FULLER H B CO
Form 10-K
January 28, 2019

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 1, 2018

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: 001-09225

H.B. FULLER COMPANY

(Exact name of registrant as specified in its charter)

Minnesota	**41-0268370**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1200 Willow Lake Boulevard, St. Paul, Minnesota	**55110-5101**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(651) 236-5900**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $1.00 per share	New York Stock Exchange
Preferred Stock Purchase Rights	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: none

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. [X] Yes [ ] No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. [ ] Yes [X] No

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. [X] Yes [ ] No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). [X] Yes [ ] No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to the Form 10-K. [X]

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

Large accelerated filer [X] Accelerated filer [ ]

Non-accelerated filer [ ] Smaller reporting company [ ]

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

The aggregate market value of the Common Stock, par value $1.00 per share, held by non-affiliates of the registrant as of June 1, 2018 was approximately $2,601,453,076 (based on the closing price of such stock as quoted on the New York Stock Exchange of $51.84 on such date).

The number of shares outstanding of the Registrant's Common Stock, par value $1.00 per share, was 50,767,021 as of January 22, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to portions of the registrant's Proxy Statement for the Annual Meeting of Shareholders to be held on April 4, 2019.

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H.B. FULLER COMPANY

2018 Annual Report on Form 10-K

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PART I

Item 1. Business

H.B. Fuller Company was founded in 1887 and incorporated as a Minnesota corporation in 1915. Our stock is traded on the New York Stock Exchange ("NYSE") under the ticker symbol FUL. As used herein, "H.B. Fuller", "we", "us", "our", "management" or "company" includes H.B. Fuller and its subsidiaries unless otherwise indicated. Where we refer to 2018, 2017 and 2016 herein, the reference is to our fiscal years ended December 1, 2018, December 2, 2017 and December 3, 2016, respectively.

We are a leading worldwide formulator, manufacturer and marketer of adhesives, sealants and other specialty chemical products. Sales operations span 34 countries in North America, Europe, Latin America, the Asia Pacific region, India, the Middle East and Africa. Industrial adhesives represent our core product offering. Customers use our adhesives products in manufacturing common consumer and industrial goods, including food and beverage containers, disposable diapers, windows, doors, flooring, roofing, appliances, sportswear, footwear, multi-wall bags, water filtration products, insulation, textiles, automobiles, recreational vehicles, buses, trucks and trailers, marine products, solar energy systems, electronics and products for the aerospace and defense industries. Our adhesives help improve the performance of our customers' products or improve their manufacturing processes. We also provide our customers with technical support and unique solutions designed to address their specific needs. In addition, we have established a variety of product offerings for residential construction markets, such as tile-setting adhesives, grouts, sealants and related products.

Recent Acquisitions

Adecol

On November 1, 2017, we acquired Adecol Industria Quimica, Limitada ("Adecol"), headquartered in Guarulhos, Brazil. Adecol works with customers to develop innovative, high-quality hot melt, reactive and polymer-based adhesive solutions in the packaging, converting and durable assembly markets. The purchase price of $40.3 million was funded through borrowings on our revolving credit facility and existing cash and is reported in our Americas Adhesives operating segment.

Royal Adhesives

On October 20, 2017, we acquired Royal Adhesives and Sealants ("Royal Adhesives"), a manufacturer of high-value specialty adhesives and sealants. Royal Adhesives is a supplier of industrial adhesives in a diverse set of end markets, including aerospace, transportation, commercial roofing, insulating glass, solar, packaging and flooring applications and operates 19 manufacturing facilities in five countries. The purchase price of $1,620.3 million was funded through new debt financing. Royal Adhesives is included in multiple operating segments.

Wisdom Adhesives

On January 27, 2017, we acquired substantially all of the assets of H.E. Wisdom & Sons, Inc. and its affiliate Wisdom Adhesives Southeast, L.L.C., ("Wisdom Adhesives") headquartered in Elgin, Illinois. Wisdom Adhesives is a provider of adhesives for the packaging, paper converting and durable assembly markets. The purchase price of $123.5 million was financed through borrowings on our revolving credit facility and is reported in our Americas Adhesives operating segment.

Non-U.S. Operations

The principal markets, products and methods of distribution outside the United States vary with each of our regional operations, generally maintaining integrated business units that contain dedicated supplier networks, manufacturing, logistics and sales organizations. The vast majority of the products sold within any region are produced within the region, and the respective regions do not import significant amounts of product from other regions. As of December 1, 2018, we had sales offices and manufacturing plants in 21 countries outside the United States and satellite sales offices in another 12 countries.

We have detailed Code of Conduct policies that we apply across all of our operations around the world. These policies represent a set of common values that apply to all employees and all of our business dealings. We have adopted policies and processes, and conduct employee training, all of which are intended to ensure compliance with various economic sanctions and export controls, including the regulations of the U.S. Treasury Department's Office of Foreign Assets Control ("OFAC"). We do not conduct any business in the following countries that are subject to U.S. economic sanctions: Cuba; Iran; North Korea; Syria and the Crimea region of the Ukraine. See Item 3. Legal Proceedings for additional disclosures regarding past business conducted in Iran.

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Competition

Many of our markets are highly competitive. However, we compete effectively due to the quality and breadth of our adhesives, sealants and specialty chemical portfolio and the experience and expertise of our commercial organizations. Within the adhesives and other specialty chemical markets, we believe few suppliers have comparable global reach and corresponding ability to deliver quality and consistency to multinational customers. Our competition is made up generally of two types of companies: (1) similar multinational suppliers and (2) regional or specialty suppliers that typically compete in only one region or within a narrow geographic area within a region. The multinational competitors typically maintain a broad product offering and range of technology, while regional or specialty companies tend to have limited or more focused product ranges and technology.

Principal competitive factors in the sale of adhesives and other specialty chemicals are product performance, supply assurance, technical service, quality, price and customer service.

Customers

We have cultivated strong, integrated relationships with a diverse set of customers worldwide. Our customers are among the technology and market leaders in consumer goods, construction, and industrial markets. We pride ourselves on long-term, collaborative customer relationships and a diverse portfolio of customers in which no single customer accounted for more than 10 percent of consolidated net revenue.

Our leading customers include manufacturers of food and beverages, hygiene products, clothing, major appliances, electronics, automobiles, aerospace and defense products, solar energy systems, filters, construction materials, wood flooring, furniture, cabinetry, windows, doors, tissue and towel, corrugation, tube winding, packaging, labels and tapes.

Our products are delivered directly to customers primarily from our manufacturing plants, with additional deliveries made through distributors and retailers.

Backlog

No significant backlog of unfilled orders existed at December 1, 2018 or December 2, 2017.

Raw Materials

We use several principal raw materials in our manufacturing processes, including tackifying resins, polymers, synthetic rubbers, vinyl acetate monomer and plasticizers. We generally avoid sole source supplier arrangements for raw materials.

The majority of our raw materials are petroleum/natural gas based derivatives. Under normal conditions, raw materials are available on the open market. Prices and availability are subject to supply and demand market mechanisms. Raw material costs are primarily determined by the balance of supply against the aggregate demand from the adhesives industry and other industries that use the same raw material streams. The cost of crude oil and natural gas, the primary feedstocks for our raw materials, can also impact the cost of our raw materials.

Patents, Trademarks and Licenses

Much of the technology we use in our products and manufacturing processes is available in the public domain. For technology not available in the public domain, we rely on trade secrets and patents when appropriate to protect our competitive position. We also license some patented technology from other sources. Our business is not materially dependent upon licenses or similar rights or on any single patent or group of related patents.

We enter into agreements with many employees to protect rights to technology and intellectual property. Confidentiality commitments also are routinely obtained from customers, suppliers and others to safeguard proprietary information.

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We own numerous trademarks and service marks in various countries. Trademarks, such as H.B. Fuller®, Swift®, Advantra®, Clarity®, Sesame®, TEC®, Foster®, Rakoll®, Rapidex®, Full-CareTM, Thermonex®, Silaprene®, Eternabond®, Cilbond®, and TONSAN® are important in marketing products. Many of our trademarks and service marks are registered. U.S. trademark registrations are for a term of ten years and are renewable every ten years as long as the trademarks are used in the regular course of trade.

