2010

Annual Report to Shareholders

and Form 10-K

ICU Medical, Inc.

ICU Medical, Inc.

March 21, 2011

Dear Stockholder:

2010 was a successful year for ICU Medical due to many improving aspects of our business. We reported record sales of $284.6 million, record net income of $30.9 million, or a $2.23 per diluted share, and continued to make strategic investments in many facets of our business in order to build upon our proven track record of industry-leading products, manufacturing capabilities and customer satisfaction.

Our strong top line growth was driven by double digit improvements in all products lines. Domestic distributors and direct sales were up 54%, while international revenue increased 32% from 2009. New products grew 28%, and our oncology business posted a 24% increase year over year.

In 2010, we successfully transitioned the critical care operations from Hospira to our operational team, expanded and trained our sales force, and implemented a marketing strategy to position the critical care business for further improvements. Critical care sales were up 21% to $50.4 million, representing almost 18% of our total revenue, and we believe these products are positioned to make solid contributions to our growth and profitability in the future.

To support momentum of our custom products in the European markets, we successfully completed construction on our new plant in Slovakia and started initial product shipments beginning early this year. Favorably located in the center of Europe, the new facility provides us with significant distribution advantages, further expanding our international presence and enhancing our operating efficiencies.

While we continued to make additional investments in research and development, and manufacturing efficiencies, we remained focused on cost controls. As a result, our operating income increased 30% to $49.3 million, and operating margins expanded 90 basis points to 17.3%, compared to 2009.

We ended the year with a healthy, debt-free balance sheet. As of December 31, 2010, we had $93.4 million in cash, cash equivalents and investment securities, and $182.1 million in working capital. Additionally, we generated operating cash flow of $33.1 million for the full year.

We are proud of our accomplishments in 2010 and with expanded manufacturing facility in Ensenada, Mexico, a new plant in Europe, and premier distribution partnerships with GPOs, such as Premier and MedAssets, we are well positioned to continue to expand our market share worldwide and to drive long-term profitable growth. We will continue to leverage our strong operating cash flow to finance our immediate capital needs, develop new product lines, and enhance value for our shareholders.

On behalf of our management team and board of directors, I thank you for your confidence in ICU Medical and look forward to reviewing more successes with you in the months and years to come.

Respectfully,

George A. Lopez, M.D.
George A. Lopez, M.D.
President and Chief Executive Officer

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2010 or

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

For the transition period from to

Commission File 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	The NASDAQ Stock Market LLC
Preferred Stock Purchase Rights	(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. ☐ Yes ☒ No

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

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. ☐

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

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

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2010, the last business day of registrant's most recently completed second fiscal quarter, was $366,883,923*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2011 was 13,666,301.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2011 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2010, are incorporated by reference into Part III of this Report.

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* 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.

ICU Medical, Inc.
Form 10-K
For the Year Ended December 31, 2010
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PART I

Item 1. Business.

We are a leader in the development, manufacture and sale of innovative medical devices used in vascular therapy, oncology and critical care applications. Our products improve patient outcomes by helping prevent bloodstream infections and protect healthcare workers and patients from exposure to infectious diseases or hazardous drugs and monitor the hemodynamic status of critical care patients. Our product line includes custom I.V. systems, closed delivery systems for hazardous drugs, needleless I.V. connectors, catheters 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 35% of our revenue in 2010, 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 all types of I.V. therapy 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.

We are a product-oriented company that is a 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. Our custom infusion set sales accounted for approximately 27% of our revenue in 2010.

We have been expanding our product offerings by introducing internally developed products and systems and acquiring product lines. We have launched internally developed products for use in oncology therapy, dialysis and diabetes that accounted for 9% of our revenue in 2010. These products include 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. In 2005, we acquired Hospira, Inc.'s ("Hospira") 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 provided us control over all aspects of our critical care product line.

We continue to expand 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. 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 44% of our worldwide revenues in 2010.

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.

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 needle-safe 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, which 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 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. Both the original CLAVE and the Y-CLAVE are marketed 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 35% and $98.4 million of our revenue in 2010. 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 and iFactory 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 2010, net sales of custom sets were approximately $100.6 million, 42% of these sales were to domestic distributors and domestic direct sales, 35% with Hospira and 23% 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.

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.

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 that 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 that 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 that 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 2010 standard critical care sales were $50.4 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.

Standard Oncology

Standard Oncology products are used to prepare and deliver hazardous medications such as those used in chemotherapy which, if released can have harmful effects to the healthcare worker and environment. In 2007, we introduced a series of CLAVE ancillary devices that were specific to use in Oncology. Also in 2007, we introduced the Spiros™ closed male luer connector. In 2008, we introduced the Genie™ closed vial access device.

Our 2010 oncology product sales were $7.8 million. Additional information regarding standard oncology sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

The preparation of hazardous drugs typically takes place in a pharmacy location where drugs are removed from vials and prepared for delivery to a patient. Those prepared drugs are then transferred to a nursing unit where the chemotherapy is administered via infusion pump sets to a patient. The Genie and other CLAVE ancillary products are used in the pharmacy on drug vials during the preparation of hazardous medications. The Spiros is used both in the pharmacy on syringes to remove the drugs from vials and in the patient delivery areas on the disposable infusion sets.

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 are developing several new products that we intend to introduce in 2011 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 continuing to be 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 to secure favorable fixed pricing. In this increasingly challenging market place, we believe it will continue to be important to secure comprehensive, multi-product contracts with all major buying organizations in order to be better positioned when targeting specific healthcare providers.

As of December 31, 2010, we employed 171 people worldwide in sales and marketing and expect this to increase in 2011. Over the past few years, we built our sales team to add more direct sales to market our products rather than rely exclusively on distributors and OEM. 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 deliver support programs necessary to train the manufacturing and distribution salespeople, as well as our end-use customers' clinical 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 44% of our revenue in 2010. 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, 2010, we had 43 independent distributors in the United States and Canada who employ approximately 700 salespeople in the aggregate and which accounted for approximately 36% of our revenues in 2010. We include Canada as "domestic" for administrative purposes. Distributors purchase and stock our products for resale to healthcare providers.

One distributor accounted for 6% of revenue in 2010. All other independent distributors accounted for less than 5% of revenue in 2010. 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.

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 23%, 21% and 15% of our revenues in 2010, 2009 and 2008. As of December 31, 2010, we had approximately 82 international distributors. Customers in Europe are served by our facilities in Slovakia, Italy and Germany. We serve the rest of the world from our facilities in the U.S. and Mexico. We have 15 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 2011.

Administrative operations are in San Clemente, California, Vrable, Slovakia, Roncanova, Italy 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, 2010 and 2009, our long-lived assets located outside the United States was $64.9 million and $51.3 million.

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, 2010, this facility was equipped with 66 injection molding machines and ancillary equipment and approximately 44 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.

Most of our manual assembly is done at our facility in Ensenada, Mexico and beginning in December 2010, in Vrable, Slovakia. Our facility in Mexico has approximately 241,000 square feet of production, warehousing space and an electron beam ("e-beam") sterilizer. In 2010, we began an additional expansion of our production facility in Mexico that was completed in January 2011. Principal products assembled manually in Mexico are I.V. therapy systems, critical care systems, kits, CLAVE and oncology ancillary products and accessories. Our facility in Slovakia has approximately 77,000 square feet of production, warehousing space and an electron beam sterilizer. Principal products to be assembled manually in Slovakia are I.V. therapy systems, critical care 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.

The majority of the non-critical care products we manufacture are sterilized in processes which use 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 facilities at our plants in Mexico and Slovakia that are used to sterilize most of the product assembled in the respective plants. All other sterilization is done by independent contractors.

We have a 23,000 square foot building in northern Italy where we currently assemble I.V. therapy systems and use as a distribution warehouse for Europe. We also manufacture I.V. sets and compounders in our leased facility in Ludenscheid, Germany. I.V. sets and therapy systems currently built at these two locations are expected to transfer to our new facility in Slovakia this year.

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, International Organization for Standardization ("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.

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. therapy, oncology and critical care products is intensely competitive. We believe that our ability to compete depends upon our continued innovation and the quality, convenience, reliability, patent protection and pricing of our products, in addition to access to distribution channels. 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 ("Baxter"), Edwards LifeSciences, 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 and is based on pricing, customer service and product features. The overall market for critical care products has been declining in recent years in certain segments as customers increasingly seek 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 gain 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 competitors 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 relating to the technologies found in the CLAVE® Connector, CLC 2000® Connector, Orbit 90® Infusion Set, TEGO® Connector, Click Lock® Technology, Y-CLAVE™ Connector With Integral Check Valve, Spiros® Closed Male Connector, Genie® Closed Vial Access Device, and Custom Set Design and Manufacturing Methods. We have applications pending for additional United States and foreign patents on TEGO Connector, Y-CLAVE Connector With Integral Check Valve, Orbit 90 Infusion Set, CLC2000 Connector, CLAVE Connector, Spiros Closed Male Connector, Diana™ Fluid Delivery System, and Genie Closed Vial Access Device.

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, Spiros, Genie 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	07/2011 - 07/2015
Custom Set Design and Manufacturing	01/2021
Orbit 90® infusion set	03/2022 - 11/2023
Spiros® connector	12/2024 - 07/2026
Genie 90® connector	05/2026
Y-Site Check Valve	02/2025
Tego® connector	07/2020-11/2025

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. See Item 3. "Legal Proceedings" below. 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 Europe, the healthcare business generally slows down in the summer months due to vacations resulting in fewer elective surgeries. Also in Europe, hospitals' budgets tend to finish at the end of the year which may cause fewer purchases in the last three months of the year as hospitals await their new budgets in January. 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, 2010 we had 2,216 full-time employees, consisting of 266 engaged in sales, marketing and administration and 1,950 in manufacturing, molding, product development and quality control, including 1,410 in Mexico and 83 in Slovakia. We contract with independent temporary agencies to provide some production personnel who are not our employees. At December 31, 2010, we had 21 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.

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, 2010, 2009 and 2008 (dollars in millions):

	Years ended December 31,					
	2010		2009		2008	
Hospira (U.S.)	$ 114.1	40%	$ 112.4	49%	$ 132.6	65%
Other manufacturers	3.8	1%	3.6	2%	3.7	2%
Domestic distributors/direct sales	101.4	36%	65.9	28%	35.9	17%
International distributors/direct sales	64.7	23%	49.1	21%	30.8	15%
Other revenue	0.6	0%	0.5	0%	1.7	1%

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 in significant part 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.

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. Any failure on our part to adequately market and sell the critical care line will have an adverse effect on our financial results.

Although the 2009 transaction has reduced 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, the amount of such sales varies from quarter to quarter. In addition, we can provide no assurances that our relationship with Hospira will not change, resulting in adverse effects on sales and operations.

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

We continue to expand our production in Mexico and Slovakia. Any political or economic disruption in Mexico or Slovakia or a change in the local economies could have an adverse effect on our operations. In 2010, production costs in Mexico were approximately $86.8 million. Most of the material we use in manufacturing is imported into Mexico and Slovakia, and substantially all of the products we manufacture in Mexico and Slovakia are exported. We depend on our ability to move goods across borders quickly. Any disruption in the free flow of goods across national borders could have an adverse effect on our business.

As of December 31, 2010, we employed 1,410 people in our plant in Ensenada, Mexico and 83 people in our plant in Vrable, Slovakia, and we expect these numbers to increase in 2011. 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. In 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were signed into law introducing comprehensive health insurance and healthcare reforms in the United States. Among the provisions of such legislation that may have an adverse impact on us is a 2.3% excise tax to be imposed on medical device manufacturers for the sale of certain medical devices occurring after December 31, 2012. The ultimate implementation of any healthcare reform legislation, and its impact on us, is impossible to predict. Any significant reforms made to the healthcare system in the United States, or in other jurisdictions, may have an adverse effect on our financial condition and results of operations.

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 have built additional production facilities 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 2010, we completed construction of 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.

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.

