.23	\$ 0.49	\$ 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	\$ 13,065	\$ 5,329	\$ 32,457
Weighted average common shares outstanding single class (2)	54,630,610	56,774,983	54,630,610	56,016,978
Diluted common share equivalent: stock options	4,747,848	3,601,755	4,747,848	4,159,815
	59,378,458	60,376,738	59,378,458	60,176,793
Diluted net income per share for period during which single class of equity securities was outstanding	\$ 0.10	\$ 0.22	\$ 0.09	\$ 0.54

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Diluted net income per common share	\$	0.16	\$	0.22	\$	0.40	\$	0.54
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- (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.

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- (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.

New Accounting Pronouncements

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141(R), or SFAS No. 141(R), *Business Combinations*. SFAS No.141(R) provides greater consistency in the accounting and financial reporting of business combinations. It requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. If the Company consummates any acquisitions on or after January 4, 2009, the purchase accounting treatment could result in a material difference from current accounting treatment.

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

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

In May 2008, the FASB issued Statement of Financial Accounting Standard No. 162, or SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles. SFAS No. 162 will become effective on November 15, 2008. The Company does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September 29, 2007	September 27, 2008	September 29, 2007	September 27, 2008
Net income	\$ 10,550	\$ 13,065	\$ 30,200	\$ 32,457
Other comprehensive income (loss):				
Foreign currency translation adjustments	(48)	225	(356)	336
Comprehensive income	\$ 10,502	\$ 13,290	\$ 29,844	\$ 32,793

4. Masimo Laboratories, Inc.

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

Pursuant to FASB Interpretation No. 46(R), or FIN 46(R), *Consolidation of Variable Interest Entities - an Interpretation of ARB No. 51*, 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. The Company may discontinue consolidating Masimo Labs in the event it is permitted under FIN 46(R).

5. Related Party Transactions

As of December 29, 2007 and September 27, 2008, the Company had amounts due from employees of \$598,000 and \$230,000, respectively. As of December 29, 2007 and September 27, 2008, these amounts are classified in other current assets and other assets in the accompanying condensed consolidated balance sheet.

The Company's Chief Executive Officer has been a member of the board of directors of Saba Software, Inc., a human capital development and management solutions provider, since 1997. The Company has paid Saba Software \$22,000 and \$81,000 during the nine months ended September 29, 2007 and September 27, 2008, respectively, for various software products and services.

6. Royalties Receivable

The royalty receivable of \$13.9 million as of December 29, 2007 represents the amount received in February 2008, for the three months ended December 29, 2007. The royalty receivable of \$11.4 million as of September 27, 2008 represents the Company's estimated amount due for the three months ended September 27, 2008. Pursuant to the settlement agreement with Nellcor Puritan Bennett, Inc. (currently Covidien Ltd., or Covidien), the royalties are paid to the Company based on sales of Covidien U.S. based pulse oximetry products. The Company recognizes royalty revenue based on the royalty rate per the settlement agreement multiplied by its estimate of Covidien's sales for each quarter. Any adjustments to the quarterly estimate are recorded prospectively in the following quarter, when the Company receives the Covidien royalty report, which is generally 60 days after the end of each quarter.

7. Inventories

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

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Inventories consist of the following (in thousands):

	December 29, 2007	September 27, 2008
Raw materials	\$ 13,173	\$ 18,842
Work in-process	1,956	2,347
Finished goods	7,981	8,072
Total	\$ 23,110	\$ 29,261

8. Long-Term Debt

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

	December 29, 2007	September 27, 2008
Total debt	\$ 30,771	\$ 510
Less current portion of long-term debt	(11,477)	(480)
Long-term portion	\$ 19,294	\$ 30

As of September 27, 2008, the Company had one arrangement, which allows for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements. This agreement provides for an equipment line whereby draws are collateralized by (i) equipment and (ii) either a future revenue stream associated with the long-term sensor purchase agreement or a defined repayment schedule associated with the long-term sensor purchase agreement. The related equipment securing these borrowings is recorded on the Company's condensed consolidated 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. The financing arrangement is 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. As of September 27, 2008, no hospitals have defaulted under this program.

At September 27, 2008, the carrying value of the equipment collateralizing the borrowing was \$64,000. During the nine months ended September 27, 2008, the Company repaid \$26.7 million, or the entire amount owed, on a previous arrangement plus \$168,000 in prepayment fees which are included in other non-operating income (expense). As of September 27, 2008, principal and interest payments under the remaining financing agreement were \$52,000 per month based on an average interest rate of 7.1% per year.

The Company currently has seven capital leases related to office equipment. These leases have interest rates ranging from 5.2% to 8.8% per year and mature on various dates from December 2009 through April 2013. As of September 27, 2008, the total future remaining interest cost was \$27,000. Not including this interest expense, the capital lease obligations consist of the following (in thousands):

	December 29, 2007	September 27, 2008
Capital lease obligations	\$ 270	\$ 240
Less current portion of capital lease obligations	(62)	(68)
Long-term portion	\$ 208	\$ 172

9. Cash Dividends

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

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In December 2006, the Company declared an additional cash dividend of \$0.725 per share, in the aggregate amount of \$37.1 million to holders of the Company's common and preferred stock, assuming the conversion of all outstanding shares of preferred stock into an aggregate of 34,612,503 shares of common stock. Of the total cash dividends declared in both March and December 2006, the Company paid in aggregate \$37.2 million in the first six months of 2007 and \$180,000 in the third quarter of 2007. No dividends were declared or paid in the fourth quarter of 2007, or the first or second quarters of 2008. In the third quarter of 2008, the Company paid \$13,000 in dividends. The total outstanding dividends payable balances as of December 29, 2007 and September 27, 2008 were \$183,000 and \$170,000, respectively.

10. Stock Based Compensation

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

On August 7, 2007, in connection with the Company's initial public offering, the 2007 Stock Incentive Plan, or the 2007 Plan, became effective. Under the 2007 Plan, 3,000,000 shares of common stock are reserved for future issuance, plus any shares available under the prior year stock option plans, including shares that become available due to forfeitures at prices not less than the fair market value of the Company's common stock on the date the option is granted. In addition, the 2007 Plan includes an evergreen provision which automatically increases the number of shares reserved for issuance on the first day of each fiscal year by 3% of the shares outstanding on last day of the immediately preceding fiscal year. However, on February 7, 2008, the Company's Board of Directors amended the Company's 2007 Plan to decrease the number of shares reserved under the plan by 1,640,748 shares of common stock, the exact amount automatically added to the share reserve effective December 30, 2007, pursuant to the evergreen provision.

The options granted under the 2007 Plan generally vest annually over five years using the straight-line method, unless otherwise provided, and expire ten years from the date of grant. The number and weighted average exercise price of options issued and outstanding under all stock option plans, at exercise prices ranging between \$1.33 and \$41.51 per share, are as follows:

	Nine Months Ended September 27, 2008	
	Shares	Average Exercise Price
Options outstanding, beginning of period	8,321,191	\$ 7.53
Granted	2,123,550	\$ 32.58
Canceled	(742,262)	\$ 17.96
Exercised	(2,321,624)	\$ 3.65
Options outstanding, end of period	7,380,855	\$ 14.91
Options exercisable, end of period	2,740,887	\$ 5.02
Options available for grant, end of period	4,014,788	

The weighted-average fair value of options granted was \$13.88 for the nine months ended September 27, 2008.

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The Company applies the provisions of Staff Accounting Bulletin, or SAB, No. 107 *Share-Based Payment* and SAB No. 110, *Share-Based Payment* in its application of SFAS No. 123(R), *Share-Based Payment*. The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions used for grants:

	Three Months Ended		Nine Months Ended	
	September 29, 2007	September 27, 2008	September 29, 2007	September 27, 2008
Risk-free interest rate	4.8%	3.3%	4.7%	3.2%
Expected term	6.5 years	6.5 years	6.5 years	6.5 years
Estimated volatility	38.1%	36.6%	39.3%	36.7%
Expected dividends	0%	0%	0%	0%

In accordance with SFAS 123(R), the Company recorded stock-based compensation expense of \$944,000 and \$2.2 million during the three and nine months ended September 29, 2007, respectively, and \$2.0 million and \$5.7 million during the three and nine months ended September 27, 2008, respectively.

The aggregate intrinsic value of options outstanding as of September 27, 2008 was \$167.1 million. The aggregate intrinsic value of options exercisable as of September 27, 2008 was \$88.8 million. The aggregate intrinsic value of options exercised during the three months ended September 27, 2008 was \$19.1 million. The aggregate intrinsic value is calculated as the difference between the market value of the Company's common stock on the date of exercise or the respective period end, as appropriate, and the exercise price of the options. The unrecognized stock based compensation as of September 27, 2008 was \$43.3 million related to unvested options granted after January 1, 2006. The weighted average remaining contractual term of options outstanding as of September 27, 2008 was 7.2 years. The weighted average remaining contractual term of options exercisable as of September 27, 2008 was 5.2 years. The total fair value on the respective vesting dates of all options vesting during the three months ended September 27, 2008 was \$6.6 million.

In February 2007, the Company repurchased 11,640 shares of common stock at an average price of \$13.56 per share totaling \$158,000 from a former employee. The difference between the repurchase price and the original option exercise price totaled \$134,000 and was recorded as operating expense during the three months ended March 31, 2007. In May 2007, the Company repurchased another 30,000 shares of common stock at an average price of \$14.09 per share, totaling \$423,000, from another former employee. The difference between the repurchase price and the original option exercise price totaled \$283,000 and was recorded as operating expense during the three months ended June 30, 2007. All these shares were recorded in treasury stock and are available for reissue. Since these events occurred prior to the Company's initial public offering, no public announcement regarding stock repurchase was made. No shares were repurchased during the three months ended September 29, 2007.

11. Commitments and Contingencies**Leases**

The Company leases its facilities in North America, Europe and Asia under operating lease agreements expiring at various dates through August 2014. Certain facilities leases contain pre-determined price escalations. The Company recognizes the lease costs using a straight line method based on total lease payments. As of December 29, 2007 and September 27, 2008, rent expense accrued in excess of the amount paid aggregated \$625,000 and \$375,000, respectively, and is classified in other liabilities. The Company also leases automobiles in Europe and Japan that are classified as operating leases and expire at various dates through October 2010.

