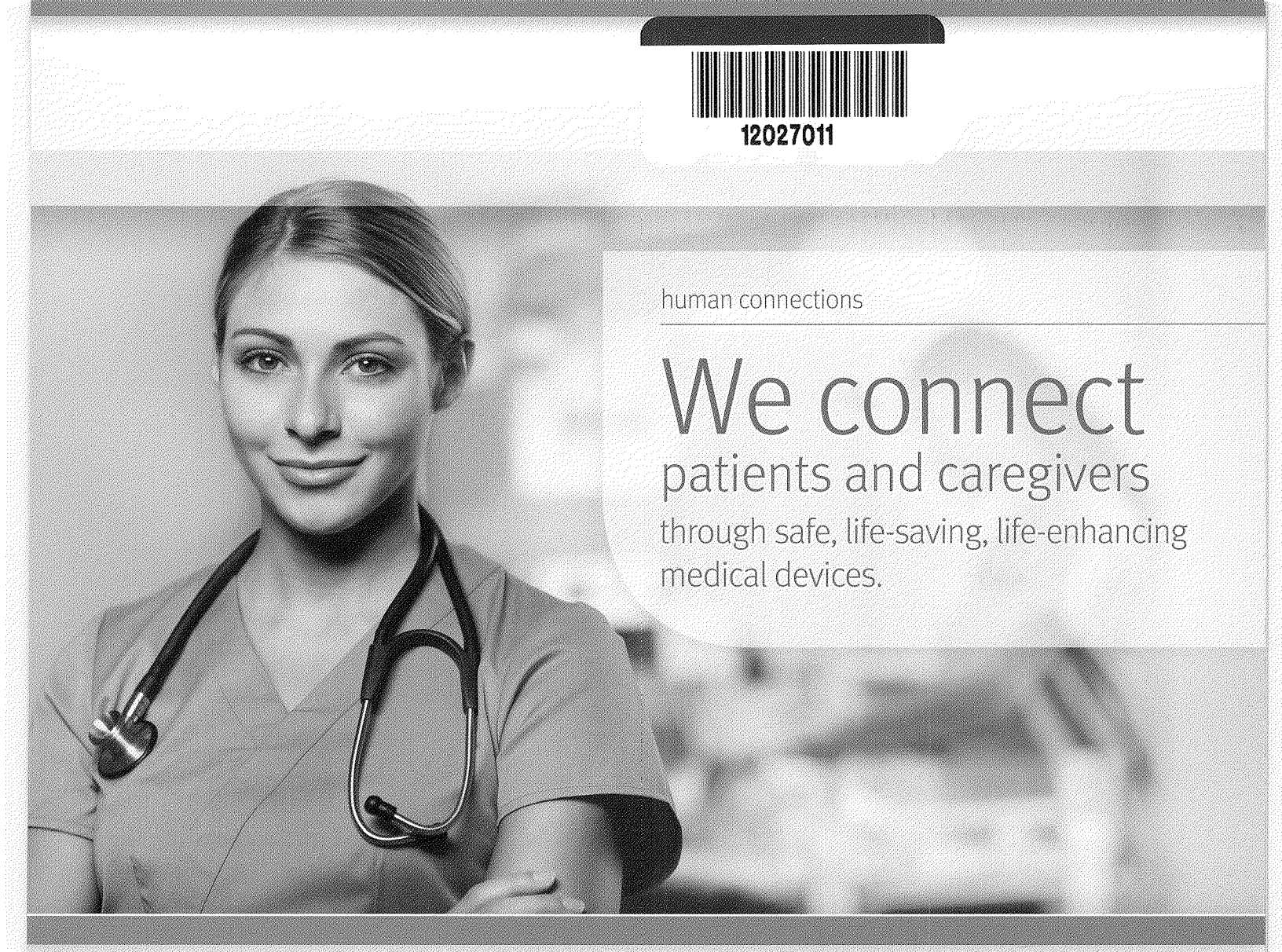


human connections

We connect

patients and caregivers

through safe, life-saving, life-enhancing medical devices.

2011 Annual Report to Shareholders

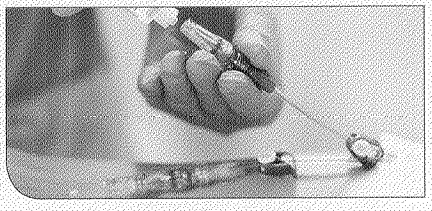
and Form 10-K

icumedical

human connections

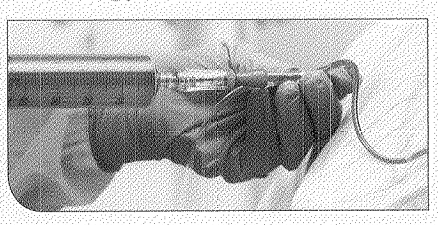
Clinicians around the world count on ICU Medical to provide them with clinically-proven, cost-effective products, and innovative patient safety solutions.

Infusion Therapy



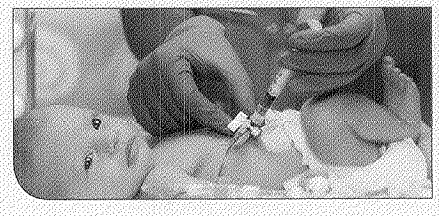
Help reduce bloodstream infections and minimize occlusions with our clinically-proven needlefree infusion access devices. Choose from hundreds of stock infusion sets or customize your own.

Oncology



Help keep pharmacists, nurses, and patients safe with the only needlefree closed system transfer devices and drug compounding systems for safely handling hazardous drugs. Easy-to-use, safe, effective, and affordable.

Critical Care



Get accurate, reliable, and real-time access to your patients' cardiovascular and hemodynamic status with our critical care products, including a full line of advanced sensor catheters comprised of no natural rubber latex components.

icumedical

human connections

March 23, 2012

Dear Stockholder:

Fiscal 2011 was a successful year in our Company's history, marked by achievement of several significant operating and financial milestones.

As we continued to expand the ICU Medical brand in most of our target markets, our revenue increased 7% to a record $302 million. This growth was driven by double-digit improvements in CLAVE, as well as oncology and TEGO products. Our oncology sales grew 34% to $24 million, validating strong demand for these revolutionary products worldwide. Our international sales increased 14%, while domestic sales were up 5% year-over-year.

To better focus on our key target markets where we see a greater growth potential, at the end of the year we sold Orbit, our diabetes infusion set business, a small non-core product line, for a net operating gain of $12.6 million. Excluding the gain on the sale, our net income for fiscal year 2011 was a record $36.7 million, or $2.59 per diluted share.

We ended the year with a healthy, debt-free balance sheet. As of December 31, 2011, our cash, cash equivalents and investment securities totaled $160.0 million and working capital was $231.1 million. Additionally we generated record cash flow from operating activities of $64.5 million for the fiscal year,

During the year, we continued to strengthen relationships with our industry leading partners and extended our two major distribution agreements with Hospira through December 31, 2018. Hospira has been our valuable partner for many years and this extension demonstrates their trust and confidence in our product offerings. We look forward to continuing our relationship and providing customers with access to our innovative CLAVE, oncology products, custom infusion sets and other products worldwide.

We also made substantial progress with establishing our strategic footprint in Europe. Today, our new plant in Slovakia is operating at 35% of its capacity and we expect to improve this capacity utilization through 2012.

We are proud of our accomplishments in 2011 and believe that our diverse and growing portfolio of products as well as solid financial condition position us well for growth in 2012 and beyond. We look forward to capitalizing on new market opportunities through our manufacturing plant strategically built in Slovakia, delivering high quality products to our customers worldwide, and building 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

This page intentionally left blank.

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, 2011 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 Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC (Global Select Market)

Securities Registered Pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ 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, 2011, the last business day of registrant's most recently completed second fiscal quarter, was $539,642,342*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2012 was 13,896,361.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2012 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2011, are incorporated by reference into Part III of this Report.

---

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

ICU Medical, Inc.
Form 10-K
For the Year Ended December 31, 2011
TABLE OF CONTENTS

PART I

Item 1. Business.

Overview

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion 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 continuous cardiac output of critical care patients. Our complete product line includes custom infusion systems, closed delivery systems for hazardous drugs, needlefree infusion connectors, catheters and cardiac monitoring systems. Our headquarters are in San Clemente, California.