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. Some of our patents expired in 2010 and other patents covering our products will expire from this year to 2026. 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	07/2011 - 07/2015
Custom Set Design and Manufacturing	01/2021
Orbit 90® infusion set	03/2022 - 11/2023
Spiros® connector	12/2024 - 07/2026
Genie 90® connector	05/2026
Y-Site Check Valve	02/2025
Tego® connector	07/2020-11/2025

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.

We have only one manufacturing facility for our CLAVE products and any damage or incapacitation of this, or any of our other manufacturing facilities could impair our ability to produce our products.

We have a single manufacturing facility for our CLAVE products located in Salt Lake City, Utah. Our Salt Lake City facility also produces other components on which our manufacturing operations in Mexico and Slovakia rely. Damage to any of our facilities could render us unable to manufacture our products or require us to reduce the output of products at the damaged facility. In addition, a severe weather event, other natural or man-made disaster, labor difficulties, political unrest or any other significant disruption affecting one of our manufacturing facilities could materially and adversely impact our business, financial condition and results of operations.

We are dependent on single and limited source suppliers which subjects our business and results of operations to risks of supplier business interruptions.

We have materials (such as resins) that are critical to our ability to manufacture our products, the supply of which is currently from a sole supplier. We cannot be certain that our current suppliers will continue to provide us with the quantities of materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. Although we believe there are other suppliers of these raw materials, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and manufacture of our products, which could have a material adverse effect on our business.

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. In 2010, we started product shipments from our new plant in Slovakia and expect to increase shipments from the plant to customers in Europe. 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 2010, CLAVE products accounted for approximately 35% 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.

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 $100.6 million in 2010, compared with $78.6 million in 2009. The success of our custom product sales program will require continued increases in sales in the future 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.

Because we operate in international markets, we are subject to political and economic risks that we do not face in the United States.

We operate in a global market. Global operations are subject to risks, including political and economic instability, general economic conditions, imposition of government controls, the need to comply with a wide variety of foreign and United States export laws, trade restrictions and the greater difficulty of administering business overseas. As our operations and sales located in Europe and other areas outside the United States increase, we may face new challenges and uncertainties, although we can give no assurance that such operations and sales will increase.

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 and higher credit 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. To date we have exported most of our products sold internationally from the United States and Mexico, but going forward, we also expect to export products sold internationally from our new plant in Slovakia. 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. As a result of our recent acquisition of the Hospira critical care assets, we moved from selling our products from an OEM (Hospira) to numerous customers, including hospitals in Europe. The European hospitals tend to be significantly slower in payment which has resulted in an increase to our days sales outstanding over the past year. 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.

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

We market our products in certain foreign markets through our subsidiaries and other international distributors. The related sales agreements may provide for payments in a foreign currency. Accordingly, our operating results are subject to fluctuations in foreign currency exchange rates. When the U.S. dollar weakens against these currencies, the dollar value of foreign-currency denominated revenue and expense increases, and when the dollar strengthens against these currencies, the dollar value of foreign-currency denominated revenue and expense decreases. We are exposed to foreign currency risk on outstanding foreign currency denominated receivables and payables. Changes in exchange rates may adversely affect our results of operations. Our primary foreign currency exchange rate exposures are currently with the Euro and Mexican Peso against the U.S. dollar.

We currently do not hedge against our foreign currency exchange rate risks and therefore believe our exposure to these risks may be higher than if we entered into hedging transactions, including forward exchange contracts or similar instruments. If we decide in the future to enter into forward foreign exchange contracts to attempt to reduce the risk related to foreign currency exchange rates, these contracts may not mitigate the potential adverse impact on our financial results due to the variability of timing and amount of payments under these contracts. In addition, these types of contracts may themselves cause financial harm to us and have inherent levels of counterparty risk over which we would have no control.

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, group purchasing organizations 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.

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 and group purchasing organizations 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.

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

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success and profit margins depend upon the development and successful commercialization of new products, new or improved technologies and additional applications of our technology. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. We can give no assurance that any such new products will be successful or that they will be accepted in the marketplace.

The high level of competition and group purchasing organizations place pressure on our profit margins and we may not be able to compete successfully.

The disposable medical device segment of the health care industry in which we operate is highly competitive and is experiencing both horizontal and vertical consolidation. The high level of competition in our industry places pressure on profit margins. Some of our competitors have greater resources than we have. These competitive pressures could have a material adverse affect on our business, financial condition or results of operations.

Health care reform and the related pressure to contain costs have led to the advent of group purchasing organizations in the United States. These group purchasing organizations enter into preferred supplier arrangements with one or more manufacturers of medical products in return for price discounts to members of the group purchasing organizations. If we are not able to obtain new preferred supplier commitments from major group purchasing organizations or retain those commitments that we currently have, which are generally terminable by either party for any reason upon the expiration of a defined notice period, our sales and profitability could be adversely affected. However, even if we are able to obtain and retain preferred supplier commitments from group purchasing organizations, they may not deliver high levels of compliance by their members, meaning that we may not be able to offset the negative impact of lower per-unit prices or lower margins with increases in unit sales or in market share.

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 have moved labor intensive assembly operations to our facilities in Mexico and Slovakia. 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 other new products in 2011. 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 may 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.

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.

We are dependent on single and limited source suppliers which subjects our business and results of operations to risks of supplier business interruptions.

We have materials (such as resins) that are critical to our ability to manufacture our products, the supply of which is currently from a sole supplier. We cannot be certain that our current suppliers will continue to provide us with the quantities of materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. Although we believe there are other suppliers of these raw materials, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and manufacture of our products, which could have a material adverse effect on our business.

We have only one manufacturing facility for our CLAVE products and any damage or incapacitation of this, or any of our other manufacturing facilities could impair our ability to produce our products.

We have a single manufacturing facility for our CLAVE products located in Salt Lake City, Utah. Our Salt Lake City facility also produces other components on which our manufacturing operations in Mexico and Slovakia rely. Damage to any of our facilities could render us unable to manufacture our products or require us to reduce the output of products at the damaged facility. In addition, a severe weather event, other natural or man-made disaster, labor difficulties, political unrest or any other significant disruption affecting one of our facilities could materially and adversely impact our business, financial condition and results of operations.

Because we depend to a significant extent on our founder for new product concepts, the loss of his services could have a material 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 been directly involved in 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 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, which cover the methods and documentation of the design, testing, production, component suppliers control, quality assurance, labeling, packaging, storage and shipping of our products.

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.

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.

We may be required to implement a costly product recall.

In the event that any of our products proves to be defective, we can voluntarily recall, or the FDA or other regulatory agencies could require us to redesign or implement a recall of, any of our products. We believe that any recall could result in significant costs to us and significant adverse publicity, which could harm our ability to market our products in the future. Though it may not be possible to quantify the economic impact of a recall, it could have a material adverse effect on our business, financial condition and results of operations.

We generally offer a limited warranty for product returns which are due to defects in quality and workmanship. We attempt to estimate our potential liability for future product returns and establish reserves on our financial statements in amounts that we believe will be sufficient to address our warranty obligations; however, our actual liability for product returns may significantly exceed the amount of our reserves. If we underestimate our potential liability for future product returns, or if unanticipated events result in returns that exceed our historical experience, our financial condition and operating results could be materially and adversely affected.

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.

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

As of January 31, 2011, our current directors and executive officers and their affiliates, in the aggregate, beneficially owned 15% of our outstanding stock. Subject to any fiduciary duties owed to our other stockholders under Delaware law, the stockholders may be able to exercise a significant influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have some control over our management and policies. Some of these persons or entities may have interests that are different from yours. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your best interests. The concentration of ownership could delay or prevent a change in control of us or otherwise discourage a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our stock. In addition, these stockholders, some of whom have representatives sitting on our board of directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes in control of us, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

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 2010, 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 54% of our outstanding shares. If one or more of the institutions or our other large shareholders 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, 2010 was 1,518,665 shares, or approximately 11% 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.

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

At December 31, 2010, we had outstanding stock options to purchase 2.9 million shares, 82% 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 241,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico, a 7,200 square foot, a 23,000 square foot building in Roncanova, Italy and a 77,000 square foot building on approximately 11 acres of land in Vrable, Slovakia. 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 Technologies, Inc. ("RyMed") infringes certain of ICU's patents through the manufacture and sale of certain products, including its InVision-Plus valves. We seek monetary damages and injunctive relief and intend to vigorously pursue this matter. Trial commenced on December 13, 2010, and on December 17, 2010, the jury returned a verdict in our favor on two patents. The parties are engaged in post-trial briefings and motion practice, and will request a re-trial on certain matters.

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 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, 2011.

	Age	Office Held
George A. Lopez, M.D.	63	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar.....	38	Vice President of Product Development
Richard A. Costello	47	Vice President of Sales
Scott E. Lamb	48	Chief Financial Officer
Steven C. Riggs	52	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 since 1997, 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.

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:

2010	High	Low
First quarter	$ 37.31	$ 32.31
Second quarter	36.00	30.73
Third quarter	38.39	31.06
Fourth quarter	38.15	35.35

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

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, 2011, we had 92 stockholders of record and we believe we have approximately 9,000 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. As of December 31, 2010, all but $54,000 of the $55.0 million authorized had been used. This plan has no expiration date.

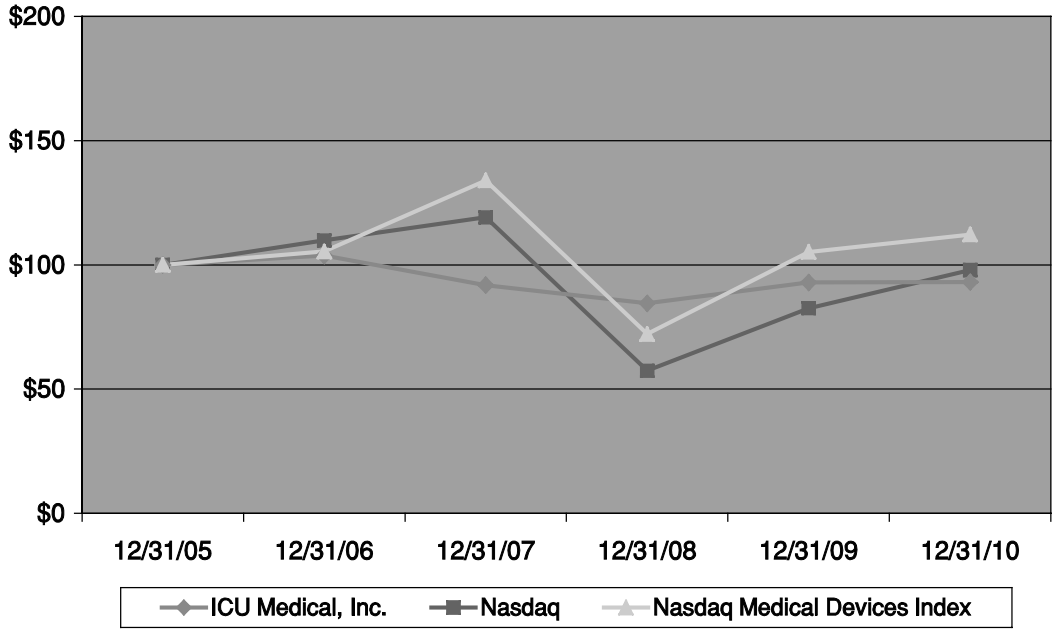
In July 2010, our Board of Directors approved a new common stock purchase plan to purchase $40.0 million of our common stock. This plan has no expiration date.

The following is a summary of our stock repurchasing activity during the fourth quarter of 2010:

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
10/1/2010 - 10/31/2010	—	$ —	—	$ 40,054,000
11/1/2010 - 11/30/2010	—	$ —	—	40,054,000
12/1/2010 - 12/31/2010	—	$ —	—	40,054,000
Fourth quarter 2010 total	—	$ —	—	40,054,000

COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2006 TO DECEMBER 31, 2010 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, 2005 to December 31, 2010 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.



	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010
ICU Medical, Inc.	$ 100.00	$ 103.75	$ 91.84	$ 84.52	$ 92.94	$ 93.09
Nasdaq	$ 100.00	$ 109.84	$ 119.14	$ 57.41	$ 82.53	$ 97.95
Nasdaq Medical Devices Index	$ 100.00	$ 105.40	$ 134.02	$ 72.17	$ 105.24	$ 112.23

Assumes $100 invested on December 31, 2005 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.

