ICU MEDICAL INC/DE
Form 10-K
February 19, 2010
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2009 or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0022692**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
951 Calle Amanecer **San Clemente, California**	**92673**
(Address of principal executive offices)	(Zip Code)

Registrant s Telephone Number, Including Area Code: (949) 366-2183

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 $0.10 per share Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC (Global Select Market)

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. o Yes x No

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

Indicate by check mark whether 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 registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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 this Form 10-K. o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Small reporting company o

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2009, the last business day of registrant s most recently completed second fiscal quarter, was $524,011,096*.

The number of shares outstanding of registrant s common stock, $.10 par value, as of January 31, 2010 was 14,019,330.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant s 2010 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant s fiscal year ended December 31, 2009, are incorporated by reference into Part III of this Report.

* Without acknowledging that any person other than Dr. George A. Lopez is an affiliate, all directors and executive officers have been included as affiliates solely for purposes of this computation.

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For the Year Ended December 31, 2009

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PART I

Item 1. Business.

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in vascular therapy applications. Our devices are designed to protect patients from catheter related bloodstream infections and healthcare workers from exposure to diseases through accidental needlesticks or hazardous drugs. We are also a leader in the production of custom infusion sets and we incorporate our proprietary products into many of those custom infusion sets. In addition, we are a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems. Our headquarters are in San Clemente, California.

In 1993, we launched the CLAVE, an innovative one-piece, needleless I.V. connection device that accounted for approximately 37% of our revenue in 2009, exclusive of CLAVEs incorporated into custom infusion sets. We believe that the CLAVE offers significant infection control benefits for the patient as well as a combination of safety, ease of use, reliability and cost effectiveness for healthcare providers that gives us a leading position in the market. It allows protected, secure and sterile I.V. connections without needles and without failure-prone mechanical valves used in the I.V. connection systems of some competitors. The CLAVE is a successor to our protected needle products first introduced in 1984. We designed the CLAVE to eliminate needles from certain applications in acute care hospitals, home healthcare, ambulatory surgical centers, nursing homes, convalescent facilities, physicians offices, medical clinics, and emergency centers. Reduction in the use of needles not only decreases needlesticks but also reduces the number of needles to be disposed of and certain safety risks inherent in needle handling and disposal.

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE®. In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom infusion sets, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system. We have furthered this effort to include all of our proprietary devices on all of our custom systems beyond the CLAVE.

We are reducing our dependence on our current proprietary products by introducing new products and systems and acquiring product lines. For example, under one of our several agreements that we have entered into with Hospira, Inc. (Hospira), we manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. Additionally, in 2005, we acquired Hospira s Salt Lake City manufacturing facility and entered into an agreement with Hospira to produce their critical care products, including invasive monitoring, angiography products and certain other products they had manufactured at that facility. On August 31, 2009, we purchased the commercial rights and physical assets from Hospira s critical care product line which provide us control over all aspects of our critical care product line. We also contract with group purchasing organizations and independent dealer networks for inclusion of all our products in the product offerings of those entities.

We are expanding our custom products business through increased sales to medical product manufacturers, independent distributors and through direct sales to the end users of our products. These expansions include our 2008 agreement with Premier and an agreement extension with MedAssets. Both organizations are U.S. healthcare purchasing networks. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately 34% of total revenue in 2009. We have recently introduced a number of new products: the TEGO® for use in dialyses, the Orbit 90® diabetes set, and a line of oncology products including the Spiros male luer connector device, the Genie vial access device, custom I.V sets and ancillary products specifically designed for chemotherapy. There is no assurance that we will be successful in finding future acquisition opportunities or integrating these new product lines into our existing business.

We currently sell substantially all of our products to I.V. product manufacturers, independent distributors and direct sales to the end user. Hospira, our largest customer, accounted for 53% of our worldwide revenues in 2009.

First person pronouns used in this Report, such as we, us, and our, refer to ICU Medical, Inc. and its subsidiaries unless context requires otherwise.

Our website address is http://www.icumed.com. We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to those reports free of charge on our website as soon as reasonably practicable after filing them with the Securities and Exchange Commission. We also have our code of ethics posted on our website (http://www.icumed.com). The information on our website is not incorporated into this Annual Report.

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The public may read and copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC and state the address of that site (http://www.sec.gov).

I.V. Products

I.V. therapy lines, used in hospitals, and ambulatory clinics, consist of a tube running from a bottle or plastic bag containing an I.V. solution to a catheter inserted in a patient s vein. The tube typically has several injection ports or Y-sites (conventionally, entry tubes covered by rubber caps) to which a secondary I.V. line can be connected to permit constant intravenous administration of medications, fluids and nutrients, and to allow instantaneous intravenous administration of emergency medication.

Prior to the introduction of needlesafe connectors, conventional practice was to make, primary I.V. system connections by inserting an exposed steel hollow-bore needle attached to the primary I.V. line into an injection port connected to the catheter. Conventional secondary I.V. connections, so called piggyback connections, were made by inserting an exposed steel hollow-bore needle attached to a secondary I.V. line into an injection port or other I.V. connector. In those I.V. connections, the needles, which typically were secured only with tape, could detach from the catheter or injection port resulting in disconnection and a serious and sometimes fatal interruption of the flow of the I.V. solution to the patient. The exposed needles could easily be contaminated by contact with unsterile objects or through contact with fluid in the I.V. lines. Accidental needlesticks from contaminated needles can result in infection to healthcare workers and, less frequently, patients.

Hepatitis B and C and HIV are transmitted through blood and other body fluids, and workers who come in contact with such infectious materials are at risk of contracting these diseases. Transmission may occur from needlesticks by contaminated needles or exposure of mucous membranes to infectious body fluids containing blood traces. Following each needlestick, the healthcare employer is required to perform a series of tests on the healthcare worker for both Hepatitis B and C and HIV, as well as track and record each needlestick incident. Thus, needlesticks result in time lost from work and substantial expense regardless of whether transmission of an infectious disease is detected. By eliminating needles from primary and secondary I.V. connections, our protective I.V. connectors prevent accidental needlesticks in those applications.

Heightened awareness of the risk of infection from needlesticks and the substantial expense to healthcare providers of complying with regulatory protocols when needlesticks occur have led to growing demand for safe medical devices such as our needleless I.V. connectors. This awareness has also lead to significant federal and state legislation. The federal Needlestick Safety and Prevention Act, enacted in 2000, modified standards promulgated by the Occupational Safety and Health Administration (OSHA) to require employers to use needle-safe systems where appropriate to reduce risk of injury to employees from needlesticks. This was a significant expansion of the previous OSHA mandate that universal precautions be observed to minimize exposure to blood and other body fluids. In 1998, the State of California enacted the bloodborne pathogen standard under the state s occupational safety and health statute. This standard mandates use of needlestick prevention controls, including needleless systems. California was the first state to enact such legislation, and since then many other states have enacted similar legislation. Our devices will help enable a healthcare provider to comply with any of these standards.

Hospital Acquired Infection (HAI) is a substantial concern for healthcare providers today. HAI can be caused by a variety of issues, one being a vascular catheter becoming contaminated with bacteria. This result is what is known as a Catheter Related Bloodstream Infection (CRBSI) and has a high rate of patient morbidity and mortality. The Centers for Medicare Services (CMS) discontinued payment for HAI that are a result of Vascular Catheter Associated Infections in late 2008. The reported cost for treatment of a single CRBSI can be as high as $60,000. The CLAVE technology is designed to prevent bacterial contamination of the vascular catheter and will assist healthcare facilities in the effort to reduce these

types of infections. We believe that the CLAVE has certain design features, as discussed below, that are important for the prevention of CRBSI. Additionally, we believe that these important design features are not available in competitive products.

CLAVE Products

Prior to the introduction of needle-safe connectors, a conventional I.V. line terminated with a male luer connector to which a hollow-bore needle would be attached to penetrate a latex or non-latex rubber covered injection port to make a primary or secondary I.V. connection. With the CLAVE system, instead of attaching a hollow-bore needle to the male luer, a CLAVE is used in place of the injection port and the male luer, without a needle, is simply threaded into the CLAVE with a half turn. The CLAVE consists of a cylindrical housing, which contains a silicone compression seal and an internal blunt cannula. As the luer tip enters the CLAVE housing, it depresses the silicone seal back into the housing and slides over the

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blunt cannula, which penetrates through the pre-slit silicone. Fluid channels in the blunt cannula create a continuous fluid pathway from the I.V. line, through the CLAVE into the primary I.V. line and into the catheter. The luer tip creates a tight seal against the top of the silicone thereby preventing contaminants from entering the fluid pathway or fluid from escaping the connection. When the I.V. line is disconnected from the CLAVE, the silicone compression seal expands to again fill the housing and reseal the opening. When the CLAVE is not in use, the silicone compression seal fills the opening in the housing and covers the internal blunt cannula, thus completely sealing the connector and presenting a flush surface that can be cleansed with an alcohol swab. The CLAVE contains no natural rubber latex.

Emergency medications and I.V. fluids can be administered through the CLAVE by using a standard syringe without a hypodermic needle attached or various pre-filled syringe devices. The CLAVE can be used with any conventional peripheral or central vascular access systems, both for venous and arterial applications. The resilience of the silicone compression seal permits repeated connections and disconnections without replacing the CLAVE.

The Y-CLAVE is designed to be integrated directly into primary and secondary I.V. sets, thus eliminating the need for special adapters, pre-slit injection ports, or metal needles when making piggyback I.V. connections. The Y-CLAVE will not replace CLAVE products used in non-piggyback connections. Unlike the original CLAVE site, the Y-CLAVE is marketed exclusively to I.V. set manufacturers, such as Hospira, to build directly into their I.V. sets or used by us in our custom I.V. sets.

The MicroCLAVE® is smaller than the standard CLAVE but is functionally similar. The MicroCLAVE has a feature where upon disconnection of an I.V. administration set or syringe, there is a neutral displacement of fluid. This allows clinicians to utilize known protocols without the risk of device failure and a saline flush regimen which reduces cost and exposure to the drug Heparin, an anti-clotting agent. The MicroCLAVE is intended for use on all peripheral and central catheters, which allows it to be used throughout the Hospital and reduces line items that the Hospital may need to carry and the educational burden of having multiple devices. The MicroCLAVE is being marketed as an extension of the CLAVE product line for use where the infection control, neutral displacement and saline flush features are advantageous.

CLAVE products are our largest selling product line, and accounted for 37% and $85.2 million of our revenue in 2009. Additional information regarding CLAVE product sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

Custom Sets

Our custom sets include custom infusion sets, custom oncology sets and custom critical care sets.

In the late 1990 s, we entered the market for custom sets. To promote the growth of the business, we have developed innovative software systems and manufacturing processes known as SetMaker that permits us to design a custom infusion set to a hospital s or clinician s exact specifications, commence production in Mexico or Europe within less than a day after we receive the customer order and ship smaller orders of the custom infusion sets to the customer within three days of receipt. While we are capable of meeting customer demand on this accelerated three-day schedule, in normal circumstances we ship within twenty-one to thirty days of receipt of the customers order. This is a fraction of the time required by other custom set manufacturers. The use of sophisticated design, validation, ordering and order tracking systems and streamlined assembly and distribution processes allows us to sell custom infusion sets at prices substantially lower than those charged by other producers of custom infusion sets.

Under a 2001 agreement with Hospira, we manufacture all new custom infusion sets for sale by Hospira, and the two companies jointly promote the products under the name SetSource. The current term of the agreement extends through 2014. Sales of custom infusion sets continue to increase as a result of the agreement and we expect further increases in sales of custom infusion sets, although there is no assurance that such increases will be achieved.

We have committed significant resources to the strategic initiative to expand our custom infusion set businesses and expect to incur additional expenses for continuing software development and enhancements in the manufacturing process.

A substantial portion of the invasive monitoring and angiography products are custom critical care products designed to meet the specific needs of the customer. Most of the critical care products can be sold in custom systems containing specific components to meet the specific needs of the customer, and in some cases, custom made or acquired components

For the year ended December 31, 2009, net sales of custom sets were approximately $78.6 million, 38% of these sales were with domestic distributors and domestic direct sales, 37% with Hospira and 25% from international distributors and international direct sales. Additional information regarding custom sets sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

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CLC2000®

The CLC2000 is a one piece, swabbable connector used to connect I.V. lines to catheters, which is engineered to have a positive displacement of fluid on disconnection which in turn will prevent the back-flow of blood into the catheter. The CLC2000 does not permit the use of needles, thereby ensuring compliance with needle-free policies of healthcare providers. The CLC2000 also contains no natural rubber latex. The CLC2000 was developed to reduce clotting of catheters because of back-flow when the I.V. line is disconnected. The CLC2000 consists of a T shaped cylindrical housing, which contains a poppet that is depressed as the luer tip enters the CLC2000. Fluid flows around the poppet and through the housing and into the catheter. When the luer is removed from the CLC2000, a portion of the fluid remaining in the housing is expelled out through the tip of the catheter while a constant positive pressure is maintained to prevent any back-flow into the catheter.

The CLC2000 is typically used on central venous catheters where catheter occlusion is most prevalent. Generally, when an I.V. line is disconnected from the catheter, there is a back-flow of blood from the patient s vein into the catheter. That blood in time coagulates and occludes the catheter. Occlusion (clotting off) of catheters requires expensive drugs and procedures to flush the catheter, or if those procedures are not effective, replacement of the catheter. We concentrate the marketing of the CLC2000 where its no back-flow features are of maximum benefit in patient care. These are generally therapies that use long-term indwelling central venous catheters such as oncology and long-term infusion of medication. CLC2000 accounted for $5.9 million of our revenue in 2009.

Standard Critical Care Products

Standard critical care products are used to monitor vital signs as well as specific physiological functions of key organ systems. In 2005, we acquired Hospira s Salt Lake City manufacturing facility and entered into an agreement with Hospira to produce their critical care products, including invasive monitoring, angiography products and certain other products they had manufactured at that facility. On August 31, 2009, we purchased the commercial rights and physical assets from Hospira s critical care product line which provide us control over all aspects of our critical care product line.