Research and Development

Our investment in research and development creates new and innovative adhesive technology platforms, enhances product performance, ensures a competitive cost structure and leverages available raw materials. New product development is a key research and development outcome, providing higher-value solutions to existing customers or meeting new customers' needs. Projects are developed in local laboratories in each region, where we understand our customer base the best. Platform developments are coordinated globally through our network of laboratories.

Through designing and developing new polymers and new formulations, we expect to continue to grow in our current markets. We also develop new applications for existing products and technologies, and improve manufacturing processes to enhance productivity and product quality. Research and development efforts are closely aligned to customer needs, but we do not engage in customer sponsored activities. We foster open innovation, seek supplier-driven new technology and use relationships with academic and other institutions to enhance our capabilities.

Environmental, Health and Safety

We comply with applicable regulations relating to environmental protection and workers' safety. This includes regular review of and upgrades to environmental, health and safety policies, practices and procedures as well as improved production methods to minimize our facilities' outgoing waste, based on evolving societal standards and increased environmental understanding.

Expenditures to comply with environmental regulations over the next two years are estimated to be approximately $13.8 million, including approximately $1.4 million of capital expenditures. See additional disclosure under Item 3. Legal Proceedings.

Seasonality

Our operating segments have historically had lower net revenue in winter months, which is primarily our first fiscal quarter, mainly due to international holidays and the seasonal decline in construction and consumer spending activities.

Employees

We employed approximately 6,500 individuals on December 1, 2018, of which approximately 2,700 were located in the United States.

Executive Officers of the Registrant

The following table shows the name, age and business experience for the past five years of the executive officers as of January 7, 2019. Unless otherwise noted, the positions described are positions with the company or its subsidiaries.

Name	Age	Positions	Period Served
James J. Owens	54	President and Chief Executive Officer	November 2010 - Present
		Senior Vice President, Engineering Adhesives	February 2016 - Present
Zhiwei Cai	56	Vice President, TONSAN and Electronics	2014 - 2016
		Director, Electronics Materials	2012 - 2014
Heather A. Campe	45	Senior Vice President, Americas Adhesives	October 2016 - Present
		Vice President, Asia Pacific	2013 - 2016
Theodore M. Clark	65	Senior Vice President, Royal Adhesives	October 2017 - Present
		President and CEO of Royal Adhesives and Sealants	2003 - 2017

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Paula M. Cooney	50	Vice President, Human Resources	April 2016 - Present
		Director, Global Human Resources Strategic Programs	2010 - 2016
John J. Corkrean	53	Executive Vice President and Chief Financial Officer	May 2016 - Present
		Senior Vice President, Finance - Global Energy Services, NALCO Champion, an Ecolab Inc. company (supplier of chemicals and related services to the oil and gas industry)	2014 - 2016
		Senior Vice President and Corporate Controller, Ecolab Inc. (global provider of water, hygiene and energy technologies and services)	2008 - 2014
Dietrich J. Crail	48	Vice President, Asia Pacific	October 2016 - Present
		Vice President, Paper Converting and Construction, Henkel Corporation (global manufacturer of adhesives, sealants and surface treatments)	2013 - 2016
		Vice President and Global Segment Leader, Pressure Sensitive Adhesives, Henkel Corporation	2008 - 2014
Traci L. Jensen	52	Senior Vice President, Global Construction Adhesives	July 2016 - Present
		Senior Vice President, Americas Adhesives	January 2013 - July 2016
Timothy J. Keenan	61	Vice President, General Counsel and Corporate Secretary	December 2006 - Present
Patrick M. Kivits	51	Senior Vice President, EIMEA	September 2015 - Present
		Corporate Vice President and General Manager, Henkel Corporation (global manufacturer of adhesives, sealants and surface treatments)	2013 - 2015
David W. Moorman	50	Vice President, Operations Excellence	March 2017 - Present
		Director, Global Information Technology	2010 - 2017
Ebrahim Rezai	67	Vice President and Chief Technology and Innovation Officer	October 2016 - Present
		Associate Director, Baby and Feminine Care Global Material Development and Supply Organization, Procter and Gamble (multinational manufacturer of family, personal and household care products)	2015 - 2016
		Associate Director, Baby Care Global Material Development and Supply Organization, Procter and Gamble	2005 - 2015

The Board of Directors elects the executive officers annually.

Available Information

For more information about us, visit our website at: www.hbfuller.com.

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We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission ("SEC") via EDGAR. Our SEC filings are available free of charge to the public at our website as soon as reasonably practicable after they have been filed with or furnished to the SEC.

Item 1A. Risk Factors

As a global manufacturer of adhesives, sealants and other specialty chemical products, we operate in a business environment that is subject to various risks and uncertainties. Below are the most significant factors that could adversely affect our business, financial condition and results of operations.

Macroeconomic and Industry Risks

Uncertainties in foreign economic, political, regulatory and social conditions and fluctuations in foreign currency may adversely affect our results.

Approximately 55 percent, or $1.7 billion, of our net revenue was generated outside the United States in 2018. International operations could be adversely affected by changes in economic, political, regulatory, and social conditions, especially in Brazil, Russia, China, the Middle East, including Turkey and Egypt, and other developing or emerging markets where we do business. An economic downturn in the businesses or geographic areas in which we sell our products could reduce demand for these products and result in a decrease in sales volume that could have a negative impact on our results of operations. Product demand often depends on end-use markets. Economic conditions that reduce consumer confidence or discretionary spending may reduce product demand. Challenging economic conditions may also impair the ability of our customers to pay for products they have purchased, and as a result, our reserves for doubtful accounts and write-offs of accounts receivable may increase. In addition, trade protection measures, anti-bribery and anti-corruption regulations, restrictions on repatriation of earnings, differing intellectual property rights and changes in legal and regulatory requirements that restrict the sales of products or increase costs could adversely affect our results of operations.

Fluctuations in exchange rates between the U.S. dollar and other currencies could potentially result in increases or decreases in net revenue, cost of raw materials and earnings and may adversely affect the value of our assets outside the United States. In 2018, the change in foreign currencies negatively impacted our net revenue by approximately $2.0 million. In 2018, we spent approximately $1.7 billion for raw materials worldwide of which approximately $869.1 million was purchased outside the United States. Based on 2018 financial results, a hypothetical one percent change in our cost of sales due to foreign currency rate changes would have resulted in a change in net income of approximately $8.3 million or $0.16 per diluted share. Although we utilize risk management tools, including hedging, as appropriate, to mitigate market fluctuations in foreign currencies, any changes in strategy in regard to risk

management tools can also affect revenue, expenses and results of operations and there can be no assurance that such measures will result in cost savings or that all market fluctuation exposure will be eliminated.

Distressed financial markets may result in dramatic deflation of financial asset valuations and a general disruption in capital markets.

Adverse equity market conditions and volatility in the credit markets could have a negative impact on the value of our pension trust assets, our future estimated pension liabilities and other postretirement benefit plans. In addition, we could be required to provide increased pension plan funding. As a result, our financial results could be negatively impacted. Reduced access to capital markets may affect our ability to invest in strategic growth initiatives such as acquisitions. In addition, the reduced credit availability could limit our customers' ability to invest in their businesses, refinance maturing debt obligations, or meet their ongoing working capital needs. If these customers do not have sufficient access to the financial markets, demand for our products may decline.

The interest rates of our term loans are priced using a spread over LIBOR.

LIBOR, the London interbank offered rate, is the basic rate of interest used in lending between banks on the London interbank market and is widely used as a reference for setting the interest rate on loans globally. We typically use LIBOR as a reference rate in our term loans such that the interest due to our creditors pursuant to a term loan extended to us is calculated using LIBOR. Most of our term loan agreements contain a stated minimum value for LIBOR.