Item 6. Selected Financial Data.

ICU MEDICAL, INC.
SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2010	2009	2008	2007	2006
INCOME DATA:					
Revenue					
Net sales	$ 283,980	$ 230,973	$ 203,026	$ 185,618	$ 198,788
Other	602	540	1,700	2,520	2,825
Total revenue	284,582	231,513	204,726	188,138	201,613
Cost of goods sold	153,989	122,695	114,910	109,895	120,929
Gross profit	130,593	108,818	89,816	78,243	80,684
Selling, general and administrative expenses	76,636	68,205	53,611	45,484	44,245
Research and development expenses	4,678	2,645	4,822	8,111	7,659
Gain on sale of building	—	—	—	—	(2,093)
Total operating expenses	81,314	70,850	58,433	53,595	49,811
Income from operations	49,279	37,968	31,383	24,648	30,873
Other income	129	1,181	4,695	8,698	4,462
Income before income taxes and minority interest	49,408	39,149	36,078	33,346	35,335
Provision for income taxes	(18,479)	(12,592)	(11,778)	(10,337)	(10,240)
Non-controlling interest	—	—	—	70	565
Net income	$ 30,929	$ 26,557	$ 24,300	$ 23,079	$ 25,660
Net income per common share					
Basic	$ 2.27	$ 1.80	$ 1.72	$ 1.62	$ 1.78
Diluted	$ 2.23	$ 1.77	$ 1.67	$ 1.51	$ 1.64
Weighted average number of shares					
Basic	13,611	14,720	14,144	14,282	14,412
Diluted	13,855	14,984	14,565	15,265	15,599
Cash dividends per share	$ —	$ —	$ —	$ —	$ —
CASH FLOW DATA:					
Total cash flows from operations	$ 33,095	$ 51,139	$ 30,322	$ 41,512	$ 31,608

	Year ended December 31, (in thousands)				
	2010	2009	2008	2007	2006
BALANCE SHEET DATA:					
Cash, cash equivalents, restricted cash and current and long-term investment securities	$ 93,357	$ 108,135	$ 129,153	$ 95,643	$ 116,918
Working capital	182,071	174,242	157,428	131,782	155,519
Total assets	312,226	309,153	283,434	242,594	244,248
Stockholders' equity	274,286	265,005	253,031	213,904	224,887

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 innovative medical devices used in vascular therapy, oncology and critical care applications. Our products improve patient outcomes by helping prevent bloodstream infections and protect healthcare workers and patients from exposure to infectious diseases or hazardous drugs and monitor the hemodynamic status of critical care patients. Our product line includes custom I.V. systems, closed delivery systems for hazardous drugs, needleless I.V. connectors, catheters and cardiac monitoring systems.

Business Overview

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 beyond the CLAVE.

One of our strategies has been to acquire new product lines. For example, in August 2009, we purchased the commercial rights and physical assets of Hospira's critical care product line, which resulted in our control over all aspects of the critical care product line, including production, sales, marketing, customer contracting and distribution. We had previously manufactured for sale, exclusively to Hospira, the critical care products. Pursuant to the prior arrangements, Hospira retained commercial responsibility for the products that we manufactured, including sales to end customers, marketing, pricing, distribution, customer contracts, customer service and billing and we had little ability to directly influence Hospira's sales and marketing efforts, and our sales under this arrangement were subject to fluctuations over which we had little control. The purchase of Hospira's critical care line has resulted in an increase in direct sales and sales to independent distributors but a decrease in sales to Hospira. There is no assurance that we will be successful in finding future acquisition opportunities or integrating these new product lines into our existing business.

Another strategy for reducing our dependence on our current proprietary products has been to introduce new products. We have introduced a new line of oncology products including the Spiros male lure connector device, the Genie vial access device and ancillary products specifically designed for chemotherapy. We can provide no assurance that we will be able to successfully manufacture, market and sell these new products.

We are also expanding our business through increased sales to medical product manufacturers, independent distributors and through direct sales to the end users of our product. These expansions include our 2008 agreement with Premier, the extension of the term of our agreement with MedAssets, our recent entry into an agreement with Novation of all our critical care products and the growth of our internal sales and marketing group. Each of these organizations is a U.S. healthcare purchasing network. Custom products, which include custom infusion, custom oncology and custom critical care products, accounted for approximately $100.6 million or 35% of total revenue in 2010. CLAVE sales were $98.4 million or 35% of revenue in 2010. Standard critical care sales were $50.4 million or 18% of sales in 2010. We expect continued growth in 2011 compared to 2010 in these products, but at a modest growth rate. We also potentially face substantial increases in competition in our CLAVE business. 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.

Our largest customer is Hospira. Our relationship with Hospira has been and will continue to be important for our growth. We currently manufacture custom infusion sets for sale by Hospira and jointly promote the products under the name SetSource. Additionally, as discussed above, prior to our acquisition of its critical care line, we previously manufactured Hospira's critical care products. In the years ended December 31, 2010, 2009 and 2008, our revenues from worldwide sales to Hospira were 44%, 53% and 69%, respectively, of total revenues. Although we can provide no assurances, as a result of our purchase of Hospira's critical care product line, we expect the percentage of revenues from sales to Hospira will continue to decrease because we now sell critical care products directly to the distributor or end user instead of to Hospira. However, we expect revenues from sales of CLAVE products, custom infusion sets and new products to Hospira to remain a significant percentage of our revenues. Hospira has a significant share of the I.V. set market in the U.S. and provides us access to that market, and we expect that Hospira will be important to our growth for CLAVE, custom infusion sets, and our other products worldwide.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development; however, 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 additional 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	2010	2009	2008
CLAVE	35%	37%	39%
Custom products	35%	34%	34%
Standard critical care products	18%	18%	17%
Standard oncology products	3%	2%	1%
Other products/other revenue	9%	9%	9%
	100%	100%	100%

We sell our I.V. administration products to independent distributors, via direct sales and through agreements with Hospira and certain other medical product manufacturers. Most of our independent distributors handle the full line of our I.V. administration products. We sell our I.V. administration and oncology products under two agreements with Hospira. Under a 1995 agreement, Hospira purchases CLAVE products, principally bulk, non-sterile connectors, oncology products 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.

We have an ongoing effort 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 2010, we began an additional expansion of our production facility in Mexico that was completed in January 2011. In late 2010, we completed construction of an assembly plant in Slovakia that will serve our European product distribution. Product shipments from this plant commenced in the fourth quarter of 2010. We may establish additional production facilities outside the U.S. There is no assurance that we will achieve 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	2010	2009	2008
Medical product manufacturers	41%	50%	67%
Domestic distributors/direct	36%	29%	18%
International customers	23%	21%	15%
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 Europe, the healthcare business generally slows down in the summer months due to vacations resulting in fewer elective surgeries. Also in Europe, hospitals' budgets tend to finish at the end of the year which may cause fewer purchases in the last three months of the year as hospitals await their new budgets in January. 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.

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		
	2010	**2009**	**2008**
Revenue			
Net sales	100%	100%	99%
Other	0%	0%	1%
Total revenues	100%	100%	100%
Gross profit	46%	47%	44%
Selling, general and administrative expenses	27%	30%	26%
Research and development expenses	2%	1%	2%
Total operating expenses	29%	31%	28%
Income from operations	17%	16%	16%
Other income	0%	1%	2%
Income before income taxes	17%	17%	18%
Income taxes	6%	5%	6%
Minority interest	0%	0%	0%
Net income	11%	12%	12%

Comparison of 2010 to 2009

Revenues were $284.6 million in 2010, compared to $231.5 million in 2009.

Distribution channels: Net U.S. sales to Hospira in 2010 were $114.1 million, compared to net sales of $112.4 million in 2009, an increase of 2%. The overall modest increase of $1.7 million was due to the change in product mix. Our CLAVE and custom infusion set sales were $9.0 million and $9.7 million higher in 2010 over 2009, respectively. Our standard and custom critical care sales to Hospira decreased by $21.1 million in 2010 from 2009. The increase in CLAVE and custom infusion set sales was from higher unit sales due to increased market share through Hospira and from additional orders as they prepared for potential business due to market conditions

and switched their IV tubing from DEHP to non-DEHP material, which concluded in the fourth quarter of 2010. The decreased standard and custom critical care sales to Hospira were primarily related to our acquisition of the critical care assets from Hospira. As a result of this acquisition, which closed on August 31, 2009, we no longer sell critical care products to Hospira. Excluding the additional CLAVE and custom infusion set orders in 2010, we expect moderate growth in sales to Hospira in 2011 from 2010, although there is no assurance that these expectations will be realized.

Net sales to domestic distributors/direct in 2010 (including Canada) were $101.4 million compared to $65.9 million in 2009, an increase of 54%. The $35.5 million increase was primarily from $19.7 million in higher standard critical care sales, $5.1 million in higher custom critical care sales and $6.7 million in increased custom infusion set sales. As a result of our purchase of Hospira's critical care line, we ceased selling critical care products to Hospira and began selling the critical care products directly to distributors and through direct sales in September 2009. The increase in standard and custom critical care sales is primarily due to only four months of sales in 2009 compared to twelve months of sales in 2010. The increase in custom infusion set sales was due to higher unit volume sales. We expect increases in domestic distributor/direct sales in 2011 compared to 2010, principally from growth in CLAVE, oncology and renal products although there is no assurance that these expectations will be realized.

Net sales to international customers (excluding Canada) were $64.7 million in 2010, compared with $49.1 million in 2009, an increase of 32%. The $15.6 million increase was primarily from $5.8 million in higher standard critical care sales, $2.1 million in higher custom critical care sales, $3.3 million in increased CLAVE sales and $1.7 million of increased custom infusion set sales. The increase in standard and custom critical care sales is primarily due to only four months of sales in 2009 compared to twelve months of sales in 2010. The CLAVE and custom infusion set increases are from increased unit volume due to increased market share and demographic growth. Approximately 51% and 41% of the increase was attributable to increased sales in Europe and the Pacific Rim, respectively. As we grow our sales in Europe, we increase our exposure to foreign exchange rate fluctuations when the sales are translated to the U.S. dollar. For 2010, our international sales were unfavorably impacted by the decline in the Euro to the U.S. dollar. Our international sales would have been approximately $1.9 million higher if the 2010 average exchange rates were the same as the 2009 average exchange rates. We expect modest increases in international customer sales in 2011 compared to 2010, primarily from higher CLAVE and standard critical care sales, although there is no assurance that these expectations will be realized.

Product and other revenue: Net sales of CLAVE products were $98.4 million in 2010 compared to $85.2 million in 2009, an increase of 15%. The $13.2 million increase was primarily from higher U.S. Hospira sales and higher international sales from increased market share and demographic growth and additional Hospira orders as they prepared for potential additional business due to market conditions and product line changes. We expect modest increases in CLAVE product sales for 2011 compared to 2010 because of the additional sales to Hospira in 2010 from preparing for additional business and orders from product line changes that were completed in 2010, although there is no assurance that these expectations will be realized.

Net sales of custom products, were $100.6 million in 2010 compared to $78.6 million in 2009, an increase of 28%. The $22.0 million increase was primarily comprised of increased sales of custom infusion sets of $18.1 million and increased custom critical care product sales of $3.1 million. 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 and product line changes for Hospira. The increase in custom critical care sales is due to higher average selling prices and more months of revenue recognized after the purchase of this product line from Hospira. In addition, our 2010 sales are to distributors and through direct sales which are at higher average selling prices than we previously charged to Hospira, which is an OEM. Also, in 2009, we only recognized custom critical care sales to Hospira for slightly more than six months, to July 8, 2009, when our asset purchase agreement with Hospira was signed. We only had distributor and direct sales for four months in 2009, from September through December 2009. We expect modest growth in custom product sales in 2011 from 2010 because of the additional sales to Hospira in 2010 for product line changes that were completed in 2010, although there is no assurance that these expectations will be realized.