The standard critical care products we manufacture are invasive hemodynamic monitoring systems that are used to monitor cardiac function and blood flow in critically ill patients. They include all components of the invasive monitoring system. The products we manufacture at our Salt Lake City facility, almost all of which are disposable, are the following:

Pressure monitoring devices: Disposable pressure-sensing devices provide accurate and continuous blood pressure readings and show the immediate effect of fluid management and drug administration. These products are used most commonly on patients with suspected pulmonary disease or cardiovascular dysfunction.

Blood sampling systems: Blood sampling systems provide the clinician with a convenient, needleless method to obtain a patient s blood sample and to administer I.V. fluids or drugs in conjunction with blood pressure monitoring devices. They are designed to protect the clinician from exposure to bloodborne pathogens and reduce the risk of I.V. line contamination.

Angiography kits: A broad range of devices for use in the cardiac catheterization laboratory enable physicians to monitor the function of the heart and examine the coronary arteries. They are various types of Left Heart and Right Heart procedural kits which include manifolds, syringes, stopcocks, specialized injection tubing and dye management systems, many of which contain pressure-sensing devices, and waste management systems.

Advanced sensory catheters: Catheters used to measure cardiac output and blood oxygen levels. Depending on specific design, these catheters contain up to five lumens and use fiber-optics to continuously measure mixed venous oxygen saturation, blood pressure and cardiac output. They may also permit administration of fluids and drugs, monitoring patient temperature and pressures and blood sampling.

Pulmonary artery thermodilution catheters: Catheters used for cardiac output determinations, fluid and drug administration, temperature and pressures and blood sampling. Depending on specific design, these catheters contain up to five lumens.

Multi-lumen central venous catheters: Catheters used for monitoring central venous pressure, blood sampling, and simultaneous administration of multiple I.V. solutions or drugs at individual flow rates.

Our 2009 standard critical care sales were $41.8 million. Additional information regarding standard critical care sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

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Other Products and Revenues

We have a significant number of patents on the technology in our products and methods used to manufacture them. We have continuing royalty and revenue share income from our technology and from time to time may receive license fees or royalties from other entities for the use of our technology.

New Products

We have recently introduced a number of new products: the TEGO for use in dialysis, a line of oncology products that includes the Spiros male luer connector device, the Genie vial access device, the Orbit 90 diabetes set and custom I.V. sets and ancillary products specifically designed for oncology therapy. Sales of these new products were $19.4 million in 2009.

We are developing several new products that we intend to introduce in 2010 and later. We believe innovative products continue to be important to maintaining and increasing our sales levels.

Marketing and Distribution

The influence of managed care and the growing trend toward consolidation among healthcare providers are the driving forces behind our sales and marketing strategies. Many healthcare providers are consolidating to create economies of scale and to increase negotiating power with suppliers. In an effort to further control costs, many of these consolidated groups are entering into long-term contracts with medical suppliers at fixed pricing. In this changing market place, we believe it is becoming increasingly important to secure contracts with major buying organizations in addition to targeting specific healthcare providers.

As of December 31, 2009, we employed 168 people worldwide in sales and marketing and expect this to increase in 2010. Our sales function includes product specialists worldwide who support our medical product manufacturing customers, our independent domestic distributors and end users of our products. Our product specialists call on prospective customers, demonstrate products and support programs to train the salespeople and customers staffs in the use of our products.

Medical Product Manufacturers

We have a strategic supply and distribution relationship with Hospira, a major I.V. product supplier, which has a significant share of the U.S. I.V. set market under contract. The agreement runs through 2014 and provides Hospira with conditional rights to distribute certain of our CLAVE and other products to certain categories of customers both in the United States and foreign countries. Depending on the product and category of customer, these rights may be exclusive or nonexclusive.

Hospira purchases CLAVE products packaged separately for distribution to healthcare providers and in bulk for assembly into Hospira s full range of I.V. products. The MicroCLAVE, CLC2000, Lopez Valve, Spiros, Genie and Rhino products are purchased and packaged separately.

Under another agreement with Hospira that extends through 2014, we have the exclusive right to manufacture all new custom gravity I.V. sets for sale by Hospira, other than those custom sets that Hospira was manufacturing before we entered into the agreement in 2001. We jointly promote the products under the name SetSource with Hospira. Hospira is the exclusive and non-exclusive distributor and co-promoter of SetSource products to certain categories of customers, including SetSource products containing both companies proprietary products.

Worldwide sales to Hospira accounted for approximately 53% of our revenue in 2009. The loss of Hospira as a customer would have a significant adverse effect on our business and operating results.

Independent Domestic Distributors

As of December 31, 2009, we had 43 independent distributors in the United States and Canada who employ approximately 707 salespeople in the aggregate and which accounted for approximately 28% of our revenues in 2009. We include Canada as domestic for administrative purposes. Distributors purchase and stock our products for resale to healthcare providers.

No single independent distributor accounted for more than five percent of revenue in 2009. Although the loss of one or more of our larger distributors could have an adverse affect on our business, we believe we could readily locate other distributors in the same territories who could continue to distribute our products to the same customers.

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International

International distribution is concentrated principally in Europe, Asia Pacific, Southeast Asia, Latin America, South Africa and the Middle East. Foreign sales (excluding Canada) accounted for approximately 21%, 15% and 13% of our revenues in 2009, 2008 and 2007, respectively. As of December 31, 2009, we had approximately 91 international distributors. Customers in Europe are served by our facilities in Italy and Germany. We serve the rest of the world from our facilities in the U.S. and Mexico. We have 17 business development personnel serving Europe and seven serving Asia Pacific, Southeast Asia, the Middle East, Africa and Latin America. We expect to add more business development personnel in 2010.

Administrative operations are in San Clemente, California, Roncanova in northern Italy (at the site of our assembly plant) and Ludenscheid, Germany. Currently, all shipments from the United States are invoiced in U.S. dollars and sales from Europe are invoiced in Euros. At December 31, 2009 and 2008, our long-lived assets located outside the United States was $51.3 million and $44.0 million, respectively.

Manufacturing

Manufacturing of our products involves injection molding of plastic and silicone parts, manual and automated assembly of the molded plastic parts, needles and other components, quality control inspection, packaging and sterilization. We mold all of our proprietary components, and perform all assembly, quality control, inspection, packaging, labeling and shipping of our products. Our manufacturing operations function as a separate group, producing products for the marketing and sales groups.

We own a fully integrated medical device manufacturing facility in Salt Lake City, Utah with approximately 450,000 square feet of state-of-the art manufacturing space. This building includes approximately 82,500 square feet of class 100,000 clean room area, approximately 36,000 square feet of other manufacturing space, approximately 104,000 square feet of warehouse space and approximately 155,000 square feet of office space. As of December 31, 2009, this facility was equipped with 66 injection molding machines and ancillary equipment and approximately 40 automated or semi-automated assembly machines. These sophisticated, highly automated assembly systems are designed to minimize human intervention and assemble the CLAVE, Y-CLAVE, MicroCLAVE, CLAVE vial access spike, CLC2000, RF150 and some of our critical care products. The assembly systems are custom designed and manufactured for us. Our mold maintenance shop supports the repair and maintenance needs of our molding. In addition, the mold maintenance shop serves as a research and development prototype shop, and utilizes advanced computer assisted design systems and automated machining equipment.

Most of our manual assembly is done at our facility in Ensenada, Mexico. This facility has approximately 241,000 square feet of production and warehousing space and an electron beam sterilizer. Principal products assembled manually are I.V. therapy systems, critical systems, custom angiography systems, kits, CLAVE and oncology ancillary products and accessories.

Our state-of-the-art injection molding technology and highly automated assembly systems are designed to maintain a high level of product quality and achieve high volume production at low unit manufacturing costs. To achieve these advantages and to gain greater control over raw material and finished product delivery times, we mold our entire requirements of proprietary molded components. The raw materials for our molding operation are principally resins and silicones, and these materials are available from several sources. Generic, off-the-shelf items are purchased from outside vendors unless significant cost savings can be achieved by molding in-house. We have no contracts with our suppliers

beyond the terms of purchase orders issued. Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes has not been material to date. We are not dependent upon any single source for any of our principal raw materials and we believe all such materials and products are readily available.

The majority of the non-critical care products we manufacture are sterilized in processes which use electron beam (e-beam) radiation. Most critical care products and other certain products are currently sterilized in processes using gamma radiation or ethylene oxide gas (EO). The products we assemble in Italy are sterilized using gamma radiation. We have our own sterilization facility at our plant in Mexico that is used to sterilize most of the product assembled in Mexico. All other sterilization is done by independent contractors.

We have a 21,000 square foot building in northern Italy where we assemble I.V. therapy systems. We also manufacture I.V. sets and compounders in our leased facility in Ludenscheid, Germany. We are building a manufacturing plant in Slovakia that will produce custom products to supply our European market.

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Government Regulation

Government regulation is a significant factor in the development, marketing and manufacturing of our products. The Food and Drug Administration (FDA) regulates medical product manufacturers and their products under a number of statutes including the Food, Drug and Cosmetic Act (FDC Act), and we and our products are subject to the regulations of the FDA. The FDC Act provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDC Act, under which the manufacturer gives the FDA a pre-market notification of the manufacturer s intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the Section 510(k) procedure, the manufacturer must file a pre-market approval (PMA) application. This requires substantially more extensive pre-filing testing than the Section 510(k) procedure and involves a significantly longer FDA review process. FDA approval of a PMA application occurs only after the applicant has established safety and efficacy to the satisfaction of the FDA. Each of our current products has qualified for the Section 510(k) procedure, and we anticipate that any new products that we are likely to market will qualify, for the expedited Section 510(k) clearance procedure. However, certain of our new products may require a lengthier time for clearance than we have experienced in the past and there can be no assurance that a PMA application will not be required. Further, there is no assurance that other new products we develop or any manufacturers that we might acquire, or claims that we may make concerning those products, will qualify for expedited clearance rather than the more time consuming PMA procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. All of the regulated products that we currently manufacture are classified as Class II medical devices by the FDA. Class II medical devices are subject to performance standards relating to one or more aspects of the design, manufacturing, testing and performance or other characteristics of the product in addition to general controls involving compliance with labeling and record keeping requirements.

We must comply with FDA, ISO and European Council Directive 93/42/EEC (Medical Device Directive) regulations governing medical device manufacturing practices. The FDA, state, foreign agencies and ISO require manufacturers to register and subject manufacturers to periodic FDA, state, foreign agencies and ISO inspections of their manufacturing facilities. We are a FDA and ISO registered medical device manufacturer, and must demonstrate that we and our contract manufacturers comply with the FDA s current Quality System Regulations (QSR). Under these regulations, the manufacturing process must be regulated and controlled by the use of written procedures and the ability to produce devices that meet the manufacturer s specifications must be validated by extensive and detailed testing of every critical aspect of the process. They also require investigation of any deficiencies in the manufacturing process or in the products produced and detailed record keeping. Further, the FDA and ISO s interpretation and enforcement of these requirements has been increasingly strict in recent years and seems likely to be even more stringent in the future. Failure to adhere to QSR and ISO standards would cause the products produced to be considered in violation of the applicable law and subject to enforcement action. The FDA and ISO monitor compliance with these requirements by requiring manufacturers to register with the FDA and ISO, and by subjecting them to periodic FDA and ISO inspections of manufacturing facilities. If an FDA or ISO inspector observes conditions that might be violative, the manufacturer must correct those conditions or explain them satisfactorily, or face potential regulatory action that might include physical removal of the product from the marketplace.

We believe that our products and procedures are in compliance with all applicable FDA and ISO regulations. There is no assurance, however, that other products we are developing or products that we may develop in the future will be cleared by the FDA and classified as Class II products, or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the FDA, ISO or agencies in other jurisdictions. In addition, changes in FDA, ISO or other federal or state health, environmental or safety regulations or their applications could adversely affect our business.

To market our products in the European Community (EC), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of EN ISO 13485. Those quality standards are similar to the QSR regulations.

Manufacturers of medical devices must also conform to EC Directives such as Council Directive 93/42/EEC and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the CE Mark may be affixed to its devices. The CE Mark gives devices unobstructed entry to all the member countries of the EC.

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We have demonstrated conformity to the regulation of EN ISO 13485 and the Medical Device Directive and we affix the CE Mark to our device labeling for product sold in member countries of the EC.

We believe our products and systems are in compliance with all EC requirements. There can be no assurance, however, that other products we are developing or products that we may develop in the future will conform or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the EC.

Competition

The market for I.V. products, oncology and critical care products is intensely competitive. We believe that our ability to compete depends upon our continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection, and pricing. We encounter significant competition in this market both from large established medical device manufacturers and from smaller companies. Our ability to compete effectively depends on our ability to differentiate our products based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as our ability to perceive and respond to changing customer needs. In the long term, we expect that our ability to compete will continue to be affected by our ability to reduce unit manufacturing costs through improved production processes and higher volume production.

Our present and future products compete with needleless I.V. connection systems like those marketed by Baxter Healthcare Corporation, B. Braun Medical, Inc. (B. Braun), Carefusion, Inc. (Carefusion) formerly Cardinal Healthcare, Becton Dickinson and others. Although we believe that our needleless devices have distinct advantages over competing systems, there is no assurance that they will be able to compete successfully with these products.

The market for critical care devices is highly competitive. Competition is based on pricing, customer service and product features. The overall market for the critical care products has been declining in recent years in certain segments and is turning to less invasive products. Given our new expanded customer base, as a result of the critical care asset purchase from Hospira, we are better positioned to take advantage of new product introductions and gaining back market share.

Manufacturers of products with which we currently compete, or might compete in the future, include large companies with an established presence in the healthcare products market and substantially greater financial, marketing and distribution, managerial and other resources. In particular, Baxter, Carefusion, Hospira, Fresenius and B. Braun are leading distributors of I.V. therapy systems, Edwards Life Sciences has a significant share of the critical care catheter market, invasive monitoring disposables market and arterial blood sampling system market, while Navilyst, formerly part of Boston Scientific, and Merit Medical are competitive in the angiography kit market. Several of these competitors have broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply substantially all of their product requirements in these areas. In order to achieve greater market penetration or maintain our existing market position, we have established strategic relationships with customers such as Hospira.