Our products are used in hospitals and alternate medical sites in more than 50 countries throughout the world. We categorize our products into three main product lines: Infusion Therapy, Critical Care and Oncology. Products outside of our main product lines are grouped under Other. Our primary products include:

Infusion Therapy

- Needlefree connector products
  - CLAVE
  - MicroCLAVE/ MicroCLAVE Clear
  - Y-CLAVE
  - Anti-Microbial CLAVE
  - Anti-Microbial MicroCLAVE
- Custom infusion sets

Critical Care

- Hemodynamic monitoring systems
  - Transpac disposable pressure transducers
  - SAFESET closed needlefree blood conservation systems
  - Custom monitoring systems
- Catheters
  - Advanced sensor catheters
  - Pulmonary artery thermodilution catheters
  - Multi-lumen central venous catheters
- Custom angiography and interventional radiology kits

Oncology

- Vial and bag access devices
- Genie closed vial access device
- Spiros closed male luer
- Custom preparation and administration sets and accessories
-

Other

- TEGO needlefree hemodialysis connector
- Lopez enteral valve

We currently sell substantially all of our products to medical product manufacturers, independent distributors and directly to the end user. Revenues for 2011, 2010 and 2009 were $302.2 million, $283.0 million and $229.0 million, respectively. Hospira, our largest customer, accounted for 42%, 44% and 54% of our worldwide revenues in 2011, 2010 and 2009, respectively. Income from operations was $65.2 million, $47.7 million and $35.4 million in 2011, 2010 and 2009, respectively. Total assets were $361.1 million, $309.6 million and $307.6 million in 2011, 2010 and 2009, respectively.

Company Background

ICU Medical, Inc. was founded by our Chief Executive Officer in 1984, and our initial public offering was in 1992. In 1993, we launched the CLAVE, an innovative one-piece needlefree I.V. connection device. In 1998, we developed a computerized manufacturing process called SetMaker that enables us to design a custom infusion set to a customer's exact specifications and commence production in less than one day from receiving the order. Since the late 1990's, we have expanded our product offerings by introducing internally developed products and systems and acquiring product lines. We launched internally developed products for use in dialysis and oncology therapy. These products include the TEGO for use in dialysis and a line of oncology products including the Spiros male luer connector device, the Genie vial access device, custom infusion 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 exclusively for Hospira. In August 2009, we purchased all 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 extended our 1995 supply and distribution agreement and 2001 co-promotion and distribution agreement with Hospira to 2018. We are also expanding our business through increased sales to other medical product manufacturers, independent distributors and through direct sales to the end users of our products. These expansions also include agreements with U.S. healthcare purchasing networks including our 2008 agreement with Premier, the extension of the term of our agreement with MedAssets and our 2011 agreement with Novation of all our critical care products. Also, over the past few years we have made a significant investment in expanding our marketing team and building up a direct sales force.

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 ("SEC"). 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).

Products

Infusion Therapy

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 needlefree 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 needlefree 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 needlefree 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 CRBSI in late 2008. The reported cost for treatment of a single CRBSI can be as high as $60,000. The CLAVE technology is designed to prevent bacterial contamination of the vascular catheter and will assist healthcare facilities in the effort to reduce these types of infections. We believe that the CLAVE has certain design features, as discussed below, that are important for the prevention of CRBSI. Additionally, we believe that these important design features are not available in competitive products.

CLAVE Products

Prior to the introduction of needle-safe connectors, a conventional I.V. line terminated with a male luer connector to which a hollow-bore needle would be attached to penetrate a latex or non-latex rubber covered injection port to make a primary or secondary I.V. connection. With the CLAVE system, instead of attaching a hollow-bore needle to the male luer, a CLAVE is used in place of the injection port, and the male luer, without a needle, is simply threaded into the CLAVE with a half turn. The CLAVE consists of a cylindrical housing, which contains a silicone compression seal and an internal blunt cannula. As the luer tip enters the CLAVE housing, it depresses the silicone seal back into the housing and slides over the 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 does 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 infusion 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 $109.2 million, or 36%, of our revenue in 2011, $98.2 million, or 35%, of our revenue in 2010 and $84.8 million, or 37%, of our revenue in 2009. Additional information regarding CLAVE product sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

Custom Infusion Sets

In the late 1990's, we entered the market for custom infusion sets. To promote the growth of the business, we have developed innovative software systems and manufacturing processes known as SetMaker and iFactory that permit 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 2018. 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.

Custom infusion set sales accounted for $76.6 million, or 25%, of our revenue in 2011, $75.6 million, or 27%, of our revenue in 2010 and $57.0 million, or 25%, of our revenue in 2009. Additional information regarding custom infusion sets sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

Critical Care Products

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. In August 2009, we purchased the commercial rights and physical assets from Hospira's critical care product line which provide us control over all aspects of our critical care product line.

We manufacture hemodynamic monitoring systems, vascular and cardiac catheters and monitoring systems and custom and interventional radiology kits that are used to monitor cardiac function and blood flow in critically ill patients. They include all components of the invasive monitoring system. A substantial portion of the invasive monitoring and angiography products are custom critical care products designed to meet the particular needs of the customer. Most of our 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.

The primary critical care products we manufacture are the following:

Transpac Disposable Pressure Transducers: 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.

Safeset Closed Needlefree Blood Conservation Systems: Blood sampling systems that provide the clinician with a convenient, needlefree 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.

Critical care sales accounted for accounted for $61.4 million, or 20%, of our revenue in 2011, $63.6 million, or 23%, of our revenue in 2010 and $51.9 million, or 23%, of our revenue in 2009. Additional information regarding critical care sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

Oncology

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 and the Spiros closed male luer connector. In 2008, we introduced the Genie closed vial access device.

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.

The primary oncology products we manufacture are the following:

Genie® Vial Access Device: The Genie is a closed, needlefree vial access device that automatically equalizes drug vial pressure for the safe preparation of hazardous drugs.

Spiros® *Closed Male Luer:* The Spiros creates a needlefree closed system for the safe mixing, transfer, administration and disposal of hazardous drugs. Upon disconnecting from a needlefree connector, the Spiros automatically self seals and closes the system, preventing spills from syringes or I.V. sets.

Bag Spikes: Our bag spikes include the CLAVE Bag Spike for use on any solution container, the Bag Spike with CLAVE additive Port and Dry Spike that is dedicated lumen for direct access to the solution bag and the Mini CLAVE Bag Spike for use with automated robotic systems, ambulatory and home infusion pumps.

Vial Spikes: Our vial spikes include the CLAVE for use on any drug vial. Vial spikes come in many different configurations and both vented and non-vented to meet various market needs.

Oncology sales accounted for $24.4 million, or 8%, of our revenue in 2011, $18.3 million, or 6%, of our revenue in 2010 and $14.7 million, or 6%, of our revenue in 2009. Additional information regarding oncology sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

Other Products and Revenues

TEGO

The TEGO® is a needlefree hemodialysis connector that creates a mechanically and microbiologically closed system when attached to the hub of a catheter, eliminating open catheter hubs and lowering the chance of contamination and infection. TEGO sales accounted for $8.0 million, or 3%, of our revenue in 2011, $4.3 million, or 2%, of our revenue in 2010 and $3.0 million, or 1%, of our revenue in 2009. Additional information regarding TEGO sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

Other Revenue

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 2012 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 is continuing to be the driving force 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, 2011, we employed 198 people worldwide in sales and marketing. Over the past few years, we built our sales team to add more direct sales personnel 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.

Our administrative operations are in San Clemente, California, Vrable, Slovakia, Roncanova, Italy and Ludenscheid, Germany. The majority of our shipments from the United States are invoiced in U.S. dollars and sales in Europe are invoiced in Euros.

Domestic Sales

Domestic sales include sales to Hospira, other medical product manufacturers, domestic distributors and directly to the end customer. Total domestic sales were $228.4 million, $218.2 million and $179.9 million in 2011, 2010 and 2009, respectively.

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. Our agreement with Hospira runs through 2018 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 2018, 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.

Domestic sales to Hospira accounted for approximately 39% of our revenue in 2011. 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, 2011, we had 72 independent distributors in the United States and Canada who employ approximately 710 salespeople in the aggregate and which accounted for approximately 27% of our revenues in 2011. We include Canada as "domestic" for administrative purposes. Distributors purchase and stock our products for resale to healthcare providers.

One distributor accounted for 7% of revenue in 2011. All other independent distributors accounted for less than 5% of revenue in 2011. 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 Sales

International sales were $73.7 million, $64.7 million and $49.1 million in 2011, 2010 and 2009, respectively.