Standard critical care product sales were $50.4 million in 2010 compared to $41.8 million in 2009, an increase of 21%. The $8.6 million increase is due to higher average selling prices and more months of revenue recognized after the purchase of this product line from Hospira. In addition, our 2010 sales are to distributors and through direct sales which are at higher average selling prices than we previously charged to Hospira, which is an OEM. Also, in 2009, we only recognized critical care sales to Hospira for slightly more than six months, to July 8,

2009, when the asset purchase agreement with Hospira was signed. We only had distributor and direct sales for four months in 2009, from September through December 2009. We expect modest increases in standard critical care sales in 2011 compared to 2010, although there is no assurance that these expectations will be realized.

Our standard oncology product sales were $7.8 million in 2010 compared to $5.1 million in 2009. The $2.7 million increase was from higher sales in all our distribution channels. We expect higher standard oncology sales in 2011 compared to 2010, although there is no assurance that these expectations will be realized.

Other revenue consists of license, royalty and revenue share income and was approximately $0.6 million in 2010 compared to $0.5 million in 2009.

Gross margins for 2010 and 2009 were 46% and 47%, respectively. The decrease was primarily from critical care integration costs and higher freight costs, which were partially offset by favorable product mix.

Selling, general and administrative expenses **("SG&A")** were $76.6 million and 27% of revenues in 2010, compared with $68.2 million and 30% of revenues in 2009. The $8.4 million increase was primarily from increased sales compensation and benefits of $6.2 million, higher sales travel expenses of $1.3 million, higher dealer and group organization fees of $2.8 million which were primarily from critical care sales and our agreements with Group Purchasing Organizations ("GPO's"), pre-startup costs for our Slovakia plant of $1.2 million and $0.6 million in higher stock compensation expense, partially offset by $4.3 million in lower legal expenses. The increase in sales compensation and benefits and travel expenses is primarily a result of the expansion of our sales workforce by 26 employees from 2009 compared to 2010 for our critical care products and growth in other products. The decrease in legal expenses is primarily from lower patent litigation costs. We expect SG&A expenses in 2011 to be approximately 27.0%-27.5% of revenue, although there is no assurance that these expectations will be realized.

Research and development expenses **("R&D")** were $4.7 million and 2% of revenue in 2010 compared to $2.6 million and 1% of revenue in 2009. The increase in R&D expenses was due to an increased effort in product development, including 7 new employees in 2010 compared to 2009. We expect R&D expenses in 2011 to be approximately 2% of revenue, although there is no assurance that these expectations will be realized.

Other income was $0.1 million in 2010 compared to $1.2 million in 2009. The decrease is primarily due to lower interest income earned because of lower invested balances and lower interest rates.

Income taxes were accrued at an estimated annual effective tax rate of 37% in 2010 compared to 32% in 2009. The rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, tax exempt income and deductions for domestic production activities. While we can provide no assurances, we expect our effective tax rate to be approximately 36% in 2011.

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.

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.

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.

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.

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.

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.

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.

Liquidity and Capital Resources

During 2010, our cash, cash equivalents and investment securities decreased by $14.7 million from $108.1 million at December 31, 2009 to $93.4 million at December 31, 2010.

***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.

Our cash provided by operations was $33.1 million in 2010, which was mainly comprised of net income of $30.9 million, depreciation and amortization of $17.3 million and $3.5 million of stock compensation expense, partially offset by changes in our operating assets and liabilities. The $8.0 million increase in accounts receivable and $8.2 million decrease in accounts payable, were the largest contributors to the change in our operating assets and liabilities. The increase in accounts receivable was primarily due to higher sales in the fourth quarter of 2010 compared to 2009 and longer collection periods for our international customers. The decrease in accounts payable was primarily due to larger payables at the end of 2009 related to critical care inventory from Hospira that were not recurring purchases at the end of 2010.

Investing Activities: Our cash provided by investing activities was $19.6 million in 2010, which was primarily comprised of net investment sales of $41.3 million, partially offset by $23.2 million in capital purchases. Our property, plant and equipment purchases were primarily comprised of investments in land, building construction and equipment for our Slovakia plant, other equipment and mold additions in our United States and Mexico plants and software purchases that benefit all worldwide locations. In the spring of 2010, our Slovakia plant flooded and we incurred $3.0 million of additional capital expenditures to restore our fixed assets to their original condition prior to the flood. The $23.2 million in capital additions includes the $3.0 million from the flood, which is reimbursed by insurance. We received approximately $0.6 million in insurance proceeds in 2010 and expect to receive the remaining $2.4 million in 2011.

While we can provide no assurances, we estimate that our capital expenditures in 2011 will approximate $16.0 million to $19.0 million, which is primarily for investments in molds, machinery and equipment in our manufacturing operations in the United States and investments in information technology that benefit world-wide operations. 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 $22.9 million in 2010. We purchased $28.7 million of our own stock in 2010. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was $5.8 million from the sale of 241,919 shares. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

In 2010, we completed all but less than $0.1 million of our $55.0 million share purchase program originally announced in July 2008 and amended in October 2009, by our Board of Directors. In July 2010, our Board of Directors approved a new share purchase plan to purchase up to $40.0 million of our common stock. This plan has no expiration date.

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.

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 certificates of deposits and tax-exempt state and municipal government debt which are classified as available-for-sale. 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 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.

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 Manufacturing, Commercialization and Development Agreement with Hospira, Inc. dated May 1, 2005 (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, 2010, 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, amounts related to such purchase orders are excluded from the table below. We have excluded from the table below pursuant to ASC 740-10-25 (formerly FIN 48), an interpretation of ASC 740-10 (formerly SFAS 109), a noncurrent liability of $4.2 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)			
Contractual Obligations	**Total**	**2011**	**2012**	**2013**
Operating leases	$ 166	$ 166	$ —	$ —
Warehouse service agreements	1,950	873	873	204
Capital purchase obligations	2,642	2,642	—	—
	$ 4,758	$ 3,681	$ 873	$ 204

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 "anticipate," "believe," "expect," "estimate," "intend," "plan," "will," "continue," "could," "may," and by similar 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 growth; 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; expected increases in sales; deferred revenue; future license, royalty and revenue share income; production costs; gross margins; litigation expense; SG&A and R&D expenses; future costs of expanding our business; income; losses; cash flow; amortization; source of funds for capital purchases; 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; adequacy of production capacity; results of R&D; 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; future sales to and revenues from Hospira and the importance of Hospira to our growth; 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 and our positioning with respect to new product introductions and market share; 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:

- general economic and business conditions, both in the U.S. and internationally;
- unexpected changes in our arrangements with Hospira or our other large customers;
- 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;
- 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 tax exempt state and municipal government debt securities and certificates of deposit of $14.5 million as of December 31, 2010. The securities are all "investment grade", comprised of $9.8 million of pre-refunded municipal securities, $1.9 million of non pre-refunded municipal securities and $2.8 million of certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk. Our investment securities totaled $56.9 million at December 31, 2009 and were comprised of $46.4 million in pre-refunded municipal securities, $0.9 million in "auction rate securities" and $9.6 million in certificates of deposit.

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 tax-exempt securities, 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 $0.1 million to investment income based on the investment securities balance at December 31, 2010. A two-thirds to three-quarters of a percentage point change in our earnings on investment securities in 2009 would have created a change to investment income by approximately $0.4 million.

Foreign currency exchange risk for financial instruments on our balance sheet, which consist of cash, accounts receivable, insurance 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 2010 and our manufacturing spending from 2010 would impact our cost of goods sold by approximately $2.0 million. 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. Cash and receivables in those countries have been insignificant and are generally offset by accounts payable in the same foreign currency, except for our European operations, where our net Euro asset position at December 31, 2010 and 2009 were approximately €16.9 million and €8.4 million, respectively. A 10% change in the conversion of the Euro to the U.S. dollar for our cash, accounts receivable, insurance receivable and accounts payable from the December 31, 2010 spot rate would impact our consolidated amounts on these balance sheet items by approximately $2.2 million or less than 2% of these net assets. 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. Based on our average price for resin in fiscal year 2010 and 2009, a 10% increase to the price of resin would result in approximately a $0.7 million change and $0.6 million change in material cost, respectively.

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, 2010 and 2009, and the related consolidated statements of income, stockholders' equity and comprehensive income, and cash flows for each of the three years in the period ended December 31, 2010. Our audit also included the financial statement schedule as of and for the years ended December 31, 2010, 2009 and 2008, listed in the Index at Item 15. We also have audited the Company's internal control over financial reporting as of December 31, 2010, 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 audits 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide 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 ICU Medical, Inc. and subsidiaries as of December 31, 2010 and 2009 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 18, 2011

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except per share data)

	December 31, 2010	December 31, 2009
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 78,850	$ 51,248
Investment securities	14,507	56,887
Cash, cash equivalents and investment securities	93,357	108,135
Accounts receivable, net of allowance for doubtful accounts of $742 in 2010 and $324 in 2009	55,106	47,777
Inventories	44,056	41,327
Prepaid income taxes	687	1,994
Prepaid expenses and other current assets	9,574	5,462
Deferred income taxes	5,053	3,243
Total current assets	207,833	207,938
PROPERTY AND EQUIPMENT, net	83,545	77,449
PROPERTY HELD FOR SALE	—	940
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	14,806	16,782
DEFERRED INCOME TAXES	4,564	3,710
INCOME TAXES RECEIVABLE	—	856
	$ 312,226	$ 309,153
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 10,879	$ 18,423
Accrued liabilities	14,629	12,884
Deferred revenue	254	2,389
Total current liabilities	25,762	33,696
COMMITMENTS AND CONTINGENCIES	—	—
DEFERRED INCOME TAXES	8,023	5,698
INCOME TAX LIABILITY	4,155	4,754
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 14,855 shares in 2010 and 14,811 shares in 2009, outstanding 13,659 shares in 2010 and 14,239 shares in 2009	1,486	1,481
Additional paid-in capital	56,502	54,357
Treasury stock, at cost — 1,196 shares in 2010 and 572 shares in 2009	(41,428)	(19,881)
Retained earnings	258,790	227,861
Accumulated other comprehensive (loss) income	(1,064)	1,187
Total stockholders' equity	274,286	265,005
	$ 312,226	$ 309,153

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME
(Amounts in thousands, except per share data)

	Years ended December 31,		
	2010	2009	2008
REVENUES:			
Net sales	$ 283,980	$ 230,973	$ 203,026
Other	602	540	1,700
TOTAL REVENUE	284,582	231,513	204,726
COST OF GOODS SOLD	153,989	122,695	114,910
Gross profit	130,593	108,818	89,816
OPERATING EXPENSES:			
Selling, general and administrative	76,636	68,205	53,611
Research and development	4,678	2,645	4,822
Total operating expenses	81,314	70,850	58,433
Income from operations	49,279	37,968	31,383
OTHER INCOME, net	129	1,181	4,695
Income before income taxes	49,408	39,149	36,078
PROVISION FOR INCOME TAXES	(18,479)	(12,592)	(11,778)
NET INCOME	$ 30,929	$ 26,557	$ 24,300
NET INCOME PER COMMON SHARE			
Basic	$ 2.27	$ 1.80	$ 1.72
Diluted	$ 2.23	$ 1.77	$ 1.67
Weighted average number of shares			
Basic	13,611	14,720	14,144
Diluted	13,855	14,984	14,565

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME
(Amounts in thousands)

	Common Stock Number of Shares Outstanding	Common Stock Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive Income	Total	Comprehensive Income
BALANCE, December 31, 2007	13,689	1,475	74,805	(40,776)	177,004	1,396	213,904	
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 loss 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
Purchase of treasury stock	(821)	—	—	(28,648)	—	—	(28,648)	
Exercise of stock options, including excess income tax benefits of $1,680	188	3	(1,622)	5,823	—	—	4,204	
Proceeds from employee stock purchase plan	53	2	296	1,278	—	—	1,576	
Stock compensation	—	—	3,471	—	—	—	3,471	
Comprehensive income								
Net income	—	—	—	—	30,929	—	30,929	$ 30,929
Other comprehensive loss, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $(785)	—	—	—	—	—	(2,251)	(2,251)	(2,251)
BALANCE, December 31, 2010	13,659	$ 1,486	$ 56,502	$ (41,428)	$ 258,790	$ (1,064)	$ 274,286	$ 28,678