We believe the success of the CLAVE has, and will continue to motivate others to develop one-piece needleless connectors, which may incorporate many of the same functional and physical characteristics as the CLAVE. We are aware of a number of such products. We believe some of those products were developed by companies who currently have the distribution or financial capabilities equivalent to or greater than

those that we have, and by other companies that we believe do not have similar capabilities, although some of those products may be distributed in the future by larger companies that do have such capabilities. We believe these products have had a moderate impact on our CLAVE business to date, but there is no assurance that our current or future products will be able to successfully compete with these or future products developed by others.

We believe that our ability to compete in the custom products market depends upon the same factors affecting our existing products, but will be particularly affected by cost to the customer and delivery times. While we believe we have advantages in these two areas, there is no assurance that other companies will not be able to compete successfully with our custom products.

Patents

We have United States and certain foreign patents on the CLAVE, CLC2000, Orbit 90, 1o2 Valve, TEGO, Click Lock technology, Custom Set Design and Manufacturing Methods. We have applications pending for additional United States and foreign patents on TEGO, Y-CLAVE with integral check value, Orbit 90, CLC2000, CLAVE, Spiros Closed Male Connector, Genie Closed Vial Access Device and Custom Set Design and Manufacturing Methods. The expiration dates of our patents range from 2010 to 2023. While we no longer manufacture and sell the Click Lock and Piggy Lock, the patents have considerable value for potential use in other devices.

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Our success may depend in part on our ability to obtain patent protection for our products and to operate without infringing the proprietary rights of third parties. While we have obtained certain patents and applied for additional United States and foreign patents covering certain of our products, there is no assurance that any additional patents will be issued, that the scope of any patent protection will prevent competitors from introducing similar devices or that any of our patents will be held valid if subsequently challenged. We also believe that patents on the Click Lock products may have been, and that patent protection on the CLAVE may be, important in preventing others from introducing competing products that are as effective as our products. The loss of patent protection on CLAVE, CLC2000 or Click Lock products could adversely affect our ability to exclude other manufacturers from producing effective competitive products and could have an adverse impact on our financial results.

United States patents related to our principal products expire as follows:

Product	Expiration dates
CLAVE® connector	12/2011 - 07/2016
CLC2000® connector	12/2016
Click Lock® connector	04/2010 - 07/2015
Custom Set Design and Manufacturing	01/2021
Orbit 90® infusion set	03/2022 - 11/2023

The fact that a patent is issued to us does not eliminate the possibility that patents owned by others may contain claims that are infringed by our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation, which would result in substantial cost to us and in diversion of our resources, may be necessary to defend us against claimed infringement of the rights of others and to determine the scope and validity of the proprietary rights of others. Adverse determinations in such litigation could subject us to significant liabilities to third parties or could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using our products, any of which could have a material adverse effect on our business. In addition, we have initiated litigation, and will continue to initiate litigation in the future, to enforce our intellectual property rights against those we believe to be infringing on our patents. Such litigation could result in substantial cost and diversion of resources.

Seasonality

The healthcare business in the United States is subject to seasonal fluctuations, and activity tends to diminish somewhat in the summer months of June, July and August, when illness is less frequent than in winter months and patients tend to postpone elective procedures. This typically causes seasonal fluctuations in our business. In addition, we can experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which may be driven more by production scheduling and their inventory levels, and less by seasonality. Our expenses often do not fluctuate in the same manner as net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

Employees

At December 31, 2009 we had 1,911 full-time employees, consisting of 256 engaged in sales, marketing and administration and 1,655 in manufacturing, molding, product development and quality control, including 1,134 in Mexico. We contract with independent temporary agencies to provide some production personnel who are not our employees. At December 31, 2009, we had 25 temporary production personnel.

Item 1A. Risk Factors.

In evaluating an investment in our common stock, investors should consider carefully, among other things, the following risk factors, as well as the other information contained in this Annual Report and our other reports and registration statements filed with the Securities and Exchange Commission.

Unexpected changes in our arrangements with Hospira or unexpected difficulties in connection with the purchase of Hospira s critical care product line may cause a decline in our sales and could result in a significant reduction in our sales and profits.

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We depend on Hospira for a high percentage of our sales. The table below shows our total revenue and percentage of total revenue attributable to various types of customers for the years ended December 31, 2009, 2008 and 2007 (dollars in millions):

	Years ended December 31,					
	2009		2008		2007	
Hospira (U.S.)	$ 112.4	49%	$ 132.6	65%	$ 129.7	69%
Other manufacturers	3.6	2%	3.7	2%	2.7	1%
Domestic distributors/direct sales	65.9	28%	35.9	17%	29.5	16%
International distributors/direct sales	49.1	21%	30.8	15%	23.7	13%
Other revenue	0.5	0%	1.7	1%	2.5	1%

Our principal agreements with Hospira are the MCDA and a strategic supply and distribution agreement for most of our other medical devices in the domestic and international markets and an agreement to sell Hospira custom infusion systems. The MCDA is scheduled to expire in 2025 and the latter two agreements are scheduled to expire in 2014. In connection with the closing of our asset purchase of Hospira s critical care product line in August 2009, our commitments under the MCDA to fund certain research and development to improve critical care products and develop new products for sale to Hospira and to provide sales specialists focused on critical care were terminated.

Under the terms of our agreements with Hospira, we are dependent on the marketing and sales efforts of Hospira for a large percentage of our sales, and Hospira determines the prices at which the products that we sell to Hospira will be sold to its customers. Hospira has conditional exclusive rights to sell CLAVE and our other products as well as custom infusion systems under the SetSource program in many of its major accounts. If Hospira is unable to maintain its position in the marketplace, our sales and operations could be adversely affected.

In 2004, Hospira substantially reduced its purchases of CLAVE products because it was reducing its inventories of our products. This caused a significant reduction in our sales and led to a net loss in the third and fourth quarters of 2004. If the steps we have taken to monitor and control the amount of Hospira s inventory of CLAVE products to avoid future inventory reductions are not successful we could experience sharp fluctuations in sales of CLAVE products to Hospira in the future.

Our ability to maintain and increase our market penetration depends on the success of our arrangement with Hospira and Hospira s arrangements with major buying organizations and its ability to renew such arrangements, as to which there is no assurance. Our business could be materially adversely affected if Hospira terminates its arrangement with us, negotiates lower prices, sells competing products or increases it sales of competing products, whether manufactured by Hospira or others, or otherwise alters the nature of its relationship with us. Although we believe that Hospira views us as a source of innovative and profitable products, there is no assurance that our relationship with Hospira will continue in its current form.

In contrast to our dependence on Hospira, our principal competitors in the market for protective I.V. connection systems are much larger companies that dominate the market for I.V. products and have broad product lines and large internal distribution networks. In many cases, these competitors are able to establish exclusive relationships with large hospitals, hospital chains, major buying organizations and home healthcare providers to supply substantially all of their requirements for I.V. products. In addition, we believe that there is a trend among individual hospitals and alternate site healthcare providers to consolidate into or join large major buying organizations with a view to standardizing and obtaining price advantages on disposable medical products. These factors may limit our ability to gain market share through our independent dealer network, resulting in continued concentration of sales to and dependence on Hospira.

On August 31, 2009, we completed an asset purchase with Hospira, acquiring the commercial and physical assets of Hospira s critical care line. We are responsible for all aspects of the critical care line, including sales, marketing, customer contracting and distribution. In connection with the closing of this transaction, our commitments under the MCDA to fund certain research and development to improve critical care products and develop new products for sale to Hospira and to provide sales specialists focused on critical care were terminated. We entered into a transition services agreement with Hospira to facilitate the transition, but we can provide no assurances that the transition will occur without delays, disruptions or significant costs. Any delay, disruption or significant costs in the transition may reduce or eliminate the expected benefits from the transaction.

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We began distribution of critical care products directly to existing customers on September 1, 2009. We can provide no assurances, however, that we will be successful in maintaining relationships with major buying organizations fostered by Hospira. Even if we can maintain such relationships, we can provide no assurances that customers will purchase products from us, with the same or similar terms. Furthermore, we can provide no assurances that we will be as successful as Hospira in marketing the critical care product line. Any failure on our part to adequately market and sell the critical care line will have an adverse effect on our financial results.

Although we expect the transaction will reduce the percentage of our revenues attributable to Hospira, we expect that Hospira will continue to be one of our most important customers, particularly with respect to our CLAVE products and custom infusion systems. With respect to these products, we remain dependent on our continued relationship with Hospira as well as Hospira s position in the marketplace. While we do not anticipate changes in our sales to Hospira of these products, we can provide no assurances that our relationship will not change, resulting in adverse effects on sales and operations.

We are increasingly dependent on manufacturing in Mexico and could be adversely affected by any economic, social or political disruptions

We continue to expand our production in Mexico. Any political or economic disruption in Mexico or a change in the local economy could have an adverse effect on our operations. In 2009, production costs in Mexico were approximately $59.1 million. Most of the material we use in manufacturing is imported into Mexico, and substantially all of the products we manufacture in Mexico are exported. We depend on our ability to move goods across the border quickly. Any disruption in the free flow of goods across the border could have an adverse effect on our business.

As of December 31, 2009, we employed 1,134 people in our plant in Ensenada, Mexico, and we expect this number to increase in 2010. Business activity in the Ensenada area has expanded significantly, providing increased employment opportunities. This could have an adverse effect on our ability to hire or retain necessary personnel and result in an increase in labor rates. We continue to take steps to compete for labor through attractive employment conditions and benefits, but there is no assurance that these steps will continue to be successful or that we will not face increasing labor costs in the future.

Additionally, political and social instability resulting from increased violence in certain areas of Mexico have raised concerns about the safety of our personnel. These concerns may hinder our ability to send domestic personnel abroad and to hire and retain local personnel. Such concerns may require us to increase security for personnel traveling to our Mexico facility or to conduct more operations from the United States rather than Mexico, which may negatively impact our operations and result in higher costs and inefficiencies.

Healthcare reform legislation could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Recently, the current administration and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. The federal fiscal year 2010 budget includes proposals to limit Medicare payments. In addition, members of

Congress have previously proposed a single-payer healthcare system, a government health insurance option to compete with private plans and other expanded public healthcare measures as well as a tax on manufacturers of medical devices and diagnostic products. The ultimate content or timing of any future healthcare reform legislation, and its impact on us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have an adverse effect on our financial condition and results of operations.

The expansion of our distribution facilities may face significant risks inherent in construction projects, including receipt of necessary government approvals.

In July 2009, we purchased land in Slovakia to construct a new assembly plant. We commenced construction on the Slovakian plant in the third quarter of 2009, and when completed, it will serve our European product distribution. We expect this plant to be operational in the second half of 2010.

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This project, and any other development projects we may undertake, will be subject to the many risks inherent in the construction of a new enterprise, including unanticipated design, construction, regulatory, environmental and operating problems. Our current and future projects could also experience:

- delays and significant cost increases;
- shortages of materials;
- shortages of skilled labor or work stoppages;
- unforeseen construction scheduling, engineering, environmental, permitting, construction or geological problems; and
- weather interference, floods, fires or other casualty losses.

The completion dates of any of our projects could differ significantly from expectations for construction-related or other reasons. Our initial project costs and construction periods are based upon budgets, conceptual design documents and construction schedule estimates prepared at inception of the project in consultation with architects and contractors. Many of these costs can increase over time as the project is built to completion. The cost of any project may vary significantly from initial budget expectations and we may have a limited amount of capital resources to fund cost overruns. If we cannot finance cost overruns on a timely basis, the completion of one or more projects may be delayed until adequate funding is available. We can provide no assurance that any project will be completed on time, if at all, or within established budgets, or that any project will result in increased earnings to us. Significant delays, cost overruns, or failures of our projects could have a material adverse effect on our business, financial condition and results of operations. Furthermore, our projects may not help us compete with new or increased competition in our markets.

Certain permits, licenses and approvals necessary for some of our current or anticipated projects have not yet been obtained. The scope of the approvals required for expansion, development, investment or renovation projects can be extensive and may require land-use permits and building and zoning permits. Unexpected changes or concessions required by regulatory authorities could involve significant additional costs and delay the scheduled openings of the facilities. We may not obtain the necessary permits, licenses and approvals within the anticipated time frames, or at all.

If we are unable to effectively manage our internal growth or growth through acquisitions of companies, assets or products, our financial performance may be adversely affected.

We intend to continue to expand our marketing and distribution capability internally, by expanding our sales and marketing staff and resources and may expand it externally, by acquisitions both in the United States and foreign markets. We may also consider expanding our product offerings through acquisitions of companies or product lines. For example, in August 2009, we completed our purchase of the commercial rights and the physical assets of Hospira s critical care line. We can provide no assurance that we will be able to identify, acquire, develop or profitably manage additional companies or operations or successfully integrate such companies or operations into our existing operations without substantial costs, delays or other problems.

We intend to build additional production facilities or contract for manufacturing in markets outside the United States, to reduce labor costs and eliminate transportation and other costs of shipping finished products from the United States and Mexico to customers outside North America. In addition, we are currently constructing a new assembly plant in Slovakia that will serve our European product distribution. The expansion of our manufacturing, marketing, distribution and product offerings both internally and through acquisitions or by contract may place substantial burdens on our management resources and financial controls. Decentralization of assembly and manufacturing could place further burdens on management to manage those operations, and maintain efficiencies and quality control.

The increasing burdens on our management resources and financial controls resulting from internal growth and acquisitions could adversely affect our operating results. In addition, acquisitions may involve a number of special risks in addition to the difficulty of integrating cultures and operations and the diversion of management s attention, including adverse short-term effects on our reported operating results, dependence on retention, hiring and training of key personnel, risks associated with unanticipated problems or legal liabilities and amortization of acquired intangible assets, some or all of which could materially and adversely affect our operations and financial performance.

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Our business could be materially and adversely affected if we fail to defend and enforce our patents, if our products are found to infringe patents owned by others or if the cost of patent litigation becomes excessive or as our key patents expire.

We have patents on certain products, software and business methods, and pending patent applications on other intellectual property and inventions. There is no assurance, however, that patents pending will issue or that the protection from patents which have issued or may issue in the future will be broad enough to prevent competitors from introducing similar devices, that such patents, if challenged, will be upheld by the courts or that we will be able to prove infringement and damages in litigation.