International sales are primarily concentrated in Europe, Asia Pacific, Southeast Asia, Latin America, Africa and the Middle East. As of December 31, 2011, we had approximately 52 international distributors. Customers in Europe are served by our facilities in Slovakia and Germany. We serve the rest of the world from our facilities in the U.S. and Mexico. We have 22 business development personnel serving Europe and 12 serving Asia Pacific, Southeast Asia, Latin America, Africa and the Middle East.

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, 2011, this facility was equipped with 67 injection molding machines and ancillary equipment and approximately 41 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, Spin Luer, 1o2 Valves and 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 facilities in Ensenada, Mexico and Vrable, Slovakia. Our facility in Mexico has approximately 241,000 square feet of production, warehousing space and an electron beam ("e-beam") sterilizer. Principal products assembled manually in Mexico are infusion 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 e-beam sterilizer. Principal products assembled manually in Slovakia are infusion therapy 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.

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"). 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 also assemble compounders in our leased facility in Ludenscheid, Germany.

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. Some Medical Devices may qualify for the FDA as a Class II, 510(k) Exempt (Special Controls) medical device per 21 CFR 880.5440. These "Special Controls" are defined as: "Adherence to the normal FDA regulations such as the QSR, Complaints, etc. and a specific guidance document" but require no pre-market notification to the FDA. If a medical device does not qualify for the Section 510(k) procedure or the special controls exemption, 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, if needed, and we anticipate that any new products that we are likely to market will qualify, for the expedited Section 510(k) clearance procedure, if needed. 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 infusion 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 innovation, safety, 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 enhanced by our ability to reduce unit manufacturing costs through improved production processes and higher volume production.

Our present and future products compete with needlefree I.V. sets and systems marketed by Baxter Healthcare Corporation ("Baxter"), B. Braun Medical, Inc. ("B. Braun"), CareFusion, Inc. ("CareFusion") formerly Cardinal Healthcare, Becton Dickinson, and others. Although we believe that our needlefree devices and custom set manufacturing capabilities have distinct advantages over competing systems, there is no assurance that they will be able to compete successfully with these products.

In the oncology market, we compete with other manufacturers of closed system transfer devices for the safe handling of oncology drugs, most notably Becton Dickinson (with their purchase of Carmel Pharma's PhaSeal system), CareFusion, B Braun and Baxter. We believe that our current product offering provides benefits over these competing systems in several areas related to safety, ease of use, and cost; however on-going innovation in this market space will be required, and there is no assurance that these innovations will be able to sustain continued growth.

The market for our critical care devices is highly competitive and our success in this area is based on pricing, customer service and product features. The overall market for critical care products has been declining in recent years in the pulmonary artery catheter segment as customers increasingly seek less invasive products to deliver patient hemodynamic status data. Given our expanded customer base, as a result of the critical care asset purchase from Hospira, we believe 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, Becton Dickinson 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 our market-leading needlefree connector line has and will continue to motivate others to develop one-piece needlefree connectors, which may incorporate many of the same functional and physical characteristics as ours. 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 needlefree connector 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, 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, CLC2000 Connector, CLAVE Connector, Spiros Closed Male Connector 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	11/2014-07/2016
CLC2000® connector	12/2016
Click Lock® connector	11/2014-07/2015
Custom Set Design and Manufacturing	01/2021
Spiros® connector	12/2/24-05/2028
Genie® Vial Access Device	05/2026
CLAVE 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 may 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/Quarterly Results

The healthcare business in the United States is subject to quarterly fluctuations due to frequency of illness during the seasons, elective procedures, and over the last few years, the economy. 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, 2011, we had 2,106 full-time employees, consisting of 295 engaged in sales, marketing and administration and 1,791 in manufacturing, molding, product development and quality control, including 1,220 in Mexico and 126 in Slovakia. We contract with independent temporary agencies to provide some production personnel who are not our employees. At December 31, 2011, we had 22 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 SEC.

Unexpected changes in our arrangements with Hospira 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. Worldwide sales to Hospira were 42%, 44% and 54% of revenue for the years ended December 31, 2011, 2010 and 2009, respectively.

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 infusion connection systems are much larger companies that dominate the market for infusion 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 infusion 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.

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 2011, production costs in Mexico were approximately $85.9 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, 2011, we employed 1,220 people in operations in our plant in Ensenada, Mexico and 126 people in operations in our plant in Vrable, Slovakia. 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.

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.

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, which may include external expansion through 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 serves 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 2011 and other patents covering our products will expire at various dates through 2028. 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	11/2014-07/2016
CLC2000® connector	12/2016
Click Lock® connector	11/2014-07/2015
Custom Set Design and Manufacturing	01/2021
Spiros® connector	12/2024-05/2028
Genie 90® connector	05/2026
Y-Site Check Valve	02/2025
TEGO® connector	07/2020-11/2025

Damage to any of our manufacturing facilities could impair our ability to produce our products.

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 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.

In 2010, our Slovakia plant was severely flooded from unusually high levels of rainfall that resulted in a delay in opening this plant for production and required extensive repairs to the facility and machinery.

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.

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. An additional expansion

of our Mexico facility was completed in January 2011. 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 and manual assembly work in Mexico and Slovakia. 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 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 CLAVE products for a major portion of our sales, any decline in sales of CLAVE products could result in a significant reduction in our sales and profits.

In 2011, CLAVE products accounted for approximately 36% of our revenue. We depend heavily on sales of CLAVE products, especially sales of CLAVE products to Hospira. Most of our sales of CLAVE products 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 infusion 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.

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.

The recent European debt crisis, instability in the global credit markets and concerns regarding the stability of the Euro could negatively affect our European customers and demand for our product, which could adversely affect our business and results of operations.

International sales pose additional risks related to competition with larger international companies and established local companies, our possibly higher cost structure, our ability to open foreign manufacturing facilities that can operate profitably 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, Middle East, Latin America and South Africa. We plan to sell in most other areas of the world. We export most of our products sold internationally from the United States, Mexico and 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 some local markets 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 2009 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 from previous years. Our prices to our international distributors, outside of Europe, for product shipped to the customers from the United States or Mexico are generally 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 counter-party 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.

Increased competition in our critical care product line resulted in management's decision to decrease our average selling prices on all critical care products. The price reductions went into effect in the middle of 2011 with the goal of retaining existing customers and attracting new customers. We can provide no assurances that customers will purchase products from us. Continued price pressures could reduce our ability to effectively compete in this market.

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 infusion 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 infusion 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.

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 product family. If the demand for 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 2012. 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 its 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 reached record highs in recent years. 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.

Our business could suffer if we lose the services of key personnel.

We are dependent upon the management and leadership of our executive team, as well as other members of our senior management team. If one or more of these individuals were unable or unwilling to continue in his or her present position, our business would be disrupted and we might not be able to find replacements on a timely basis or with the same level of skill and experience, which could have an adverse effect on our business. The Company does not have in place "key person" life insurance policies on any of its employees.

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.

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

The market for small and mid-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 2009 through December 2011, our trading price ranged from a high of $45.99 per share to a low of $26.18 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 at the end of 2011. 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, 2011 was 2,132,575 shares, or approximately 15% 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.

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 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 (the "District Court"), ICU Medical, Inc. ("ICU") alleged that RyMed Technologies, Inc. ("RyMed") infringes certain ICU patents through the manufacture and sale of its original and current InVision-Plus valves. ICU seeks monetary damages and injunctive relief and continues to vigorously pursue this matter.

A jury trial commenced on December 13, 2010. On December 17, 2010, the jury returned a verdict that: (1) RyMed's original device literally infringed ICU's U.S. Patent No. 5,685,866 ('866 Patent) and ICU's U.S. Patent No. 5,873,862 ('862 Patent); (2) RyMed's current device infringes the '862 Patent both literally and under the doctrine of equivalents; (3) RyMed's current device infringes the '866 Patent under the doctrine of equivalents; (4) RyMed has engaged in contributory infringement and induced infringement of ICU's '862 Patent; and (5) ICU's '866 and '862 Patents are valid.

Following the verdict, ICU filed a Motion for a New Trial on whether RyMed's current device literally infringes ICU's '866 Patent and RyMed filed a Motion for Judgment as a Matter of Law seeking a ruling that its current device does not literally infringe ICU's '866 Patent, as well as a Motion for New Trial on the literal infringement of ICU's '862 Patent by RyMed's current device. Following a hearing on September 16, 2011, the District Court granted ICU's Motion for a New Trial and denied RyMed's Motions.