Future minimum lease payments under operating and capital leases for each of the following fiscal years ending on or about December 31 are (in thousands):

	As of September 27, 2008		
	Operating Leases	Capital Leases	Total
2008 (balance of year)	\$ 818	\$ 20	\$ 838
2009	2,650	81	2,731

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2010	988	70	1,058
2011	521	56	577
2012	508	40	548
Thereafter	812		812
Total	\$ 6,297	\$ 267	\$ 6,564

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Rental expense related to operating leases was \$560,000 and \$1.6 million for the three and nine months ended September 29, 2007, respectively, and was \$842,000 and \$2.5 million for the three and nine months ended September 27, 2008, respectively.

Employee Retirement Savings Plan

The Masimo Retirement Savings Plan, or the Plan, 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 \$251,000 and \$710,000 to the Plan for the three and nine months ended September 29, 2007, respectively, and \$287,000 and \$864,000 to the Plan for the three and nine months ended September 27, 2008, respectively.

Employment Agreements

As of September 27, 2008, the Company had an employment agreement with one of its key employees that provides for an aggregate annual base salary of \$686,400, plus other benefits, with annual increases at the discretion of the Board of Directors. The agreement with the Company also provides for an annual bonus based on the Company's attainment of certain objectives and goals. The agreement automatically renews on a daily basis and terminates three years from the date either party gives notice of termination to the other party.

As of September 27, 2008, the Company had an additional employment agreement with one of its key employees, which provides for an annual base salary of EUR 150,000 (approximately \$219,000 as of September 27, 2008). The agreement also contemplates an annual bonus based on the attainment of certain revenue, gross margin and operating income milestones. The agreement also contains a non-compete provision. If the Company enforces the non-compete 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 must be paid in equal installments over the term of the non-competition period.

Severance Agreements

On January 11, 2008, the Company entered into a severance plan participation agreement with three of its executive officers. The participation agreements, or Agreements, are governed by the terms and conditions of the Company's 2007 Severance Protection Plan, or Severance Plan, which became effective on July 19, 2007. Under an Agreement, the executive officer may be entitled to receive certain salary, equity, medical and life insurance benefits if he is terminated by the Company without cause or terminates his employment for good reason under certain circumstances.

Purchase Commitments

Pursuant to contractual obligations with vendors, the Company had \$16.9 million of purchase commitments as of September 27, 2008. 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. As of September 27, 2008, the Company had \$6.9 million of bank balances of which \$6.5 million was in excess of the Federal Deposit Insurance Corporation limit. The Company invests its excess cash deposits in U.S. Treasury bills and money market accounts with major financial institutions. As of September 27, 2008, the Company had \$103.8 million in U.S. Treasury bills which are backed by the U.S. federal government. Also, as of September 27, 2008, the Company had \$11.9 million in money market accounts, of which \$6.9 million was covered under the U.S. Treasury Department Temporary Guarantee Program for Money Market Funds effective on September 19, 2008.

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

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The Company's ability to sell its products to U.S. hospitals depends in part on its relationships with Group Purchasing Organizations, or GPOs. Many existing and potential customers for the Company's products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. During the three and nine months ended September 29, 2007, shipments of the Company's pulse oximetry products to U.S. hospitals that are members of GPOs amounted to \$24.4 million and \$72.9 million, respectively. In the three and nine months ended September 27, 2008, shipments to U.S. hospitals that are members of GPOs were \$35.4 million and \$99.1 million, respectively.

For the three months ended September 29, 2007, no customers represented over 10% of the Company's total revenue. For the nine months ended September 29, 2007, one customer represented 10.6% of the total revenue. For the three and nine months ended September 27, 2008, one customer represented 10.3% and 11.7% of the total revenue, respectively.

At December 29, 2007, two customers represented 8.4% and 5.3% of accounts receivable. At September 27, 2008, one customer represented 5.2% of accounts receivable.

Litigation

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

In March 2005, a jury found that Tyco Healthcare's use of sole-source contracts, product bundling, market share-based compliance pricing contracts and co-marketing agreements with patient monitoring companies were unlawful restraints of trade and exclusionary dealing arrangements and, as a result, violated federal antitrust laws. The jury awarded the Company \$140 million in damages. Under the antitrust laws, if the jury verdict is sustained in whole or in part, all damages are trebled. Tyco Healthcare filed post-trial motions requesting that the District Court either override the jury decision or grant a new trial. In March 2006, the District Court upheld a portion of the jury verdict and vacated the remaining verdict. In addition, the District Court vacated the jury's damages award and granted Tyco Healthcare a new trial on damages. As a result, the Company may not receive any damages in this lawsuit. The District Court held an evidentiary hearing in October 2006 to re-try the damages. On January 25, 2007, the District Court issued a preliminary ruling which did not set damages, but resolved some issues of dispute about damages, and ordered another evidentiary hearing on issues still undecided by the District Court. The District Court held this evidentiary hearing in March 2007. On July 2, 2007, the District Court entered its final judgment awarding the Company damages which were trebled to \$43.5 million and denying the Company's request for a permanent injunction with respect to Tyco Healthcare's business practices found to be anti-competitive. The Company and Tyco Healthcare have each filed a notice of appeal from the judgment. The Company filed its opening brief on December 17, 2007 with the United States Court of Appeals for the 9th Circuit. On December 27, 2007, the Consumer Federation of America and Medical Device Manufacturers Association filed an Amicus brief supporting Masimo. Tyco filed its opposition and appeal brief on March 3, 2008 and a group of law professors filed an Amicus brief supporting Tyco on March 10, 2008. Even if the Company is ultimately awarded damages in this litigation, the amount will be subject to a 50% legal fee contingency agreement, in which case the Company would receive 50% of the net (of costs) proceeds from the award. Even though most of the legal expenses to date have been on a contingency basis, the Company expects to incur expenses related to the appellate work, which will be reported as operating expense within the Company's statements of income.

The Company believes the jury verdict it received in the Tyco Healthcare antitrust litigation has been important in its efforts to increase its market share among certain large hospital systems and GPOs that were formerly closed as a result of Tyco Healthcare's anti-competitive conduct. See **Risk Factors** for a description of the risks related to the Company's litigation against Tyco Healthcare.

On July 24, 2007, Shaklee Corporation filed suit against the Company in the United States District Court, Central District of California, alleging that the Company's pulse oximeters incorporate patented calibration methods that are licensed to Shaklee. NIR Diagnostics, Inc., the original licensee of the patents, was originally named as a defendant, but then agreed to become a plaintiff in the action. Shaklee and NIR sought an injunction and damages against the

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Company. On August 27, 2008, the Company settled all pending litigation brought by Shaklee and NIR against the Company. Pursuant to the settlement, Shaklee and NIR dismissed all outstanding claims against the Company with prejudice, and the Company dismissed all outstanding claims against Shaklee and NIR without prejudice. The settlement was reached without the Company incurring any liability to either Shaklee or NIR.

On February 19, 2008, the Company filed a lawsuit against Respironics, Inc. for breach of contract, breach of the covenant of good faith and fair dealing, and interference with prospective economic advantage, based on a January 16, 2006, contract between Respironics and the Company. On April 7, 2008, Respironics filed a demurrer seeking to dismiss the lawsuit on the grounds that the Company's complaint fails to state sufficient facts to constitute valid claims. The court subsequently denied Respironics' demurrer. On July 16, 2008, Respironics answered the Company's complaint and filed a cross-complaint. The Company answered the cross-complaint on August 15, 2008, denying all material allegations. There is no guarantee that the Company will prevail in this suit or receive any damages or other relief if it does prevail.

From time to time, the Company may be involved in litigation relating to claims arising out of its operations in the normal course of business. The Company believes that it currently is not a party to any legal proceedings which, individually or in the aggregate, would have a material adverse effect on its consolidated financial position, results of operations, or cash flows.

Voluntary Recall

On July 31, 2007, the Company initiated a voluntary recall of its Rad-9 pulse oximeter, a standalone bedside pulse oximeter product, sales of which represented less than 0.2% and 0.3% of the Company's product revenue in the three and nine months ended September 27, 2008, respectively. In accordance with its original design and similar to other pulse oximeter devices, the Rad-9 gives a visual alarm if there is a sensor fault; under other circumstances, the Rad-9 gives both a visual and audio alarm. In late 2006, the Company sent notice to owners of the Rad-9 that a free upgrade was available to add an audio alarm to the Rad-9 when a sensor fault is detected. Although the Company received notification from the U.S. Food and Drug Administration, or FDA, that recall of its Rad-9 was not mandatory, the Company decided to voluntarily recall the Rad-9 and implement this upgrade. The Company does not believe that a non-upgraded Rad-9 poses a significant risk to health or would cause serious injury or death. The Company decided to voluntarily recall the Rad-9 because it believes it has the possibility of improving the care of patients. This decision follows a customer report that an elderly patient, who may have damaged her pulse oximeter sensor, had died after removing her tracheostomy tube. Based on what is currently known, the Rad-9 appears to have been operating in accordance with its specifications. The Company had originally estimated that the total costs resulting from this voluntary recall would be approximately \$300,000, although this was an estimate and the actual costs could differ. The Company incurred this charge in the quarter ended September 29, 2007. As of September 27, 2008, the Company had incurred actual upgrade costs of approximately \$292,000 and does not expect to incur any additional costs in the future related to this recall. Any other future recalls could result in a diversion of management resources, substantial cost and negative publicity, all of which could adversely affect the Company's business, financial condition and results of operations.

12. Segment Information and Enterprise Reporting

The Company's chief decision maker, the Chief Executive Officer, reviews financial information presented on a consolidated basis, accompanied by disaggregated information about revenues by geographic region for purposes of making operating decisions and assessing financial performance. Accordingly, the Company considers itself to be in a single reporting segment, specifically non-invasive patient monitoring solutions and related products. The Company does not assess the performance of its geographic regions on other measures of income or expense, such as depreciation and amortization, operating income or net income. In addition, the Company's assets are primarily located in the United States and are not allocated to any specific region. The Company does not produce reports for, or measure the performance of, its geographic regions on any asset-based metrics. Therefore, geographic information is presented only for revenues.

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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 29, 2007		September 27, 2008		September 29, 2007		September 27, 2008	
North and South America	\$ 40,964	80.2%	\$ 51,494	78.0%	\$ 113,167	78.3%	\$ 144,515	77.1%
Europe, Middle East and Africa	6,309	12.3	9,202	14.0	20,029	13.9	27,767	14.8
Asia and Australia	3,849	7.5	5,305	8.0	11,317	7.8	15,242	8.1
Total product revenues	\$ 51,122	100%	\$ 66,001	100%	\$ 144,513	100%	\$ 187,524	100%

Sales to customers located in the United States were \$40.5 million and \$110.7 million for the three and nine months ended September 29, 2007, respectively, and \$50.0 million and \$140.0 million for the three and nine months ended September 27, 2008, respectively.