We are substantially dependent upon the patents on our proprietary products, such as the CLAVE, to prevent others from manufacturing and selling products similar to ours. We have pending litigation against RyMed Technologies, Inc. for alleged infringement of our patents. We believe the alleged infringement had and continues to have an adverse effect on our sales. Failure to prevail in this or in other litigation we bring against third parties for violating our patents could adversely affect our sales.

We are substantially dependent upon the patents on our proprietary products to prevent others from manufacturing and selling products similar to ours. We generally have multiple patents covering various features of a product, and as each patent expires, the protection afforded by that patent is no longer available to us, even though protection of features that are covered by other unexpired patents may continue to be available to us. The loss of patent protection on certain features of our products may make it possible for others to manufacture and sell products with features similar to ours, which could adversely affect our business.

If others choose to manufacture and sell products similar to or substantially the same as our products, it could have a material adverse effect on our business through loss of unit volume or price erosion, or both, and could adversely affect our ability to secure new business.

In the past, we have faced patent infringement claims related to the CLAVE, the CLC2000 and TEGO. We believe these claims had no merit, and all have been settled or dismissed. We may also face claims in the future. Any adverse determination on these claims related to the CLAVE or other products, if any, could have a material adverse effect on our business.

From time to time we become aware of newly issued patents on medical devices which we review to evaluate any infringement risk. We are aware of a number of patents for I.V. connection systems that have been issued to others. While we believe these patents will not affect our ability to market our products, there is no assurance that these or other issued or pending patents might not interfere with our right or ability to manufacture and sell our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Patent infringement litigation, which may be necessary to enforce patents issued to us or to defend ourselves against claimed infringement of the rights of others, can be expensive and may involve a substantial commitment of our resources which may divert resources from other uses. Adverse determinations in litigation or settlements could subject us to significant liabilities to third parties, could require us to seek licenses from third parties, could prevent us from manufacturing and selling our products or could fail to prevent competitors from manufacturing products similar to ours. Any of these results could materially and adversely affect our business.

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Expiring patents may affect our future sales

Most of our products are covered by patents that, if valid, give us a degree of market exclusivity during the term of the patent. The legal life of a patent in the U.S. is 20 years from application. Patents covering our products will expire from this year to 2023. Upon patent expiration, our competitors may introduce products using the same technology. As a result of this possible increase in competition, we may need to reduce our prices to maintain sales of our products, which would make them less profitable. If we fail to develop and successfully launch new products prior to the expiration of patents for our existing products, our sales and profits with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

United States patents related to our principal products expire as follows:

Product	**Expiration dates**
CLAVE® connector	12/2011 - 07/2016
CLC2000® connector	12/2016
Click Lock® connector	04/2010 - 07/2015
Custom Set Design and Manufacturing	01/2021
Orbit 90® infusion set	03/2022 - 11/2023

Our operating results may be adversely affected by unfavorable economic conditions which affect our customers ability to buy our products and could affect our relationships with our suppliers.

Disruptions in financial markets worldwide and other worldwide macro-economic challenges may cause our customers and suppliers to experience cash flow concerns. If job losses and the resulting loss of health insurance and personal savings cause individuals to forgo or postpone treatment, the resulting decreased hospital use could affect the demand for our products. As a result, customers may modify, delay or cancel plans to purchase our products and suppliers may increase their prices, reduce their output or change terms of sales. Additionally, if customers or suppliers operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, customers may not be able to pay, or may delay payment of, accounts receivable owed to us and suppliers may impose different payment terms. Any inability of current and/or potential customers to pay us for our products or any demands by suppliers for different payment terms may adversely affect our earnings and cash flow.

Expansion of our manufacturing facilities may result in inefficiencies which could have an adverse effect on our operations and financial results.

In the fourth quarter of 2006, we experienced significant production inefficiencies following a large increase in production volume in Mexico and the transfer of San Clemente production to Salt Lake City. In 2007, we expanded our Mexico facility and, anticipating further increases in volume at that facility, increased the workforce. Turnover among new employees is unusually high in Mexico, and the additional time spent in classroom training and on the job training could create production inefficiencies in Mexico in the future. The addition of new products will require additional molding in Salt Lake City, manual assembly work in Mexico and eventually additional automated assembly work in Salt Lake City. The effect of any inefficiencies can be particularly expensive in Salt Lake City because of the high fixed costs in this highly automated facility. Expansions of our production capacity will require significant management attention to avoid inefficiencies of the type experienced in

2006.

Because we are dependent on the CLAVE for a major portion of our sales, any decline in CLAVE sales could result in a significant reduction in our sales and profits.

In 2009, CLAVE products accounted for approximately 37% of our revenue. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. Most of our CLAVE sales are in the United States, where we expect moderate sales growth in the future as further penetration of markets available to our existing customers in the United States becomes increasingly difficult. Future significant sales increases for CLAVE products may depend on increases in sales of custom I.V. systems, expansion in the international markets or acquisition of new customers in the United States. We cannot give any assurance that sales of CLAVE products will increase indefinitely or that we can sustain current profit margins on CLAVE products indefinitely.

We believe that the success of the CLAVE has motivated, and will continue to motivate, competitors to develop one piece needleless connectors. In addition to products that emulate the characteristics of the CLAVE, it is possible that others could develop new product concepts and technologies that are functionally equivalent or superior to the CLAVE. If other manufacturers successfully develop and market effective products that are competitive with CLAVE products, CLAVE sales could decline, we could lose market share, and we could encounter sustained price and profit margin erosion.

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If our efforts to increase our custom products business are not successful or we cannot increase sales of other products and develop new, commercially successful products, our sales may not grow.

Our future success may be dependent both on the success of our strategic initiatives to substantially increase our custom product business and develop significant market share on a profitable basis and on new product development. Our total sales of custom products including custom infusion sets, custom oncology products and custom critical care products were $78.6 million in 2009, compared with $69.8 million in 2008. The success of our custom product sales program will require a larger increase in sales in the future than was achieved in 2009 and there is no assurance that such an increase will be achieved or sustained. Although we are seeking to continue to develop a variety of new products, there is no assurance that any new products will be commercially successful or that we will be able to recover the costs of developing, testing, producing and marketing such products. Certain healthcare product manufacturers, with financial and distribution resources substantially greater than ours, have developed and are marketing products intended to fulfill the same functions as our products which may adversely affect our results of operations.

International sales pose additional risks related to competition with larger international companies and established local companies, our possibly higher cost structure, our ability to open foreign manufacturing facilities that can operate profitably, higher credit risks and exchange rate risk.

We have undertaken a program to increase our international sales, and have distribution arrangements in all the principal countries in Western Europe, the Pacific Rim and Latin America, and in South Africa. We plan to sell in most other areas of the world. Currently, we export most of our products sold internationally from the United States and Mexico. Our principal competitors in international markets consist of much larger companies as well as smaller companies already established in the countries into which we sell our products. Our cost structure is often higher than that of our competitors because of the relatively high cost of transporting product to the local market as well as our competitors lower local labor costs in some markets. For these reasons, among others, we expect to open manufacturing facilities in foreign locations. There is no certainty that we will be able to open local manufacturing facilities or that those facilities will operate on a profitable basis.

Our international sales are subject to higher credit risks than sales in the United States. Many of our distributors are small and may not be well capitalized. Payment terms are relatively long. Our prices to our international distributors, outside of Europe, for product shipped to the customers from the United States or Mexico are denominated in U.S. dollars, but their resale prices are set in their local currency. A decline in the value of the local currency in relation to the U.S. dollar may adversely affect their ability to profitably sell in their market the products they buy from us, and may adversely affect their ability to make payment to us for the products they purchase. Legal recourse for non-payment of indebtedness may be uncertain. These factors all contribute to a potential for credit losses.

We distribute products in Europe through our subsidiaries in Italy and Germany. Sales and most other transactions by this subsidiary are denominated in Euros. As the Euro-denominated sales increase in relation to our total sales, a decline in the value of the Euro in relation to the U.S. dollar could have an adverse effect on our reported operating results. There is no assurance as to the growth of this subsidiary or its future operating results.

Continuing pressures to reduce healthcare costs may adversely affect our prices. If we cannot reduce manufacturing costs of existing and new products, our sales may not grow and our profitability may decline.

Increasing awareness of healthcare costs, public interest in healthcare reform and continuing pressure from Medicare, Medicaid and other payers to reduce costs in the healthcare industry, as well as increasing competition from other protective products, could make it more difficult for us to sell our products at current prices. In the event that the market will not accept current prices for our products, our sales and profits could be adversely affected. We believe that our ability to increase our market share and operate profitably in the long term may depend in part on our ability to reduce manufacturing costs on a per unit basis through high volume production using highly automated molding and assembly systems. If we are unable to reduce unit manufacturing costs, we may be unable to increase our market share for CLAVE products or may lose market share to alternative products, including competitors products. Similarly, if we cannot reduce unit manufacturing costs of new products as production volumes increase, we may not be able to sell new products profitably or gain any meaningful market share. Any of these results would adversely affect our future results of operations.

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If we are unable to compete successfully on the basis of product innovation, quality, convenience, price and rapid delivery with larger companies that have substantially greater resources and larger distribution networks than us, we may be unable to maintain market share, in which case our sales may not grow and our profitability may be adversely affected.

The market for I.V. products is intensely competitive. We believe that our ability to compete depends upon continued product innovation, the quality, convenience and reliability of our products, access to distribution channels, patent protection and pricing. The ability to compete effectively depends on our ability to differentiate our products based on safety features, product quality, cost effectiveness, ease of use and convenience, as well as our ability to perceive and respond to changing customer needs. We encounter significant competition in our markets both from large established medical device manufacturers and from smaller companies. Many of these firms have introduced competitive products with protective features not provided by the conventional products and methods they are intended to replace. Most of our current and prospective competitors have economic and other resources substantially greater than ours and are well established as suppliers to the healthcare industry. Several large, established competitors offer broad product lines and have been successful in obtaining full-line contracts with a significant number of hospitals to supply all of their I.V. product requirements. There is no assurance that our competitors will not substantially increase resources devoted to the development, manufacture and marketing of products competitive with our products. The successful implementation of such a strategy by one or more of our competitors could materially and adversely affect us.

We may not be able to significantly expand our sales of custom I.V. systems, or critical care products, if we are unable to lower manufacturing costs, price our products competitively and shorten delivery times significantly.

We believe that the success of our I.V. systems operations will depend on our ability to lower per unit manufacturing costs and price our products competitively and on our ability to significantly shorten the time from customer order to delivery of finished product, or both. To reduce costs, we moved labor intensive assembly operations to our facility in Mexico. To shorten delivery times, we developed proprietary systems for order processing, materials handling, tracking, labeling and invoicing and innovative procedures to expedite assembly and distribution operations. Many of these systems and procedures require continuing enhancement and development. There is a possibility that our systems and procedures may not continue to be adequate and meet their objectives.

We are introducing many of the systems and procedures that we used in our I.V. systems operations into the production of critical care products. If we are unable to complete this process successfully, we may not be successful in increasing sales of critical care products.

If demand for our products were to decline significantly, we might not be able to recover the cost of our expensive automated molding and assembly equipment and tooling, which could have an adverse effect on our results of operations.

Our production tooling is relatively expensive, with each module, which consists of an automated assembly machine and the molds and molding machines which mold the components, costing several million dollars. Most of the modules are for the CLAVE and the integrated Y-CLAVE. If the demand for either of these products changes significantly, which could happen with the loss of a customer or a change in product mix, it may be necessary for us recognize an impairment charge for the value of the production tooling because its cost may not be recovered through production of saleable product, which could adversely affect our financial condition.

We have been and will be ordering production molds and equipment for our new products. We expect to order semi-automated or fully automated assembly machines for the other new products in 2010. If we do not achieve significant sales of these new products, it might be necessary for us to recognize an impairment charge for the value of the production tooling because it costs may not be recovered through production of saleable product, which could adversely affect our financial condition.

If we cannot obtain additional custom tooling and equipment on a timely basis to enable us to meet demand for our products, we might be unable to increase our sales or might lose customers, in which case our sales could decline.

We expanded our manufacturing capacity substantially in recent years, and we expect that continued expansion will be necessary. Molds and automated assembly machines generally have a long lead-time with vendors, often nine months or longer. Inability to secure such tooling in a timely manner, or unexpected increases in production demands, could cause us to be unable to meet customer orders. Such inability could cause customers to seek alternatives to our products.

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Increases in the cost of petroleum-based and natural gas-based products or loss of supply could have an adverse effect on our profitability.

Most of the materials used in our products are resins, plastics and other material that depend upon oil or natural gas as their raw material. Crude oil markets are affected by political uncertainty in the Middle East, and there is no assurance that crude oil supplies will not be interrupted in the future. Any such interruption could have an adverse effect on our ability to produce, or the cost to produce, our products. Also, crude oil and natural gas prices recently reached record highs. Our suppliers have passed some of their cost increases on to us, and if such prices are sustained or increase further, our suppliers may pass further cost increases on to us. In addition to the effect on resin prices, transportation costs have increased because of the effect of higher crude oil prices, and we believe most of these costs have been passed on to us. Our ability to recover these increased costs may depend upon our ability to raise prices on our products. In the past, we have rarely raised prices and it is uncertain that we would be able to raise them to recover higher prices from our suppliers. Our inability to raise prices in those circumstances, or to otherwise recover these costs, could have an adverse effect on our profitability.

Because we depend to a significant extent on our founder for new product concepts, the loss of his services could have a material adverse effect on our business.

We depend on Dr. George A. Lopez, our founder, Chairman of the Board, President and Chief Executive Officer for new product concepts and manufacturing innovation. Dr. Lopez has conceived substantially all of our current and proposed new products and the systems and procedures to be used in the custom I.V. products and their manufacturing. We believe that the loss of his services could have a material adverse effect on our business.

Our ability to market our products in the United States and other countries may be adversely affected if our products or our manufacturing processes fail to qualify under applicable standards of the FDA and regulatory agencies in other countries.