The new jury trial on whether RyMed's current device literally infringes ICU's '866 Patent is scheduled to commence on May 7, 2012, and will be followed by a one-day bench trial addressing any remaining issues.

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

Item 4. Mine Safety Disclosures.

Not applicable

Part II

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

Our common stock 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:

2011	High	Low
First quarter	$ 43.78	$ 35.57
Second quarter	45.21	41.23
Third quarter	45.79	36.41
Fourth quarter	45.53	35.99

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

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, 2012, we had 85 stockholders of record and we believe we have approximately 9,000 beneficial owners of our common stock.

Issuer Repurchase of Equity Securities

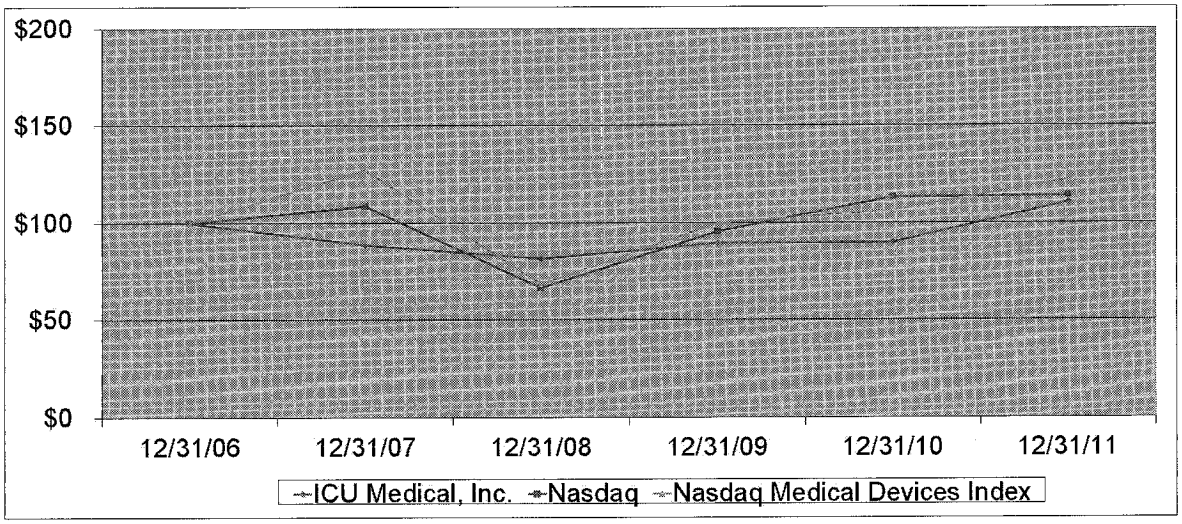
In July 2010, our Board of Directors approved a common stock purchase plan to purchase $40.0 million of our common stock. This plan has no expiration date.

The following is a summary of our stock repurchasing activity during the fourth quarter of 2011:

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
10/01/2011 - 10/31/2011	—	$ —	—	$ 30,054,000
11/01/2011 - 11/30/2011	49,587	$ 39.63	49,587	28,089,000
12/01/2011 - 12/31/2011	—	$ —	—	28,089,000
Fourth quarter 2011 total	49,587	$ 39.63	49,587	28,089,000

COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2007 TO DECEMBER 31, 2011 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, 2006 to December 31, 2011 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.



	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011
ICU Medical, Inc.	$ 100.00	$ 88.52	$ 81.47	$ 89.58	$ 89.72	$ 110.62
Nasdaq	$ 100.00	$ 108.47	$ 66.35	$ 95.38	$ 113.19	$ 113.81
Nasdaq Medical Devices Index	$ 100.00	$ 127.15	$ 68.47	$ 99.85	$ 106.48	$ 122.33

Assumes $100 invested on December 31, 2006 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.

The table below reflects the effects of the restatement discussed in Note 16 in Item 8. "Financial Statements and Supplementary Data."

ICU MEDICAL, INC.
SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2011	2010	2009	2008	2007
INCOME DATA:					
Revenue					
Net sales	$ 301,642	$ 282,357	$ 228,431	$ 203,026	$ 185,618
Other	553	602	540	1,700	2,520
Total revenue	302,195	282,959	228,971	204,726	188,138
Cost of goods sold	159,841	153,989	122,695	114,910	109,895
Gross profit	142,354	128,970	106,276	89,816	78,243
Selling, general and administrative expenses	85,287	76,636	68,205	53,611	45,484
Research and development expenses	8,588	4,678	2,645	4,822	8,111
Legal settlement	(2,500)	—	—	—	—
Gain on sale of assets	(14,242)	—	—	—	—
Total operating expenses	77,133	81,314	70,850	58,433	53,595
Income from operations	65,221	47,656	35,426	31,383	24,648
Other income	1,201	129	1,181	4,695	8,698
Income before income taxes and non-controlling interest	66,422	47,785	36,607	36,078	33,346
Provision for income taxes	(21,753)	(17,862)	(11,626)	(11,778)	(10,337)
Non-controlling interest					70
Net income	$ 44,669	$ 29,923	$ 24,981	$ 24,300	$ 23,079
Net income per common share					
Basic	$ 3.23	$ 2.20	$ 1.70	$ 1.72	$ 1.62
Diluted	$ 3.15	$ 2.16	$ 1.67	$ 1.67	$ 1.51
Weighted average number of shares					
Basic	13,835	13,611	14,720	14,144	14,282
Diluted	14,161	13,855	14,984	14,565	15,265
Cash dividends per share	$ —	$ —	$ —	$ —	$ —
CASH FLOW DATA:					
Total cash flows from operations	$ 64,487	$ 33,095	$ 51,139	$ 30,322	$ 41,512

	As of December 31, (in thousands)				
	2011	2010	2009	2008	2007
BALANCE SHEET DATA:					
Cash, cash equivalents, restricted cash and current and long-term investment securities	$ 159,985	$ 93,357	$ 108,135	$ 135,153	$ 95,643
Working capital	$ 231,098	$ 179,489	$ 172,666	$ 157,428	$ 131,782
Total assets	$ 361,112	$ 309,644	$ 307,577	$ 283,434	$ 242,594
Stockholders' equity	$ 320,577	$ 271,704	$ 263,429	$ 253,031	$ 213,904

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

The consolidated financial information for 2010 and 2009 has been updated within the Management's Discussion and Analysis of Financial Condition and Results of Operations to reflect the effects of the restatement as more fully described in Note 16, "Restatement of Previously Issued Consolidated Financial Statements" included in Item 8. "Financial Statements and Supplementary Data" of this Report.

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion 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 continuous cardiac output of critical care patients. Our complete product line includes custom infusion systems, closed delivery systems for hazardous drugs, needlefree infusion connectors, catheters and cardiac monitoring systems.

Business Overview

In the early 1990's, we launched the CLAVE, an innovative one-piece, needlefree infusion connection device. The CLAVE is a leader in worldwide connector sales. The CLAVE's unique design ensures compliance with needlefree policies because of its passive technology which cannot accept a needle. Our CLAVE products accounted for 36% of our revenues in 2011.

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 infusion 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 new product lines into our existing business.

Another strategy for reducing our dependence on our current proprietary products has been to introduce new products. In 2007 and 2008, we introduced a 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 2011 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. 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 infusion systems, oncology products, critical care products and other products that lend themselves to customization and new products in the U.S. and international markets.

Our products are used in hospitals and alternate medical sites in more than 50 countries throughout the world. We categorize our products into three main product lines: Infusion Therapy, Critical Care and Oncology. Products outside of our main product lines are grouped under Other. Our primary products include:

Infusion Therapy

- Needlefree connector products
  - CLAVE
  - MicroCLAVE/ MicroCLAVE Clear
  - Y-CLAVE
  - Anti-Microbial CLAVE
  - Anti-Microbial MicroCLAVE
- Custom infusion sets

Critical Care

- Hemodynamic monitoring systems
  - Transpac disposable pressure transducers
  - SAFESET closed needlefree blood conservation systems
  - Custom monitoring systems
- Catheters
  - Advanced sensor catheters
  - Pulmonary artery thermodilution catheters
  - Multi-lumen central venous catheters
- Custom angiography and interventional radiology kits

Oncology

- Vial and bag access devices
- Genie closed vial access device
- Spiros closed male luer
- Custom preparation and administration sets and accessories

Other

- TEGO needlefree hemodialysis connector
- Lopez enteral valve

Our largest customer is Hospira. Hospira accounted for 42%, 44% and 54% of our worldwide revenues in 2011, 2010 and 2009, respectively. Our relationship with Hospira has been and will continue to be important for our growth. We currently manufacture custom I.V. 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. 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.