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On July 27, 2017, the United Kingdom's Financial Conduct Authority, which regulates LIBOR, announced that it intends to phase out LIBOR by the end of 2021. It is unclear if at that time whether or not LIBOR will cease to exist or if new methods of calculating LIBOR will be established such that it continues to exist after 2021. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with a new index calculated by short-term repurchase agreements, backed by Treasury securities ("SOFR"). SOFR is observed and backward looking, which stands in contrast with LIBOR under the current methodology, which is an estimated forward-looking rate and relies, to some degree, on the expert judgment of submitting panel members. Given that SOFR is a secured rate backed by government securities, it will be a rate that does not take into account bank credit risk (as is the case with LIBOR). SOFR is therefore likely to be lower than LIBOR and is less likely to correlate with the funding costs of financial institutions. Whether or not SOFR attains market traction as a LIBOR replacement tool remains in question. As such, the future of LIBOR at this time is uncertain. If LIBOR ceases to exist, we may need to renegotiate our credit agreements with that utilize LIBOR as a factor in determining the interest rate to replace LIBOR with the new standard that is established.

Operational Risks

Increases in prices and declines in the availability of raw materials could negatively impact our financial results.

In 2018, raw material costs made up approximately 75 percent of our cost of sales. Accordingly, changes in the cost of raw materials can significantly impact our earnings. Raw materials needed to manufacture products are obtained from a number of suppliers and many of the raw materials are petroleum and natural gas based derivatives. Under normal market conditions, these raw materials are generally available on the open market from a variety of producers. While alternate supplies of most key raw materials are available, supplier production outages may lead to strained supply-demand situations for certain raw materials. The substitution of key raw materials requires us to identify new supply sources, reformulate and re-test and may require seeking re-approval from our customers using those products. From time to time, the prices and availability of these raw materials may fluctuate, which could impair our ability to procure necessary materials, or increase the cost of manufacturing products. If the prices of raw materials increase in a short period of time, we may be unable to pass these increases on to our customers in a timely manner and could experience reductions to our profit margins. Based on 2018 financial results, a hypothetical one percent change in our raw material costs would have resulted in a change in net income of approximately $12.1 million or $0.23 per diluted share.

We experience substantial competition in each of the operating segments and geographic areas in which we operate.

Our wide variety of products are sold in numerous markets, each of which is highly competitive. Our competitive position in markets is, in part, subject to external factors. For example, supply and demand for certain of our products

is driven by end-use markets and worldwide capacities which, in turn, impact demand for and pricing of our products. Many of our direct competitors are part of large multinational companies and may have more resources than we do. Any increase in competition may result in lost market share or reduced prices, which could result in reduced profit margins. This may impair the ability to grow or even to maintain current levels of revenues and earnings. While we have an extensive customer base, loss of certain top customers could adversely affect our financial condition and results of operations until such business is replaced, and no assurances can be made that we would be able to regain or replace any lost customers.

Failure to develop new products and protect our intellectual property could negatively impact our future performance and growth.

Ongoing innovation and product development are important factors in our competitiveness. Failure to create new products and generate new ideas could negatively impact our ability to grow and deliver strong financial results. We continually apply for and obtain U.S. and foreign patents to protect the results of our research for use in our operations and licensing. We are party to a number of patent licenses and other technology agreements. We rely on patents, confidentiality agreements and internal security measures to protect our intellectual property. Failure to protect this intellectual property could negatively affect our future performance and growth.

We may be required to record impairment charges on our goodwill or long-lived assets.

Weak demand may cause underutilization of our manufacturing capacity or elimination of product lines; contract terminations or customer shutdowns may force sale or abandonment of facilities and equipment; or other events associated with weak economic conditions or specific product or customer events may require us to record an impairment on tangible assets, such as facilities and equipment, as well as intangible assets, such as intellectual property or goodwill, which would have a negative impact on our financial results.

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Catastrophic events could disrupt our operations or the operations of our suppliers or customers, having a negative impact on our financial results.

Unexpected events, including natural disasters and severe weather events, fires or explosions at our facilities or those of our suppliers, acts of war or terrorism, supply disruptions or breaches of security of our information technology systems could increase the cost of doing business or otherwise harm our operations, our customers and our suppliers. Such events could reduce demand for our products or make it difficult or impossible for us to receive raw materials from suppliers and deliver products to our customers.

A failure in our information technology systems could negatively impact our business.

We rely on information technology to record and process transactions, manage our business and maintain the financial accuracy of our records. Our computer systems are subject to damage or interruption from various sources, including power outages, computer and telecommunications failures, computer viruses, security breaches, vandalism, catastrophic events and human error. Interruptions of our computer systems could disrupt our business, for example by leading to plant downtime and/or power outages, and could result in the loss of business and cause us to incur additional expense.

Information technology security threats are increasing in frequency and sophistication. Our information technology systems could be breached by unauthorized outside parties or misused by employees or other insiders intent on extracting sensitive information, corrupting information or disrupting business processes. Such unauthorized access and a failure to effectively recover from breaches could compromise confidential information, disrupt our business, harm our reputation, result in the loss of assets including trade secrets and other intellectual property, customer confidence and business, result in regulatory proceedings and legal claims, and have a negative impact on our financial results.

We are in the process of implementing a global Enterprise Resource Planning (“ERP”) system that we refer to as Project ONE, which will upgrade and standardize our information system. The North America adhesives business went live in 2014. In 2017, we began the implementation and upgrade of our ERP system in our Latin America adhesives business and implementation for all countries, with the exception of Brazil, has been completed as of the end of 2018. During 2019 and beyond, we will continue implementation in North America, EIMEA (Europe, India, Middle East and Africa) and Asia Pacific.

Any delays or other failure to achieve our implementation goals may adversely impact our financial results. In addition, the failure to either deliver the application on time or anticipate the necessary readiness and training needs could lead to business disruption and loss of business. Failure or abandonment of any part of the ERP system could

result in a write-off of part or all of the costs that have been capitalized on the project.

Risks Related to Acquisitions

Risks associated with acquisitions could have an adverse effect on us and the inability to execute organizational restructuring may affect our results.

As part of our growth strategy, we have made and intend to pursue additional acquisitions of complementary businesses or products and joint ventures. The ability to grow through acquisitions or joint ventures depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions or joint venture arrangements. If we fail to successfully integrate acquisitions into our existing business, our results of operations and our cash flows could be adversely affected. Our acquisition strategy also involves other risks and uncertainties, including distraction of management from current operations, greater than expected liabilities and expenses, inadequate return on capital, unidentified issues not discovered in our investigations and evaluations of those strategies and acquisitions and difficulties implementing and maintaining consistent standards, controls, procedures, policies and systems. Future acquisitions could result in debt, dilution, liabilities, increased interest expense, restructuring charges and amortization expenses related to intangible assets.

In addition, our profitability is dependent on our ability to drive sustainable productivity improvements such as cost savings through organizational restructuring. Delays or unexpected costs may prevent us from realizing the full operational and financial benefits of such restructuring initiatives and may potentially disrupt our operations.

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We may not realize the revenue growth opportunities and cost synergies that are anticipated from the Royal Adhesives acquisition as we may experience difficulties in integrating Royal Adhesives' business with ours.

The benefits that are expected to result from the Royal Adhesives acquisition will depend, in part, on our ability to realize the anticipated revenue growth opportunities and cost synergies as a result of the acquisition. Our success in realizing these revenue growth opportunities and cost synergies, and the timing of this realization, depends on the successful integration of Royal Adhesives. There is a significant degree of difficulty and management distraction inherent in the process of integrating an acquisition as sizable as Royal Adhesives. The process of integrating operations could cause an interruption of, or loss of momentum in, our Royal Adhesives' activities. Members of our senior management may be required to devote considerable amounts of time to this integration process, which will decrease the time they will have to manage our company, service existing customers, attract new customers and develop new products or strategies. If senior management is not able to effectively manage the integration process, or if any significant business activities are interrupted as a result of the integration process, our business could suffer. There can be no assurance that we will successfully or cost-effectively integrate Royal Adhesives. The failure to do so could have a material adverse effect on our business, financial condition or results of operations.