Government regulation is a significant factor in the development, marketing and manufacturing of our products. Our products are subject to clearance by the United States Food and Drug Administration (FDA) under a number of statutes including the Food Drug and Cosmetics Act (FDC Act). Each of our current products has qualified, and we anticipate that any new products we are likely to market will qualify for clearance under the FDA s expedited pre-market notification procedure pursuant to Section 510(k) of the FDC Act. However, certain of our new products may require a longer time for clearance than we have experienced in the past and there can be no assurance that a PMA application will not be required. Further, there is no assurance that other new products developed by us or any manufacturers that we might acquire will qualify for expedited clearance rather than a more time consuming pre-market approval procedure or that, in any case, they will receive clearance from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to the time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions. In addition, we must manufacture our products in compliance with the FDA s Quality System Regulations.

The FDA has broad discretion in enforcing the FDC Act, and noncompliance with the FDC Act could result in a variety of regulatory actions ranging from warning letters, product detentions, device alerts or field corrections to mandatory recalls, seizures, injunctive actions and civil or criminal penalties. If the FDA determines that we have seriously violated applicable regulations, it could seek to enjoin us from marketing our products or we could be otherwise adversely affected by delays or required changes in new products. In addition, changes in FDA, or other federal or state, health, environmental or safety regulations or in their application could adversely affect our business.

To market our products in the European Community (EC), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of ISO 13485 (2003). Those quality standards are similar to the FDA s Quality System Regulations. Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC (Medical Device Directive) and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the CE Mark maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. There is no assurance that we will continue to meet the requirements for distribution of our products in Europe.

Distribution of our products in other countries may be subject to regulation in those countries, and there is no assurance that we will obtain necessary approvals in countries in which we want to introduce our products.

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Product liability claims could be costly to defend and could expose us to loss.

The use of our products exposes us to an inherent risk of product liability. Patients, healthcare workers or healthcare providers who claim that our products have resulted in injury could initiate product liability litigation seeking large damage awards against us. Costs of the defense of such litigation, even if successful, could be substantial. We maintain insurance against product liability and defense costs in the amount of $10,000,000 per occurrence. There is no assurance that we will successfully defend claims, if any, arising with respect to products or that the insurance we carry will be sufficient. A successful claim against us in excess of insurance coverage could materially and adversely affect us. Furthermore, there is no assurance that product liability insurance will continue to be available to us on acceptable terms.

Our Stockholder Rights Plan, provisions in our charter documents and Delaware law could prevent or delay a change in control, which could reduce the market price of our common stock.

On July 15, 1997, our Board of Directors adopted a Stockholder Rights Plan (the Plan) and, pursuant to the Plan, declared a dividend distribution of one Right for each outstanding share of our common stock to stockholders of record at the close of business on July 28, 1997. The Plan expired in 2007 and our Board of Directors adopted an Amended and Restated Rights Agreement in July 2007. Under its current provisions, each Right entitles the registered holder to purchase from us one one-hundredth of a share of Series A Junior participating Preferred Stock, no par value, at a purchase price of $225 per one one-hundredth of a share, subject to adjustment. The Plan is designed to afford the Board of Directors a great deal of flexibility in dealing with any takeover attempts and is designed to cause persons interested in acquiring us to deal directly with the Board of Directors, giving it an opportunity to negotiate a transaction that maximizes stockholder values. The Plan may, however, have the effect of discouraging persons from attempting to acquire us.

Investors should refer to the description of the Plan in our 2007 10-K filed with the Securities and Exchange Commission.

Our Certificate of Incorporation and Bylaws include provisions that may discourage or prevent certain types of transactions involving an actual or potential change of control, including transactions in which the stockholders might otherwise receive a premium for their shares over then current market prices. In addition, the Board of Directors has the authority to issue shares of Preferred Stock and fix the rights and preferences thereof, which could have the effect of delaying or preventing a change of control otherwise desired by the stockholders. In addition, certain provisions of Delaware law may discourage, delay or prevent someone from acquiring or merging with us.

The price of our common stock has been and may continue to be highly volatile due to many factors.

The market for small-market capitalization companies can be highly volatile, and we have experienced significant volatility in the price of our common stock in the past. From January 2008 through December 2009, our trading price ranged from a high of $44.06 per share to a low of $22.14 per share We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts expectations and actual quarterly and annual results, new product introductions by us or our competitors, changing regulatory environments, litigation, changes in healthcare reimbursement policies, sales or the perception in the market of possible sales of common stock by insiders and substantial product orders could contribute to the volatility in the price of our common stock. General economic trends unrelated to our performance such as recessionary cycles and changing interest rates may also adversely affect the market price of our common stock; the recent macroeconomic downturn could depress our stock price for some time.

Most of our common stock is held by, or included in accounts managed by, institutional investors or managers. Several of those institutions own or manage a significant percentage of our outstanding shares, with the ten largest interests accounting for 51% of our outstanding shares. If one or more of the institutions should decide to reduce or eliminate its position in our common stock, it could cause a decrease in the price of the common stock that could be significant.

For the past several years there has been a significant short position in our common stock, consisting of borrowed shares sold, or shares sold for future delivery which may not have been borrowed. We do not know whether any of these short positions are covered by long positions owned by the short seller. The short position, as reported by the Nasdaq Stock Market on December 31, 2009 was 956,559 shares, or approximately seven percent of our outstanding shares. Any attempt by the short sellers to liquidate their position over a short period of time could cause very significant volatility in the price of our common stock.

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We have outstanding stock options which may dilute the ownership of existing shareholders

At December 31, 2009, we had outstanding stock options to purchase 2.9 million shares, 86% of which had an exercise price below the market price of our stock. Exercise of those options would dilute the ownership interest of existing shareholders. Equity awards will continue to be a source of compensation for employees and directors.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We own a 39,000 square foot building and a 28,000 square foot building in San Clemente, California, a 450,000 square foot building in Salt Lake City, Utah, a 37,500 square foot building in Vernon, Connecticut, a 241,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico, a 17,000 square foot and a 21,000 square foot building in Roncanova, Italy. We also own 11 acres of land in Vrable, Slovakia and are constructing a 77,000 square foot building on the land that we expect to be completed in the second half of 2010. We lease a building in Ludenscheid, Germany.

Item 3. Legal Proceedings

We have not been required to pay any penalty to the IRS for failing to make disclosures required with respect to certain transactions that have been identified by the IRS as abusive or that have a significant tax avoidance purpose.

In an action filed July 27, 2007 entitled ICU Medical, Inc. v. RyMed Technologies, Inc. in the United States District Court for the District of Delaware, we alleged that RyMed infringes certain of our patents through the manufacture and sale of certain products, including its InVision-Plus valves. Trial was been scheduled for January 19, 2010, but has been continued pending a Petition by RyMed for Interlocutory Appeal to the Federal Circuit. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. In response to this action, RyMed denied our allegations and sued us in the United States District Court for the Central District of California seeking a declaratory judgment of non-infringement and invalidity of our patents and alleging that we have infringed RyMed s trademark and engaged in unfair competition and other improper conduct. The Central District Court transferred all patent claims to Delaware. The Central District Court granted summary judgment on RyMed s trademark and unfair competition claims, and entered Judgment in our favor on October 8, 2009. We will continue to vigorously pursue its patent infringement claims against RyMed in the Delaware action.

We are from time to time involved in various other legal proceedings, either as a defendant or plaintiff, most of which are routine litigation in the normal course of business. We believe that the resolution of the legal proceedings in which we are involved will not have a material adverse effect on our financial position or results of operations.

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

Not Applicable.

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Item 4A. Executive Officers of Registrant

The following table lists the names, ages, certain positions and offices held by our executive officers as of January 31, 2010.

	Age	Office Held
George A. Lopez, M.D.	62	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	37	Vice President of Product Development
Richard A. Costello	46	Vice President of Sales and Marketing
Scott E. Lamb	47	Chief Financial Officer
Steven C. Riggs	51	Vice President of Operations

Dr. Lopez has served as our Chairman of the Board and Chief Executive Officer since his hire date in 1989. Ms. Burcar, the niece of Dr. Lopez, has served as our Vice President of Product Development since July 2009, was our Vice President of Marketing from 2002 to July 2009, our Marketing Operations Manager from 1998 to 2002 and held research and development project/program management positions from 1995 to 1998. Mr. Costello has served as our Vice President of Sales and Marketing since July 2009, our Vice President of Sales from 1997 to July 2009, our National Sales Manager from 1996 to 1997 and a Product Specialist from 1992 to 1996. Mr. Lamb has served as our Chief Financial Officer since 2008 and as our Controller from 2003 to 2008. Mr. Riggs has served as our Vice President of Operations since 2002, was Director of Operations from 1998 to 2002 and was Senior Manager of Quality Assurance and Quality Control from 1992 to 1998.

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Part II

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

Our common stock has been traded on the NASDAQ Global Select Market under the symbol ICUI since our initial public offering on March 31, 1992. The following table sets forth, for the quarters indicated, the high and low closing prices for our common stock quoted by NASDAQ:

2009	High	Low
First quarter	$ 35.82	$ 26.81
Second quarter	41.89	30.89
Third quarter	43.95	35.73
Fourth quarter	37.86	32.85

2008	High	Low
First quarter	$ 38.08	$ 24.19
Second quarter	30.00	22.14
Third quarter	33.65	22.69
Fourth quarter	35.11	24.32

We have never paid dividends and do not anticipate paying dividends in the foreseeable future as the Board of Directors intends to retain future earnings for use in our business or to purchase our shares. Any future determination as to payment of dividends or purchase of our shares will depend upon our financial condition, results of operations and such other factors as the Board of Directors deems relevant.

As of January 31, 2010, we had 97 stockholders of record and we believe we have approximately 8,900 beneficial owners of our common stock.

Issuer Repurchase of Equity Securities

In July 2008, our Board of Directors authorized a program to purchase $40.0 million of our common stock. In October 2009, our Board of Directors increased the amount that may be purchased under this plan by $15.0 million, bringing the total authorized amount that may be purchased under the plan to $55.0 million. This plan has no expiration date. All shares of common stock that we repurchased in the fourth quarter of 2009 were repurchased pursuant to this plan.

The following is a summary of our stock repurchasing activity during the fourth quarter of 2009:

Period	Shares purchased		Average price paid per share	Shares purchased as part of a publicly announced program		Approximate dollar value that may yet be purchased under the program
10/1/2009 - 10/31/2009	39,376	$	35.46	39,376	$	47,187,000
11/1/2009 - 11/30/2009	300,668	$	34.89	300,668		36,695,000
12/1/2009 - 12/31/2009	232,259	$	34.41	232,259		28,702,000
Fourth quarter 2009 total	572,303	$	34.74	572,303		

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COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2005 TO DECEMBER 31, 2009 OF ICU MEDICAL, INC., NASDAQ AND NASDAQ MEDICAL DEVICES INDEX

The following graph shows the total stockholder return on our common stock based on the market price of the common stock from December 31, 2004 to December 31, 2009 and the total returns of the NASDAQ U.S. Index and NASDAQ Medical Devices, Instruments and Supplies, Manufacturers and Distributers Stocks Index for the same period.

	12/31/2004	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009
ICU Medical, Inc.	$ 100.00	$ 143.42	$ 148.79	$ 131.71	$ 121.21	$ 133.28
Nasdaq	$ 100.00	$ 102.13	$ 112.19	$ 121.68	$ 58.64	$ 84.28
Nasdaq Medical Devices Index	$ 100.00	$ 109.79	$ 115.72	$ 147.14	$ 79.23	$ 115.55

Assumes $100 invested on December 31, 2004 in ICU Medical Inc. s common stock, the NASDAQ U.S. Index and the Nasdaq Medical Devices, Instruments and Supplies, Manufacturers and Distributers Stocks Index and that all dividends, if any, were reinvested.

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Item 6. Selected Financial Data.

ICU MEDICAL, INC.

SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2009	2008	2007	2006	2005
INCOME DATA:					
Revenue					
Net sales	$ 230,973	$ 203,026	$ 185,618	$ 198,788	$ 154,621
Other	540	1,700	2,520	2,825	2,911
Total revenue	231,513	204,726	188,138	201,613	157,532
Cost of goods sold	122,695	114,910	109,895	120,929	88,128
Gross profit	108,818	89,816	78,243	80,684	69,404
Selling, general and administrative expenses	68,205	53,611	45,484	44,245	36,992
Research and development expenses	2,645	4,822	8,111	7,659	4,817
Gain on sale of building				(2,093)	
Total operating expenses	70,850	58,433	53,595	49,811	41,809
Income from operations	37,968	31,383	24,648	30,873	27,595
Other income	1,181	4,695	8,698	4,462	2,721
Income before income taxes and minority interest	39,149	36,078	33,346	35,335	30,316
Provision for income taxes	(12,592)	(11,778)	(10,337)	(10,240)	(10,459)
Minority interest			70	565	417
Net income	$ 26,557	$ 24,300	$ 23,079	$ 25,660	$ 20,274
Net income per common share					
Basic	$ 1.80	$ 1.72	$ 1.62	$ 1.78	$ 1.47
Diluted	$ 1.77	$ 1.67	$ 1.51	$ 1.64	$ 1.35
Weighted average number of shares					
Basic	14,720	14,144	14,282	14,412	13,811
Diluted	14,984	14,565	15,265	15,599	15,040
Cash dividends per share	$	$	$	$	$
CASH FLOW DATA:					
Total cash flows from operations	$ 48,609	$ 30,226	$ 41,512	$ 31,608	$ 27,342
BALANCE SHEET DATA:					
Cash, cash equivalents, restricted cash and current and long-term investment securities	$ 108,135	$ 129,153	$ 95,643	$ 116,918	$ 86,742
Working capital	174,242	157,428	131,782	155,519	123,875
Total assets	309,153	283,434	242,594	244,248	204,537
Stockholders equity	265,005	253,031	213,904	224,887	189,198

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

We are a leader in the development, manufacture and sale of proprietary, disposable medical connection systems for use in vascular therapy applications. Our devices are designed to protect patients from catheter related bloodstream infections and healthcare workers from exposure to diseases through accidental needlesticks or hazardous drugs. We are also a leader in the production of custom I.V. systems and we incorporate our proprietary products into many of those custom I.V. systems. In addition, we are a significant manufacturer of critical care medical devices, including catheters, angiography kits and cardiac monitoring systems.