13. Income Taxes

In July 2006, the FASB issued Interpretation No. 48, or FIN 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109*, 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 September 27, 2008, the balance of the gross unrecognized tax benefit was \$3.5 million, of which \$2.3 million (net of federal benefit on state taxes), if recognized, would affect the effective tax rate. It is reasonably possible that the amount of unrecognized tax benefits will decrease in the next 12 months by \$242,000 primarily related to certain timing differences.

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

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

The provision for income taxes was \$6.9 million and \$20.4 million, or an effective tax rate of 39.7% and 40.3% for the three and nine months ended September 29, 2007, respectively. The provision for income taxes was \$7.6 million and \$20.0 million, or an effective tax rate of 36.6% and 38.1% for the three and nine months ended September 27, 2008, respectively. The effective tax rate differs from the statutory U.S. federal income tax rate of 35.0% primarily due to state taxes and other permanent differences between pre-tax income for financial reporting purposes and taxable income.

Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations

This quarterly report on Form 10-Q contains forward-looking statements as defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, in connection with the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. Such forward-looking statements include any expectation of earnings, revenues or other financial items; any statements of the plans, strategies and objectives of management for future operations; factors that may affect our operating results; statements concerning new products,

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technologies or services; statements related to future capital expenditures; statements related to future economic conditions or performance; statements as to industry trends and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as anticipate, believe, continue, could, estimate, expect, intend, may, or will, and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially and adversely from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled Risk Factors included elsewhere in this Form 10-Q and in our other SEC filings, including our Annual Report on Form 10-K for the fiscal year ended December 29, 2007, which we filed with the SEC on March 4, 2008. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statements.

Overview

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

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

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

The building of our installed base of pulse oximeters, Pulse Co-Oximeters and circuit boards generates recurring sales of our consumables, primarily single-patient use sensors. A user of one of our pulse oximeters or our OEMs' pulse oximeters can obtain the benefit of the Masimo SET or Masimo Rainbow SET only by using our proprietary sensors that are designed for our system. We estimate that our worldwide installed base was approximately 540,000 units as of September 27, 2008, up from 448,000 units as of September 29, 2007. We estimate our installed base to be the number of bedside pulse oximeters and circuit boards that we have shipped in the prior seven year period.

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

Masimo Laboratories

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

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

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

Pursuant to FASB Interpretation No. 46(R), or FIN 46(R), *Consolidation of Variable Interest Entities - an Interpretation of ARB No. 51*, Masimo Labs is consolidated within our financial statements for all periods presented. Accordingly, all royalties, option and license fees and other charges between us and Masimo Labs have been eliminated in the consolidated financial statements. We anticipate that we will continue to consolidate Masimo Labs pursuant to the guidance set forth in FIN 46(R); however, we may discontinue consolidating Masimo Labs in the event it is permitted under FIN 46(R).

Results of Operations

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

Upon closing of our 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, we use the if-converted method under SFAS 128 to calculate earnings per share.

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We believe that the following non-GAAP earnings per share information for the three and nine months ended September 29, 2007 is relevant and useful information that can be used by analysts, investors and other interested parties to assess our performance on a comparable basis to the three and nine months ended September 27, 2008 and future reported earnings per share. Accordingly, we are disclosing this unaudited information to permit additional analysis of our performance (in thousands, except share data):

	2007				2008	
	As Reported		Non-GAAP		As Reported	
	Three Months Ended September 29, 2007	Nine Months Ended September 29, 2007	Three Months Ended September 29, 2007	Nine Months Ended September 29, 2007	Three Months Ended September 27, 2008	Nine Months Ended September 27, 2008
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	\$ 13,065	\$ 32,457
Weighted average common shares outstanding single class (2)	54,630,610	54,630,610	53,064,738	51,860,652	56,774,983	56,016,978
Basic net income per share for period during which single class of equity securities was outstanding	\$ 0.10	\$ 0.10				
Basic net income per common share	\$ 0.18	\$ 0.49	\$ 0.20	\$ 0.58	\$ 0.23	\$ 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				

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	2007				2008	
	As Reported		Non-GAAP		As Reported	
	Three Months Ended September 29, 2007	Nine Months Ended September 29, 2007	Three Months Ended September 29, 2007	Nine Months Ended September 29, 2007	Three Months Ended September 27, 2008	Nine Months Ended September 27, 2008
Net income for period during which single class of equity securities was outstanding (1)	\$ 5,565	\$ 5,329	\$ 10,550	\$ 30,200	\$ 13,065	\$ 32,457
Weighted average common shares outstanding single class (2)	54,630,610	54,630,610	53,064,738	51,860,652	56,774,983	56,016,978
Diluted common share equivalent: stock options	4,747,848	4,747,848	4,527,282	4,231,074	3,601,755	4,159,815
	59,378,458	59,378,458	57,592,020	56,091,726	60,376,738	60,176,793
Diluted net income per share for period during which single class of equity securities was outstanding	\$ 0.10	\$ 0.09				
Diluted net income per common share	\$ 0.16	\$ 0.40	\$ 0.18	\$ 0.54	\$ 0.22	\$ 0.54

(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.

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

	Three Months Ended				Nine Months Ended			
	September 29, 2007	% of Revenue	September 27, 2008	% of Revenue	September 29, 2007	% of Revenue	September 27, 2008	% of Revenue
Revenue:								
Product	\$ 51,122	79.4%	\$ 66,001	84.5%	\$ 144,513	77.3%	\$ 187,524	83.7%
Royalty and license fee	13,254	20.6	12,131	15.5	42,497	22.7	36,484	16.3
Total revenue	64,376	100.0	78,132	100.0	187,010	100.0	224,008	100.0
Cost of goods sold	18,809	29.2	22,393	28.7	53,630	28.7	64,917	29.0
Gross profit	45,567	70.8	55,739	71.3	133,380	71.3	159,091	71.0
Operating expenses:								
Research and development	6,540	10.2	6,020	7.7	17,455	9.3	18,298	8.2
Selling, general and administrative	21,594	33.5	29,167	37.3	64,575	34.5	89,062	39.8

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Antitrust litigation	508	0.8	46	0.1	982	0.5	491	0.2
Total operating expenses	28,642	44.5	35,233	45.1	83,012	44.3	107,851	48.2

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	Three Months Ended				Nine Months Ended			
	September 29, 2007	% of Revenue	September 27, 2008	% of Revenue	September 29, 2007	% of Revenue	September 27, 2008	% of Revenue
Operating income	16,925	26.3	20,506	26.2	50,368	26.9	51,240	22.8
Non-operating income (expense):								
Interest income	726	1.1	545	0.7	1,270	0.7	2,129	1.0
Interest expense	(719)	(1.1)	(19)		(1,831)	(1.0)	(722)	(0.3)
Other	559	0.9	(413)	(0.5)	770	0.4	(235)	(0.1)
Total non-operating income (expense)	566	0.9	113	0.2	209	0.1	1,172	0.6
Income before provision for income taxes	17,491	27.2	20,619	26.4	50,577	27.0	52,412	23.4
Provision for income taxes	6,941	10.8	7,554	9.7	20,377	10.9	19,955	8.9
Net income	10,550	16.4	13,065	16.7	30,200	16.1	32,457	14.5
Accretion of preferred stock	(925)	(1.4)			(4,837)	(2.6)		
Undistributed income attributable to preferred stockholders	(2,739)	(4.3)			(13,526)	(7.2)		
Net income attributable to common stockholders	\$ 6,886	10.7%	\$ 13,065	16.7%	\$ 11,837	6.3%	\$ 32,457	14.5%

Comparison of the Three Months ended September 27, 2008 to the Three Months ended September 29, 2007

Revenue. Total revenue increased \$13.7 million, or 21.4%, to \$78.1 million for the three months ended September 27, 2008 from \$64.4 million for the three months ended September 29, 2007.

Product revenues increased \$14.9 million, or 29.1%, to \$66.0 million for the three months ended September 27, 2008 from \$51.1 million for the three months ended September 29, 2007. This increase was primarily due to higher consumable sales resulting from an increase in our installed base of circuit boards and pulse oximeters which totaled 540,000 units at September 27, 2008 up from 448,000 units at September 29, 2007. Revenue generated through our direct and distribution sales channels increased \$16.3 million, or 45.6%, to \$52.0 million for the three months ended September 27, 2008 compared to \$35.7 million for the three months ended September 29, 2007. Contributing to the increase in our direct and distribution sales channel revenue was our Rainbow technology product revenues which increased \$1.4 million to \$3.0 million in the three months ended September 27, 2008, from \$1.6 million in the three months ended September 29, 2007. For the three months ended September 27, 2008, \$672,000 of contract product revenue was deferred as compared to \$888,000 for the three months ended September 29, 2007. During the three months ended September 27, 2008, \$2.6 million of previously deferred revenue was recognized, including \$1.9 million related to an agreement in which VSOE was established as a result of a contract amendment and \$683,000 related to the collection of cash for excess sensor sales which had been deferred due to uncertainty over collectability. During the three months ended September 29, 2007 \$2.0 million of previously deferred revenue was recognized upon the delivery of a contract element. During the three months ended September 27, 2008 revenues from our OEM channel decreased \$1.4 million, or 9.1%, to \$14.0 million from \$15.4 million in the three months ended September 29, 2007.

Our royalty and license fee revenue decreased \$1.2 million, to \$12.1 million in the three months ended September 27, 2008 from \$13.3 million in the three months ended September 29, 2007, primarily due to a lower royalty rate associated with our 2006 settlement agreement with Tyco Healthcare (currently Covidien). For the three months ended September 29, 2007, our reported Covidien royalties were based upon Covidien's actual reported U.S. pulse oximeter sales for that period. For the three months ended September 27, 2008, our reported Covidien royalties are based upon our estimate of Covidien's U.S. pulse oximeter sales for that period and the contractual royalty rate as prescribed by the 2006 settlement agreement. Any adjustments to the quarterly estimate are recorded prospectively in the following quarter, when we receive the Covidien royalty report, which is generally 60 days after the end of each quarter.