Revenues for 2011, 2010 and 2009 were $302.2 million, $283.0 million and $229.0 million, respectively. We currently sell substantially all of our products to medical product manufacturers, independent distributors and through direct sales to the end user. Most of our independent distributors handle the full line of our infusion 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 2018. 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 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 market segment and its major product groups as a percentage of total revenues:

Product line	2011	2010	2009
CLAVE products	36%	35%	37%
Custom infusion therapy	25%	27%	25%
Other infusion therapy	5%	4%	5%
Infusion therapy	**66%**	**66%**	**67%**
Critical care	**20%**	**23%**	**23%**
Oncology	**8%**	**6%**	**6%**
TEGO	3%	2%	1%
Other products/other revenue	3%	3%	3%
Other	**6%**	**5%**	**4%**
	100%	**100%**	**100%**

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 and early 2011, we expanded our production facility in Mexico. In late 2010, we completed construction of an assembly plant in Slovakia that serves our European product distribution. 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	2011	2010	2009
Medical product manufacturers	40%	42%	51%
Domestic distributors/direct sales	36%	35%	28%
International customers	24%	23%	21%
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.

The shift from medical product manufacturers to domestic distributors and direct sales from 2009 to 2010 and 2011 was primarily due to our August 2009 purchase of the commercial rights and the physical assets of Hospira's critical care line pursuant to which 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.

Seasonality/Quarterly Results

The healthcare business in the United States is subject to quarterly fluctuations due to frequency of illness during the seasons, elective procedures, and over the last few years, the economy. 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		
	2011	2010	2009
Revenue			
Net sales	100 %	100%	100%
Other	— %	—%	—%
Total revenues	100 %	100%	100%
Gross margin	47 %	46%	46%
Selling, general and administrative expenses	28 %	27%	30%
Research and development expenses	3 %	2%	1%
Legal settlement	(1)%	—%	—%
Gain on sale of assets	(5)%	—%	—%
Total operating expenses	25 %	29%	31%
Income from operations	22 %	17%	15%
Other income	— %	—%	1%
Income before income taxes	22 %	17%	16%
Income taxes	7 %	6%	5%
Net income	15 %	11%	11%

Comparison of 2011 to 2010

Revenues were $302.2 million in 2011, compared to $283.0 million in 2010.

Domestic sales: Net domestic sales in 2011 were $228.4 million, compared to net domestic sales of $218.2 million in 2010, an increase of 5%. Net domestic sales to Hospira accounted for 51% and 53% of our domestic sales in 2011 and 2010, respectively. Domestic sales to distributors, through direct sales, through other OEM and other revenue account for the balance of domestic sales, making up 49% and 47% in 2011 and 2010, respectively. For reporting purposes, we include Canada in our domestic sales figures.

Net domestic sales to Hospira in 2011 were $116.6 million, an increase of $2.5 million from 2010. Infusion therapy sales increased $0.9 million from 2010 and oncology sales increased $2.1 million. Infusion therapy sales included a $6.4 million, or 9%, increase in sales of CLAVE products and a $5.8 million, or 17%, decrease in sales of custom infusion sets. The increase in CLAVE product sales was from higher unit sales due to conversion of products sold for needlefree connectors and increased market share through Hospira. The decrease in custom infusion set sales was primarily due to our 2010 sales to Hospira that included $7.8 million in additional orders as they switched their I.V. tubing from DEHP to non-DEHP material, which concluded in the fourth quarter of 2010. The increase in oncology sales was from higher unit sales due to increased market share through Hospira. We expect modest increases in U.S. sales to Hospira in 2012 compared to 2011, primarily from higher oncology sales, although there is no assurance that these expectations will be realized.

Net other domestic sales (excluding Hospira) in 2011 were $111.2 million , an increase of $7.7 million from 2010. Infusion therapy sales increased $5.6 million, or 13%, from 2010, which was primarily from a $3.8 million increase in CLAVE product sales and a $3.3 million increase in custom infusion set sales, partially offset by lower other standard infusion therapy product sales. The increased CLAVE and custom infusion set sales were primarily due to increased unit sales. Critical care sales decreased $1.9 million, or 4%, from 2010. The critical care decrease was primarily from increased competition in this market that resulted in lower average sales prices and lower unit sales on certain items. We expect modest increases in other domestic sales (excluding Hospira) in 2012 compared to 2011, primarily from higher infusion therapy and oncology sales, although there is no assurance that these expectations will be realized.

International sales: Net sales to international customers were $73.7 million in 2011, an increase of $9.0 million from 2010. Infusion therapy sales increased $4.3 million, or 12%, from 2010, which was primarily from a $3.5 million increase in custom infusion set sales and a $0.9 million increase in CLAVE product sales. Oncology sales increased $3.6 million from 2010. Critical care sales were flat year over year. The increases in infusion therapy and oncology were from increased unit sales from increased market share and demographic growth.

Geographically, our international sales were primarily in Europe, the Pacific Rim and Latin America. Approximately 47% and 29% of the $9.0 million increase was attributable to increased sales in Europe and Latin America, 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 2011, our international sales were favorably impacted by the increase in the Euro to the U.S. dollar compared to 2010. Our international sales would have been approximately $1.9 million lower if the 2011 average exchange rates were the same as the 2010 average exchange rates. We expect moderate increases in international sales from higher infusion therapy and oncology sales, partially offset by lower critical care sales, although there is no assurance that these expectations will be realized.

Sales by market segment and other revenue: Net infusion therapy sales were $198.9 million, an increase of $10.8 million, or 6%, from 2010. The increase was primarily from increased CLAVE product sales which increased $11.0 million from 2010. Custom infusion set sales increased by $1.0 million from 2010. Other standard infusion therapy product sales decreased by $1.2 million from 2010. The increase in CLAVE product sales was primarily from higher domestic sales to both U.S. Hospira and other domestic customers. Custom infusion set sales in 2010 included $7.8 million in additional orders from Hospira as they switched their I.V. tubing from DEHP to non-DEHP material, which concluded in the fourth quarter of 2010. These non-recurring sales were the primary reason for our minimal growth from 2010 in custom infusion set sales. The decrease in other standard therapy product sales was from lower unit volume. We expect modest increases in infusion therapy sales in 2012 compared to 2011, primarily from higher sales in CLAVE products and custom infusion set sales. There is no assurance that these expectations will be realized.

Net critical care sales were $61.4 million in 2011, a decrease of $2.2 million, or 4%, from 2010. The decrease was primarily due to lower domestic sales from increased competition. We experienced lower unit sales in certain products and decreased our domestic critical care prices in the middle of 2011 to retain existing customers and attract new customers. We expect critical care sales to decrease in 2012 compared to 2011 from our price decreases and increased competition, although there is no assurance that these expectations will be realized.

Net oncology sales were $24.4 million in 2011, an increase of $6.1 million, or 34%, from 2010. The increase was from higher domestic and international sales. The increase in domestic sales was primarily from higher sales to Hospira. The increase in international sales was primarily from higher sales in Europe. The increased sales was from increased market share and demographic growth. We expect significant growth in oncology sales in 2012 compared to 2011, 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 both 2011 and 2010.

Gross margins for 2011 and 2010 were 47% and 46%, respectively. Our favorable product mix and lower freight costs added 2% to our margin and were partially offset by higher manufacturing costs at our Slovakia plant, higher raw material costs and the decrease in our critical care average selling price.

Selling, general and administrative expenses **("SG&A")** were $85.3 million, or 28%, of revenues in 2011, compared with $76.6 million, or 27%, of revenues in 2010. The increase was primarily from a one-time expense for the Long-Term Retention Plan ("LTRP") of $2.0 million, $1.6 million in compensation expense related to the sale of our Orbit diabetes infusion set product line, increases sales and marketing compensation and benefits and travel of $3.8 million, increases in general and administrative compensation and benefits of $1.1 million and increased information technology ("IT") costs of $0.9

million, partially offset by $1.1 million in lower legal costs. In January 2011, our Compensation Committee determined to pay out the 2005 LTRP grants and to not make any future payments for the 2006 and 2007 awards, thus effectively cancelling the plan. The increase in sales and marketing compensation and benefits and travel is primarily the result of the expansion of our sales and marketing workforce by 17 employees and compensation increases. The increase in general and administrative compensation and benefits is primarily a result of compensation increases. Increased IT costs were primarily from increased software maintenance fees. The decrease in legal expenses is due to lower general legal costs. We expect SG&A expenses in 2012 to be approximately 26.5% to 27.0% of revenue, although there is no assurance that these expectations will be realized.