Even if we are able to integrate Royal Adhesives successfully, this integration may not result in the realization of the full benefits of the growth opportunities and cost synergies that we currently expect from this integration, and we cannot guarantee that these benefits will be achieved within anticipated timeframes or at all. For example, we may not be able to eliminate duplicative costs. Moreover, we may incur substantial expenses in connection with the integration of Royal Adhesives. While it is anticipated that certain expenses will be incurred to achieve cost synergies, such expenses are difficult to estimate accurately, and may exceed current estimates. Accordingly, the benefits from the acquisition may be offset by costs incurred to, or delays in, integrating the businesses.

The debt incurred in connection with the Royal Adhesives acquisition could have a negative impact on our liquidity or restrict our activities.

As a result of the Royal Adhesives acquisition, our outstanding indebtedness has significantly increased. Our current indebtedness contains various covenants that limit our ability to engage in specified types of transactions. Our overall leverage and the terms of our financing arrangements could:

- limit our ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions;
- make it more difficult to satisfy our obligations under the terms of our indebtedness;
- limit our ability to refinance our indebtedness on terms acceptable to us or at all;
- limit our flexibility to plan for and adjust to changing business and market conditions in the industries in which we operate and increase our vulnerability to general adverse economic and industry conditions;
- require us to dedicate a substantial portion of our cash flow to make interest and principal payments on our debt, thereby limiting the availability of our cash flow to fund future acquisitions, working capital, business activities, and

other general corporate requirements;
limit our ability to obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity, particularly if any ratings assigned to our debt securities by rating organizations were revised downward; and
subject us to higher levels of indebtedness than our competitors, which may cause a competitive disadvantage and may reduce our flexibility in responding to increased competition.

In addition, the restrictive covenants require us to maintain specified financial ratios and satisfy other financial condition tests. Our ability to meet those financial ratios and tests will depend on our ongoing financial and operating performance, which, in turn, will be subject to economic conditions and to financial, market and competitive factors, many of which are beyond our control. A breach of any of these covenants could result in a default under the instruments governing our indebtedness.

Legal and Regulatory Risks

The impact of changing laws or regulations or the manner of interpretation or enforcement of existing laws or regulations could adversely impact our financial performance and restrict our ability to operate our business or execute our strategies.

New laws or regulations, or changes in existing laws or regulations or the manner of their interpretation or enforcement, could increase our cost of doing business and restrict our ability to operate our business or execute our strategies. In addition, compliance with laws and regulations is complicated by our substantial global footprint, which will require significant and additional resources to ensure compliance with applicable laws and regulations in the various countries where we conduct business.

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Our global operations expose us to trade and economic sanctions and other restrictions imposed by the U.S., the EU and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the Foreign Corrupt Practices Act (the "FCPA") and other federal statutes and regulations, including those established by the Office of Foreign Assets Control ("OFAC"). Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws, regulations, policies or procedures could adversely impact our business, results of operations and financial condition.

Although we have implemented policies and procedures in these areas, we cannot assure you that our policies and procedures are sufficient or that directors, officers, employees, representatives, manufacturers, suppliers and agents have not engaged and will not engage in conduct in violation of such policies and procedures.

We have lawsuits and claims against us with uncertain outcomes.

Our operations from time to time are parties to or targets of lawsuits, claims, investigations and proceedings, including product liability, personal injury, asbestos, patent and intellectual property, commercial, contract, environmental, antitrust, health and safety, and employment matters, which are handled and defended in the ordinary course of business. The results of any future litigation or settlement of such lawsuits and claims are inherently unpredictable, but such outcomes could be adverse and material in amount. See Item 3. Legal Proceedings for a discussion of current litigation.

Costs and expenses resulting from compliance with environmental laws and regulations may negatively impact our operations and financial results.

We are subject to numerous environmental laws and regulations that impose various environmental controls on us or otherwise relate to environmental protection, the sale and export of certain chemicals or hazardous materials, and various health and safety matters. The costs of complying with these laws and regulations can be significant and may increase as applicable requirements and their enforcement become more stringent and new rules are implemented. Adverse developments and/or periodic settlements could negatively impact our results of operations and cash flows. See Item 3. Legal Proceedings for a discussion of current environmental matters.

Additional income tax expense or exposure to additional income tax liabilities could have a negative impact on our financial results.

We are subject to income tax laws and regulations in the United States and various foreign jurisdictions. Significant judgment is required in evaluating and estimating our provision and accruals for these taxes. Our income tax liabilities are dependent upon the location of earnings among these different jurisdictions. Our income tax provision and income tax liabilities could be adversely affected by the jurisdictional mix of earnings, changes in valuation of deferred tax assets and liabilities and changes in tax laws and regulations. In the ordinary course of our business, we are also subject to continuous examinations of our income tax returns by tax authorities. Although we believe our tax estimates are reasonable, the final results of any tax examination or related litigation could be materially different from our related historical income tax provisions and accruals. Adverse developments in an audit, examination or litigation related to previously filed tax returns, or in the relevant jurisdiction's tax laws, regulations, administrative practices, principles and interpretations could have a material effect on our results of operations and cash flows in the period or periods for which that development occurs, as well as for prior and subsequent periods.

Federal income tax reform could have unforeseen effects on our financial condition and results of operations.

On December 22, 2017, the President of the United States signed into law H.R. 1, originally known as the "Tax Cuts and Jobs Act", hereafter referred to as "U.S. Tax Reform". Since the passing of U.S. Tax Reform, additional guidance in the form of notices and proposed regulations which interpret various aspects of U.S. Tax Reform have been issued. As of the filing of this document, additional guidance is expected. Changes could be made to the proposed regulations as they become finalized, future legislation could be enacted, more regulations and notices could be issued, all of which may impact our financial results. We will continue to monitor all of these changes and will reflect the impact as appropriate in future financial statements. Many state and local tax jurisdictions are still determining how they will interpret elements of U.S. Tax Reform. Final state and local governments' conformity, legislation and guidance relating to U.S. Tax Reform may impact our financial results.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Principal executive offices and central research facilities are located in the St. Paul, Minnesota area. These facilities are company-owned and contain 247,630 square feet. Manufacturing operations are carried out at 38 plants located throughout the United States and at 36 plants located in 21 other countries. In addition, numerous sales and service offices are located throughout the world. We believe that the properties owned or leased are suitable and adequate for our business. Operating capacity varies by product line, but additional production capacity is available for most product lines by increasing the number of shifts worked. The following is a list of our manufacturing plants as of December 1, 2018 (each of the listed properties are owned by us, unless otherwise specified):

Segment	Manufacturing Sq Ft	Segment	Manufacturing Sq Ft
Americas Adhesives		**EIMEA**	
California - Roseville	82,202	Egypt - 6th of October City	8,525
Georgia - Covington	73,500	France - Blois	48,438
- Tucker	69,000	- Surbourg	21,743
- Dalton	21,980	Germany - Lueneburg	64,249
Illinois - Seneca	24,621	- Nienburg	139,248
- Elgin - River Ridge[1]	35,239	- Pirmasens[2]	48,438
- Elgin - Executive	30,000	Germany - Langelsheim[1]	123,353
- Huntley[2]	29,000	- Pirmasens	81,278
Indiana - South Bend	128,218	Greece - Lamia	11,560
Kentucky - Paducah	252,500	India - Pune	38,782
Ohio - Blue Ash	102,000	Italy - Pianezze	36,500
Michigan - Grand Rapids	65,689	Portugal - Mindelo	90,193
Minnesota - Fridley[1]	15,850	Kenya - Nairobi[1]	5,262
- Vadnais Heights	53,145	United Kingdom - Dukinfield	17,465
New Jersey - Wayne[1]	16,000	**EIMEA Total**	**735,034**
New York - Syracuse[1]	23,000		
South Carolina - Simpsonville	23,722	**Asia Pacific**	
Texas - Mesquite	25,000	Australia - Dandenong South	43,540
Washington - Vancouver	35,768	- Sydney [1]	12,968
Argentina - Buenos Aires	10,367	People's Republic of China - Guangzhou	36,055
Brazil - Sorocaba[2]	7,535	- Nanjing	55,224
- Curitiba[1]	9,896	- Nanjing[1]	62,430