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Years ended December 31,		
	2010	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 30,929	$ 26,557	$ 24,300
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	17,345	15,671	14,220
Provision for doubtful accounts	443	1	(270)
Stock compensation expense	3,471	2,708	1,890
Loss on disposal, impairment or sale of property and equipment or property held for sale	338	—	653
Bond premium amortization	1,092	2,530	96
Cash provided (used) by changes in operating assets and liabilities, net of assets purchased and business acquisition			
Accounts receivable	(8,001)	(9,043)	(12,375)
Inventories	(3,670)	2,012	1,447
Prepaid expenses and other assets	(2,518)	(3,150)	197
Accounts payable	(8,222)	10,380	(525)
Accrued liabilities	1,946	(2,046)	1,093
Deferred revenue	(2,135)	2,389	—
Prepaid and deferred income taxes, including excess tax benefits	2,077	3,130	(404)
Net cash provided by operating activities	33,095	51,139	30,322
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(23,171)	(16,690)	(11,351)
Assets purchased	—	(29,447)	—
Proceeds from sale of asset	893	—	—
Business acquisition, net of cash acquired	—	(5,662)	—
Proceeds from insurance	622	—	
Proceeds from finance loan repayments	—	—	646
Change in restricted cash	—	6,014	(6,014)
Purchases of investment securities	(23,382)	(99,185)	(63,041)
Proceeds from sale of investment securities	64,670	107,211	83,272
Net cash provided by (used in) investing activities	19,632	(37,759)	3,512
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	2,517	1,375	9,471
Proceeds from employee stock purchase plan	1,576	1,271	1,373
Excess tax benefits from exercise of stock options	1,680	101	8,997
Purchase of treasury stock	(28,648)	(20,441)	(5,859)
Net cash provided by (used in) financing activities	(22,875)	(17,694)	13,982
Effect of exchange rate changes on cash	(2,250)	(134)	7
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	27,602	(4,448)	47,823
CASH AND CASH EQUIVALENTS, beginning of year	51,248	55,696	7,873
CASH AND CASH EQUIVALENTS, end of year	$ 78,850	$ 51,248	$ 55,696
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for income taxes	$ 15,249	$ 9,034	$ 3,073
NON-CASH INVESTING ACTIVITIES:			
Accrued liabilities for property and equipment	$ 716	$ —	$ —

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

(Amounts in tables in thousands, except per share data)

Note 1: Summary of Significant Accounting Policies

a. Introduction/Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

ICU Medical, Inc. (the "Company" - a Delaware corporation) operates in one business segment engaged in the development, manufacturing and marketing of disposable medical devices. The Company's devices are sold principally to distributors and medical product manufacturers throughout the United States and internationally. All subsidiaries are wholly or majority-owned and are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

Subsequent to the issuance of the Company's 2009 consolidated financial statements, the Company reclassified $2.5 million and $0.1 million of bond premium amortization, a noncash item, from investing activities in the consolidated statement of cash flows for the years ended December 31, 2009 and 2008 to a noncash item in cash flows from operating activities as an adjustment to reconcile net income to net cash provided by operating activities. The Company considers this an immaterial reclassification and has changed the 2009 and 2008 consolidated statements of cash flows.

b. Cash and Cash Equivalents

Cash equivalents are investments with an original maturity of three months or less.

c. Inventories

Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method. Inventory costs include material, labor and overhead related to the manufacturing of medical devices.

Inventories consist of the following at December 31:

	2010	2009
Raw material	$ 22,805	$ 16,268
Work in process	3,806	2,711
Finished goods	17,445	22,348
Total	$ 44,056	$ 41,327

d. Property and Equipment

Property and equipment consist of the following at December 31:

	2010	2009
Machinery and equipment	$ 62,680	$ 57,966
Land, building and building improvements	57,810	50,200
Molds	22,521	18,939
Computer equipment and software	14,613	12,196
Furniture and fixtures	2,107	1,928
Construction in progress	9,866	9,565
Total property and equipment, cost	169,597	150,794
Accumulated depreciation	(86,052)	(73,345)
Net property and equipment	$ 83,545	$ 77,449

All property and equipment are stated at cost. The Company uses the straight-line method for depreciating property and equipment over their estimated useful lives. Estimated useful lives are:

Buildings	15 - 30 years
Building improvements	15 years
Machinery and equipment	2 - 10 years
Furniture, fixtures and molds	2 - 5 years
Computer equipment and software	3 - 5 years

The Company follows the policy of capitalizing expenditures that materially increase the life of the related assets; maintenance and repairs are expensed as incurred. The costs and related accumulated depreciation applicable to property and equipment sold or retired are removed from the accounts and any gain or loss is reflected in the statements of income at the time of disposal. Depreciation expense was $14.6 million, $13.4 million and $12.4 million in the years ended December 31, 2010, 2009 and 2008, respectively.

e. Goodwill

The Company tests goodwill for impairment on an annual basis. If the carrying amount of goodwill exceeds the implied estimated fair value, an impairment charge to current operations is recorded to reduce the carrying value to the implied estimated fair value. There have been no impairment charges recorded on goodwill.

The changes in the carrying amount of goodwill for the year ended December 31, 2010 are as follows:

Balance at 01/01/2010	$ 1,478
Goodwill acquired	—
Impairment losses	—
Balance at 12/31/2010	$ 1,478

f. Intangible Assets

Intangible assets, carried at cost less accumulated amortization and amortized on a straight-lined basis, were as follows:

	Weighted Average Amortization Life in Years	December 31, 2010		
		Cost	Accumulated Amortization	Net
Patents	9	$ 11,060	$ 4,463	$ 6,597
MCDA contract *	10	8,571	4,857	3,714
Customer contracts	9	5,319	1,050	4,269
Trademarks	4	425	199	226
Total		$ 25,375	$ 10,569	$ 14,806

	Weighted Average Amortization Life in Years	December 31, 2009		
		Cost	Accumulated Amortization	Net
Patents	9	$ 10,276	$ 3,300	$ 6,976
MCDA contract *	10	8,571	4,000	4,571
Customer contracts	9	5,319	416	4,903
Trademarks	4	425	93	332
Total		$ 24,591	$ 7,809	$ 16,782

*MCDA contract: Manufacturing, Commercialization and Development Agreement with Hospira, Inc. (“Hospira”), dated May 1, 2005 (“the MCDA”).

Amortization expense in 2010, 2009 and 2008 was $2.8 million, $2.3 million and $1.8 million, respectively. Estimated annual amortization for each of the next five years is approximately $2.8 million annually for 2011, $2.7 million for 2012, $2.6 million for 2013, $2.3 million for 2014 and $1.6 million for 2015.

g. Impairment or Disposal of Long-Lived Assets

The Company periodically evaluates the recoverability of long-lived assets whenever events and changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. When indicators of impairment are present, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of the underlying business. The net book value of the underlying asset is adjusted to fair value if the sum of the expected discounted cash flows is less than book value. Fair values are based on estimates of market prices and assumptions concerning the amount and timing of estimated future cash flows and discount rates, reflecting varying degrees of perceived risk.

The Company recorded impairment charge in the year ended December 31, 2008, which is discussed in Note 10.

h. Research and Development

The Company expenses research and development costs as incurred.

i. Net Income Per Share

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of the average market value for the period), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 524,000, 407,000 and 1,490,000 shares for the years ended December 31, 2010, 2009 and 2008, respectively.

The following table presents the calculation of net earnings per common share ("EPS") — basic and diluted.

	Years ended December 31, (in thousands, except per share data)		
	2010	2009	2008
Net income	$ 30,929	$ 26,557	$ 24,300
Weighted average number of common shares outstanding (for basic calculation)	13,611	14,720	14,144
Dilutive securities	244	264	421
Weighted average common and common equivalent shares outstanding (for diluted calculation)	13,855	14,984	14,565
EPS - basic	$ 2.27	$ 1.80	$ 1.72
EPS - diluted	$ 2.23	$ 1.77	$ 1.67

There were no potentially dilutive securities excluded from the computation of diluted earnings per share for these periods if their effect would have been anti-dilutive.

j. Investment Securities

The Company's short-term investments consist principally of certificates of deposits and tax-exempt state and municipal government debt which are classified as available-for-sale. Available-for-sale securities are recorded at fair value, and unrealized holding gains and losses are recorded, net of tax, as a component of accumulated other comprehensive income. Unrealized losses on available-for-sale securities are charged against net earnings when a decline in fair value is determined to be other than temporary. The Company's management reviews several factors to determine whether a loss is other than temporary, such as the length and extent of the fair value decline, the financial condition and near term prospects of the issuer, and for equity investments, the Company's intent and ability to hold the security for a period of time sufficient to allow for any anticipated recovery in fair value. For debt securities, management also evaluates whether the Company has the intent to sell or will likely be required to sell before its anticipated recovery. Realized gains and losses are accounted for on the specific identification method.

k. Income Taxes

The Company's deferred taxes are determined based on the differences between the financial statements and the tax bases using rates as enacted in the laws. A valuation allowance is established if it is "more likely than not" that all or a portion of the deferred tax assets will not be realized.

The Company recognizes interest and penalties related to unrecognized tax benefits in the tax provision. The Company recognizes liabilities for uncertain tax positions when it is more likely than not that a tax position will not be sustained upon examination and settlement with various taxing authorities. Liabilities for uncertain tax positions are measured based upon the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company has not recorded any material interest or penalties during any of the years presented.

The deduction the Company receives from indirect tax benefits from the exercise of stock options, such as those recognized for research and development credits and domestic production activities deductions, are recorded as net reductions of the tax provision. The direct tax benefits of share based compensation are recorded through additional-paid-in capital.

l. Revenue Recognition

All of Company's product sales are FOB shipping point and ownership of the product transfers to the customer on shipment by the Company. The Company records 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. The Company's customers are distributors, medical product manufacturers and end-users. The Company's only post-sale obligations are warranty and certain rebates. With certain exceptions, customers do not retain any right of return and there is no price protection with respect to unsold product; returns from customers with return rights have not been historically significant, therefore no accrual is recorded for this.

The Company warrants products against defects and has a policy permitting the return of defective products. The Company assesses if a reserve for warranty returns is needed. Total warranty expense has been insignificant. The Company accrues rebates based on agreements and on historical experience as a reduction in revenue at the time of sale; adjustments to amounts accrued have not been significant.

Other revenue consists of license, royalty and revenue sharing payments. Payments expected to be received are estimated and recorded in the period earned, and adjusted to actual amounts when reports are received from payers; if there is insufficient data to make such estimates, payments are not recorded until reported by the payers.

m. Shipping Costs

Costs incurred by the Company to ship finished goods to its customers are included in cost of goods sold on the consolidated statements of operations.

n. Accounts Receivable

Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on an assessment of various factors. The Company considers prior payment trends, the age of the accounts receivable balances, 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. The Company regularly reviews individual past due balances for collectability.

o. Post-retirement and Post-employment Benefits

The Company does not provide retirement or post-employment benefits to employees other than its Section 401(k) retirement plan for employees. Company contributions to the plan in 2010, 2009 and 2008 were approximately $1.1 million, $0.9 million and $0.9 million, respectively.

p. Accounting Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

q. Foreign Currency Translation

The Company has international operations where the functional currency is their local currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date. Income and expense accounts are translated at the average monthly exchange rates during the year. Resulting translation adjustments are recorded as a component of accumulated other comprehensive income on the consolidated balance sheets. Foreign currency transaction gains and losses are less than $0.1 million in 2010, 2009 and 2008.

r. New Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06 for Fair Value Measurements and Disclosures (Topic 820): "Improving Disclosures about Fair Value Measurements". This Update requires new disclosures for transfers in and out of Level 1 and 2 and activity in Level 3. This Update also clarifies existing disclosures for level of disaggregation and about inputs and valuation techniques. The new disclosures are effective for interim and annual periods beginning after December 15, 2009, except for the Level 3 disclosures, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those years.