Research and development expenses **("R&D")** were $8.6 million, or 3%, of revenue in 2011 compared to $4.7 million, or 2%, of revenue in 2010. The increase in R&D expenses was primarily from $3.0 million of higher project related R&D expenses supporting all our infusion therapy, critical care and oncology market segments, $0.3 million in one-time expense for the LTRP payout and $0.5 million in increased compensation and benefits from an expanded workforce. Our R&D projects focus on filling in product line gaps for our product line target markets and creating additional market opportunities. We expect R&D expenses in 2012 to be approximately 2.5% to 3.0% of revenue, although there is no assurance that these expectations will be realized.

Legal settlement income of $2.5 million was received in 2011 and recorded in operating expenses. The payment was the result of a settlement of litigation against a law firm that formerly represented us in patent litigation.

Gain on sale of assets of $14.2 million in 2011 resulted from the sale of assets of our Orbit diabetes infusion set product line. We sold this product line because it was one of our smallest, non-core product lines and the sale allows us to focus our operations on our key markets.

Other income was $1.2 million in 2011 compared to $0.1 million in 2010. The increase is primarily due to higher interest income earned because of higher invested balances and higher interest rates in 2011 and a small gain on disposal of assets in 2011 versus a loss on disposal of assets in 2010.

Income taxes were accrued at an estimated annual effective tax rate of 32.7% in 2011 compared to 37.4% in 2010. The rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits and deductions for domestic production activities. While we can provide no assurances, we expect our effective tax rate to be approximately 35% in 2012.

Comparison of 2010 to 2009

Revenues were $283.0 million in 2010, compared to $229.0 million in 2009.

Domestic sales: Net domestic sales in 2010 were $218.2 million, compared to net domestic sales of $179.9 million in 2009, an increase of 21%. Net domestic sales to Hospira accounted for 53% and 62% of our domestic sales in 2010 and 2009, respectively. Domestic sales to distributors, through direct sales and through other OEM and other revenue account for the balance of domestic sales, making up 47% and 38% in 2010 and 2009, respectively.

Net domestic sales to Hospira in 2010 were $114.1 million, an increase of $1.7 million from 2009. Infusion therapy sales increased $20.4 million from 2009, oncology sales increased $2.3 million and critical care sales decreased by $21.1 million. The overall modest $1.7 million increase was due to the change in product mix. The infusion therapy sales increase in 2010 compared to 2009, included a $9.0 million and 15% increase in sales of CLAVE products and a $9.7 million and 41% increase in sales of custom infusion sets. 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 increase in oncology sales was from higher unit sales due to increased market share through Hospira. The decrease in critical care sales to Hospira was 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.

Net other domestic sales (excluding Hospira) in 2010 were $103.5 million, an increase of $36.5 from 2009. The increase was primarily from $24.8 million in higher critical care sales and $9.2 million in higher infusion therapy 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 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 infusion therapy sales was primarily from $7.2 million higher custom infusion set sales due to higher unit volume sales.

International sales: Net sales to international customers were $64.7 million in 2010, an increase of $15.6 million from 2009. The increase was primarily from $7.9 million in higher critical care sales and $5.9 million of higher infusion therapy sales. The increase in 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 infusion therapy was primarily from a $3.3 million increase in CLAVE product sales and a $1.7 million increase in custom infusion set sales. The CLAVE and custom infusion set increases are from increased unit volume due to increased market share and demographic growth.

Geographically, our international sales were primarily in Europe and the Pacific Rim and accounted for approximately 51% and 41% of the $15.6 million increase in international sales, 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.

Sales by market segment and other revenue: Net infusion therapy sales were $188.1 million, an increase of $35.5 million, or 23%, from 2009. The increase was due to higher sales in all infusion therapy product groups. CLAVE product sales increased $13.4 million from 2009. Custom infusion set sales and other standard infusion set sales increased by $18.6 million and $3.5 million, respectively, from 2009. The increase in CLAVE product sales 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. 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 as they switched their I.V. tubing from DEHP to non-DEHP material, which concluded in the fourth quarter of 2010.

Net critical care sales were $63.6 million in 2010, an increase of $11.7 million, or 23%, from 2009. The 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.

Net oncology sales were $18.3 million in 2010, an increase of $3.6 million, or 24%, from 2009. The increase was from higher sales in all our distribution channels.

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% in both years. Favorable product mix in 2010 was offset by critical care integration costs and higher freight costs.

Selling, general and administrative expenses **("SG&A")** were $76.6 million, or 27%, of revenues in 2010, compared with $68.2 million, or 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.

Research and development expenses **("R&D")** were $4.7 million, or 2%, of revenue in 2010 compared to $2.6 million, or 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.

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.

Liquidity and Capital Resources

During 2011, our cash, cash equivalents and investment securities increased by $66.6 million from $93.4 million at December 31, 2010 to $160.0 million at December 31, 2011.

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 $64.5 million in 2011. Net income plus adjustments for non-cash net expenses and the gain on sale of assets contributed $54.6 million to cash provided by operations. The favorable net change in operating assets and liabilities contributed an additional $9.9 million to cash provided by operations. The $6.2 million decrease in accounts receivable and the $3.2 million decrease in inventory were the largest contributors to the favorable change in operating assets and liabilities.

Investing Activities: Our cash used by investing activities was $45.7 million in 2011, which was primarily comprised of net investment purchases of $48.9 million and $15.8 million in capital purchases, partially offset by $2.8 million in insurance proceeds and $16.2 million in proceeds on the sale of assets related to our Orbit diabetes infusion set product line. Our property, plant and equipment purchases were primarily comprised of machinery, equipment and mold additions in our United States and Slovakia plants. The insurance proceeds were from the 2010 flood at our Slovakia plant.

While we can provide no assurances, we estimate that our capital expenditures in 2012 will approximate $13.0 million to $18.0 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 provided by financing activities was $2.1 million in 2011. We purchased $12.0 million of our own stock in 2011. Cash provided by stock options and the employee stock purchase plan, including tax benefits, was $14.1 million from the sale of 516,909 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. The balance of this plan was purchased in 2011. In July 2010, our Board of Directors approved a new share purchase plan to purchase up to $40.0 million of our common stock. We have purchased $11.9 million of our stock from this plan, leaving a balance of $28.1 million available for future purchases. This plan has no expiration date. We may purchase additional shares in future quarters and expect we would use our cash and investments to fund the share purchases.

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.

As of December 31, 2011, we have $11.0 million of cash and cash equivalents held outside of the United States, the majority of which is available to fund domestic operations and obligations without paying repatriation taxes.

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, corporate bonds, tax-exempt state and municipal government debt and sovereign bonds 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.

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 mis-estimate 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.

Income Taxes: We utilize the liability method of accounting for income taxes as set forth in ASC 740. Under the liability method, deferred taxes are determined based on the temporary differences between the financial statement and tax basis of assets and liabilities using tax rates expected to be in effect during the years in which the basis differences reverse. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized. In determining the need for valuation allowances we consider projected future taxable income and the availability of tax planning strategies. If in the future we determine that we would not be able to realize our recorded deferred tax assets, an increase in the valuation allowance would be recorded, decreasing earnings in the period in which such determination is made.