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Cost of Goods Sold. Cost of goods sold increased 19.1% to \$22.4 million in the three months ended September 27, 2008 from \$18.8 million in the three months ended September 29, 2007. Total gross profit margin increased to 71.3% for the three months ended September 27, 2008 from 70.8% for the three months ended September 29, 2007. This slight increase in total gross margin was due to improvements in product gross profit margins offset by the \$1.2 million year over year decline in Covidien royalty revenues which have no related cost of goods sold. The product gross profit margin rose to 66.1% for the three months ended September 27, 2008, from 63.2% in the comparable prior year period due to manufacturing efficiencies related to higher production volumes and increased sales of Rainbow related products. We incurred \$875,000 and \$789,000 in Masimo Lab's royalty expenses for the three months ended September 27, 2008 and September 29, 2007, respectively, which, in accordance with FIN 46(R), have been eliminated in our condensed consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 64.7% and 61.7% for the three months ended September 27, 2008 and September 29, 2007, respectively.

Research and Development. Research and development expenses decreased 8.0% to \$6.0 million for the three months ended September 27, 2008, from \$6.5 million for the three months ended September 29, 2007. The decrease was primarily due to increased capitalized costs of \$400,000, associated with software development during the three months ended September 27, 2008, and government credits of \$250,000 received for certain research and development activities. For the three months ended September 27, 2008, and September 29, 2007, we also incurred \$727,000 and \$464,000, respectively, of Masimo Lab's engineering expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

Selling, General and Administrative. Selling, general and administrative expenses increased \$7.6 million, or 35.1%, to \$29.2 million for the three months ended September 27, 2008 from \$21.6 million in the three months ended September 29, 2007. The increase was primarily due to a \$3.8 million increase in payroll and payroll related costs, including stock based compensation, consistent with an increase in staffing to 410 at September 27, 2008 from 350 at September 29, 2007. In addition to the increased staffing levels, professional fees increased \$1.8 million due to a combination of higher patent litigation expense and increased tax, audit and other professional fees associated with the cost of being a public company. Also, sales related travel increased \$1.2 million due to additional sales representatives and increased customer installation activities. For the three months ended September 27, 2008 and September 29, 2007, we also incurred a net \$293,000 and \$125,000, respectively, of Masimo Lab's administrative expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

Non-Operating Income (expense). Non-operating income was \$113,000 for the three months ended September 27, 2008, compared to \$566,000 for the three months ended September 29, 2007. This decrease in non-operating income was primarily due to changes in foreign currency exchange rates, which resulted in other expense of \$452,000 during the three months ended September 27, 2008 as compared to other income of \$514,000 during the three months ended September 29, 2007. In addition, interest income decreased \$181,000 resulting from a lower rate of return on investments. These decreases were offset by a decrease in interest expense of \$700,000 resulting from repayments of long term debt balances during March 2008.

Provision for Income Taxes. Our provision for income taxes was \$7.6 million, or an effective tax rate of 36.6%, for the three months ended September 27, 2008 compared to \$6.9 million, or an effective tax rate of 39.7%, for the three months ended September 29, 2007. This increase in the provision was primarily due to an increase in our taxable income for the three months ended September 27, 2008 as compared to the three months ended September 29, 2007. The decrease in the effective tax rate was due to foreign income not being taxed and an increase in the credit from research and development work. The effective tax rate differs from the statutory U.S. federal income tax rate of 35.0% primarily due to state taxes and other permanent differences between pre-tax income for financial reporting purposes and taxable income.

Comparison of the Nine Months ended September 27, 2008 to the Nine Months ended September 29, 2007

Revenue. Total revenue increased \$37.0 million, or 19.8%, to \$224.0 million for the nine months ended September 27, 2008 from \$187.0 million for the nine months ended September 29, 2007.

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Product revenues increased \$43.0 million, or 29.8%, to \$187.5 million in the nine months ended September 27, 2008 from \$144.5 million for the nine months ended September 29, 2007. This increase was primarily due to higher consumable sales resulting from an increase in our installed base of circuit boards and pulse oximeters which totaled 540,000 units at September 27, 2008 up from 448,000 units at September 29, 2007. Revenue generated through our direct and distribution sales channels increased \$43.1 million, or 42.3%, to \$145.0 million for the nine months ended September 27, 2008 compared to \$101.9 million for the nine months ended September 29, 2007. Contributing to the increase in our direct and distribution sales channel revenue was our Rainbow technology product revenues which increased \$3.6 million to \$8.7 million in the nine months ended September 27, 2008, from \$5.1 million in the nine months ended September 29, 2007. For the nine months ended September 27, 2008, \$3.1 million of contract product revenue was deferred as compared to \$3.5 million for the nine months ended September 29, 2007. As previously discussed, during the nine months ended September 27, 2008, \$2.6 million of previously deferred revenue was recognized as compared to \$2.0 million during the nine months ended September 29, 2007. During the nine months ended September 27, 2008, revenues from our OEM channel decreased \$126,000, or 0.3%, to \$42.5 million from \$42.6 million in the nine months ended September 29, 2007.

Our royalty and license fee revenue decreased \$6.0 million, to \$36.5 million in the nine months ended September 27, 2008 from \$42.5 million in the nine months ended September 29, 2007, primarily due to a lower royalty rate associated with our 2006 settlement agreement with Covidien. For the nine months ended September 29, 2007, our reported Covidien royalties were based upon Covidien's actual reported U.S. pulse oximeter sales for that period. For the nine months ended September 27, 2008, our reported Covidien royalties are the combination of our estimate of Covidien's U.S. pulse oximeter sales for the three months ended September 27, 2008 at the contractual royalty rate as prescribed by the 2006 settlement agreement and actual royalties for the six months ended June 28, 2008.

Cost of Goods Sold. Cost of goods sold increased 21.0% to \$64.9 million in the nine months ended September 27, 2008 from \$53.6 million in the nine months ended September 29, 2007. Total gross profit margin decreased to 71.0% for the nine months ended September 27, 2008 from 71.3% for the nine months ended September 29, 2007. This decline in total gross margin was partially due to the impact of the \$6.0 million year over year decline in Covidien royalty revenues which have no related cost of goods sold and offset by improvements in product gross profit margins. In the nine months ended September 27, 2008, product gross profit margins rose to 65.4% from 62.9% in the comparable prior year period due to manufacturing efficiencies related to higher production volumes, greater sensor sales and increased sales of Rainbow related products. We incurred \$2.6 million and \$2.4 million in Masimo Lab's royalty expenses for the nine months ended September 27, 2008 and September 29, 2007, respectively, which, in accordance with FIN 46(R), have been eliminated in our condensed consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 64.0% and 61.3% for the nine months ended September 27, 2008 and September 29, 2007, respectively.

Research and Development. Research and development expenses increased 4.8% to \$18.3 million for the nine months ended September 27, 2008, from \$17.5 million for the nine months ended September 29, 2007. The increase was primarily due to increased payroll and payroll related costs of \$1.9 million which were partially offset by increased capitalized costs associated with software development of \$850,000 during the nine months ended September 27, 2008. For the nine months ended September 27, 2008 and September 29, 2007, we also incurred \$1.7 million and \$1.1 million, respectively, of Masimo Lab's engineering expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

Selling, General and Administrative. Selling, general and administrative expenses increased \$24.5 million, or 37.9% to \$89.1 million for the nine months ended September 27, 2008 from \$64.6 million in the nine months ended September 29, 2007. The increase was primarily due to a \$12.8 million increase in payroll and payroll related costs, including stock based compensation, consistent with an increase in staffing to 410 at September 27, 2008 from 350 at September 29, 2007. In addition to the increased staffing levels, professional fees increased \$4.3 million due to a combination of higher patent litigation expense and increased tax, audit and other professional fees associated with the cost of being a public company. Also, sales related travel increased \$3.2 million due to additional sales representatives and their increased travel activities and tradeshow marketing expense, which increased by \$1.5 million due to an increase in the number of tradeshow attendees. For the nine months ended September 27, 2008 and September 29, 2007, we also incurred a net \$883,000 and \$404,000, respectively, of Masimo Lab's administrative expenses, which, in accordance with FIN 46(R), have been included in our condensed consolidated financial statements for the periods presented.

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Non-Operating Income (expense). Non-operating income was \$1.2 million for the nine months ended September 27, 2008, compared to \$209,000 for the nine months ended September 29, 2007. This increase in non-operating income was primarily due to a decrease in interest expense of \$1.1 million resulting from repayments of long term debt balances in March 2008. In addition, interest income increased \$859,000 resulting from higher cash balances during the nine months ended September 27, 2008 as compared to the nine months ended September 29, 2007. The remaining change in non-operating income (expense) was primarily due to changes in foreign currency exchange rates which resulted in other expense of \$194,000 during the nine months ended September 27, 2008 as compared to other income of \$610,000 during the nine months ended September 29, 2007.

Provision for Income Taxes. Our provision for income taxes was \$20.0 million, or an effective tax rate of 38.1%, for the nine months ended September 27, 2008 compared to \$20.4 million or an effective tax rate of 40.3%, for the nine months ended September 29, 2007. The decrease in the effective tax rate was due to foreign income not being taxed and an increase in research and development credits. The effective tax rate differs from the statutory U.S. federal income tax rate of 35.0% primarily due to state taxes and other 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 27, 2008, we raised \$81.7 million through seven preferred stock private equity financings, approximately \$47.8 million from our August 2007 initial public offering and \$25.3 million from the exercise of stock options, of which \$8.8 million was from exercises after our initial public offering.

As of September 27, 2008, we had cash and cash equivalents of \$122.6 million, of which \$103.8 million was invested in U.S. Treasury bills and \$11.9 million was in money market accounts with major financial institutions. These U.S. Treasury bills are classified as cash equivalents since they are highly liquid investments, with a maturity of three months or less at the date of purchase. We carry cash equivalents at cost which approximates fair value.

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

Cash Flows from Operating Activities. Cash provided by operating activities was \$52.6 million in the nine months ended September 27, 2008. The source of cash consists primarily of net income of \$32.5 million, a net tax benefit of \$14.5 million relating to employee stock option exercises for options granted prior to the adoption of FAS 123(R), which may not recur in the future, and stock based compensation expense of \$5.7 million resulting from options granted under FAS 123(R). Also, depreciation and amortization expense was \$4.2 million, royalties receivable decreased \$2.5 million due to a lower royalty rate per our agreement with Covidien and income taxes payable increased \$2.5 million resulting from higher taxable income. These increases were offset partially by an increase in inventory of \$7.3 million to meet the increasing demand for our products and the introduction of new products, an excess tax benefit from share based payments of \$2.4 million and an increase in accounts receivable of \$2.4 million due to the growth of our business.

Cash 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 and stock based compensation expense of \$2.6 million from options granted under FAS 123(R). This increase was offset partially by increases in royalties receivable of \$11.8 million due to the Covidien 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.