Note 2: Share Based Awards

At December 31, 2010, the Company has stock option plans for employees and directors and the Company has an employee stock purchase plan. Shares to be issued to satisfy future stock option exercises or stock purchase rights under the Employee Stock Purchase Plan ("ESPP") will be issued either from authorized but unissued shares or from treasury shares.

Total stock-based compensation cost recognized in the years ended December 31, 2010, 2009 and 2008 was $3.5 million, $2.7 million and $1.9 million, respectively, for stock options and the ESPP. The tax benefit from the stock-compensation cost recognized in 2010, 2009 and 2008 was $1.2 million, $0.9 million and $0.6 million, respectively. The tax benefit excludes direct tax benefits from exercise of stock options, which are separately reported in the consolidated statement of cash flows. The net indirect tax benefit from the stock compensation cost received upon the exercise of stock options that was recognized in the year ended December 31, 2010 and 2008 was $0.4 million and $1.8 million, respectively. The indirect benefits upon exercise of stock options relate to research and development tax credits and were recorded as a reduction of income tax expense. There were no indirect tax benefits from stock compensation cost in 2009.

Stock Option Plans

The 2003 Stock Option Plan ("2003 Plan") has 1,500,000 shares of common stock reserved for issuance to employees. Options may be granted with exercise prices at no less than fair market value at date of grant. Options granted under the 2003 Plan may be "non-statutory stock options" which expire no more than ten years from date of grant or "incentive stock options" as defined in Section 422 of the Internal Revenue Code of 1986, as amended. Upon exercise of non-statutory stock options, the Company is generally entitled to a tax deduction on the exercise of the option for an amount equal to the excess over the exercise price of the fair market value of the shares at the date of exercise; the Company is generally not entitled to any tax deduction on the exercise of an incentive stock option. The 2003 Plan includes conditions whereby options not vested are cancelled if employment is terminated. To date, all options granted under the 2003 Plan have been non-statutory stock options. The majority of the employee option grants become exercisable five years from the grant date or one quarter becomes exercisable after one year from the grant date and the balance vests ratably on a monthly basis over 36 months. The options generally expire 10 years from the grant date.

The Company also has the 2001 Directors' Stock Option Plan (the "Directors' Plan"), which has 750,000 shares reserved for issuance to members of the Company's Board of Directors. Options not vested terminate if the directorship is terminated. The options granted to non-employee directors generally vest one to four years from the grant date and expire 10 years from the grant date.

The fair value of stock option awards was estimated at the grant date with the following weighted average assumptions for the years ended December 31, 2010, 2009 and 2008:

	Year ended December 31,		
	2010	2009	2008
Expected term (in years)	3.4	5.8	8.0
Expected stock price volatility	40.2%	37.4%	36.5%
Risk-free interest rate	0.8%	2.4%	3.5%
Expected dividend yield	—%	—%	—%
Weighted average grant price	$ 34.70	$ 35.24	$ 27.32
Weighted average grant date fair value	$ 10.18	$ 12.98	$ 13.03

The fair value of stock grants is calculated using the Black-Scholes option valuation model. The Company granted 243,000 stock options valued at $2.5 million in 2010, 254,000 stock options valued at $3.3 million in 2009 and 230,800 stock options, valued at $3.0 million in 2008. The expected term for all periods was based on expected future employee behavior. The Company estimates the volatility of its common stock at the date of grant based on the historical volatility of its common stock, based on the average expected exercise term.

As of December 31, 2010, the Company had $6.7 million of unamortized stock compensation cost of which approximately $2.9 million will amortize in 2011, $2.3 million will amortize in 2012, $1.3 million will amortize in 2013 and $0.2 million will amortize in 2014. As of December 31, 2010, the Company had 203 unvested time-based grants totaling 905,071 options, which vest between 2011 and 2014. Vested and expected to vest stock options equal the Company's total outstanding options at December 31, 2010.

A summary of the Company's stock option activity as of and for the year ended December 31, 2010 is as follows:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2009	2,865,624	$ 28.28
Granted	243,000	34.70
Exercised	(188,180)	13.38
Forfeited or expired	(1,250)	34.72
Outstanding at December 31, 2010	2,919,194	$ 29.77
Exercisable at December 31, 2010	2,014,123	$ 28.18
Available for grant at December 31, 2010:		
2003 Plan	387,700	
Director's Plan	354,750	
	742,450	

The intrinsic value of stock options exercised in the years ended December 31, 2010, 2009 and 2008 was $4.4 million, $0.3 million and $23.7 million, respectively. The intrinsic value of options outstanding and options exercisable at December 31, 2010 was $20.6 million and $17.2 million, respectively, based on the Company's closing stock price of $36.50 on December 31, 2010. The above intrinsic values are before applicable taxes. The weighted average remaining contractual term of options outstanding and options exercisable at December 31, 2010, was 4.3 years and 2.8 years, respectively.

Employee Stock Purchase Plan

The Company has an ESPP under which U.S. employees may purchase up to $25,000 annually of common stock at 85% of its fair market value at the beginning or the end of a six-month offering period, whichever is lower.

There are 750,000 shares of common stock reserved for issuance under the ESPP, which is subject to an annual increase of the least of 300,000 shares, two percent of the shares outstanding or such a number as determined by the Board. To date, there have been no increases. The ESPP is intended to constitute an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. Employees purchased 53,739, 46,401 and 58,819 shares of common stock under the ESPP Plan in the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010, there were 439,496 shares available for future issuance.

The fair value of rights to purchase shares under the ESPP is calculated using the Black-Scholes option valuation model. Rights for the 2010, 2009 and 2008 purchase periods were valued using the following weighted average assumptions:

	Year ended December 31,		
	2010	2009	2008
Expected term (in years)	0.5	0.5	0.5
Expected stock price volatility	26.5%	48.3%	39.0%
Risk-free interest rate	0.2%	0.4%	2.1%
Expected dividend yield	0.0%	0.0%	0.0%

As of December 31, 2010, the Company has less than $0.1 million of unamortized stock compensation expense from the ESPP which will be recognized in the first quarter of 2011. The intrinsic value of ESPP shares at their date of purchase by employees in 2010, 2009 and 2008 was $0.3 million, $0.4 million and $0.3 million, respectively.

Note 3: Fair Value Measurement

The Company's investment securities, which are carried at fair value and are considered available-for-sale, consist principally of certificates of deposit and tax-exempt state and municipal government debt. The Company has $2.8 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has $11.7 million of its investment securities as Level 2 assets, which are pre-refunded and non-pre-refunded municipal securities and have observable inputs.

The following tables provide the assets and liabilities carried at fair value measured on a recurring basis.

	Fair value measurements at December 31, 2010 using			
	Total carrying value at December 31, 2010	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Available for sale securities	$ 14,507	$ 2,820	$ 11,687	$ —
	$ 14,507	$ 2,820	$ 11,687	$ —

	Fair value measurements at December 31, 2009 using			
	Total carrying value at December 31, 2009	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Available for sale securities	$ 55,987	$ 9,560	$ 46,427	$ —
Trading securities	900	—	—	900
	$ 56,887	$ 9,560	$ 46,427	$ 900

The following tables summarize the change in the fair values for Level 3 items for the years ended December 31, 2010 and 2009:

Level 3 changes in fair value (pre-tax):

	2010	2009
Beginning balance	$ 900	$ 15,925
Transfer into Level 3	—	—
Sales	(900)	(15,025)
Unrealized holding loss, included in other comprehensive income	—	—
Ending balance	$ —	$ 900

As of December 31, 2009, the Company had $0.9 million in one auction rate security. There was less than $0.1 million decrease in the market values of the Company's auction rate security in the year ended December 31, 2009.

Note 4: Investment Securities

The Company's investment securities consist of certificates of deposit and federal-tax-exempt state and municipal government debt. All 2010 investment securities are considered available-for-sale and are "investment grade", carried at fair value and there have been no gains or losses on their disposal. We accumulate unrealized gains and losses on our available-for-sale securities, net of tax, in accumulated other comprehensive income in the shareholders' equity section of our balance sheets. We had no gross unrealized gains or losses on our available-for-sale securities at December 31, 2010 or 2009. Balances consist of the following at December 31:

	2010	2009
Corporate preferred securities	$ —	$ 900
Federal tax-exempt debt securities	11,687	46,427
Certificates of deposit	2,820	9,560
	$ 14,507	$ 56,887

The scheduled maturities of the debt securities are between 2011 and 2034.

Investment income, including, money market funds and finance loans, consisted of the following for each year:

	2010	2009	2008
Corporate dividends	$ —	$ 169	$ 471
Tax-exempt interest	58	721	2,135
Other interest	77	199	385
	$ 135	$ 1,089	$ 2,991

Note 5: Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2010	2009
Salaries and benefits	$ 6,029	$ 4,802
Professional fees	1,093	1,867
Incentive compensation	2,990	2,743
Value Added Tax accrual	2,322	1,199
Other	2,195	2,273
	$ 14,629	$ 12,884

Note 6: Asset Purchase

On August 31, 2009, the Company purchased the commercial rights and physical assets of Hospira's critical care product line for $29.4 million in cash. This gives the Company control over the sales, marketing and distribution of products the Company already manufactures. The purchase price was based on estimated inventory and fixed asset values at the time of purchase, and may be subsequently adjusted with amounts due to or from

Hospira for up to 24 months after August 31, 2009. The asset purchase agreement includes a repurchase right of up to $6.0 million of finished goods inventory if the Company is not able to sell the purchased inventory by August 31, 2011. As of December 31, 2010, the purchase price was allocated to the acquired assets based on their relative fair values, as follows:

Finished goods inventory	$ 22,898
Intangible assets — customer contracts	1,522
Intangible assets — patents	1,128
Property, plant and equipment	3,899
Total assets purchased	$ 29,447

The Company entered into the asset purchase agreement with Hospira on July 8, 2009 which has been accounted for as an asset purchase as it did not include sufficient elements of a business combination. All critical care sales to Hospira from July 8, 2009 to August 31, 2009 were deferred and revenue was not recognized for these shipments. The $1.9 million of deferred revenue represented the gross profit associated with the standard and custom critical care sales to Hospira from the time of signing the asset purchase agreement to the closing of the transaction because the Company repurchased the related inventory at closing.

With the completion of the transaction, the Company is responsible for sales, marketing, customer contracting and distribution for the critical care line. In connection with the transaction, certain of the Company's obligations to fund certain critical care research and to provide sales specialist support under the MCDA were released.

Note 7: Income Taxes

Income from continuing operations before taxes for the years ended December 31, 2010, 2009 and 2008 is as follows:

	2010	2009	2008
United States	$ 48,292	$ 36,214	$ 33,111
Foreign	1,116	2,935	2,967
	$ 49,408	$ 39,149	$ 36,078

The provision (benefit) for income taxes for the years ended December 31, 2010, 2009 and 2008 is as follows:

		2010	2009	2008
Current:				
	Federal	$ 15,875	$ 10,385	$ 9,576
	State	1,273	806	2,203
	Foreign	1,109	1,126	389
		18,257	12,317	12,168
Deferred:				
	Federal	$ (781)	$ 1,056	$ (376)
	State	439	(1,002)	(1,841)
	Foreign	564	221	1,827
		222	275	(390)
		$ 18,479	$ 12,592	$ 11,778

Current income taxes payable were reduced from the amounts in the above table by $1.7 million, $0.1 million and $9.0 million in 2010, 2009 and 2008, respectively, equal to the direct tax benefit that the Company receives upon exercise of stock options by employees and directors. That benefit is allocated to stockholders' equity. The Company has accrued for tax contingencies for potential tax assessments, and in 2010 has recognized a $0.6 million net decrease of accruals most of which relates to state tax reserves.