- Guarulhos	32,292
Chile - Maipu, Santiago	7,539
Colombia - Rionegro	17,072
Americas Adhesives Total	**1,191,135**
Construction Adhesives	
California - La Mirada	15,206
Canada - Ontario[1]	63,020
- Toronto[1]	25,172
Florida - Gainesville	6,800
Georgia - Dalton	72,000
Illinois - Aurora	149,000
- Palatine[2]	55,000
Michigan - Michigan Center	115,000
New Jersey - Edison	9,780
Ohio - Chagrin Falls	16,500
Pennsylvania - Fairless Hills	19,229
Texas - Eagle Lake	26,000
- Houston	11,000
- Mansfield	28,790
Construction Adhesives Total	**612,497**

1 Leased Property
2 Idle Property

Indonesia - Mojokerto	52,991
Malaysia - Selongor	21,900
New Zealand - Auckland[1]	7,330
Philippines - Manila	9,295
Vietnam - Binh Duong[1]	26,156
Asia Pacific Total	**327,889**
Engineering Adhesives	
California - Irvine[1]	15,120
- Wilmington[1]	26,373
People's Republic of China - Beijing	78,120
- Beijing[1]	42,044
- Suzhou	73,622
- Yantai	23,890
Germany - Wunstorf	16,146
Georgia - Norcross[1]	39,727
- Ball Ground[1]	4,800
Illinois - Batavia[1]	19,169
Illinois - Frankfort - Corsair	12,500
- Frankfort - West Drive	17,000
Massachusetts - Peabody[1]	40,000
New Hampshire - Raymond[1]	12,950
United Kingdom - Preston[1]	34,000
Engineering Adhesives Total	**455,461**

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Item 3. Legal Proceedings

Environmental Matters

From time to time, we become aware of compliance matters relating to, or receive notices from, federal, state or local entities regarding possible or alleged violations of environmental, health or safety laws and regulations. We review the circumstances of each individual site, considering the number of parties involved, the level of potential liability or our contribution relative to the other parties, the nature and magnitude of the hazardous substances involved, the method and extent of remediation, the estimated legal and consulting expense with respect to each site and the time period over which any costs would likely be incurred. Also, from time to time, we are identified as a potentially responsible party ("PRP") under the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA") and/or similar state laws that impose liability for costs relating to the clean up of contamination resulting from past spills, disposal or other release of hazardous substances. We are also subject to similar laws in some of the countries where current and former facilities are located. Our environmental, health and safety department monitors compliance with applicable laws on a global basis. To the extent we can reasonably estimate the amount of our probable liabilities for environmental matters, we establish a financial provision.

Currently, we are involved in various environmental investigations, clean up activities and administrative proceedings and lawsuits. In particular, we are currently deemed a PRP in conjunction with numerous other parties, in a number of government enforcement actions associated with landfills and/or hazardous waste sites. As a PRP, we may be required to pay a share of the costs of investigation and clean up of these sites.

We are engaged in environmental remediation and monitoring efforts at a number of current and former operating facilities. As of December 1, 2018, we accrued $10.7 million, which represents our best estimate of probable liabilities with respect to environmental matters. Of the amount accrued, $4.8 million is attributable to a facility we own in Simpsonville, South Carolina as a result of our Royal Adhesives acquisition that is a designated site under CERCLA. It is reasonably possible that we may have additional liabilities related to these known environmental matters. However, the full extent of our future liability for environmental matters is difficult to predict because of uncertainty as to the cost of investigation and clean up of the sites, our responsibility for such hazardous substances and the number of and financial condition of other potentially responsible parties.

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While uncertainties exist with respect to the amounts and timing of the ultimate environmental liabilities, based on currently available information, we have concluded that these matters, individually or in the aggregate, will not have a material adverse effect on our results of operations, financial condition or cash flow. However, adverse developments and/or periodic settlements could negatively impact the results of operations or cash flows in one or more future periods.

Other Legal Proceedings

From time to time and in the ordinary course of business, we are a party to, or a target of, lawsuits, claims, investigations and proceedings, including product liability, personal injury, contract, patent and intellectual property, environmental, health and safety, tax and employment matters. While we are unable to predict the outcome of these matters, we have concluded, based upon currently available information, that the ultimate resolution of any pending matter, individually or in the aggregate, including the asbestos litigation described in the following paragraphs, will not have a material adverse effect on our results of operations, financial condition or cash flow.

We have been named as a defendant in lawsuits in which plaintiffs have alleged injury due to products containing asbestos manufactured more than 30 years ago. The plaintiffs generally bring these lawsuits against multiple defendants and seek damages (both actual and punitive) in very large amounts. In many cases, plaintiffs are unable to demonstrate that they have suffered any compensable injuries or that the injuries suffered were the result of exposure to products manufactured by us. We are typically dismissed as a defendant in such cases without payment. If the plaintiff presents evidence indicating that compensable injury occurred as a result of exposure to our products, the case is generally settled for an amount that reflects the seriousness of the injury, the length, intensity and character of exposure to products containing asbestos, the number and solvency of other defendants in the case, and the jurisdiction in which the case has been brought.

A significant portion of the defense costs and settlements in asbestos-related litigation is paid by third parties, including indemnification pursuant to the provisions of a 1976 agreement under which we acquired a business from a third party. Currently, this third party is defending and paying settlement amounts, under a reservation of rights, in most of the asbestos cases tendered to the third party.

In addition to the indemnification arrangements with third parties, we have insurance policies that generally provide coverage for asbestos liabilities (including defense costs). Historically, insurers have paid a significant portion of our defense costs and settlements in asbestos-related litigation. However, certain of our insurers are insolvent. We have entered into cost-sharing agreements with our insurers that provide for the allocation of defense costs and settlements and judgments in asbestos-related lawsuits. These agreements require, among other things, that we fund a share of settlements and judgments allocable to years in which the responsible insurer is insolvent.

A summary of the number of and settlement amounts for asbestos-related lawsuits and claims is as follows:

($ in millions)	Year Ended December 1, 2018	Year Ended December 2, 2017	Year Ended December 3, 2016
Lawsuits and claims settled	7	9	14
Settlement amounts	$ 0.4	$ 1.7	$ 1.4
Insurance payments received or expected to be received	$ 0.3	$ 1.4	$ 0.9

We do not believe that it would be meaningful to disclose the aggregate number of asbestos-related lawsuits filed against us because relatively few of these lawsuits are known to involve exposure to asbestos-containing products that we manufactured. Rather, we believe it is more meaningful to disclose the number of lawsuits that are settled and result in a payment to the plaintiff. To the extent we can reasonably estimate the amount of our probable liabilities for pending asbestos-related claims, we establish a financial provision and a corresponding receivable for insurance recoveries.

Based on currently available information, we have concluded that the resolution of any pending matter, including asbestos-related litigation, individually or in the aggregate, will not have a material adverse effect on our results of operations, financial condition or cash flow. However, adverse developments and/or periodic settlements could negatively impact the results of operations or cash flows in one or more future periods.

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During 2018, we retained legal counsel to conduct an internal investigation of the possible resale of our hygiene products into Iran by certain customers of our subsidiaries in Turkey (beginning in 2011) and India (beginning in 2014), in possible violation of the economic sanctions against Iran administered by OFAC and our compliance policy. The sales to these customers represented less than one percent of our net revenue in each of our last three fiscal years. The sales to the customers who were reselling our products into Iran ceased during fiscal year 2018 and we do not currently conduct any business in Iran. In January 2018, we voluntarily contacted OFAC to advise it of this internal investigation and our intention to cooperate fully with OFAC and, in September 2018, we submitted the results and findings of our investigation to OFAC. We have not yet received a response from OFAC. At this time, we cannot predict the outcome or effect of the investigation, however, based on the results of our investigation to date, we believe we could incur penalties ranging from zero to $10.0 million.

Item 4. Mine Safety Disclosures

Not applicable.

Part II.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the New York Stock Exchange under the symbol FUL. As of January 22, 2019, there were 1,490 common shareholders of record for our common stock.