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

Cash used in investing activities for the nine months ended September 29, 2007 was \$4.7 million consisting of \$3.9 million of property and equipment purchases and \$865,000 for the increase in intangible assets necessary to support the growth of our business.

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

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 \$37.4 million of dividends paid and repayment of long term debt of \$7.1 million.

Future Liquidity Needs. In addition to funding our working capital requirements, we anticipate our primary use of cash to be the equipment that we provide to hospitals under our long-term sensor purchase agreements. We anticipate additional capital purchases related to expanding our worldwide manufacturing capability as well as additional investments in productivity enhancing tools. Our focus on international expansion will also require additional investments in facilities and infrastructure in North and South America, Europe and Asia. The amount and timing of our actual investing activities will vary significantly depending on numerous factors, such as the progress of our product development efforts, our timetable for international sales and marketing expansion and both domestic and international regulatory requirements. Despite these capital investment requirements, we anticipate that our existing cash and cash equivalents will be sufficient to meet our working capital requirements, capital expenditures, and operations for at least the next 12 months.

Current Financing Arrangements. As of December 29, 2007, we had two long term borrowings that allowed for the financing of the equipment placed with hospitals in connection with the related long-term sensor purchase agreements. In March 2008, we repaid \$26.7 million, or the entire then outstanding balance, on one of the arrangements. This repayment terminated our borrowing arrangement. This is a non-recurring event and is not expected to occur in the future. In addition, we paid \$168,000 in prepayment fees which are included in other non-operating income (expense). Therefore, as of September 27, 2008, we had only one remaining financing arrangement with an outstanding balance of \$510,000. As of September 27, 2008, principal and interest payments under this remaining financing agreement were \$52,000 per month based on an average interest rate of 7.1%. We do not have anymore available borrowings under this remaining arrangement.

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

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statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

For a description of our critical accounting policies and estimates, please refer to the *Critical Accounting Estimates* section of the *Management's Discussion and Analysis of Financial Condition and Results of Operations* section contained in our Annual Report on Form 10-K filed with the SEC on March 4, 2008. There have been no material changes in any of our accounting policies since December 29, 2007.

New Accounting Pronouncements

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141(R), or SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) provides greater consistency in the accounting and financial reporting of business combinations. It requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values and changes other practices under SFAS No. 141. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. If we consummate any acquisitions on or after January 4, 2009, the purchase accounting treatment could result in a material difference from current accounting treatment.

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

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

In May 2008, the FASB issued Statement of Financial Accounting Standard No. 162, or SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles. SFAS No. 162 will become effective on November 15, 2008. We do not expect the adoption of this Statement to have a material effect on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense we must pay with respect to our outstanding debt instruments. Our risk associated with fluctuation to interest expense is limited to our outstanding term loans and financing arrangements, which have fixed interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We enhance the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities and government securities. A

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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 27, 2008. Declines in interest rates over time will, however, reduce our interest income and expense while increases in interest rates will increase our interest income and expense.

Foreign Currency Exchange Rate Risk

A majority of our assets and liabilities are maintained in the United States in U.S. dollars and our sales and expenditures are transacted in U.S. dollars. The expenses and capital spending of our foreign entities are transacted in the respective country's local currency and are subject to foreign exchange rate risk. In particular, we are exposed to foreign currency risk related to our international operations, including foreign denominated intercompany receivables and payables. Our foreign currency transactions are translated into U.S. dollars at prevailing rates and gains or losses resulting from foreign currency transactions are included in current period income or loss as incurred. Our foreign entities balance sheets are translated in U.S. dollars at the month end spot rates and the statements of income and cash flows using the average exchange rate for the periods and any foreign exchange gain or loss is included in equity as a component of accumulated other comprehensive income (loss). Historically, we have not engaged in foreign currency hedging transactions. We estimate that a 10% change in the ending foreign exchange rates would not have resulted in a material change to our net income during the nine months ended September 27, 2008. As our foreign operations continue to grow, our exposure to foreign currency risk may become more significant.

Inflation Risk

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

Item 4(T). Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's regulations, rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-Q. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 27, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On February 19, 2008, we filed a lawsuit against Respironics, Inc. for breach of contract, breach of the covenant of good faith and fair dealing, and interference with prospective economic advantage, based on a January 16, 2006, contract between Respironics and us. On April 7, 2008, Respironics filed a demurrer seeking to dismiss the lawsuit on the grounds that our complaint fails to state sufficient facts to constitute valid claims. The court subsequently denied Respironics' demurrer. On July 16, 2008, Respironics answered our complaint and filed a cross-complaint. We answered the cross-complaint on August 15, 2008, denying all material allegations. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

On July 24, 2007, Shaklee Corporation filed suit against us in the United States District Court, Central District of California, alleging that our pulse oximeters incorporate patented calibration methods that are licensed to Shaklee. NIR Diagnostics, Inc., the original licensee of the patents, was originally named as a defendant, but then agreed to become a plaintiff in the action. Shaklee and NIR sought an injunction and damages against us. On August 27, 2008, we settled all pending litigation brought by Shaklee and NIR against us. Pursuant to the settlement, Shaklee and NIR dismissed all outstanding claims against us with prejudice, and we dismissed all outstanding claims against Shaklee and NIR without prejudice. The settlement was reached without us incurring any liability to either Shaklee or NIR.

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

Item 1A. Risk Factors

Before you decide to invest or maintain an interest in our common stock, you should consider carefully the risks described below, which have been updated since the filing of our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on August 5, 2008, in their entirety, together with the other information contained in this Quarterly Report on Form 10-Q. We believe the risks described below are the risks that are material to us as of the date this Quarterly Report on Form 10-Q is originally filed with the SEC. If any of the following risks comes to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

The risk factors set forth below with an asterisk () next to the title are new risk factors, or risk factors containing changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 29, 2007, as filed with the SEC, or Form 10-K. The remaining risk factors set forth below do not contain any changes from the risk factors previously disclosed in our Form 10-K.*

Risks Related to Our Business

We currently derive substantially all of our revenue from our Masimo SET platform and related products. If this technology and the related products do not continue to achieve market acceptance, our business, financial condition and results of operations would be adversely affected.

We are dependent upon the success and market acceptance of our proprietary Masimo SET. Currently, our primary product offerings are based on the Masimo SET platform. Continued market acceptance of products incorporating Masimo SET will depend upon our ability to continue to provide evidence to the medical community that our products are cost-effective and provide significantly improved performance compared to conventional pulse oximeters. Health care providers that currently have significant investments in competitive pulse oximetry products may be reluctant to purchase our products. If hospitals and other health care providers do not believe our Masimo

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SET platform is cost-effective, more accurate or reliable, they may not buy our products in sufficient quantities to enable us to be profitable. If we are unable to achieve additional market acceptance of our core technology or products incorporating Masimo SET, we will not generate significant revenue growth from the sale of our products.

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

Our success depends significantly on our ability to protect our rights to the technologies used in our products, including Masimo SET and licensed Rainbow technology. We rely on patent protection, trade secrets, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect our technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, we cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The United States Patent and Trademark Office, or PTO, may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO. These proceedings could result in adverse decisions as to the claims included in our patents.

Our issued and licensed patents and those that may be issued or licensed in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Additionally, upon expiration of our issued or licensed patents, we may lose some of our rights to exclude others from making, using, selling or importing products using the technology based on the expired patents. We also must rely on contractual rights with the third parties that license technology to us to protect our rights in the technology licensed to us. There is no assurance that competitors will not be able to design around our patents. We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology with confidentiality agreements and intellectual property assignment agreements with our employees, our OEM partners, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered and common law trademarks with respect to the brand names of some of our products. Our common law trademarks provide less protection than our registered trademarks. Loss of rights in our trademarks could adversely affect our business, financial condition and results of operations.

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

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

Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage in the marketplace. Whether a technology or product infringes a patent involves complex legal and factual issues and is often difficult to determine. We face the risk of claims that we have infringed on third parties' intellectual property rights. Prior to launching major new products in our key markets, we normally evaluate existing intellectual property rights. However, searching for existing intellectual property rights may not reveal important intellectual property and our competitors may also have filed for patent protection, which is not publicly-available information, or claimed trademark rights that have not been revealed through our availability searches. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement against us, even those without merit, could:

increase the cost of our products;

be expensive and time consuming to defend;

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

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

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

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

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

divert the attention of our management and other key employees;

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

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

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

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

We believe that the success of our business depends, in significant part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets. We were previously involved in significant litigation to protect our patent position and may be required to engage in further litigation. In 2006, we settled a costly, six-year lawsuit against Mallinckrodt, Inc., now a part of Covidien Ltd. (formerly Tyco Healthcare), and one of its subsidiaries, Nellcor Puritan Bennett, Inc., in which we claimed that Covidien was infringing some of our pulse oximetry signal processing patents. We believe that other competitors of ours, including some of our OEM partners, may be infringing at least one of our patents. Our failure to pursue any potential claim could result in the loss of our proprietary rights and harm our position in the marketplace. Therefore, we may be forced to pursue litigation to enforce our rights. We cannot be certain that we will have the required financial resources to pursue litigation or otherwise to protect these rights in the future. In addition, any future litigation could result in the diversion of management's attention from the implementation of our business strategy and may not be adequate to protect our intellectual property rights.

Some of our products, including those based on licensed Rainbow technology, are in development or have been recently introduced into the market and may not achieve market acceptance, which could limit our growth and adversely affect our business, financial condition and results of operations.

Our products that have been recently introduced into the market, including, but not limited to those based on Rainbow technology, a technology that we license, may not be accepted in the market. Our first product incorporating licensed Rainbow technology was made commercially available in September 2005. Accordingly, we do not know to what degree the market will accept these products, if at all. Even if our customers recognize the benefits of our products, we cannot assure you that our customers will purchase them in quantities sufficient for us to be profitable or successful. We will need to invest in significant sales and marketing resources to achieve market acceptance of these products with no assurance of success. The degree of market acceptance of these products will depend on a number of factors, including:

perceived effectiveness of our products;

cost of our products;

perceived advantages of our products over competing products;

introduction and acceptance of competing products or technologies; and

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

In order for any of our products to be accepted in the marketplace, we must demonstrate that they are effective and commercially beneficial. Even if customers accept these products, this acceptance may not result in sales if our competitors develop similar products that our customers prefer. If our products do not gain market acceptance or if our customers prefer our competitors' products, our potential growth would be limited, which would adversely affect our business, financial condition and results of operations.

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

Under the FDA medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. We may experience events that may require reporting to the FDA pursuant to the MDR regulations. Any adverse event involving our products could result in future voluntary corrective actions, including recalls or customer notifications, or agency action, including inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as any litigation resulting from any adverse event, would require the dedication of our time and capital, distract management from operating our business and could harm our reputation, business operations and financial results.