A reconciliation of the provision for income taxes at the statutory rate to the Company's effective tax rate is as follows:

	2010		2009		2008	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ 17,292	35.0%	$ 13,702	35.0%	$ 12,619	35.0%
State income tax, net of federal effect	1,056	2.1%	894	2.3%	849	2.4%
Tax credits	(121)	-0.3%	(1,690)	-4.3%	(1,903)	-5.3%
Tax-exempt interest and dividends	(33)	-0.1%	(283)	-0.7%	(842)	-2.3%
Domestic production activities/other	(997)	-1.9%	(351)	-0.9%	(131)	-0.5%
Foreign income tax	1,282	2.6%	320	0.8%	1,186	3.3%
	$ 18,479	37.4%	$ 12,592	32.2%	$ 11,778	32.6%

Tax credits in 2010, 2009 and 2008 consist principally of research and developmental tax credits. The indirect effect of non-statutory stock options exercised on research and development tax credits and other tax credits were recorded as reductions of the effective tax provision.

The components of the Company's deferred income tax provision for the years ended December 31, 2010, 2009 and 2008 are as follows:

	2010	2009	2008
Allowance for doubtful accounts	$ (66)	$ (17)	$ 66
Inventory reserves	(1,137)	(297)	339
Accruals	(1,792)	(114)	(245)
State income taxes	(290)	(52)	786
Acquired future tax deductions	300	300	300
Depreciation and amortization	2,820	1,571	(417)
Net operating loss ("NOL") carryforward	—	—	577
Tax credits	387	(1,116)	(1,796)
	$ 222	$ 275	$ (390)

The components of the Company's deferred income tax assets (liabilities) at December 31, 2010 and 2009 are as follows

	2010	2009
Current deferred tax assets (liabilities):		
Allowance for doubtful accounts	$ 105	$ 40
Inventory reserves	2,128	991
Accruals	1,827	1,467
Tax credits	—	100
Foreign	444	208
State income taxes	549	437
	$ 5,053	$ 3,243
Non-current deferred tax asset:		
State income taxes	$ (33)	$ (19)
Tax credits state	4,597	5,070
Foreign	—	(1,341)
	$ 4,564	$ 3,710
Non-current deferred tax liability:		
Depreciation	$ (7,193)	$ (5,173)
Acquired future tax deductions	(28)	272
State income taxes	(1,661)	(1,853)
Stock-based compensation	2,943	1,746
Foreign	(2,140)	—
Foreign currency translation adjustments	56	(690)
	$ (8,023)	$ (5,698)

Acquired future tax deductions are the tax benefits included in the Company's consolidated income tax returns originating in Bio-Plexus, Inc., an entity purchased in 2002, prior to its acquisition by the Company. They consist of: (a) the net tax benefit of items expensed for financial statement purposes but capitalized and amortized for tax purposes of $1.9 million at acquisition date, less $1.8 million realized since acquisition; most of the balance of $0.1 million will be realized in approximately equal amounts over the next six years, and (b) by the tax benefited portion of Bio-Plexus's NOL carry-forward of $1.8 million, less $1.5 million realized since acquisition, which will be realized in approximately equal amounts over the next 13 years. Under Section 382 of the Internal Revenue Code, certain ownership changes limit the utilization of the NOL carry-forwards, and the amount of Bio-Plexus federal NOL carry-forwards recorded is the net federal benefit available.

The accounting for the benefits of the acquired future tax deductions as described above will not have any direct impact on the net income in the future. However, if any benefits are realized in excess of those recorded, they will be allocated to reduce non-current intangible assets related to the acquisition (royalty rights) until that amount is reduced to zero, with any excess then recognized as a reduction in tax expense.

MedScanSonics, Inc., a domestic subsidiary, was liquidated in 2008. A tax benefit of $1.1 million was realized.

The Company's Mexican subsidiary has a deferred tax liability of $3.0 million at December 31, 2010, as a result of new tax legislation enacted in 2008.

Foreign currency translation adjustments, and related tax effects, are an element of "other comprehensive income" and are not included in net income.

Undistributed foreign earnings of the Company are primarily considered to be indefinitely reinvested. Upon distribution of those earnings in the form of dividends or otherwise, some portion of the distribution would be subject to both foreign withholding taxes and U.S. income taxes. Determination of the potential amount of unrecognized deferred federal and state income tax liability and foreign withholding taxes is not practicable because of the complexities associated with its hypothetical calculation; however, unrecognized foreign tax credits would be available to reduce some portion of the federal liability.

The Company is subject to taxation in the United States and various states and foreign jurisdictions. The Company's United States federal income tax returns for tax years since 2007 are subject to examination by the Internal Revenue Service. The Company's principal state income tax returns for tax years since 2004 are subject to examination by the state tax authorities.

The total gross amount of unrecognized tax benefits as of December 31, 2010 was $4.4 million that, if recognized, would impact the effective tax rate. The Company does not anticipate that unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date.

The following table summarizes our cumulative gross unrecognized tax benefits:

	2010	2009	2008
Beginning balance	$ 5,306	$ 4,887	$ 3,555
Increases (decreases) to prior year tax positions	(649)	(29)	34
Increases to current year tax positions	518	536	1,908
Decrease related to settlements	(764)	(88)	(472)
Decrease related to lapse of statute of limitations	—	—	(138)
Ending balance	$ 4,411	$ 5,306	$ 4,887

Note 8: Products, Major Customers and Concentrations of Credit Risks

All of the Company's products are disposable medical devices. The Company's two principal products are its CLAVE needleless I.V. connection system which accounted for $98.4 million, $85.2 million and $80.6 million of revenues in 2010, 2009 and 2008, respectively and custom products, which include custom infusion sets, custom oncology products and custom critical care products, accounted for $100.6 million, $78.6 million and $69.8 million of revenues in 2010, 2009 and 2008, respectively. Also, standard critical care products accounted for $50.4 million, $41.8 million and $34.1 million of revenues in 2010, 2009 and 2008, respectively.

The Company sells products, which are sold on credit terms on an unsecured basis, principally throughout the United States to medical product manufacturers, independent medical supply distributors, and in selected cases to hospitals and homecare providers. The manufacturers and distributors, in turn, sell the Company's products to healthcare providers. For the years ended December 31, 2010, 2009 and 2008, the Company had worldwide sales to one manufacturer, Hospira, of 44%, 53% and 69%, respectively, of consolidated revenue. As of December 31, 2010 and 2009, the Company had accounts receivable from Hospira of 43% and 37%, respectively, of consolidated accounts receivable.

Export sales and sales outside the United States and Canada, which are determined by the destination of the product shipment, accounted for 23%, 21% and 15% of total revenue in 2010, 2009 and 2008, respectively.

As of December 31, 2010, approximately $64.9 million of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately $44.6 million in Mexico, $14.7 million in Slovakia, $5.4 million in Italy and $0.2 million in Germany. As of December 31, 2009, approximately $51.3 million of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately $39.9 million in Mexico, $5.2 million in Slovakia, $6.0 million in Italy and $0.2 million in Germany.

Note 9: Treasury Stock

The Company had a common stock purchase plan, authorized by its board of directors, to purchase up to $55.0 million of its common stock. As of December 31, 2010, the Company has completed all but less than $0.1 million of its $55.0 million share repurchase program. The Company purchased $28.6 million of its common stock in the year ended December 31, 2010.

In July 2010, the Company's board of directors approved a new common stock purchase plan to purchase up to $40.0 million of its common stock. This plan has no expiration date.

Note 10: Asset Held for Sale

In 2006, the Company discontinued production on the blood collection needle products purchased in 2002. In December 2008, the Company's manufacturing building in Connecticut became classified as a held for sale asset and was marked down to its fair market value less estimated selling costs on the balance sheet as of December 31, 2008, resulting in a charge to sales, general and administrative expense of $0.6 million in the year ended December 31, 2008. The fair market value at December 31, 2009, which was determined by a potential buyer, was comparable to the adjusted carrying value, so no further adjustments were required in the year ended December 31, 2009. The building was sold in January 2010 for approximately the carrying value as of December 31, 2009.

Note 11: Stockholder Rights Plan

In July 1997, the Board of Directors adopted a Stockholder Rights Plan. This plan expired in 2007 and in July 2007, the Board of Directors adopted an Amended and Restated Rights Agreement. The Company distributed a Preferred Share Purchase Right (a "Right") for each share of the Company's Common Stock outstanding. The Rights generally will not be exercisable until a person or group has acquired 15% or more of the Company's Common Stock in a transaction that is not approved in advance by the Board of Directors or ten days after the commencement of a tender offer which could result in a person or group owning 15% or more of the Common Stock.

On exercise, each Right entitles the holder to buy one share of Common Stock at an exercise price of $225. In the event a third party or group were to acquire 15% or more of the Company's outstanding Common Stock without the prior approval of the Board of Directors, each Right will entitle the holder, other than the acquirer, to buy Common Stock with a market value of twice the exercise price, for the Right's then current exercise price. In addition, if the Company were to be acquired in a merger after such an acquisition, shareholders with unexercised Rights could purchase common stock of the acquirer with a value of twice the exercise price of the Rights.

The Company's Board of Directors may redeem the Rights for a nominal amount at any time prior to the tenth business day following an event that causes the Rights to become exercisable. The Rights will expire unless previously redeemed or exercised on August 8, 2017.

Note 12: Operating Leases

The Company leases its building in Ludenscheid, Germany which expires December 31, 2011 and has an option to extend the term. The Company also leases various office equipment with expiration dates in 2011. The 2010 lease expense was $0.2 million. Our annual minimum future lease payments are $0.2 million in 2011.

Note 13: MedScanSonics, Inc.

The Company had a 94% interest in MedScanSonics, Inc., a subsidiary dedicated to the development of a new medical device for use in detecting coronary heart disease. Clinical trials determined the failure of the technology, resulting in the subsidiary ceasing operations in 2008. The Company recorded a $1.1 million tax benefit from the closure of this subsidiary. There were no other material effects on the Company's consolidated financial statements.

Note 14: Commitments and Contingencies

The Company is from time to time involved in various other legal proceedings, most of which are routine litigation, in the normal course of business. In the opinion of management, the resolution of the other legal proceedings in which the Company is involved will not have a material adverse impact on the Company's financial position or results of operations.

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

Pursuant to the Asset Purchase Agreement with Hospira, the Company agreed to indemnify Hospira and its affiliates from certain liabilities arising out of (i) inaccuracies of the Company's representations and breaches of the Company's warranties; (ii) defaults of the Company's 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, the Company is not obligated to indemnify Hospira for any liabilities for which Hospira is obligated to indemnify us or our affiliates under the MCDA.

Note 15: Quarterly Financial Data - Unaudited

	Quarter Ended			
	March 31	June 30	Sep. 30	Dec. 31
2010				
Total revenue	$ 64,363	$ 68,862	$ 75,737	$ 75,620
Gross profit	26,927	32,127	34,032	37,507
Net income	4,255	7,713	8,975	9,986
Net income per share:				
Basic	$ 0.31	$ 0.57	$ 0.67	$ 0.73
Diluted	$ 0.30	$ 0.56	$ 0.65	$ 0.72
2009				
Total revenue	$ 54,335	$ 53,399	$ 53,965	$ 69,814
Gross profit	26,566	25,789	25,079	31,414
Net income	7,062	5,741	6,324	7,430
Net income per share:				
Basic	$ 0.48	$ 0.39	$ 0.43	$ 0.51
Diluted	$ 0.47	$ 0.38	$ 0.42	$ 0.50

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Regulations 13a-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure and that such information is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities Exchange Commission.

There was no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate control over the Company's financial reporting.

Management has used the criteria in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its internal control over financial reporting.

Management of the Company has concluded that the Company has maintained effective internal control over its financial reporting as of December 31, 2010 based on the criteria in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Our independent registered public accounting firm that audited the December 31, 2010 financial statements included in this Annual Report on Form 10-K has issued us an attestation report on our internal control over financial reporting. This report is included in Part II, Item 8 of this Annual Report on Form 10-K and is incorporated herein by reference.

Item 9B. Other Information

None

PART III

Item 10. Directors and Executive Officers of Registrant and Corporate Governance.

The information required by this item about our board of directors, audit committee, including the audit committee's financial expert, and disclosure of Forms 3, 4 or 5 delinquent filers is set forth under the captions *Election of Directors*, *Audit Committee* and *Section 16(a) Beneficial Ownership Reporting Compliance* in our definitive Proxy Statement to be filed in connection with our 2011 Annual Meeting of Stockholders, and such information is incorporated herein by reference. The information required by this item about our executive officers is set forth in Part I, Item 4A of this Report under the caption "Executive Officers of Registrant."