Issuer Purchases of Equity Securities

Information on our purchases of equity securities during the fourth quarter of 2018 is as follows:

Period	**(a)**	**(b)**	**(c)**	**(d)**

	Total Number of Shares Purchased[1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of a Publicly Announced Plan or Program	Maximum Approximate Dollar Value of Shares that may yet be Purchased Under the Plan or Program (thousands)
September 2, 2018 - October 6, 2018	2,057	$ 53.42	-	$ 187,170
October 7, 2018 - November 3, 2018	297	$ 45.62	-	$ 187,170
November 4, 2018 - December 1, 2018	254	$ 48.24	-	$ 187,170

[1] The total number of shares purchased include shares withheld to satisfy employees' withholding taxes upon vesting of restricted stock.

On April 6, 2017, the Board of Directors authorized a new share repurchase program of up to $200.0 million of our outstanding common shares. Under the program, we are authorized to repurchase shares for cash on the open market, from time to time, in privately negotiated transactions or block transactions, or through an accelerated repurchase agreement. The timing of such repurchases is dependent on price, market conditions and applicable regulatory requirements. Upon repurchase of the shares, we reduced our common stock for the par value of the shares with the excess being applied against additional paid in capital. This authorization replaces the September 30, 2010 authorization to repurchase shares.

Total			
$6,937	$287	$7,224	

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

Employee Benefit Plan

In fiscal year 1996, the Company adopted the Masimo Retirement Savings Plan, or the Plan, which is a 401(k) plan covering all of the Company s full-time U.S. employees who meet certain eligibility requirements. The Company contributes to the Plan on a discretionary basis. The Company contributed $235,000 and $459,000 to the Plan for the three and six months ended June 30, 2007, respectively, and $277,000 and $577,000 to the Plan for the three and six months ended June 28, 2008, respectively.

Employment Agreements

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

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

Severance Agreements

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

Purchase Commitments

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

Concentrations of Risk

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

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

The Company s ability to sell its products to U.S. hospitals depends in part on its relationships with Group Purchasing Organizations, or GPOs. Many existing and potential customers for the Company s products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO s affiliated hospitals and other members. During the three and six months ended June 30, 2007, revenue from the sale of the Company s pulse oximetry products to U.S. hospitals that are members of GPOs amounted to $26.7 million and $48.5 million, respectively. In the three and six months ended June 28, 2008, revenue from sales to U.S. hospitals that are members of GPOs was $33.0 million and $63.7 million, respectively.

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

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

Litigation

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

In March 2005, a jury found that Tyco Healthcare s use of sole-source contracts, product bundling, market share-based compliance pricing contracts and co-marketing agreements with patient monitoring companies were unlawful restraints of trade and exclusionary dealing arrangements and, as a result, violated federal antitrust laws. The jury awarded the Company $140 million in damages. Under the antitrust laws, if the jury verdict is sustained in whole or in part, all damages are trebled. Tyco Healthcare filed post-trial motions requesting that the District Court either override the jury decision or grant a new trial. In March 2006, the District Court upheld a portion of the jury verdict and vacated the remaining verdict. In addition, the District Court vacated the jury s damages award and granted Tyco Healthcare a new trial on damages. As a result, the Company may not receive any damages in this lawsuit. The District Court held an evidentiary hearing in October 2006 to re-try the damages. On January 25, 2007, the District Court issued a preliminary ruling which did not set damages, but resolved some issues of dispute about damages, and ordered another evidentiary hearing on issues still undecided by the District Court. The District Court held this evidentiary hearing in March 2007. On July 2, 2007, the District Court entered its final judgment awarding the Company damages which were trebled to $43.5 million and denying the Company s request for a permanent injunction with respect to Tyco Healthcare s business practices found to be anti-competitive. The Company and Tyco Healthcare have each filed a notice of appeal from the judgment. The Company filed its opening brief on December 17, 2007 with the United States Court of Appeals for the 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. However, the lawsuit has been and will continue to be a diversion of management s attention from the implementation of the Company s business strategy. See Risk Factors for a description of the risks related to the Company s litigation against Tyco Healthcare.

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

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

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

Voluntary Recall

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

12. Segment Information and Enterprise Reporting

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

The following schedule presents an analysis of the Company s product revenues based upon the geographic area to which the product was shipped (in thousands):

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

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

13. Income Taxes

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

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

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

Interest and penalties related to unrecognized tax benefits are recognized in income tax expense. For the three and six months ending June 28, 2008, the Company had accrued $58,000 and $127,000 for interest.

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

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

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

This quarterly report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Such forward-looking statements include any expectation of earnings, revenues or other financial items; any statements of the plans, strategies and objectives of management for future operations; factors that may affect our operating results; statements concerning new products, technologies or services; statements related to future capital expenditures; statements related to future economic conditions or performance; statements as to industry trends and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as anticipate, believe, continue, could, estimat expect, intend, may, or will, and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled Risk Factors included elsewhere in this Form 10-Q and in our other SEC filings, including our Annual Report on Form 10-K, which we filed with the SEC on March 4, 2008. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

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

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

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

The building of our installed base of pulse oximeters, Pulse Co-Oximeters and circuit boards generates recurring sales of our consumables, primarily single-patient use sensors. A user of one of our pulse oximeters or our OEMs pulse oximeters can obtain the benefit of the Masimo SET or Masimo Rainbow SET only by using our proprietary sensors that are designed for our system. We estimate that our worldwide installed base was approximately 515,000 units as of June 28, 2008, up from 424,000 units as of June 30, 2007. We estimate our installed base to be the number of bedside pulse oximeters and circuit boards that we have shipped in the past seven years.

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

Results of Operations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Cost of Goods Sold. Cost of goods sold increased 22.1% to $42.5 million in the six months ended June 28, 2008 from $34.8 million in the six months ended June 30, 2007. Total gross profit margin decreased to 70.8% for the six months ended June 28, 2008 from 71.6% for the six months ended June 30, 2007. This decline in total gross margin was due to the impact of the $4.9 million year over year decline in Covidien royalty revenues which have no related cost of goods sold. In the six months ended June 28, 2008, product gross profit margin rose to 65.0% from 62.7% in the comparable prior year period due to greater sensor sales, increased sales of Rainbow related products and manufacturing efficiencies related to higher production volumes. We incurred $1.8 million and $1.6 million in Masimo Lab s royalty expenses for the six months ended June 28, 2008 and June 30, 2007, respectively, which, in accordance with FIN 46(R), have been eliminated in our condensed consolidated financial results for the periods presented. Had these royalty expenses not been eliminated, our reported product gross profit margin would have been 63.6% and 61.0% for the six months ended June 28, 2008 and June 30, 2007, respectively.

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

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

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

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

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Liquidity and Capital Resources

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

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

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

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

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

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

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

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

Future Liquidity Needs. In addition to funding our working capital requirements, we anticipate our primary use of cash to be the equipment that we provide to hospitals under our long-term sensor purchase agreements. We anticipate additional capital purchases related to expanding our worldwide manufacturing capability as well as additional investments in productivity enhancing tools. Our focus on international expansion will also require additional investments in facilities and infrastructure in North and South America, Europe and Asia. The amount and timing of our

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.

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

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.

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

New Accounting Pronouncements

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

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

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense we must pay with respect to our outstanding debt instruments. Our risk associated with fluctuation to interest expense is limited to our outstanding term loans and financing arrangements, which have fixed interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We enhance the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest-sensitive financial instruments at June 28, 2008. Declines in interest rates over time will, however, reduce our interest income and expense while increases in interest rates will increase our interest income and expense.

Foreign Currency Exchange Rate Risk

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

Inflation Risk

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

Item 4(T). Controls and Procedures

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

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Form 10-Q. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

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

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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. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail.

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

Item 1A. Risk Factors

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

We have marked with an asterisk (**) those risk factors below that reflect substantive changes from the risk factors included in our Quarterly Report on Form 10-Q filed with the SEC on May 1, 2008.