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

After a device is placed on the market, numerous regulatory requirements apply, including MDR 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 foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall generally must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or by one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We may initiate certain voluntary recalls involving our products in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If we determine that a recall does not require notification of the FDA, the FDA may disagree with our determination and require us to report the recall to the FDA.

From our inception through September 27, 2008, we initiated three voluntary recalls of our products, none of which was material. Each of these recalls was reported to the FDA within the appropriate regulatory timeframes. Because of our dependence upon patient and physician perceptions, any negative publicity associated with these voluntary recalls could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Of the three recalls that we have implemented, the only one that remains open is the recall of our Rad-9 pulse oximeters, a standalone bedside pulse oximeter product. Sales of our Rad-9 pulse oximeters represented less than 0.4% and 0.3% of our product revenue in the nine months ended September 29, 2007 and September 27, 2008, respectively. On July 31, 2007, we determined to initiate a voluntary recall of that product. In accordance with its original design and similar to other pulse oximeter devices, the Rad-9 gives a visual alarm if there is a sensor fault and under other circumstances, the Rad-9 gives both a visual and audio alarm. In late 2006, we sent notice to owners of our Rad-9 pulse oximeter that a free upgrade was available to add an audio alarm to the Rad-9 when a sensor fault is detected. We decided to voluntarily recall the Rad-9 to implement this upgrade. We do not believe that a non-upgraded Rad-9 poses a significant risk to health or would cause serious injury or death. We decided to voluntarily recall the Rad-9 because we believe it has the possibility of improving the care of patients. This decision follows a customer report that an elderly patient, who may have damaged her pulse oximeter sensor, had died after removing her tracheostomy tube. Based on what is currently known, the Rad-9 appears to have been operating in accordance with its specifications. We submitted an MDR to the FDA for this event on August 3, 2007. As of September 27, 2008,

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we had incurred actual upgrade costs of approximately \$292,000 and do not expect to incur any additional costs in the future related to this recall. Much of our growth may come from the introduction and sale of new products, which may result in a greater frequency of recalls. Any future recall could result in a diversion of management resources, substantial cost and negative publicity, all of which could adversely affect our business, financial condition and results of operations.

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

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

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

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

Non-vital signs measurements consist of body fluid constituents other than vital signs measurements, including but not limited to carbon monoxide, methemoglobin, blood glucose, total hemoglobin and bilirubin.

Under the Cross-Licensing Agreement, we are only permitted to sell devices utilizing Masimo SET for the measurement of non-vital signs measurements in markets where the product is intended to be used by a professional medical caregiver, including but not limited to hospital caregivers and emergency medical services, or EMS, facility caregivers, rather than by a patient or pharmacist, which we refer to as the Masimo Market. Accordingly, our ability to commercialize new products, new or improved technologies and additional applications for Masimo SET is limited. In particular, our inability to expand beyond the Masimo Market may impair our growth and adversely affect our financial condition and results of operations.

Pursuant to the Cross-Licensing Agreement, we have licensed from Masimo Labs the right to make and distribute products in the Masimo Market that utilize Rainbow technology for the measurement of only carbon monoxide, methemoglobin, fractional arterial oxygen saturation and total hemoglobin, which includes hematocrit. As a result, the opportunity to expand the market for our products incorporating Rainbow technology is limited, which could limit our ability to maintain or increase our revenue and impair our growth.

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

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

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In the event that the Cross-Licensing Agreement is terminated for any reason, or Masimo Labs grants a license to Rainbow technology to a third party, our business would be materially and adversely affected.

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

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

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

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

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

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

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

In the event we undergo a change in control, we are required to immediately pay a \$2.5 million fee to exercise an option to license technology developed by Masimo Labs for use in blood glucose monitoring. Under the Cross-Licensing Agreement, a change in control includes but is not limited to the resignation or termination of Joe E. Kiani from his position of Chief Executive Officer of either Masimo or Masimo Labs. Additionally, our per product royalties payable to Masimo Labs will become subject to specified minimums, and the minimum aggregate annual royalties for all licensed Rainbow measurements payable to Masimo Labs will increase to up to \$15.0 million for carbon monoxide, methemoglobin, fractional arterial oxygen saturation, total hemoglobin and blood glucose, plus up to \$2.0 million per other Rainbow measurements. Also, if the surviving or acquiring entity ceases to use Masimo as a company name and trademark following a change in control, all rights to the Masimo trademark will automatically be assigned to Masimo Labs. This could delay or discourage transactions involving an actual or potential change in control of us, including transactions in which our stockholders might otherwise receive a premium for their shares over our then-current trading price. In addition, our requirement to assign all future improvements for non-vital signs to Masimo Labs could impede a change in control.

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

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

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

Prior to our initial public offering in August 2007, our stockholders owned approximately 99% of the outstanding shares of capital stock of Masimo Labs and we believe that as of September 27, 2008, a number of stockholders of Masimo Labs continued to own shares of our common stock. In addition, Joe E. Kiani and Jack Lasersohn, members of our board of directors, are also members of the board of directors of Masimo Labs. Joe E. Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs. Due to the interrelated nature of Masimo Labs with us, conflicts of interest will arise with respect to transactions involving business dealings between us and Masimo Labs, potential acquisitions of businesses or products, development of products and technology, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Masimo Labs. We cannot assure you that any conflict of interest will be resolved in our favor, or that with respect to our transactions with Masimo Labs we will negotiate terms that are as favorable to us as if such transactions were with an unaffiliated third party.

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

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

Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments and such losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same loss rates that we have in the past, especially given the current turmoil of the worldwide economy. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in our receivable collections and additional allowances may be required. These additional allowances could materially affect our financial results.

Our operating results and cash flows 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 continue to expand our research and development and sales and marketing activities. As a result, if we are unable to maintain or increase our revenue, we may incur net losses and negative cash flows in the future.

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

delays or interruptions in manufacturing and shipping of our products;

varying demand for and market acceptance of our technologies and products;

the effect of competing technological and market developments resulting in lower selling prices or significant promotional costs;

changes in the timing of product orders and the volume of sales to our OEM partners;

actions taken by group purchasing organizations, or GPOs;

delays in hospital conversions to our products;

our legal expenses, particularly those related to litigation matters;

changes in our product or customer mix;

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

product recalls; and

high levels of returns and repairs.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. To respond to these and other factors, we may need to make business decisions that could result in failure to meet financial expectations. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. Most of our expenses, including our employee compensation, inventory and debt repayment obligations, are relatively fixed in the short term. Moreover, our expense levels are based, in part, on our expectations regarding future revenue levels. As a result, if our revenue for a particular period were below our expectations, we would not be able to proportionately reduce our operating expenses for that period. Any revenue shortfall would have a disproportionately negative effect on our operating results for the period.

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.

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We are, and will continue to be, dependent upon our OEM partners for a portion of our revenue through their marketing, selling and distribution of certain of their products that incorporate Masimo SET and licensed Rainbow technology. Although we expect that our OEM partners will accept and actively market, sell and distribute products that incorporate licensed Rainbow technology, they may elect not, and they have no contractual obligation, to do so in the near future or at all. The failure of our OEM partners to successfully market, sell or distribute products incorporating these technologies, the termination of OEM agreements, the loss of OEM partners or the inability to enter into future OEM partnership agreements would have a material adverse effect on our business, financial condition and results of operations. Our success will depend in part upon whether our OEM partners devote sufficient resources to the promotion of products that incorporate these technologies. These products may represent a relatively small percentage of business for some of our OEM partners and therefore they may have less incentive to promote these products rather than other products that do not incorporate these technologies. In addition, some of our OEM partners offer products that compete with ours. Therefore, we cannot guarantee that our OEM partners will vigorously promote products incorporating Masimo SET and licensed Rainbow technology, or at all. If any of our OEM partners were to be acquired, we cannot assure you that an acquiring company would devote sufficient resources to promote products that incorporate technology we own or license.

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

For the three and nine months ended September 27, 2008, one customer represented 10.3% and 11.7%, respectively, of our total revenues. We also have a concentration of OEM, distribution and direct customers. If for any reason we were to lose our ability to sell to a specific group or class of customers, we would experience a significant reduction in revenues, which would adversely impact our operating results. 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 in the future.

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

In the three and nine months ended September 27, 2008, our royalties from the Covidien settlement totaled \$12.0 million and \$36.1 million, respectively. Because these royalty payments do not carry any significant cost, they result in significant improvements to our reported gross profit and operating income levels. As a result, any decline in royalties that we earn under this settlement agreement will have a significant impact on our revenues, gross margins and operating income. Under the agreement, we earn royalties on Covidien's total U.S.-based pulse oximetry sales. The royalty rate in 2006 was nearly 20% if averaged over the entire year. The royalty rates for 2007 declined to 15%. In 2008 and through the term of the royalty agreement, at least through March 14, 2011, the royalty rate is 13%, but may decline to 10%, subject to Covidien's ability to develop new products that avoid some of our current patent coverage as negotiated in the settlement agreement. As a result of these declining royalty rates since 2006, there is a significant financial risk to our operating income if we are unable to generate sufficient revenues and gross margins to offset the impact of declining royalty rates on sales of Covidien's pulse oximetry products in the United States.

*** If we fail to maintain relationships with GPOs, sales of our products would decline.**

Our ability to sell our products to U.S. hospitals depends in part on our relationships with GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate beneficial pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors. These negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, the GPO's affiliated hospitals and other members may be less likely or unlikely to purchase our products. If a GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be prohibited from making sales to members of the GPO for the duration of the contractual arrangement. In the three and nine months ended September 27, 2008, shipments of our pulse oximetry products related to GPOs were \$35.4 million and \$99.1 million, respectively. Our failure to renew our contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. In addition, if we are unable to develop new relationships with GPOs, our competitive position would likely suffer and our business would be harmed.

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 grow our business would be impaired.

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for Masimo SET and licensed Rainbow technology. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. In particular, we may not be able to successfully commercialize our products for applications other than arterial blood oxygen saturation and pulse rate monitoring, including carboxyhemoglobin and methemoglobin monitoring. If we do not successfully adapt our products and applications both within and outside these measurements, we could lose revenue opportunities and customers. In addition, we may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business. Furthermore, one or more of our competitors may develop products that are substantially equivalent to our FDA-cleared products, or those of our OEM partners, whereby they may be able to use our products or those of our OEM partners, as predicate devices to more quickly obtain FDA clearance of their competing products.