Critical Accounting Policies

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements. In preparing our financial statements, we make estimates and assumptions that affect the expected amounts of assets and liabilities and disclosure of contingent assets and liabilities. We apply our accounting policies on a consistent basis. As circumstances change, they are considered in our estimates and judgments, and future changes in circumstances could result in changes in amounts at which assets and liabilities are recorded.

Investment securities: Investment securities consist of corporate preferred stocks, certificates of deposits and federal tax-exempt state and municipal government debt which are classified as available-for-sale or trading. See Item 7A, Quantitative and Qualitative Disclosures about Market Risk. Under our current investment policies, our available for sale securities have no significant difference between the fair value and amortized cost. If there were to be a significant difference, this amount would be reflected as a separate component of stockholders equity. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings at each subsequent reporting date.

Revenue recognition: We record sales and related costs when ownership of the product transfers to the customer, persuasive evidence of an arrangement exists, collectability is reasonably assured and the sales price is determinable. Under the terms of all our purchase orders, ownership transfers on shipment. If there are significant doubts at the time of shipment as to the collectability of the receivable, we defer recognition of the sale in revenue until the receivable is collected. Our customers are medical product manufacturers, distributors and end-users. Our only post-sale obligations are warranty and certain rebates. We warrant products against defects and have a policy permitting the return of defective products. We record warranty returns as an expense and amounts have been insignificant. With certain exceptions, customers do not retain any right of return and there is no price protection with respect to unsold products. Returns from customers with return rights have not been significant. We accrue rebates as a reduction in revenue based on agreements and historical experience. Adjustments of estimates of warranty claims, rebates or returns, which have not been, and are not expected to be material, affect current operating results when they are determined.

Accounts receivable: Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on the age of the receivable or on specific past due accounts for which we consider collection to be doubtful. We rely on prior payment trends, financial status and other factors to estimate the cash which ultimately will be received. Such amounts cannot be known with certainty at the financial statement date. We regularly review individual past due balances for collectability. Loss exposure is principally with international distributors for whom normal payment terms are long in comparison to those of our other customers and, to a lesser extent, domestic distributors. Many of these distributors are relatively small and we are vulnerable to adverse developments in their businesses that can hinder our collection of amounts due. If actual collection losses exceed expectations, we could be required to accrue additional bad debt expense, which could have an adverse effect on our operating results in the period in which the accrual occurs.

Inventories: Inventories are stated at the lower of cost (first in, first out) or market. We need to carry many components to accommodate our rapid product delivery, and if we misestimate demand or if customer requirements change, we may have components in inventory that we may not be able to use. Most finished products are made only after we receive orders except for certain standard (non-custom) products which we will carry in inventory in expectation of future orders. For finished products in inventory, we need to estimate what may not be saleable. We regularly review inventory for slow moving items and write off all items we do not expect to use in manufacturing, or finished products we do not expect to sell. If actual usage of components or sales of finished goods inventory is less than our estimates, we could be required to write off additional inventory, which could have an adverse effect on our operating results in the period in which the write-off occurs.

Property and equipment/depreciation: Property and equipment is carried at cost and depreciated on the straight-line method over the estimated useful lives. The estimates of useful lives are significant judgments in accounting for property and equipment, particularly for molds and automated assembly machines that are custom made for us. We may retire them on an accelerated basis if we replace them with larger or more technologically advanced tooling. The remaining useful lives of all

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property and equipment are reviewed regularly and lives are adjusted or assets written off based on current estimates of future use. As part of that review, property and equipment is reviewed for other indicators of impairment. An unexpected shortening of useful lives of property and equipment that significantly increases depreciation provisions, or other circumstances causing us to record an impairment loss on such assets, could have an adverse effect on our operating results in the period in which the related charges are recorded.

New Accounting Pronouncements

See Note 1of the Consolidated Financial Statements in this Annual Report on Form 10-K.

Business Overview

Until the late 1990s, our primary emphasis in product development, sales and marketing was disposable medical connectors for use in I.V. therapy, and our principal product was the CLAVE. In the late 1990s, we commenced a transition from a product-centered company to an innovative, fast, efficient, low-cost manufacturer of custom I.V. systems, using processes that we believe can be readily applied to a variety of disposable medical devices. This strategy has enabled us to capture revenue on the entire I.V. delivery system, and not just a component of the system. We have furthered this effort to include all of our proprietary devices beyond the CLAVE.

We believe the success of the CLAVE has motivated, and will continue to motivate others to develop one-piece, swabbable, needleless connectors that may incorporate many of the same functional and physical characteristics as the CLAVE. We are aware of a number of such products. We have patents covering the technology embodied in the CLAVE and intend to enforce those patents as appropriate. If we are not successful in enforcing our patents, competition from such products could adversely affect our market share and prices for our CLAVE products. Although overall pricing has been stable recently, the average price of our CLAVE products may decline in the future. There is no assurance that our current or future products will be able to successfully compete with products developed by others.

We are reducing our dependence on our current proprietary products by introducing new products and systems and acquiring product lines. Under one of our Hospira Agreements, we manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. In 2005, we acquired Hospira s Salt Lake City manufacturing facility and entered into an agreement with Hospira to produce their critical care products, including invasive monitoring, angiography products and certain other products they had manufactured at that facility. On August 31, 2009, we purchased the commercial rights and physical assets from Hospira s critical care product line which resulted in our control over all aspects of our critical care product line. We also contract with group purchasing organizations and independent dealer networks for inclusion of our non-critical care CLAVE and custom products in the product offerings of those entities. We are expanding our custom products business through increased sales to medical product manufacturers, independent distributors and direct sales to the end users of our product. These expansions include our 2008 agreement with Premier and the extension of the term of our agreement with MedAssets. Both organizations are U.S. healthcare purchasing networks. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately $78.6 million or 34% of total revenue in 2009. We expect continued increases in sales of custom infusion sets and custom oncology products. As part of this effort, we have recently introduced a number of new products: the TEGO for use in dialyses, the Orbit 90 diabetes set, and a line of oncology products including the Spiros male luer connector device, the Genie vial access device, custom I.V sets and ancillary products specifically designed for chemotherapy. There is no assurance that we will be successful in finding future acquisition opportunities or integrating these new product lines into our existing business.

Custom products and new products will be of increasing importance to us in future years. We expect continued growth in 2010 in our CLAVE products in the U.S., but at a modest growth rate. We also potentially face substantial increases in competition in our CLAVE business. Growth for all of our products outside the U.S., to date, has been relatively modest. Therefore, we are focusing on increasing product development, acquisition, sales and marketing efforts to custom products and other products that lend themselves to customization and new products in the U.S. and international markets.

In 2005, we acquired Hospira s Salt Lake City manufacturing facility, related capital equipment and entered into the MCDA under which we produced for sale, exclusively to Hospira, substantially all the products, primarily critical care, that Hospira had manufactured at that facility. Under this agreement, prior to August 31, 2009, Hospira retained commercial responsibility for the products we produced, including sales, marketing, pricing, distribution, customer contracts, customer service and billing. The U.S. market for most of the critical care products that we sell to Hospira has been declining in recent years. Under the MCDA, we manufactured the products and Hospira was responsible for sales to end customers, and we had little ability to directly influence Hospira s sales and marketing efforts, and our sales under the MCDA were subject to fluctuations over which we had little control. On August 31, 2009, we acquired the commercial rights and physical assets of

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Hospira s critical care product line. This purchase provides us with complete control over worldwide commercial responsibility for the critical care products including sales, marketing, customer contracting and distribution. Under the MCDA, we were also committed to fund certain critical care research and to provide sales specialist support. Both obligations under the MCDA were released by Hospira upon the closing of this transaction. On August 31, 2009, we entered into a transition services agreement with Hospira to facilitate the transition of services that Hospira previously provided under the MCDA relating to the critical care products. Under the transition services agreement, Hospira will provide distribution services and light manufacturing for up to eighteen months from August 31, 2009, however, we currently expect these functions will be transitioned prior to the end of this eighteen-month period. We can provide no assurances that the transition will occur without delays, disruptions or significant costs. Any delay, disruption or significant costs in the transition may reduce or eliminate the expected benefits from the transaction.

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be of singular importance to our growth. In the years ended 2009, 2008 and 2007, our revenues from worldwide sales to Hospira were 53%, 69% and 73%, respectively, of total revenues. Although we can provide no assurances, we expect this percentage will decrease because critical care sales are now sold by us directly to the distributor or end user instead of to Hospira. We expect sales to Hospira to still be a significant percentage of our revenues from sales to Hospira of CLAVE products, custom infusion sets and new products. Hospira has a significant share of the I.V. set market in the U.S., and provides us access to that market. We expect that Hospira will be important to our growth for CLAVE, custom infusion sets, and our other products worldwide.

In February 2009, we acquired a small manufacturing and distribution company based in Germany for $5.7 million. The products and distribution from this company are in the oncology and neonatal markets.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development in these markets.

There is no assurance that we will be successful in implementing our growth strategy. The custom products market is small, when compared to the larger market of standard products, and we could encounter customer resistance to custom products. Further, we could encounter increased competition as other companies see opportunity in this market. Product development or acquisition efforts may not succeed, and even if we do develop or acquire products, there is no assurance that we will achieve profitable sales of such products. An adverse change in our relationship with Hospira, or a deterioration of Hospira s position in the market, could have an adverse effect on us. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

The following table sets forth, for the periods indicated, total revenues by product as a percentage of total revenues:

Product line	**2009**	**2008**	**2007**
CLAVE	37%	39%	38%
Custom products	34%	34%	31%
Standard critical care products	18%	17%	22%
Standard oncology products	2%	1%	0%
Other products/other revenue	9%	9%	9%

100% 100% 100%

We sell our I.V. administration products to independent distributors, direct sales and through agreements with Hospira and certain other medical product manufacturers. Most independent distributors handle the full line of our I.V. administration products. We sell our invasive monitoring, angiography and I.V. administration products through three agreements with Hospira (the Hospira Agreements). Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors and the CLC2000. Under a 2001 agreement, we sell custom infusion sets to Hospira under a program referred to as SetSource. Our 1995 and 2001 agreements with Hospira provide Hospira with conditional exclusive and nonexclusive rights to distribute all existing ICU Medical products worldwide with terms that extend to 2014. We sell invasive monitoring and angiography to independent distributors and through direct sales. We also sell certain other products to a number of other medical product manufacturers.

We believe that as healthcare providers continue to either consolidate or join major buying organizations, the success of our products will depend, in part, on our ability, either independently or through strategic relationships such as our Hospira relationship, to secure long-term contracts with large healthcare providers and major buying organizations. As a result of this marketing and distribution strategy we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer s products could have a material adverse effect on our operating results.

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We have an ongoing program to increase systems capabilities, improve manufacturing efficiency, reduce labor costs, reduce time needed to produce an order, and minimize investment in inventory. These include the use of automated assembly equipment for new and existing products and use of larger molds and molding machines. In 2006, we centralized our proprietary molding in Salt Lake City and expanded our production facility in Mexico which took over the majority of our manual assembly previously done in Salt Lake City. In 2007, we began a significant initiative to improve production processes, called the ICU Production System or IPS , which we believe will enable us to further improve our manufacturing efficiency. We started IPS in our Mexico facility in 2007 and in our Salt Lake City facility in 2008. These efforts are ongoing in both facilities and will continue into 2010. In July 2009, we purchased land in Slovakia. In the third quarter of 2009, we started construction on an assembly plant in Slovakia that will serve our European product distribution. We expect this plant to be operational in the second half of 2010. We may establish additional production facilities outside the U.S. There is no assurance as to the benefits of IPS or our success in establishing manufacturing facilities outside the U.S.

We distribute products through three distribution channels. Product revenues for each distribution channel as a percentage of total channel product revenue were as follows:

Channel	2009	2008	2007
Medical product manufacturers	50%	67%	71%
Independent domestic distributors/direct sales	29%	18%	16%
International distributors/direct sales	21%	15%	13%
Total	100%	100%	100%

Sales to international customers do not include bulk CLAVE products sold to Hospira in the U.S. but used in I.V. products manufactured by Hospira and exported. Those sales are included in sales to medical product manufacturers. Other sales to Hospira for destinations outside the U.S. are included in sales to international customers.

With the completion of our purchase of the commercial rights and the physical assets of Hospira s critical care line in August 2009, we began selling critical care products in September 2009 to domestic and international distributors and through direct domestic and international sales instead of to Hospira. As a result, we expect to continue to see a shift in sales from medical product manufacturers to domestic and international distributors and direct sales.

Quarterly results: The healthcare business in the United States is subject to seasonal fluctuations, and activity tends to diminish somewhat in the summer months of June, July and August, when illness is less frequent than in winter months and patients tend to postpone elective procedures. This typically causes seasonal fluctuations in our business. In addition, we can experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which may be driven more by production scheduling and their inventory levels, and less by seasonality. Our expenses often do not fluctuate in the same manner as net sales, which may cause fluctuations in operating income that are disproportionate to fluctuations in our revenue.

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Year-to-Year Comparisons

We present summarized income statement data in Item 6. Selected Financial Data. The following table shows, for the three most recent years, the percentages of each income statement caption in relation to revenues.

	Percentage of Revenues		
	2009	**2008**	**2007**
Revenue			
Net sales	100%	99%	99%
Other	0%	1%	1%
Total revenues	100%	100%	100%
Gross profit	47%	44%	42%
Selling, general and administrative expenses	30%	26%	24%
Research and development expenses	1%	2%	5%
Total operating expenses	31%	28%	29%
Income from operations	16%	16%	13%
Other income	1%	2%	5%
Income before income taxes and minority interest	17%	18%	18%
Income taxes	5%	6%	6%
Minority interest	0%	0%	0%
Net income	12%	12%	12%

Comparison of 2009 to 2008

Revenues were $231.5 million in 2009, compared to $204.7 million in 2008.