Risks Related to Our Business

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

We are dependent upon the success and market acceptance of our proprietary Masimo SET. Currently, our primary product offerings are based on the Masimo SET platform. Continued market acceptance of products incorporating Masimo SET will depend upon our ability to continue to provide evidence to the medical community that our products are cost-effective and provide significantly improved performance compared to conventional pulse oximeters. Health care providers that currently have significant investments in competitive pulse oximetry products may be reluctant to purchase our products. If hospitals and other health care providers do not believe our Masimo SET platform is cost-effective, more accurate or reliable, they may not buy our products in sufficient quantities to enable us to be profitable. If we are unable to achieve additional market acceptance of our core technology or products incorporating Masimo SET, we will not generate significant revenue growth from the sale of our products.

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

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

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

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

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

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

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

- increase the cost of our products;
- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- force us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products and product candidates;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party s intellectual property on terms that may not be favorable or acceptable to us;
- require us to indemnify third parties pursuant to contracts in which we have agreed to provide indemnification for intellectual property infringement claims;
- divert the attention of our management;

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

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

In addition, new patents obtained by our competitors could threaten a product s continued life in the market even after it has already been introduced.

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

We believe that the success of our business depends, in significant part, on obtaining patent protection for our products and technologies, defending our patents and preserving our trade secrets. We were previously involved in significant litigation to protect our patent position and may be required to engage in further litigation. In 2006, we settled a costly, six-year lawsuit against Mallinckrodt, Inc., now a part of Covidien Ltd. (formerly Tyco Healthcare), and one of its subsidiaries, Nellcor Puritan Bennett, Inc., in which we claimed that Covidien was infringing some of our pulse oximetry signal processing patents. We believe that other competitors of ours, including some of our OEM partners, may be infringing at least one of our

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patents. Our failure to pursue any potential claim could result in the loss of our proprietary rights and harm our position in the marketplace. Therefore, we may be forced to pursue litigation to enforce our rights. We cannot be certain that we will have the required financial resources to pursue litigation or otherwise to protect these rights in the future. In addition, any future litigation could result in the diversion of management s attention from the implementation of our business strategy and may not be adequate to protect our intellectual property rights.

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

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

perceived effectiveness of our products;

cost of our products;

perceived advantages of our products over competing products;

introduction and acceptance of competing products or technologies; and

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

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

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

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

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

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

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.

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Much of our growth may come from the introduction and sale of new products, which may result in a greater frequency of recalls. From our inception through June 28, 2008, we initiated three voluntary recalls of our products, none of which was material. Each of these recalls was reported to the FDA within the appropriate regulatory timeframes. Because of our dependence upon patient and physician perceptions, any negative publicity associated with these voluntary recalls could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 June 28, 2008, a number of stockholders of Masimo Labs continued to own shares of our common stock. In addition, Joe E. Kiani and Jack Lasersohn, members of our board of directors, are also members of the board of directors of Masimo Labs. Joe E. Kiani, our Chairman and Chief Executive Officer, is also the Chairman and Chief Executive Officer of Masimo Labs. Due to the interrelated nature of Masimo Labs with us, conflicts of interest will arise with respect to transactions involving business dealings between us and Masimo Labs, potential acquisitions of businesses or products, development of products and technology, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Masimo Labs. We cannot assure you that any conflict of interest will be resolved in our favor, or that with respect to our transactions with Masimo Labs we will negotiate terms that are as favorable to us as if such transactions were with an unaffiliated third party.

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

We incurred net losses attributable to common stockholders in each year from our inception through 2004. Our net losses attributable to common stockholders were approximately $8.6 million, $15.4 million and $12.3 million in 2002, 2003 and 2004, respectively. We expect our expenses to increase as we expand our research and development and sales and marketing activities. As a result, if we are unable to maintain or increase our revenue, we may incur net losses and negative cash flows in the future.

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

- delays or interruptions in manufacturing and shipping of our products;
- varying demand for and market acceptance of our technologies and products;
- the effect of competing technological and market developments resulting in lower selling prices or significant promotional costs;
- changes in the timing of product orders and the volume of sales to our OEM partners;
- actions taken by group purchasing organizations, or GPOs;
- delays in hospital conversions to our products;
- our legal expenses, particularly those related to litigation matters;

changes in our product or customer mix;

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

product recalls; and

high levels of returns and repairs.

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

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

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

We are, and will continue to be, dependent upon our OEM partners for a portion of our revenue through their marketing, selling and distribution of certain of their products that incorporate Masimo SET and licensed Rainbow technology. Although we expect that our OEM partners will accept and actively market, sell and distribute products that incorporate licensed Rainbow technology, they may elect not to do so in the near future or at all. The failure of our OEM partners to successfully market, sell or distribute products incorporating these technologies, the termination of OEM agreements, the loss of OEM partners or the inability to enter into future OEM partnership agreements would have a material adverse effect on our business, financial condition and results of operations. Our success will depend in part upon whether our OEM partners devote sufficient resources to the promotion of products that incorporate these technologies. These products may represent a relatively small percentage of business for some of our OEM partners. In addition, some of our OEM partners offer products that compete with ours. Therefore, we cannot guarantee that our OEM partners will vigorously promote products incorporating Masimo SET and licensed Rainbow technology. If any of our OEM partners were to be acquired, we cannot assure you that an acquiring company would devote sufficient resources to promote products that incorporate technology we own or license.

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

For the three and six months ended June 28, 2008, one customer represented 11.7% and 12.5%, respectively, of our total revenues. We also have a concentration of OEM, distribution and direct customers. If for any reason we were to lose our ability to sell to a specific group or class of customers, we would experience a significant reduction in revenues. This would adversely impact our operating results because we may not be able to react quickly enough to reduce our operating expenses. Also, we cannot assure you that we will retain our current customers or groups of customers or that we will be able to attract and retain additional customers.

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

In the three and six months ended June 28, 2008, our royalties from the Covidien settlement totaled $12.7 million and $24.0 million, respectively. Because these royalty payments do not carry any significant cost, they result in significant improvements to our reported gross profit and operating income levels. As a result, any decline in royalties that we earn under this settlement agreement will have a significant impact on our revenues, gross margins and operating income. Under the agreement, we earn royalties on Covidien s total U.S.-based pulse oximetry sales. The royalty rate in 2006 was nearly 20% if averaged over the entire year. The royalty rates for 2007 declined to 15%. In 2008 and through the term of the royalty agreement, at least through March 14, 2011, the royalty rate is 13%, but may decline to 10%, subject to Covidien s ability to develop new products that avoid some of our current patent coverage as negotiated in the settlement agreement. As a result of these declining royalty rates since 2006, there is a significant financial risk to our operating income if we are unable to generate sufficient revenues and gross margins to offset the impact of declining royalty rates on sales of Covidien s pulse oximetry products in the United States.

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

Our ability to sell our products to U.S. hospitals depends in part on our relationships with GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO s affiliated hospitals and other members. If we are not one of the providers selected by a GPO, the GPO s affiliated hospitals and other members may be less likely to purchase our products. If a GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer s products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement. In addition, our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. In the three and six months ended June 28, 2008, revenue from the sale of our pulse oximetry products related to GPOs amounted to $33.0 million and $63.7 million, respectively. In the future, if we are unable to keep our relationships and develop new relationships with GPOs, our competitive position would likely suffer and our business would be harmed.

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If we do not successfully develop and commercialize enhanced or new products that remain competitive with new products or alternative techniques developed by others, we could lose revenue opportunities and customers, and our ability to achieve growth would be impaired.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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;

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

product recall or seizure;

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

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

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

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

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

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

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

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

Obtaining 510(k) clearance only permits us to promote our products for the uses cleared by the FDA. Use of a device outside its cleared or approved indications is known as off-label use. Physicians may use our products off-label because the FDA does not restrict or regulate a physician s choice of treatment within the practice of medicine. Although we may request additional cleared indications for our current products, the FDA may deny those requests, require additional expensive clinical data to support any additional indications or impose limitations on the intended use of any cleared product as a condition of clearance. We must have adequate substantiation for our product performance claims. If the

FDA determines that we or our OEM partners have promoted our products for off-label use or have made false or misleading or inadequately substantiated promotional claims, it could request that we or our OEM partners modify those promotional materials or seek regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management s attention and result in substantial damage awards against us.

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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.