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

We face substantial competition from companies developing products that compete with our Masimo SET platform for use with third-party monitoring systems. We also face competition from companies currently marketing pulse oximetry monitors. One company, Covidien, currently holds a substantial share of the pulse oximetry market. Our revenues and profit are significantly smaller than our primary competitors. A number of the companies in the pulse oximetry market have substantially greater capital resources, larger customer bases, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours, and have established stronger reputations with our target customers and built relationships with GPOs and worldwide distribution channels that are more effective than ours. Competition could result in reductions in the price of our products, fewer orders for our products, a reduction of our gross margins and a loss of our market share. Reliance on clinical studies is an important means of demonstrating the effectiveness of products in our industry. If clinical studies supporting our competitors' products are perceived to be accurate and reliable, market acceptance and sales of our products could be adversely impacted and we could lose market share to our competitors.

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

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

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

Many of our employees were previously employed at other medical device companies. We may be subject to claims that our employees have disclosed, or that we have used, trade secrets or other proprietary information of our employees' former employers. Defending against these claims could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research and development or sales personnel could limit our ability to sell our existing products and develop new products and technologies, which could adversely affect our business, financial condition and results of operations.

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

The manufacture and sale of products using Masimo SET and licensed Rainbow technology expose us to product liability claims and product recalls, including those that may arise from misuse, including but not limited to unauthorized off-label use, which is use of a device in a manner outside the measurement or measurements cleared by the FDA, or malfunction of, or design flaws or manufacturing defects in, our products or the use of our products with incompatible components or systems. Any losses that we may suffer from future liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our technology and products, together with the corresponding diversion of the attention of our key employees, could adversely affect our business, financial condition and results of operations. Any product liability claims could require significant cost and management resources and may subject us to significant damages. We currently have product liability insurance that we believe to be adequate, but we cannot be certain that it will be sufficient to cover any or all damages or claims. Furthermore, we may not be able to obtain or maintain insurance in the future at satisfactory rates or in adequate amounts to protect us against any product liability claims.

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

Each medical device that we wish to market in the United States generally must first receive either 510(k) clearance from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act by filing a 510(k) pre-market notification, or pre-market approval, or PMA, through submitting a PMA application. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed. We cannot assure you that the FDA will grant 510(k) clearance on a timely basis, if at all, for new products or uses that we propose for Masimo SET or licensed Rainbow technology. The FDA's 510(k) clearance process usually takes from four to six months, although it can take longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain and generally takes from one to three years or even longer.

To date, the FDA has regulated pulse oximeters incorporating Masimo SET and licensed Rainbow technology, and our sensors, cables and other products incorporating Masimo SET and licensed Rainbow technology for pulse oximetry under the 510(k) process. Although 510(k) clearances have been obtained for all of our current products, these clearances may be revoked by the FDA at any time if safety or effectiveness problems develop with our devices. Furthermore, our new products or significantly modified marketed products could be denied 510(k) clearance and be required to undergo the more burdensome PMA process. In that case, our ability to upgrade our products in a timely fashion could be limited. The withdrawal of existing 510(k) clearances or the inability to obtain new ones on a timely basis, or at all, could severely harm our business, financial condition and results of operations.

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

Our OEM partners will be required to obtain their own FDA clearances for products incorporating Masimo SET and licensed Rainbow technology to market these products in the United States. We cannot assure you that the FDA clearances we have obtained will make it easier for our OEM partners to obtain clearances of products incorporating these technologies, or that the FDA will ever grant clearances on a timely basis, if at all, for any future product incorporating Masimo SET and licensed Rainbow technology that our OEM partners propose to market.

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

Our products, along with the manufacturing processes and promotional activities for such products, are subject to continual review and periodic inspections by the FDA and other regulatory bodies. In particular, we and our suppliers are required to comply with the quality system regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the QSR through unannounced inspections. We are also subject to similar state requirements and licenses. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, discovery of previously unknown problems with our products (including unanticipated adverse events or adverse events of unanticipated severity or frequency), manufacturing problems, or failure to comply with regulatory requirements, or failure to adequately respond to any FDA observations concerning these issues, could result in, among other things, any of the following actions:

warning letters or untitled letters issued by the FDA;

fines and civil penalties;

unanticipated expenditures to address or defend such actions;

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

withdrawal or suspension of clearance or approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

product recall or seizure;

orders for physician notification or device repair, replacement or refund;

interruption of production;

operating restrictions;

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injunctions; and

criminal prosecution.

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

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

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

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

Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA approval. We may not be able to obtain such clearances or approvals in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business, financial condition and results of operations. We have made modifications to our devices in the past and we may make additional modifications in the future, some of which we may believe do not or will not require additional clearances or approvals. If the FDA disagrees with our conclusion and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could have an adverse effect on our business, financial conditions and results of operations.

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

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

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Federal regulatory reforms may adversely affect our ability to sell our products profitably.

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

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

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

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

increase our sales and marketing forces;

continue to maintain domestic and international OEM partners;

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

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

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

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

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

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

Our anticipated growth may strain our ability to manufacture an increasingly large supply of our products. Manufacturing facilities often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we cannot scale our manufacturing operations appropriately, maintain control over expenses or otherwise adapt to anticipated growth, or if we have underestimated our future growth, we may not have the capability to satisfy market demand, which would have an adverse effect on our business, financial condition and results of operations.

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

Both domestically and internationally, we expect to rapidly expand our operations and our research and development, product development, sales, marketing and administrative organizations. This growth and activity will likely result in new and increased responsibilities for management and place a significant strain upon our operating and financial systems and resources. To accommodate our expected growth and compete effectively, we will be required to improve our current infrastructure, including information systems, as well as create additional processes, procedures and controls and expand, train, motivate and manage our work force. We also may need to expand our manufacturing resources.

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

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

To date, we have relied on our manufacturing facilities in Irvine, California and Mexicali, Mexico. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since our Irvine, California facility is located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods and similar events. In the event that one of our facilities was affected by a natural or man-made disaster, we would be forced to rely on third-party manufacturers if we could not shift production to another one of our manufacturing facilities. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If we are forced to seek alternative facilities, we may incur additional costs and we may experience a disruption in the supply of our products until those facilities are available. Any disruption in our manufacturing capacity could have an adverse impact on our ability to produce sufficient inventory of our products or may require us to incur additional expenses in order to produce sufficient inventory, and, therefore, may adversely affect our revenue, gross margins and results of operations. Any disruption or delay at our manufacturing facilities could impair our ability to meet the demand of our customers and our customers may cancel orders or purchase products from our competitors, which could adversely affect our business, financial condition and results of operations.

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

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

We are highly dependent on our senior management, especially Joe E. Kiani, our Chief Executive Officer, and other key officers. We are also heavily dependent on our engineers and field sales team, including sales representatives and clinical specialists. Our success will depend on our ability to retain our current management, engineers and field sales team, and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management, engineers and field sales personnel is intense and we may not be able to retain our personnel. The loss of the services of members of our key personnel could prevent the implementation and completion of our objectives, including the development and introduction of our products. Each of our officers may terminate his employment at any time without notice for any reason. We carry key person life insurance on only Mr. Kiani, who is also the Chief Executive Officer of Masimo Labs. Mr. Kiani devotes substantially all of his time to us.

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

In order to expand our products and technology platform, we have acquired four businesses since our inception and we may acquire additional businesses in the future. Successful acquisitions depend upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. Even if we complete acquisitions, we may experience:

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

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

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

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

higher costs of integration than we anticipated; and

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

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

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

Although we do not provide health care services or receive payments directly from Medicare, Medicaid or other third-party payers for our products or the procedures in which our products are used, health care regulation by federal and state governments will impact our business. Health care fraud and abuse and health information privacy and security laws potentially applicable to our operations include, but are not limited to:

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

federal false claims laws which prohibit, among other things, knowingly and willfully presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which established federal crimes 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

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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, one or more of these arrangements may not meet the Federal Anti-Kickback Law's safe harbor requirements, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws.

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

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

Our manufacturing processes involve the use, generation and disposal of certain hazardous materials and wastes, including silicone adhesives, solder and solder paste, sealants, epoxies and various solvents such as methyl ethyl ketone, acetone and isopropyl alcohol. As a result, we are subject to stringent federal, state and local laws relating to the protection of the environment, including those governing the use, handling and disposal of hazardous materials and wastes. We may incur significant costs to comply with environmental regulations. Future environmental laws may significantly affect our operations because, for instance, our manufacturing processes may be required to be altered, which may increase our manufacturing costs. In our research and manufacturing activities, we use or may be exposed to materials that are hazardous to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury, including to our employees, or contamination from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any resulting damages and any such liability could exceed our reserves. Although we maintain general liability insurance, we do not specifically insure against environmental liabilities. If an enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action on terms favorable to us. Similarly, if the physicians or other providers or entities with which we do business are found to violate applicable laws, they may be subject to sanctions, which could also have a negative impact on our reputation and business.

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

We derive a portion of our net sales from international operations. In 2006, 2007 and the nine months ended September 27, 2008, 22.6%, 23.6% and 25.4%, 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, but are not limited to:

the imposition of additional U.S. and foreign governmental controls or regulations;

the imposition of costly and lengthy new export licensing requirements;

a shortage of high-quality sales people and distributors;

loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;

changes in duties and tariffs, license obligations and other non-tariff barriers to trade;

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the imposition of new trade restrictions;

the imposition of restrictions on the activities of foreign agents, representatives and distributors;

scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;

pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles; and

difficulties in enforcing or defending intellectual property rights.

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

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

We market our products in certain foreign markets through our subsidiaries and other international distributors. The related distribution agreements may provide for payments in a foreign currency. When the United States dollar weakens against these currencies, the dollar value of the foreign-currency denominated expense increases, and when the dollar strengthens against these currencies, the dollar value of the foreign-currency denominated expense decreases. Accordingly, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations. We currently do not hedge against our foreign currency risks.

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. Therefore, our customers' inability to obtain adequate coverage and reimbursement for our products would have a material adverse effect on our business.

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

controls on reimbursement for health care services and price controls on medical products and services;

limitations on coverage and reimbursement for new medical technologies and procedures; and

the introduction of managed care and prospective payment systems in which health care providers contract to provide comprehensive health care for a fixed reimbursement amount per person or per procedure.

These trends could lead to pressure to reduce prices for our current products and product candidates and could cause a decrease in the size of the market or a potential increase in competition that could adversely affect our business, financial condition and results of operations.

Legislative and regulatory changes in the health care industry could have a negative impact on our financial performance.