Distribution channels: Net U.S. sales to Hospira in 2009 were $112.4 million, compared to net sales of $132.6 million in 2008, a decrease of 15%. The $20.2 million decrease was primarily due to $23.1 million in decreased standard and custom critical care sales, $1.6 million in decreased custom oncology sales, partially offset by $4.1 million in increased custom infusion set sales and a $2.9 million increase in CLAVE sales. The decreased standard and custom critical care sales to Hospira were primarily related to our acquisition of the critical care assets from Hospira. We entered into the asset purchase agreement with Hospira on July 8, 2009 and closed the transaction on August 31, 2009. Sales to Hospira for critical care products were only recognized for the first seven days of the second half of 2009 since the sales for all standard and custom critical care shipments to Hospira between signing the agreement and closing the transaction were not recognized as revenue and our critical care sales after the asset purchase are no longer to Hospira. The decrease in custom oncology sales was from lower unit sales. The increases in custom infusion set sales and CLAVE sales were from higher unit sales. Excluding critical care products, we expect modest growth in sales to Hospira in 2010. There is no assurance that these expectations will be realized.

Net sales to domestic distributors and through direct sales (including Canada) were $65.9 million in 2009, compared to $35.9 million in 2008, an increase of 84%. The increased sales were primarily from new standard and custom critical care sales, increased custom infusion set sales and increased standard oncology and TEGO sales, both newer product lines. We began selling standard and custom critical care directly to

distributors and through direct sales in September 2009. New standard and custom critical care sales from September to December 2009 were $19.2 million and $4.0 million, respectively. Custom infusion set sales increased by $2.5 million because of increased unit volume sales. TEGO and standard oncology sales increased by $2.7 million from 2008.

Net sales to international distributors and through direct sales (excluding Canada) were $49.1 million in 2009, compared with $30.8 million in 2008, an increase of 59%. The increased sales were primarily from new standard critical care sales of $5.3 million, new custom critical care sales of $1.3 million, other new product sales of $2.1 million, new custom oncology sales of $2.2 million, increased unit sales in custom infusion sets adding $2.5 million and increased unit sales in CLAVE adding $1.0 million. Our international growth in other new product sales includes standard oncology products, TEGO used in dialysis and Orbit 90 diabetes sets. The majority of the increase was attributable to increased sales in Europe and the Pacific Rim.

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Product and other revenue: Net sales of CLAVE products increased from $80.6 million 2008 to $85.2 million in 2009, an increase of $4.6 million. This increase was primarily from increased sales to Hospira from increased market share and demographic growth.

Net sales of custom products, which include custom infusion, custom oncology products and custom critical care products, were $78.6 million in 2009 compared to $69.8 million in 2008. This increase was primarily from $9.1 million increased sales of custom infusion sets from higher unit sales. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from a competitor s standard sets to our custom systems. During the period of time between signing the purchase agreement with Hospira and closing the transaction, we did not recognize any sales of custom critical care products, which accounts for sales being $0.9 million lower in 2009 compared to 2008.

Standard critical care product sales were $41.8 million in 2009 compared to $34.1 million in 2008. Prior to September 2009, our critical care sales were through OEM with Hospira. These sales are now direct to the end customer. The increases sales were due to higher sales to domestic and international distributors and through direct sales compared to sales to Hospira. While we can provide no assurances, we expect critical care sales to increase in 2010 compared to 2009.

Sales of our standard oncology products, a newer product line, were $5.1 million in 2009 compared to $2.7 million in 2008.

Other revenue consists of license, royalty and revenue share income and was approximately $0.5 million in 2009 and $1.7 million in 2008. The decrease from 2008 was due to an exclusivity payment we received in 2008 that did not recur in 2009. We may receive other license fees or royalties in the future for the use of our technology. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

Gross margins for 2009 and 2008 were 47% and 44%, respectively. Favorable exchange rates contributed two percentage points of the 3% increase in our gross margin. The balance of the margin change was from favorable product mix and improved manufacturing efficiencies at our Mexico facility.

We estimate our gross margin in 2010 will approximate 43%. There is no assurance that these expectations will be realized.

Selling, general and administrative expenses **(SG&A)** were $68.2 million and 30% of revenues in 2009, compared with $53.6 million and 26% of revenues in 2008. The increase was primarily from increased legal expenses of $5.3 million, increased compensation and benefits of $5.5 million and increased sales and marketing promotion costs and travel of $1.8 million. The increase in legal expenses is primarily from higher patent litigation costs. The increase in compensation and benefits is primarily from 58 new hires in sales and marketing, which include the addition of personnel from our acquisition in Germany and the increase in our sales force to take over the commercial rights of our critical care product line. While we can provide no assurances, we expect SG&A expenses to be approximately 27%-28% of total revenue in 2010.

Research and development expenses **(R&D)** were $2.6 million and 1% of revenue in 2009 compared to $4.8 million and 2% of revenue in 2008. The decrease is primarily due to our increased focus on our core projects that started in the latter half of 2008 and MedScanSonics ceasing

operations in 2008.

Other income decreased $3.5 million to $1.2 million in 2009 compared to $4.7 million in 2008. Other income in 2009 is primarily comprised of interest income. Other income in 2008 includes $3.0 million of interest income and $1.8 million from a payment under a settlement agreement. The decrease in interest income was due to lower interest rates.

Income taxes were accrued at an estimated annual effective tax rate of 32.2% in 2009 compared to 32.6% in 2008. The 2009 rate differed from the statutory corporate rate of 35% principally because of tax credits, tax exempt interest and dividends, domestic production activities exclusion, state taxes and foreign taxes. While we can provide no assurances, we expect our effective tax rate to be approximately 35% in 2010.

Comparison of 2008 to 2007

Revenues were $204.7 million in 2008, compared to $188.1 million in 2007.

Distribution channels: Net U.S. sales to Hospira in 2008 were $132.6 million, compared to net sales of $129.7 million in 2007. The $2.9 million increase was primarily comprised of a $5.4 million increase in CLAVE sales, a $2.5 million increase in custom product sales, a $0.9 million increase in oncology sales, partially offset by a $7.0 million decrease

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in critical care product sales. The increase in CLAVE sales was from higher unit sales due to increased market share through Hospira. The unit growth in custom I.V. sets and custom oncology products more than offset the decline we experienced in custom critical care sales. The unit growth in custom I.V. sets was primarily due to the conversion by certain of our customers from a competitor s standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008. The decrease in critical care sales was due to lower prices charged under the MCDA and lower unit sales of certain critical care products.

Net sales to domestic distributors and through direct sales in 2008 (including Canada) were $35.9 million compared to $29.5 million in 2007, an increase of $6.4 million or 22%. The increase was primarily from increased sales in custom products of $4.9 million and CLAVE of $1.1 million. The CLAVE increase is from increased unit volume due to increased market share and demographic growth. The unit growth in custom I.V. sets was primarily due to the conversion by certain of our customers from a competitor s standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008.

Net sales to international customers (excluding Canada) were $30.8 million in 2008, compared with $23.7 million in 2007. The increased sales were primarily from $4.2 million of increased custom product sales and $1.5 million of increased CLAVE sales. The CLAVE increase is from increased unit volume due to increased market share and demographic growth. The unit growth in custom I.V. sets was primarily due to the conversion by certain of our customers from a competitor s standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008. Approximately 55% of the increase was attributable to increased sales in Europe and 24% of the increase was attributable to increased sales in the Pacific Rim.

Product and other revenue: Net sales of CLAVE products increased from $72.3 million in 2007 to $80.6 million in 2008, an increase of $8.3 million or 11%. This increase was from increased sales in all channels from increased market share and demographic growth, including $5.4 million in sales to Hospira.

Net sales of custom products were $69.8 million in 2008 compared to $58.1 million in 2007. This increase was comprised of increased sales of custom oncology products of $8.5 million and custom infusion sets of $4.0 million, partially offset by a $0.8 million decline in custom critical care sales. The unit growth in custom infusion sets was primarily due to the conversion by certain of our customers from a competitor s standard sets to our custom systems. The unit growth in custom oncology is due to a nationwide product launch of this line in 2008. The decrease in custom critical care revenue was due to lower unit sales and lower prices to Hospira under the MCDA.

Standard critical care product sales were $34.1 million in 2008 compared to $40.9 million in 2007. This decrease was due to lower unit sales and lower prices to Hospira under the MCDA.

Other revenue consists of license, royalty and revenue share income and was approximately $1.7 million in 2008 and $2.5 million in 2007. We may receive other license fees or royalties in the future for the use of our technology. There is no assurance as to amounts or timing of any future payments, or whether such payments will be received.

Gross margins for 2008 and 2007 were 44% and 42%, respectively. The margin improvement is attributed to a favorable product mix, improved efficiencies and productivity gains at our Mexico manufacturing facility and an increase in production volumes, offset by an increase in raw material and transportation costs and a decrease in pricing for critical care.

SG&A expenses were $53.6 million and 26% of revenues in 2008, compared with $45.5 million and 24% of revenues in 2007. The increase was primarily from increased compensation and benefits of $2.9 million, stock compensation expense of $0.8 million, sales and marketing promotional costs of $2.1 million and outside services of $1.4 million. The increase in compensation and benefits is primarily in incentive compensation and higher salary costs.

R&D expenses were $4.8 million and 2% of revenue in 2008 compared to $8.1 million and 4% of revenue in 2007. The decrease is primarily due to our increased focus on our core projects in the latter half of 2008.

Other income decreased $4.0 million to $4.7 million in 2008 compared to $8.7 million in 2007. Other income in 2008 is primarily comprised of $3.0 million in interest income and $1.8 million of payments from a settlement agreement. Other income in 2007 includes $4.4 million of interest income, an $8.0 million payment to us for a settlement of litigation against a law firm that formerly represented us in patent litigation, and $1.0 million of payment under another settlement agreement, partially offset by a $5.0 million charge for an award against us in our litigation with Alaris Medical Systems. The decrease in interest income was primarily due to lower interest rates.

Income taxes were accrued at an effective tax rate of 33% in 2008 compared to 31% in 2007. The 2008 rate differed from the statutory corporate rate of 35% because of tax credits, tax exempt interest and dividends, Domestic Production Activities exclusions and foreign taxes.

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Liquidity and Capital Resources

During 2009, our cash, cash equivalents, restricted cash and current and long-term investment securities decreased by $21.0 million from $129.1 million at December 31, 2008 to $108.1 million at December 31, 2009.

Operating Activities*:* Our cash provided by operating activities tends to increase over time because of our positive operating results. However, it is subject to fluctuations, principally from the impact of integrating new locations from acquisitions, changes in net income, accounts receivable, inventories and the timing of tax payments.

During 2009, our cash provided by operations was $48.6 million, which was mainly comprised of net income of $26.6 million, depreciation and amortization of $15.7 million, stock compensation expense of $2.7 million and changes in our operating assets and liabilities. The $9.0 million increase in accounts receivable and $10.4 million increase in accounts payable, which primarily offset each other, were the largest contributors to the change in our operating assets and liabilities. The increase in accounts receivable was primarily due to higher critical care sales in the fourth quarter of 2009 compared to 2008. The increase in accounts payable was primarily due to increased purchases associated with our critical care product line.

Investing Activities: Our cash used in investing activities in 2009 was $35.2 million. This was primarily comprised of our critical care asset purchase from Hospira of $29.4 million and purchases of property, plant and equipment of $16.7 million, partially offset net investment sales of $10.6 million. Our property, plant and equipment purchases were primarily comprised of $5.2 million for the land, building construction and equipment down-payments for our Slovakia plant and other equipment and mold additions in our United States and Mexico plants.

While we can provide no assurances, we estimate that our capital expenditures in 2010 will approximate $17.0 million to $20.0 million. This includes an estimated $10.0 million to complete the building construction of our manufacturing plant for our custom products in Slovakia and purchases for a new sterilizer and other machinery and equipment in our Slovakia plant. We also estimate approximately $9.0 million in capital expenditures for various molds, machinery and equipment used in our manufacturing operations in the United States and Mexico. We expect to use our cash and investments to fund our capital purchases. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Financing Activities: Our cash used in financing activities was $17.7 million in 2009. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was $2.7 million from the sale of 96,513 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options. In July 2008, we announced a program to purchase up to $40.0 million of our common stock. In October 2009, our Board of Directors authorized to increase the maximum to purchase under this plan by $ 15.0 million, bringing the total authorized to purchase to $55.0 million. We purchased $5.9 million in 2008 and $ 20.4 million in 2009. We plan to purchase additional share repurchases in 2010.

We have a substantial cash and investment security position generated from profitable operations and stock sales, principally from the exercise of employee stock options. We maintain this position to fund our growth, meet increasing working capital requirements, fund capital expenditures, and to take advantage of acquisition opportunities that may arise. Our primary investment goal is capital preservation, as further described in Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We believe that our existing cash, cash equivalents and investment securities along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months. In the event that we experience illiquidity in our investment securities, downturns or cyclical fluctuations in our business that are more severe or longer than anticipated or if we fail to achieve anticipated revenue and expense levels, we may need to obtain or seek alternative sources of capital or financing, and we can provide no assurances that the terms of such capital or financing will be available to us on favorable terms, if at all.

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Balance Sheet Commentary

Inventory: Our inventory balance increased from $17.9 million at December 31, 2008 to $41.3 million at December 31, 2009. The increase in our inventory is primarily due to our growth in global direct sales to customers which is increasing faster than our sales to OEM customers. This naturally increases the length of our supply chain and the amount of inventory we must carry for those direct customers, instead of selling to OEM customers who carry the inventory for the end users.

Intangibles: Our intangible assets increased from $10.8 million at December 31, 2008 to $16.8 million at December 31, 2009. The increases were primarily from a small business acquisition and our critical care asset purchase with Hospira. We acquired customer contracts, patents and trademarks in these two transactions.

Deferred revenue: Our deferred revenue balance at December 31, 2009 of $2.4 million is the gross profit on critical care inventory components sold to Hospira that will be purchased from Hospira as a finished good. We will recognize the gross profit when the inventory is sold to the end customer.

Off Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, we have never incurred, nor do we expect to incur, any liability for indemnification.

Pursuant to the Asset Purchase Agreement with Hospira, we have agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of our representations and breaches of our warranties; (ii) defaults of our covenants or obligations; (iii) certain assumed obligations and (iv) use of the acquired assets after the date of closing. Most of Hospira s rights to indemnification will terminate eighteen months after the closing of the transaction on August 31, 2009, except for liabilities arising out of certain provisions of the asset purchase agreement and liabilities for which notice was previously provided. Notwithstanding the foregoing, we are not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify us or our affiliates under the MCDA. Although we can provide no assurances, we do not expect to incur material liability arising out of the indemnification provision of the asset purchase agreement.