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

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

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

- increase our sales and marketing forces;
- continue to maintain domestic and international OEM partners;
- ensure that distributors and OEM partners provide the technical and educational support customers need to use products incorporating Masimo SET and Rainbow technology successfully;
- promote monitoring systems using Masimo SET and Rainbow technology so that sales of those systems and our sensors increase; and
- be prepared to provide services, as necessary, to geographically dispersed users of monitoring systems using Masimo SET and Rainbow technology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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higher costs of integration than we anticipated; and

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

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

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

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

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

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

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which established federal crimes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services, as well as imposed certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental third-party payers, including commercial insurers, and state laws governing the privacy of certain health information.

We have certain arrangements with hospitals that may be affected by these laws. For instance, under our standard customer arrangements, we provide hospitals with free pulse oximetry monitoring devices in exchange for their agreement to purchase future pulse oximetry sensor requirements from us. In addition, we occasionally provide our customers with rebates in connection with their annual purchases. While we believe that we are currently in compliance with applicable federal and state health care laws, certain of these arrangements may not meet the Federal Anti-Kickback Law s safe harbor requirements, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws.

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

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

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

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to human health, safety or the environment. These materials and various wastes resulting from their use are stored at our facility pending ultimate use and disposal. The risk of accidental injury, including to our employees, or contamination from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any resulting damages and any such liability could exceed our reserves. Although we maintain general liability insurance, we do not specifically insure against environmental liabilities. If an enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action on terms favorable to us. Similarly, if the physicians or other providers or entities with which we do business are found to violate applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

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

We derive a portion of our net sales from operations in international markets. In 2006, 2007 and the six months ended June 28, 2008, 22.6%, 23.6% and 25.9%, respectively, of our product revenue was derived from our international operations. In addition, we purchase a portion of our raw materials and components on the international market. The sale and shipping of our products across international borders, as well as the purchase of materials and components from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and we would be exposed to potentially significant penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include, but are not limited to:

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- a shortage of high-quality sales people and distributors;
- loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles; and

difficulties in enforcing or defending intellectual property rights.

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

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

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

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

Sales of our products depend in part on the reimbursement and coverage policies of governmental and private health care payers. The ability of our health care provider customers, including hospitals, to obtain adequate coverage and reimbursement for our products, or for the procedures in which our products are used, may impact our customers purchasing decisions and, therefore, could have a material adverse effect on our business.

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

- controls on reimbursement for health care services and price controls on medical products and services;
- limitations on coverage and reimbursement for new medical technologies and procedures; and
- the introduction of managed care and prospective payment systems in which health care providers contract to provide comprehensive health care for a fixed reimbursement amount per person or per procedure.

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

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

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

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

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

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

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

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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. Even if we are ultimately awarded damages in this litigation, the amount will be subject to a 50% legal fee contingency agreement, in which case we would receive 50% of the net (of costs) proceeds from any award.

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

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

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

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

- cause substantial dilution of the percentage ownership of our security holders at the time of the issuance;
- cause substantial dilution of our earnings per share;
- subject us to the risks associated with increased leverage, including a reduction in our ability to obtain financing or an increase in the cost of any financing we obtain;
- subject us to restrictive covenants that could limit our flexibility in conducting future business activities; and
- adversely affect the prevailing market price for our outstanding securities.

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

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

or respond to competitive pressures or unanticipated requirements.

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

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

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and restrict our ability to access financing. In addition, we are required under applicable law and regulations to evaluate and provide a management report of our systems of internal controls over financial reporting. We plan to evaluate our existing internal controls with respect to the standards adopted by the Public Company Accounting Oversight Board. During the course of our evaluation, we may identify areas requiring improvement and may be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time from other activities.

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

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

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

Risks Related to Our Common Stock

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

There has been significant volatility in the market price and trading volume of equity securities, which is unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our common stock. From March 31, 2008 to June 28, 2008, our closing stock price ranged from $25.06 to $35.00.You may not be able to resell your shares at or above the price you paid for them due to fluctuations in the market price of our common stock caused by changes in our operating performance or prospects and other factors.

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

- actual or anticipated fluctuations in our operating results or future prospects;
- our announcements or our competitors announcements of new products;
- the public s reaction to our press releases, our other public announcements and our filings with the SEC;
- strategic actions by us or our competitors, such as acquisitions or restructurings;

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

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

changes in our growth rates or our competitors growth rates;

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

our inability to raise additional capital as needed;

concern as to the efficacy of our products;

changes in financial markets or general economic conditions;

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

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

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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 June 28, 2008, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned approximately 14.5% of our outstanding common stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, the stockholders will be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of us or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock. In addition, these stockholders, some of whom have representatives sitting on our board of directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes in control of us, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

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

As of June 28, 2008, an aggregate of 11,961,538 shares of our common stock were reserved for future issuance under our three equity incentive plans, 7,601,990 of which were subject to options outstanding as of that date at a weighted average exercise price of $12.86 per share. To the extent outstanding options are exercised, our existing stockholders may incur dilution. We rely heavily on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders.

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

As of June 28, 2008, there were 56,447,961 shares of our common stock outstanding, including 3,287,494 shares sold by us and 10,416,626 shares sold by our selling stockholders in our initial public offering, or IPO, in August 2007. A significant portion of our shares of common stock outstanding prior to our IPO that were not sold by selling stockholders became eligible for sale in the public market on February 4, 2008 upon expiration of lock-up agreements entered into in connection with our IPO, although as of June 28, 2008, 7,232,129 of these shares were held by directors, executive officers and other affiliates and subject to volume limitations under Rule 144 as of that date. A large portion of our outstanding shares are held by a small number of persons and investment funds. Resales by these stockholders of a substantial number of shares, announcements of the proposed resales of substantial amounts of our common stock or the perception that substantial resales may be made, could significantly reduce the market price of our common stock. Moreover, the holders of 2,447,129 shares of common stock at June 28, 2008 have rights, subject to some conditions, to require us to file registration statements covering the shares they currently hold or to include these shares in registration statements that we may file for ourselves or other stockholders from time to time.

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

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

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

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

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

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

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

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

We will be exposed to risks relating to evaluations of internal controls required by Section 404 of the Sarbanes-Oxley Act.

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

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

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

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

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

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

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

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

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

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

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

1. Elected two Class I directors to hold office until the 2011 Annual Meeting of Stockholders or until their successors are duly elected and qualified; and

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

At the Annual Meeting, the stockholders voted as follows:

1. Election of Directors

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

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

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

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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: August 5, 2008

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

Date: August 5, 2008

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

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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	(1)	Amended and Restated Bylaws (Exhibit 3.4)
4.1	(1)	Form of Common Stock Certificate (Exhibit 4.1)
4.2	(1)	Fifth Amended and Restated Registration Rights Agreement made and entered into as of September 14, 1999 between the Registrant and certain of its stockholders (Exhibit 4.2)
4.3	(2)	Rights Agreement, dated November 9, 2007, between the Company and Computershare Trust Company, N.A., as Rights Agent (Exhibit 4.1)
4.4	(3)	Masimo Retirement Savings Plan. (Exhibit 4.7)
10.1	(4)++	Lease Agreement, effective as of September 1, 2007, by and among Industrias Asociadas Maquiladoras, S.A. de C.V., Industrial Vallera de Mexicali, S.A. de C.V. and the Company, as guarantor. (Exhibit 10.1)
31.1		Certification of Joe E. Kiani, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2		Certification of Mark P. de Raad, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32		Certification of Joe E. Kiani, Chief Executive Officer, and Mark P. de Raad, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to the exhibits to the Company s Registration Statement on Form S-1 (No. 333-142171) originally filed on April 17, 2007. The number given in parentheses indicates the corresponding exhibit number in such Form S-1, as amended.

(2) Incorporated by reference to the exhibits to the Company s Current Report on Form 8-K filed on November 9, 2007. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

(3) Incorporated by reference to the exhibits to the Company s Registration Statement on Form S-8 filed on February 11, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form S-8.

(4) Incorporated by reference to the exhibit to the Company s Current Report on Form 8-K, filed on June 5, 2008. The number given in parentheses indicates the corresponding exhibit number in such Form 8-K.

++ Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

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.