Changes in the health care industry in the United States and elsewhere could adversely affect the demand for our products as well as the way in which we conduct our business. Additionally, there have been, and we expect there will continue to be, federal, state or local legislative and regulatory changes and proposals to change the health care system, which could affect our business. For instance, the Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicare and Medicaid programs, determined that beginning in 2007 certain uses of pulse oximetry monitoring are eligible for separate Medicare payment in the hospital outpatient setting and are no longer bundled into payments for other services. The result of this change could be an increase in Medicare payments to hospitals for use of our products. However, each year CMS examines the reimbursement rates for both

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the inpatient and outpatient settings and could either increase or decrease the reimbursement rate for procedures utilizing our products. In addition, as a result of the focus on health care reform in connection with the 2008 presidential election, there is risk that Congress may implement changes in laws and regulations governing health care service providers, including measures to control costs or reductions in reimbursement levels. Overall, we are unable to predict when legislation or regulation that affects our business may be proposed or enacted in the future or what effect any such legislation or regulation would have on our business. Any such legislation, regulation or policies that affect the coverage and reimbursement of our current or future products, or the procedures utilizing our current or future products, could cause our sales to decrease and, as a result, our revenues to decline.

Further, our success in international markets also depends upon the eligibility of reimbursement for our products through government-sponsored health care payment systems and other third-party payers. Outside of the United States, reimbursement systems vary by country. These systems are often subject to the same pressures to curb rising health care costs and control health care expenditures as those in the United States. In addition, as economies of emerging markets develop, these countries may implement changes in their health care delivery and payment systems. If adequate levels of reimbursement from third-party payers outside of the United States are not obtained, sales of our products outside of the United States may be adversely affected.

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

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

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 July 2, 2007, the District Court entered its final judgment, awarding us damages which were trebled to \$43.5 million and denying our request for a permanent injunction with respect to the Tyco Healthcare business practices found to be anti-competitive. We and Tyco Healthcare have each filed a notice of appeal from the judgment. We filed our opening brief on December 17, 2007 with the United States Court of Appeals for the 9th Circuit. On December 27, 2007, the Consumer Federation of America and Medical Device Manufacturers Association filed an Amicus brief supporting us. Tyco filed its opposition and appeal brief on March 3, 2008. A group of law professors filed an Amicus brief supporting Tyco on March 10, 2008. We filed our response and reply brief on May 19, 2008. The Consumer Federation of America and Medical Device Manufacturers Association filed an additional Amicus brief in support of us on May 29, 2008. Tyco filed its second appeal brief on July 17, 2008. The case is fully briefed and is awaiting oral argument which is expected in December 2008. Even if we are ultimately awarded damages in this litigation, the amount will be subject to a 50% legal fee contingency agreement, in which case we would receive 50% of the net (of costs) proceeds from any award.

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

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

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

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

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

cause substantial dilution of our earnings per share;

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

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

adversely affect the prevailing market price for our outstanding securities.

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

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

*** If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934 and Section 404 of the Sarbanes-Oxley Act of 2002, or if we fail to achieve and maintain adequate internal control over financial reporting, our business, results of operations and financial condition and investors' confidence in us could be materially adversely affected.**

As a public company, we are required to comply with the periodic reporting obligations of the Securities Exchange Act of 1934, or Exchange Act, including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner and meet our reporting obligations in their entirety could subject us to penalties under federal securities laws and regulations of The Nasdaq Stock Market, LLC, or Nasdaq, expose us to lawsuits and restrict our ability to access financing on favorable terms, or at all.

In addition, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, we are required to evaluate and provide a management report of our systems of internal control over financial reporting and our independent registered public accounting firm will be required to attest to, our internal control over financial reporting. We have dedicated, and we expect to continue to dedicate, significant management, financial and other resources in connection with obtaining and seeking to maintain compliance with Section 404 based on the standards adopted by the Public Company Accounting Oversight Board. These efforts include reviewing our existing internal control structure and performing the system and process evaluation and testing (and any necessary remediation). As a result of this review, we may either hire or outsource additional personnel to expand and strengthen our finance function. In addition, during the course of the evaluation of our internal control over financial reporting, we may identify areas requiring improvement and may be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time from other activities.

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We cannot provide any assurance that we will be able to successfully meet the certification requirements of Section 404 by the time that we are required to file our annual report on Form 10-K for the year ending January 3, 2009, or at all, or that our independent registered public accounting firm will be able to provide an attestation report required under the regulations. If we fail to achieve and maintain the adequacy of our internal control over financial reporting, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal

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control over financial reporting in accordance with the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. Our failure to meet the requirements of Section 404 in a timely manner may subject us investigations by regulatory authorities, including the SEC or Nasdaq, and sanctions. As a result, our failure to satisfy the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business, negatively impact the trading price of our common stock, and adversely affect investors' confidence in our company and our ability to access capital markets for financing.

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

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

Risks Related to Our Common Stock

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

There has been significant volatility in the market price and trading volume of equity securities, which is unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our common stock. From June 29, 2008 to September 27, 2008, our closing stock price ranged from \$33.49 to \$41.95. You may not be able to resell your shares at or above the price you paid for them due to fluctuations in the market price of our common stock caused by changes in our operating performance or prospects and other factors.

Some specific factors that may have a significant effect on our common stock market price, many of which we cannot control, include but are not limited to:

actual or anticipated fluctuations in our operating results or future prospects;

our announcements or our competitors' announcements of new products;

the public's reaction to our press releases, our other public announcements and our filings with the SEC;

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

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 or our Board of Directors; and

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

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

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

As of September 27, 2008, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 13.1% of our outstanding common stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, the stockholders may be able to exercise a significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have some control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of us or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock. In addition, these stockholders, some of whom have representatives sitting on our board of directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes in control of us, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

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

As of September 27, 2008, an aggregate of 11,395,643 shares of our common stock were reserved for future issuance under our three equity incentive plans, 7,380,855 of which were subject to options outstanding as of that date at a weighted average exercise price of \$14.91 per share. To the extent outstanding options are exercised, our existing stockholders may incur dilution. We rely heavily on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

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

As of September 27, 2008, there were 57,013,856 shares of our common stock outstanding, including 3,287,494 shares sold by us and 10,416,626 shares sold by our selling stockholders in our initial public offering, or IPO, in August 2007. A significant portion of our shares of common stock outstanding prior to our IPO that were not sold by selling stockholders became eligible for sale in the public market on February 4, 2008 upon expiration of lock-up agreements entered into in connection with our IPO, although as of September 27, 2008, 7,441,709 of these shares were held by directors, executive officers and other affiliates and subject to volume limitations under Rule 144 as of that date. A large portion of our outstanding shares are held by a small number of persons and investment funds. Resales by these stockholders of a substantial number of shares, announcements of the proposed resales of substantial amounts of our common stock or the perception that substantial resales may be made, could significantly reduce the market price of our common stock. Moreover, the holders of 1,018,590 shares of common stock at September 27, 2008 have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold or to include these shares in registration statements that we may file for ourselves or other stockholders from time to time.

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

In December 2007, we registered an aggregate of 11,218,285 shares reserved under our equity plans under a Registration Statement on Form S-8. All shares issued pursuant to a Registration Statement on Form S-8 can be freely sold in the public market upon issuance, subject to restrictions on our affiliates under Rule 144. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

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

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

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

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

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

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

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

We currently intend to retain all future earnings for the operation and expansion of our business and do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends on our common stock will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our board of directors.

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

Securities analysts may elect not to provide research coverage of our common stock. If securities analysts do not cover our common stock, the lack of research coverage may cause the market price of our common stock to decline.

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The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about our business or the pulse oximetry market. If one or more of the analysts who elects to cover us downgrades our stock, our stock price could decline rapidly. If one or more of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, recently adopted rules mandated by the Sarbanes-Oxley Act, and a global settlement reached in 2003 between the SEC, other regulatory agencies and a number of investment banks, has led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms are required to contract with independent financial analysts for their stock research. As long as we have a smaller market capitalization, it may be difficult for us to attract independent financial analysts that will cover our common stock, which could have a negative effect on the market price of our stock.

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

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

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

As of September 27, 2008, we used over \$27.0 million of the net proceeds from our IPO for working capital, purchase and installation of equipment and general corporate purposes. We anticipate that we will continue to use the remaining net proceeds from our IPO for additional working capital, purchase and installation of equipment and general corporate purposes. The timing and amount of our actual expenditures of the remaining IPO net proceeds 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 U.S. Treasury bills with maturities of 3 months or less, and short-term money market securities. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus filed with the SEC on August 8, 2007 pursuant to Rule 424(b) under the Securities Act of 1933.

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Item 6. Exhibits

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

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SIGNATURES

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

Date: October 28, 2008

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

Date: October 28, 2008

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

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

Number	Description of Document
2.1	(1) Asset Purchase Agreement, dated December 21, 2005, between the Registrant, Masimo Canada ULC and Andromed Inc. (Exhibit 2.1)
2.1	(a)(1) List briefly identifying the contents of schedules omitted from Exhibit 2.1 (Exhibit 2.1(a))
3.1	(1) Amended and Restated Certificate of Incorporation (Exhibit 3.2)
3.2	(2) Certificate of Designation of Series A Junior Participating Preferred Stock (Exhibit 3.1)
3.3	(3) Amended and Restated Bylaws (Exhibit 3.1)
4.1	(1) Form of Common Stock Certificate (Exhibit 4.1)
4.2	(1) Fifth Amended and Restated Registration Rights Agreement made and entered into as of September 14, 1999 between the Registrant and certain of its stockholders (Exhibit 4.2)
4.3	(2) Rights Agreement, dated November 9, 2007, between the Company and Computershare Trust Company, N.A., as Rights Agent (Exhibit 4.1)
4.4	(4) Masimo Retirement Savings Plan. (Exhibit 4.7)
31.1	Certification of Joe E. Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Mark P. de Raad, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification of Joe E. Kiani, Chief Executive Officer, and Mark P. de Raad, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-1 (No. 333-142171) originally filed on April 17, 2007. The number given in parentheses indicates the corresponding exhibit number in such Form S-1, as amended.
- (2) Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed on November 9, 2007. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
- (3) Incorporated by reference to the exhibit to the Company's Current Report on Form 8-K filed on October 10, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.
- (4) Incorporated by reference to the exhibit to the Company's Registration Statement on Form S-8 filed on February 11, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form S-8.

Pursuant to Item 601(b)(2) of Regulation S-K, the schedules to this agreement have been omitted. A list identifying the contents of the omitted schedules is included as Exhibit 2.1(a). The Company agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.