Contractual Obligations

We have contractual obligations, at December 31, 2009, of approximately the amount set forth in the table below. This amount excludes purchase orders for goods and services for current delivery. The majority of our purchase orders are blanket purchase orders that represent an estimated forecast of goods and services. We do not have a commitment liability on the blanket purchase orders. Since we do not have the ability to separate out blanket purchase orders from non-blanket purchase orders for goods and services for current delivery, these amounts are excluded from the table below. We have excluded from the table below the ASC 740-10-25 (formerly FIN 48), an interpretation of ASC 740-10

(formerly SFAS 109) noncurrent liability of $5.3 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)		
Contractual Obligations	**Total**	**2010**	**2011**
Operating lease	$ 280	$ 138	$ 142
Capital purchase obligations	9,512	9,512	
	$ 9,792	$ 9,650	$ 142

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Forward Looking Statements

Various portions of this Annual Report on Form 10-K, including this Management s Discussion and Analysis, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are forward looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we identify them by using words such as believe, expect, estimate, plan, will, continue, could, may, and by expressions and statements about aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, without limitation, statements about:

- future operating results and various elements of operating results, including future expenditures on sales and marketing and product development; future sales and unit volumes of products; deferred revenue; future license, royalty and revenue share income; production costs; gross margins; litigation expense; SG&A; R&D expense; future costs of expanding our business; income; losses; cash flow; tax rates; changes in working capital items such as receivables and inventory; selling prices; and income taxes;

- factors affecting operating results, such as shipments to specific customers; reduced dependence on current proprietary products; expansion in international markets, selling prices; future increases or decreases in sales of certain products and in certain markets and distribution channels; increases in systems capabilities; introduction and sales of new products; qualification of our new products for the expedited Section 510(k) clearance procedure; planned increases in marketing; warranty claims; rebates; product returns; bad debt expense; inventory requirements; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment of production facilities outside the U.S.; planned new orders for semi-automated or fully automated assembly machines for new products; plans and timing of the establishment of a plant in Slovakia; adequacy of production capacity; results of R&D; initiatives to improve the ICU Production System; our plans to repurchase shares of our common stock; asset impairment losses; relocation of manufacturing facilities and personnel; planned increases in the number of personnel; our expectation that sales will shift from medical product manufacturers to domestic and international distributors and direct sales; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; the effect of costs to customers and delivery times; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and

- new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; effect of the acquisition of Hospira s Salt Lake City manufacturing facility and the acquisition of Hospira s critical care product line, including its effect on future revenues from Hospira; the transition services we expect to receive from Hospira during the eighteen-month period following the acquisition; the timing of the transition; growth of our CLAVE products in future years; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; competitive and market factors, including continuing development of competing products by other manufacturers; consolidation of the healthcare provider market and downward pressure on selling prices; future purchases of treasury stock; working capital requirements; liquidity and realizable value of our investment securities; future investment alternatives; foreign currency denominated financial instruments; foreign exchange risk; commodity price risk; our expectations regarding liquidity and capital resources over the next twelve months; capital expenditures; acquisitions of other businesses or product lines, indemnification liabilities and contractual liabilities.

Forward-looking statements involve certain risks and uncertainties, which may cause actual results to differ materially from those discussed in each such statement. First, one should consider the factors and risks described in the statements themselves or otherwise discussed herein. Those factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our current expectations.

Second, investors should read the forward looking statements in conjunction with the Risk Factors discussed in Item 1A of this Annual Report on Form 10-K. Also, actual future operating results are subject to other important factors and risks that we cannot predict or control, including without limitation, the following:

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- general economic and business conditions, both in the U.S. and internationally;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- Increases in costs or availability of the raw materials need to manufacture our products;
- unexpected delays or complications in the closing of the purchase of Hospira s critical care product line;
- the effect of price and safety considerations on the healthcare industry;
- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- the successful development and marketing of new products;
- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;

- the effects of additional governmental regulations;

- unanticipated production problems; and

- the availability of patent protection and the cost of enforcing and of defending patent claims.

The forward-looking statements in this report are subject to additional risks and uncertainties, including those detailed from time to time in our other filings with the Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof and, except as required by law, we undertake no obligation to update or revise any of them, whether as a result of new information, future events or otherwise.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We had a portfolio of corporate preferred stocks, federal-tax exempt state and municipal government debt securities and certificates of deposit of $56.9 million as of December 31, 2009. The securities are all investment grade . As of December 31, 2009, $46.4 million of our investment securities were invested in pre-refunded municipal securities, $0.9 million were invested in auction rate securities and $9.6 million were certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk. For the year ended December 31, 2009, we had less than $0.1 million in increases in the market values of the auction rate securities. Our investment securities totaled $67.4 million at December 31, 2008 and were comprised of $44.4 million in pre-refunded municipal securities, $15.4 million in auction rate securities , $7.1 million in commercial paper and $0.5 million in put option assets related to the auction rate securities.

Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the discount rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of federal-tax-exempt securities, commercial paper and corporate preferred stocks in our portfolio and market conditions specific to the securities in which we invest. A two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately $0.4 million to investment income based on the investment securities balance at December 31, 2009. A two-thirds to three-quarters of a percentage point change in our earnings on investment securities in 2008, would have created a change to investment income by approximately $0.5 million

Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable and accounts payable, is not significant to our financial statements. Sales from the U.S. and Mexico to foreign distributors are all denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, principally the Euro and Mexican Peso. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2009 and our manufacturing spending from 2009 would impact our cost of goods sold by approximately $1.6 million. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2008 and

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our manufacturing spending from 2008 would impact our cost of goods sold by approximately $1.8 million. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable and accruals in the same foreign currency, except for our European operations, where our net Euro asset position at December 31, 2009 and 2008 were approximately 8.4 million and 9.1 million, respectively. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to increase. We currently do not hedge our foreign currency exposures.

Our exposure to commodity price changes relates primarily to certain manufacturing operations that use resin. We manage our exposure to changes in those prices through our procurement and supply chain management practices and the effect of price changes has not been material to date. We are not dependent upon any single source for any of our principal raw materials and we believe all such materials and products are readily available. Based on our average price for resin in fiscal year 2009 and 2008, a 10% increase to the price of resin would result in approximately a $0.6 million change in material cost in each year.

Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ICU Medical, Inc.

San Clemente, CA

We have audited the accompanying consolidated balance sheets of ICU Medical, Inc. and subsidiaries (the Company) as of December 31, 2009 and 2008, and the related consolidated statements of income, stockholders equity and comprehensive income, and cash flows for each of the two years in the period ended December 31, 2009. Our audit also included the financial statement schedule as of and for the year ended December 31, 2009and 2008, listed in the Index at Item 15. We also have audited the Company s internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these financial statements and financial statement schedule and an opinion on the Company s internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the ICU Medical, Inc. and subsidiaries as of December 31, 2009 and 2008 and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ Deloitte & Touche, LLP

Costa Mesa, California
February 19, 2010

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ICU Medical, Inc.

We have audited the accompanying consolidated statements of income, stockholders equity and comprehensive income and cash flows for the year ended December 31, 2007 of ICU Medical, Inc. and subsidiaries. Our audit also included the 2007 financial statement schedule of ICU Medical, Inc. listed in Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of their operations of ICU Medical, Inc. and their cash flows for the year ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related 2007 financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ McGladrey & Pullen, LLP
Irvine, California
February 21, 2008

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ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except per share data)

	December 31, 2009	December 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 51,248	$ 55,696
Investment securities	56,887	56,093
Cash, cash equivalents and investment securities	108,135	111,789
Accounts receivable, net of allowance for doubtful accounts of $324 in 2009 and $320 in 2008	47,777	38,423
Inventories	41,327	17,930
Prepaid income taxes	1,994	4,544
Prepaid expenses and other current assets	5,462	3,471
Deferred income taxes	3,243	3,231
Total current assets	207,938	179,388
PROPERTY AND EQUIPMENT, net	77,449	69,897
PROPERTY HELD FOR SALE	940	940
RESTRICTED CASH		6,014
INVESTMENT SECURITIES		11,350
GOODWILL	1,478	
INTANGIBLE ASSETS, net	16,782	10,780
DEFERRED INCOME TAXES	3,710	3,855
INCOME TAXES RECEIVABLE	856	1,210
	$ 309,153	$ 283,434
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 18,423	$ 7,879
Accrued liabilities	12,884	14,081
Deferred revenue	2,389	
Total current liabilities	33,696	21,960
COMMITMENTS AND CONTINGENCIES		
DEFERRED INCOME TAXES	5,698	4,007
INCOME TAX LIABILITY	4,754	4,436
STOCKHOLDERS EQUITY:		
Convertible preferred stock, $1.00 par value Authorized 500 shares; Issued and outstanding none		
Common stock, $0.10 par value Authorized 80,000 shares; Issued 14,811 shares in 2009 and 14,784 shares in 2008, outstanding 14,239 shares in 2009 and 14,731 shares in 2008	1,481	1,478
Additional paid-in capital	54,357	50,970
Treasury stock, at cost 572 shares in 2009 and 53 shares in 2008	(19,881)	(1,623)
Retained earnings	227,861	201,304
Accumulated other comprehensive income	1,187	902
Total stockholders equity	265,005	253,031
	$ 309,153	$ 283,434

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

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ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME

(Amounts in thousands, except per share data)

	For the years ended December 31,		
	2009	2008	2007
REVENUES:			
Net sales	$ 230,973	$ 203,026	$ 185,618
Other	540	1,700	2,520
TOTAL REVENUE	231,513	204,726	188,138
COST OF GOODS SOLD	122,695	114,910	109,895
Gross profit	108,818	89,816	78,243
OPERATING EXPENSES:			
Selling, general and administrative	68,205	53,611	45,484
Research and development	2,645	4,822	8,111
Total operating expenses	70,850	58,433	53,595
Income from operations	37,968	31,383	24,648
OTHER INCOME	1,181	4,695	8,698
Income before income taxes and minority interest	39,149	36,078	33,346
PROVISION FOR INCOME TAXES	(12,592)	(11,778)	(10,337)
MINORITY INTEREST			70
NET INCOME	$ 26,557	$ 24,300	$ 23,079
NET INCOME PER COMMON SHARE			
Basic	$ 1.80	$ 1.72	$ 1.62
Diluted	$ 1.77	$ 1.67	$ 1.51
Weighted average number of shares			
Basic	14,720	14,144	14,282
Diluted	14,984	14,565	15,265

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

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ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME

(Amounts in thousands)

	Common Stock Number of Shares Outstanding	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive Income	Total	Comprehensive Income
BALANCE, December 31, 2006	14,620	$ 1,475	$ 74,489	$ (5,383)	$ 153,925	$ 381	$ 224,887	
Purchase of treasury stock	(1,063)			(41,000)			(41,000)	
Exercise of stock options, including excess income tax benefits of $551	89		(1,106)	3,746			2,640	
Proceeds from employee stock purchase plan	43		(459)	1,861			1,402	
Stock compensation			1,052				1,052	
Minority interest share transfer			289				289	
Research and development tax credit originating from stock options and other tax benefits			540				540	
Comprehensive income								
Net income					23,079		23,079	$ 23,079
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $(472)						1,015	1,015	1,015
BALANCE, December 31, 2007	13,689	1,475	74,805	(40,776)	177,004	1,396	213,904	$ 24,094
Purchase of treasury stock	(180)			(5,858)			(5,858)	
Exercise of stock options, including excess income tax benefits of $8,996	1,163	3	(24,794)	42,706			17,915	
Proceeds from employee stock purchase plan	59		(932)	2,305			1,373	
Stock compensation			1,891				1,891	
Comprehensive income								
Net income					24,300		24,300	$ 24,300
Other comprehensive income, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $74						(494)	(494)	(494)
BALANCE, December 31, 2008	14,731	1,478	50,970	(1,623)	201,304	902	253,031	$ 23,806
Purchase of treasury stock	(589)			(20,441)			(20,441)	
Exercise of stock options, including excess income tax benefits of $101	50	1	18	1,457			1,476	
Proceeds from employee stock purchase plan	47	2	543	726			1,271	

Stock compensation				2,708							2,708					
Research and development tax credit originating from stock options and other tax benefits				118							118					
Comprehensive income																
Net income							26,557				26,557	$	26,557			
Other comprehensive income, net of tax benefit:																
Foreign currency translation adjustment net of tax effect of $(175)									285		285		285			
BALANCE, December 31, 2009	14,239	$	1,481	$ 54,357	$	(19,881)	$ 227,861	$	1,187	$	265,005	$	26,842			

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

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ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

	For the years ended December 31,		
	2009	**2008**	**2007**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 26,557	$ 24,300	$ 23,079
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	15,671	14,220	11,796
Provision for doubtful accounts	1	(270)	331
Stock compensation expense	2,708	1,890	1,052
Minority interest			(70)
Loss (gain) on disposal or sale of property and equipment or property held for sale		653	(130)
Cash provided (used) by changes in operating assets and liabilities, net of assets purchased and business acquisition			
Accounts receivable	(9,043)	(12,375)	523
Inventories	2,012	1,447	(3,033)
Prepaid expenses and other assets	(3,150)	197	(240)
Accounts payable	10,380	(525)	250
Accrued liabilities	(2,046)	1,093	5,144
Deferred revenue	2,389		
Prepaid and deferred income taxes	3,130	(404)	2,810
Net cash provided by operating activities	48,609	30,226	41,512
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(16,690)	(11,351)	(23,645)
Assets purchased	(29,447)		(3,224)
Business acquisition, net of cash acquired	(5,662)		
Proceeds from sale of assets			504
Proceeds from finance loan repayments		646	73
Change in restricted cash	6,014	(6,014)	
Purchases of investment securities	(96,655)	(62,945)	(38,863)
Proceeds from sale of investment securities	107,211	83,272	54,858
Net cash provided by (used in) investing activities	(35,229)	3,608	(10,297)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	1,375	9,471	2,090
Proceeds from employee stock purchase plan	1,271	1,373	1,402
Excess tax benefits from exercise of stock options	101	8,997	551
Purchase of treasury stock	(20,441)	(5,859)	(41,000)
Net cash provided by (used in) financing activities	(17,694)	13,982	