New Accounting Pronouncements

See Note 1 of 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 have terminated, 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, 2011, of approximately the amount set forth in the table below. This amount excludes inventory-related purchase orders for goods and services for current delivery. The majority of our inventory 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 inventory-related 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 non-current income tax liability of $4.1 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)					
Contractual Obligations	**Total**	**2012**	**2013**	**2014**	**2015**	**2016**
Operating leases	$ 1,050	$ 347	$ 319	$ 170	$ 151	$ 63
Warehouse service agreements	2,045	1,214	546	285	—	—
Purchase obligations	8,525	8,525	—	—	—	—
	$ 11,620	$ 10,086	$ 865	$ 455	$ 151	$ 63

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 and effects with respect to sales and marketing and product development and acquisition efforts; future sales and unit volumes of products; expected increases and decreases in sales; deferred revenue; future license, royalty and revenue share income; production costs; gross margins; litigation expense; future SG&A and R&D expenses; manufacturing expenses; future costs of expanding our business; income; losses; cash flow; amortization; source of funds for capital purchases and operations; future tax rates; alternative sources of capital or financing; 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; domestic sales; expansion in international markets, selling prices; future increases or decreases in sales of certain products and in certain markets and distribution channels; maintaining strategic relationships and securing long-term contracts with large healthcare providers and major buying organizations; increases in systems capabilities; introduction and sales of new products; benefits of our products over competing systems; 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; lives of property and equipment; 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; 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 current relationship with Hospira, including its effect on future revenues 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; patent protection and intellectual property landscape; 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 government bonds, corporate bonds and certificates of deposit of $60.4 million as of December 31, 2011. The securities are all "investment grade", comprised of $36.4 million of pre-refunded municipal securities, $3.4 million of non-pre-refunded municipal securities, $13.3 million in corporate bonds, $1.9 million in sovereign bonds and $5.4 million of certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk.

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 interest rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of federal-tax-exempt securities in our portfolio and market conditions specific to the securities in which we invest. Two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately $0.4 million to investment income based on the investment securities balance at December 31, 2011.

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 2011 and our manufacturing spending from 2011 would have impacted our cost of goods sold by approximately $2.1 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, 2011 and 2010 were approximately €13.0 million and €16.2 million, respectively. A 10% change in the conversion of the Euro to the U.S. dollar for our cash and investments, accounts receivable, accounts payable and accrued liabilities from the December 31, 2011 spot rate would impact our consolidated amounts on these balance sheet items by approximately $1.7 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 2011 and 2010, a 10% increase to the price of resin would have resulted in approximately a $0.9 million change and $0.7 million change in material cost, respectively.

Item 8. Financial Statements and Supplementary Data.

[THE REMAINDER OF THIS PAGE IS INTENIONALLY LEFT BLANK]

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, 2011 and 2010, 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, 2011. Our audits also included the financial statement schedule as of and for the years ended December 31, 2011, 2010 and 2009, listed in the Index at Item 15. We also have audited the Company's internal control over financial reporting as of December 31, 2011, 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 provides a reasonable basis for our opinions.

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

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ICU Medical, Inc. and subsidiaries as of December 31, 2011 and 2010 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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
March 23, 2012

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except per share data)

	December 31, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 99,590	$ 78,850
Investment securities	60,395	14,507
Cash, cash equivalents and investment securities	159,985	93,357
Accounts receivable, net of allowance for doubtful accounts of $1,293 at December 31, 2011 and $742 at December 31, 2010	43,571	50,941
Inventories	40,423	44,056
Prepaid income taxes	5,589	2,270
Prepaid expenses and other current assets	6,759	9,574
Deferred income taxes	4,081	5,053
Total current assets	260,408	205,251
PROPERTY AND EQUIPMENT, net	83,048	83,545
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	11,419	14,806
DEFERRED INCOME TAXES	4,759	4,564
	$ 361,112	$ 309,644
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 13,251	$ 10,879
Accrued liabilities	16,059	14,629
Deferred revenue	—	254
Total current liabilities	29,310	25,762
COMMITMENTS AND CONTINGENCIES	—	—
DEFERRED INCOME TAXES	7,144	8,023
INCOME TAX LIABILITY	4,081	4,155
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 at December 31, 2011 and December 31, 2010, outstanding 13,871 shares at December 31, 2011 and 13,659 shares at December 31, 2010	1,486	1,486
Additional paid-in capital	56,796	56,502
Treasury stock, at cost — 984 shares at December 31, 2011 and 1,196 shares at December 31, 2010	(35,348)	(41,428)
Retained earnings	300,877	256,208
Accumulated other comprehensive loss	(3,234)	(1,064)
Total stockholders' equity	320,577	271,704
	$ 361,112	$ 309,644

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,		
	2011	2010	2009
REVENUES:			
Net sales	$ 301,642	$ 282,357	$ 228,431
Other	553	602	540
TOTAL REVENUE	302,195	282,959	228,971
COST OF GOODS SOLD	159,841	153,989	122,695
Gross profit	142,354	128,970	106,276
OPERATING EXPENSES:			
Selling, general and administrative	85,287	76,636	68,205
Research and development	8,588	4,678	2,645
Legal settlement	(2,500)	—	—
Gain on sale of assets	(14,242)	—	—
Total operating expenses	77,133	81,314	70,850
Income from operations	65,221	47,656	35,426
OTHER INCOME	1,201	129	1,181
Income before income taxes	66,422	47,785	36,607
PROVISION FOR INCOME TAXES	(21,753)	(17,862)	(11,626)
NET INCOME	$ 44,669	$ 29,923	$ 24,981
NET INCOME PER SHARE			
Basic	$ 3.23	$ 2.20	$ 1.70
Diluted	$ 3.15	$ 2.16	$ 1.67
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	13,835	13,611	14,720
Diluted	14,161	13,855	14,984

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		Additional			Accumulated Other		
	Shares	Amount	Paid-In Capital	Treasury Stock	Retained Earnings	Comprehensive Income (Loss)	Total	Comprehensive Income
Balance,December 31, 2008	14,731	1,478	50,970	(1,623)	201,304	902	253,031	
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	0	0	118	0	0	0	118	
Comprehensive income:								
Net income	—	—	—	—	24,981	—	24,981	$ 24,981
Other comprehensive income net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $74	—	—	—	—	—	285	285	285
Balance,December 31, 2009	14,239	1,481	54,357	(19,881)	226,285	1,187	263,429	25,266
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	—	—	—	—	29,923	—	29,923	$ 29,923
Other comprehensive loss, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $(175)	—	—	—	—	—	(2,251)	(2,251)	(2,251)
Balance,December 31, 2010	13,659	1,486	56,502	(41,428)	256,208	(1,064)	271,704	27,672
Purchase of treasury stock	(305)	—	—	(11,956)	—	—	(11,956)	
Exercise of stock options, including excess income tax benefits of $4,288	459	—	(3,753)	16,015	—	—	12,262	
Proceeds from employee stock purchase plan	58	—	(193)	2,021	—	—	1,828	
Stock compensation	—	—	4,016	—	—	—	4,016	
Research and development tax credit originating from stock options and other tax benefits	0	0	224	0	0	0	224	
Comprehensive income:								
Net income	—	—	—	—	44,669	—	44,669	$ 44,669
Other comprehensive loss, net of tax benefit:								
Foreign currency translation adjustment net of tax effect of $(578)	—	—	—	—	—	(2,170)	(2,170)	(2,170)
Balance,December 31, 2011	13,871	1,486	56,796	(35,348)	300,877	(3,234)	320,577	42,499

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,		
	2011	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 44,669	$ 29,923	$ 24,981
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	18,294	17,345	15,671
Provision for doubtful accounts	648	443	1
Stock compensation	4,016	3,471	2,708
Loss (gain) on disposal of property and equipment	(42)	338	—
Gain on sale of assets	(14,242)	—	—
Bond premium amortization	1,294	1,092	2,530
Cash provided (used) by changes in operating assets and liabilities:			
Accounts receivable	6,232	(6,378)	(6,501)
Inventories	3,170	(3,670)	2,012
Prepaid expenses and other assets	(920)	(2,518)	(3,150)
Accounts payable	2,673	(8,222)	10,380
Accrued liabilities	1,684	1,946	(2,046)
Deferred revenue	(254)	(2,135)	2,389
Prepaid and deferred income taxes, including excess tax benefits	(2,735)	1,460	2,164
Net cash provided by operating activities	64,487	33,095	51,139
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment, net	(15,824)	(23,171)	(16,690)
Proceeds from sale of assets	16,201	893	—
Proceeds from insurance	2,781	622	—
Assets purchased	—	—	(29,447)
Business acquisition, net of assets acquired	—	—	(5,662)
Change in restricted cash	—	—	6,014
Purchases of investment securities	(90,502)	(23,382)	(99,185)
Proceeds from sale of investment securities	41,610	64,670	107,211
Net cash provided (used) by investing activities	(45,734)	19,632	(37,759)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	7,974	2,517	1,375
Proceeds from employee stock purchase plan	1,828	1,576	1,271
Tax benefits from exercise of stock options	4,288	1,680	101
Purchase of treasury stock	(11,956)	(28,648)	(20,441)
Net cash provided (used) by financing activities	2,134	(22,875)	(17,694)
Effect of exchange rate changes on cash	(147)	(2,250)	(134)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	20,740	27,602	(4,448)
CASH AND CASH EQUIVALENTS, beginning of period	78,850	51,248	55,696
CASH AND CASH EQUIVALENTS, end of period	$ 99,590	$ 78,850	$ 51,248
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the year for income taxes	$ 20,110	$ 15,249	$ 9,034
NON-CASH INVESTING ACTIVITIES			
Accrued liabilities for property and equipment	$ 418	$ 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 sale of innovative medical technologies used in infusion therapy, oncology and critical care applications. The Company's devices are sold directly or to distributors and medical product manufacturers throughout the United States and internationally. All subsidiaries are wholly owned and are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