We have a Code of Business Conduct and Ethics for Directors and Officers. A copy is available on our website, www.icumed.com. We will disclose any future amendments to, or waivers from, the Code of Business Conduct and Ethics for Directors and Officers on our website.

Item 11. Executive Compensation.

The information required by this item is set forth under the caption E*xecutive Officer and Director Compensation*, *Compensation Committee* and *Compensation Committee Interlocks and Insider Participation* in our

definitive Proxy Statement to be filed in connection with our 2011 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is set forth under the caption *Security Ownership of Certain Beneficial Owners and Management* in our definitive Proxy Statement to be filed in connection with our 2011 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

We have a 2003 Stock Option Plan under which -we may grant options to purchase our common stock to our employees and have a 2001 Directors' Stock Option Plan under which we may grant options to purchase our common stock to our directors. We had a 1993 Stock Incentive Plan, under which we granted options to purchase common stock to the employees which expired in January 2005. We also have an Employee Stock Purchase Plan. All plans were approved by our stockholders. Further information about the plans is in Note 2 to the Consolidated Financial Statements. Certain information about the plans at December 31, 2010, is as follows:

Number of shares to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a))
(a)	(b)	(c)*
2,919,194	$ 29.77	1,181,946

*As of December 31, 2010, there were 439,496 shares of common stock available for issuance under our Employee Stock Purchase Plan, which are included in this amount.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is set forth under the caption *Transactions with Related Persons*, *Policies and Procedures Regarding Transactions with Related Persons* and *Director Independence* in our definitive Proxy Statement to be filed in connection with our 2011 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item is set forth under the caption *Selection of Auditors* in our definitive Proxy Statement to be filed in connection with our 2011 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this Report:

1. Financial Statements

	Form 10-K Page No.
The financial statements listed below are set forth in Item 8 of this Annual Report.	
Reports of Independent Registered Public Accounting Firms	37
Consolidated Balance Sheets at December 31, 2010 and 2009	38
Consolidated Statements of Income for the Years Ended December 31, 2010, 2009 and 2008	39
Consolidated Statements of Stockholders' Equity and Comprehensive Income for the Years Ended December 31, 2010, 2009 and 2008	40
Consolidated Statements of Cash Flows for the Years Ended December 31, 2010, 2009 and 2008	41
Notes to Consolidated Financial Statements	42

2. Financial Statement Schedules

The Financial Statement Schedules required to be filed as a part of this Report are:

Schedule II — Valuation and Qualifying Accounts	62

Schedules other than those listed above are omitted since they are not applicable, not required or the information required to be set forth therein is included in Consolidated Financial Statements or Notes thereto included in this Report.

3. Exhibits	63

Exhibits required to be filed as part of this Report are:

Exhibit Number	Description
2.1	Asset Purchase Agreement dated February 25, 2005 between Registrant and Hospira, Inc. (11)
2.2	Letter Agreement dated May 1, 2005 between Registrant and Hospira, Inc. (11)
2.3	Real Estate Purchase Agreement dated February 25, 2005 between Registrant and Hospira, Inc. (11)
2.4	List of schedules and exhibits to Asset Purchase Agreement, Letter Agreement, Real Estate Purchase Agreement and Transition Services Agreement. (11)
2.5	Letter Agreement dated July 13, 2005 between Registrant and Hospira, Inc. re: Asset Purchase Agreement dated February 25, 2005. (12)
2.6	Asset Purchase Agreement made and entered into as of July 8, 2009, by and between Registrant and Hospira, Inc. (19) #
3.1	Registrant's Certificate of Incorporation, as amended. (1)
3.2	Registrant's Bylaws, as amended. (20)
10.1	Form of Indemnity Agreement with Directors and Executive Officers.(1)
10.2	Registrant's Amended and Restated 1993 Incentive Stock Plan.(2)*

10.3 Manufacture and Supply Agreement dated September 13, 1993 between Registrant and B. Braun, Inc. relating to the Protected Needle product.(3)

10.4 Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the CLAVE product.(4)

10.5 Amended and Restated Rights Agreement dated October 18, 2007 between Registrant and American Stock Transfer & Trust Company as Rights Agent.(14)

10.6 SafeLine Agreement effective October 1, 1999 by and between Registrant and B.Braun Medical, Inc.(5)

10.7 Amendment to April 3, 1995 Supply and Distribution Agreement, dated January 1, 1999, between Registrant and Abbott Laboratories.(6)

10.8 Co-Promotion and Distribution Agreement, dated February 27, 2001 between Registrant and Abbott Laboratories.(7)

10.9 Registrant's 2001 Directors' Stock Option Plan.(8)*

10.10 Registrant's 2002 Employee Stock Purchase Plan.(8)*

10.11 Registrant's 2003 Stock Option Plan.(9)*

10.12 Amendment to April 3, 1995 Supply and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories.(10)

10.13 Amendment to February 27, 2001 Co-Promotion and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories.(10)

10.14 Manufacturing, Commercialization and Development Agreement between Registrant and Hospira, Inc. effective May 1, 2005. (12)

10.15 Employment Agreement between Registrant and George A. Lopez, M.D. effective January 1, 2009. (17)*

10.16 Form of ICU Medical, Inc. 2005 Long Term Retention Plan. (11)

10.17 Letter Agreement dated July 8, 2005 between Registrant and Hospira, Inc. re: Manufacturing, Commercialization and Development Agreement effective May 1, 2005. (12)

10.18 Settlement and Release Agreement dated as of January 2, 2007 between ICU Medical, Inc. and Fulwider Patton Lee & Utecht, LLP. (13)

10.19 Executive officer compensation*

10.20 Non-employee director compensation*

10.21 2008 Performance-Based Incentive Plan. (18)*

10.22 Amendment No. 1 to 2001 Director's Stock Plan (20)*

10.23 Amendment No. 2 to 2001 Director's Stock Plan (20)*

10.24 Amendment No. 3 to 2001 Director's Stock Plan (20)*

10.25 Form of Executive Officer Retention Agreement (21)*

10.26 Amended and Restated Retention Agreement between Registrant and Dr. George A. Lopez, dated November 3, 2010. (24)*

10.27 Schedule identifying parties to agreements with the Registrant substantially identical to the Form of Executive Officer Retention Agreement filed as Exhibit 10.25 hereto.

14.1 Code of Business Conduct and Ethics for Directors and Officers (16)

21 Subsidiaries of Registrant.

23.1 Consent of Deloitte & Touche LLP

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32 Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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*Executive compensation plan or other arrangement

#Certain confidential portions of this exhibit have been omitted pursuant to a request for confidential treatment. Omitted portions have been filed separately with the Securities and Exchange Commission.

Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(1) Filed as an Exhibit to Registrant's Registration Statement Form S-1 (Registration No. 33-45734) filed on February 14, 1992, and incorporated herein by reference.

(2) Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 4, 1999 and incorporated herein by reference.

(3) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1993, and incorporated herein by reference.

(4) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1995, and incorporated herein by reference.

(5) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated June 18, 1999, and incorporated herein by reference.

(6) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated February 23, 1999, and incorporated herein by reference.

(7) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated March 7, 2001 and incorporated herein by reference.

(8) Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 2, 2002 and incorporated herein by reference.

(9) Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 25, 2003 and incorporated herein by reference.

(10) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated January 15, 2004, and incorporated herein by reference.

(11) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2005, and incorporated herein by reference.

(12) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2005, and incorporated herein by reference.

(13) Filed as an Exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 2006, and incorporated herein by reference.

(14) Filed as an Exhibit to Registrant's Registration Statement on Form 8-A/A dated October 18, 2007, and incorporated herein by reference.

(15) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated October 2, 2008 and incorporated herein by reference.

(16) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated February 2, 2009 and incorporated herein by reference.

(17) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2010, and incorporated herein by reference.

(18) Filed as Exhibit A to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 10, 2008 and incorporated herein by reference.

(19) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated September 4, 2009 and incorporated herein by reference.

(20) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2009, and incorporated herein by reference.

(21) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated February 4, 2010 and incorporated herein by reference.

(22) Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2010, and incorporated herein by reference.

(23) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated October 19, 2010, and incorporated herein by reference.

(24) Filed as an Exhibit to Registrant's Current Report on Form 8-K dated November 5, 2010, and incorporated herein by reference.

(b) The exhibits are set forth in subsection (a)(3) above.

(c) The financial statement schedules are set forth in (a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ICU MEDICAL, INC.

By: /s/ George A. Lopez, M.D.
George A. Lopez, M.D.
Chairman of the Board

Dated: February 18, 2011

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer)	February 18, 2011
/s/ Scott E. Lamb Scott E. Lamb	Chief Financial Officer (Principal Financial Officer)	February 18, 2011
/s/ Kevin J. McGrody Kevin J. McGrody	Controller (Principal Accounting Officer)	February 18, 2011
/s/ Jack W. Brown Jack W. Brown	Director	February 18, 2011
/s/ John J. Connors John J. Connors	Director	February 18, 2011
/s/ Michael T. Kovalchik, III, M.D. Michael T. Kovalchik, III, M.D.	Director	February 18, 2011
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	February 18, 2011
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	February 18, 2011
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	February 18, 2011

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands) Description	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Write-off/ Disposals	Balance at End of Period
For the year ended December 31, 2008:					
Allowance for doubtful accounts	$ 655	$ (270)	$ —	$ (65)	$ 320
For the year ended December 31, 2009:					
Allowance for doubtful accounts	$ 320	$ 4	$ —	$	$ 324
For the year ended December 31, 2010:					
Allowance for doubtful accounts	$ 324	$ 418	$ —	$	$ 742

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Board of Directors

George A. Lopez, M.D.
Chairman of the Board,
President and Chief Executive Officer

Jack W. Brown
Former Chairman of the Board and President of Gish Biomedical, Inc., disposable medical devices

John J. Connors, Esquire
Patent Attorney, founder, Connors & Associates, Inc., a legal services firm

Michael T. Kovalchik III, M.D.
Physician and Director of Davita Healthcare Kidney Center, Torrington, Connecticut; Chairman Ethics Committee, Charlotte Hungerford Hospital, Torrington, Connecticut

Joseph R. Saucedo
Chairman and President, Bolsa Resources, Inc., management consulting firm

Richard H. Sherman, M.D.
Physician, Department of Medicine, Bayhealth Medical Center, Milford Memorial Hospital, Milford, Delaware

Robert S. Swinney, M.D.
Intensive Care Unit Physician Specialist and member of the faculty of the LAC-USC Medical Center

Corporate Headquarters

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, California 92673-6212
Phone: (949) 366-2183
Facsimile: (949) 366-8368
Web Site Address: www.icumed.com

Auditors

Deloitte & Touche LLP
695 Town Center Drive
Costa Mesa, California 92626-7188

Transfer Agent and Registrar

American Stock Transfer & Trust Company
59 Maiden Lane
New York, NY 10038

Phone: (800) 937-5449
Local/International: (718) 921-8124
*live chat room available for registered shareholder assistance via "contact us/live help"
Email: investors@amstock.com

Overnight Delivery:
American Stock Transfer & Trust Co.
Operations Center
6201 15th Avenue
Brooklyn, NY 11219

Common Stock

Symbol: ICUI
The Nasdaq Global Select Market

Officers

George A. Lopez, M.D.*
Chairman of the Board,
President and Chief Executive Officer

Alison D. Burcar*
Vice President of Product Development

Richard A. Costello*
Vice President of Sales

Scott E. Lamb*
Secretary, Treasurer and Chief Financial Officer

Thomas D. McCall
Vice President of Marketing

Kevin J. McGrody
Controller

Gregory P. Pratt
Vice President of Sales - International

Steven C. Riggs*
Vice President of Operations

"Executive Officer" under the Securities Exchange Act of 1934

ICU Medical, Inc.
951 Calle Amanecer
San Clemente
California 92673