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:

	2011	2010
Raw material	$ 25,227	$ 22,805
Work in process	2,901	3,806
Finished goods	12,295	17,445
Total	$ 40,423	$ 44,056

d. Property and Equipment

Property and equipment consist of the following at December 31:

	2011	2010
Machinery and equipment	$ 73,390	$ 62,680
Land, building and building improvements	60,334	57,810
Molds	24,133	22,521
Computer equipment and software	17,518	14,613
Furniture and fixtures	2,298	2,107
Construction in progress	5,277	9,866
Total property and equipment, cost	182,950	169,597
Accumulated depreciation	(99,902)	(86,052)
Net property and equipment	$ 83,048	$ 83,545

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 $15.6 million, $14.6 million and $13.4 million in the years ended December 31, 2011, 2010 and 2009, respectively.

The cost of property and equipment are presented net of government incentive reimbursement the Company received from the Slovakian government for building a manufacturing plant in their country. As of December 31, 2011 and 2010, government incentives recorded in property and equipment were $3.5 million and $1.8 million, respectively.

e. Goodwill

The Company tests goodwill for impairment on an annual basis in the month of November. 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 goodwill additions or impairment charges in the years ended December 31, 2011 and 2010 .

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, 2011 Cost	Accumulated Amortization	Net
Patents	9	$ 9,142	$ 4,335	$ 4,807
MCDA contract *	10	8,571	5,714	2,857
Customer contracts	9	5,319	1,684	3,635
Trademarks	4	425	305	120
Total		$ 23,457	$ 12,038	$ 11,419

	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

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

Amortization expense in 2011, 2010 and 2009 was $2.7 million, $2.8 million and $2.3 million, respectively. Estimated annual amortization for each of the next five years is approximately $2.6 million for 2012, $2.4 million for 2013, $2.1 million for 2014, $1.4 million for 2015 and $0.9 million for 2016.

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.

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 217,000, 524,000 and 407,000 shares for the years ended December 31, 2011, 2010 and 2009 , 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)		
	2011	2010	2009
Net income	$ 44,669	$ 29,923	$ 24,981
Weighted average number of common shares outstanding (basic)	13,835	13,611	14,720
Dilutive securities	326	244	264
Weighted average common and common equivalent shares outstanding (diluted)	14,161	13,855	14,984
EPS - basic	$ 3.23	$ 2.20	$ 1.70
EPS - diluted	$ 3.15	$ 2.16	$ 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 investment securities, which are carried at fair market value and are considered available-for-sale, consist principally of certificates of deposits, corporate bonds, tax-exempt state and municipal government debt and sovereign bonds. 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 2011, 2010 and 2009 were approximately $1.2 million, $1.1 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 2011, 2010 and 2009.

r. New Accounting Pronouncements

In September 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-08 for Intangibles - Goodwill and Other (Topic 350): "Testing Goodwill for Impairment". This Update simplifies how entities test goodwill for impairment. The amendments in the Update permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the entity determines that it is more likely than not that the fair value of a reporting unit is more than the carrying amount in step one, performing step two is not required. If the entity determines that the fair value of a reporting unit is less than the carrying value in step one, step two is required to determine the impairment loss. Under the amendments, an entity is no longer permitted to carry forward its detailed calculation of a reporting unit's fair value from a prior year as previously permitted. This Update is effective for fiscal years beginning after December 15, 2011 and is not expected to have a material effect on our financial statements.

In May 2011, the Financial Accounting Standards Board issued Accounting Standards Update No. 2011-04 for Fair Value Measurement (Topic 820): "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs". This Update addresses how to measure fair value and requires new disclosures about fair value measurements. The amendments in this Update are effective for interim and annual periods beginning after December 15, 2011 and are not expected to have a material effect on our financial statements.

Note 2: Sale of Assets

The Company's management and Board of Directors made the decision to sell its Orbit diabetes infusion set product line to focus the Company's operations on its core products in infusion therapy, oncology and critical care applications. The assets, which were comprised of $1.7 million in intangible assets and $0.1 million in fixed assets, were sold in November 2011 for $16.2 million at a net gain of $14.2 million. The net gain is included as a credit in operating expenses on the Consolidated Statements of Income for the year ended December 31, 2011.

Note 3: Legal Settlement

In February 2011, the Company reached a settlement in its litigation against a law firm that formerly represented the Company in patent litigation matters, representing reimbursement of legal fees previously paid to the firm. Under the terms of the settlement, the Company received $2.5 million, which amount is included as a credit in operating expenses on the Consolidated Statements of Income for the year ended December 31, 2011.

Note 4: Exit Activity from Italy and Germany Facilities

In 2011, the Company's new plant in Slovakia became the Company's European product distribution facility. Product assembly previously done in the Company's Italy and Germany facilities is now done in its Slovakia plant. As a result of this,

the Company had termination costs to certain manufacturing and operations employees from the Italy facility. The product assembly transition from the Company's Italy plant to the Slovakia plant was completed in March 2011. The Italy facility continues to support sales in Europe. The product assembly transition from the Company's Germany plant to the Slovakia plant was completed in the third quarter of 2011. The Germany facility will continue to support a small amount of manufacturing that is not intended to be transferred to the Slovakia plant at this time. In the year ended December 31, 2011, the Company recorded $0.8 million in one-time termination costs, $0.7 million in cost of goods sold and $0.1 million in sales, general and administrative expense. As of December 31, 2011, $0.1 million is accrued for these exit costs.

Note 5: Share Based Awards

At December 31, 2011, the Company has a stock incentive plan for employees and directors and an employee stock purchase plan. Shares to be issued under these plans 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, 2011, 2010 and 2009, was $4.0 million, $3.5 million and $2.7 million, respectively, for stock options and the 2002 Employee Stock Purchase Plan ("ESPP"). The tax benefit from the stock-compensation cost recognized in 2011, 2010 and 2009 was $1.4 million, $1.2 million and $0.9 million, respectively. The tax benefit excludes direct tax benefits from exercise of stock options, which are separately reported in the consolidated statements 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 years ended December 31, 2011 and 2010 was $0.8 million and $0.4 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 Incentive and Stock Option Plans

The 2011 Stock Incentive Plan ("2011 Plan") replaced the 2003 Stock Option Plan ("2003 Plan"). Shares reserved for issuance under the 2011 Plan include 650,000 shares, plus the remaining available shares for grant from the 2003 Plan. In addition, any forfeited, terminated or expired shares that would otherwise return to the 2003 Plan are available under the 2011 Plan. As of December 31, 2011, the 2011 Plan has 901,700 shares of common stock reserved for issuance to employees, which includes 251,700 shares that transferred from the 2003 Plan. Shares issued as options or stock appreciation rights ("SARs") will be charged against the 2011 Plan's share reserve as one share for one share issued. Shares subject to awards other than options and SARs will be charged against the 2011 Plan's share reserve as 2.22 shares for 1 share issued. Options may be granted with exercise prices at no less than fair market value at date of grant. Options granted under the 2011 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 2011 Plan includes conditions whereby options not vested are cancelled if employment is terminated. To date, all options granted under the 2011 Plan and 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's 2001 Directors' Stock Option Plan (the "Directors' Plan"), which had 750,000 shares reserved for issuance to members of the Company's Board of Directors, expired in November 2011. Although no new grants may be made under the Director's Plan, grants made under the Director's Plan prior to its expiration continue to remain outstanding. 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, 2011, 2010 and 2009:

	Year ended December 31,		
	2011	2010	2009
Expected term (in years)	3.0	3.4	5.8
Expected stock price volatility	35.3%	40.2%	37.4%
Risk-free interest rate	0.9%	0.8%	2.4%
Expected dividend yield	—%	—%	—%
Weighted average grant price	$ 43.27	$ 34.70	$ 35.24
Weighted average grant date fair value	$ 10.72	$ 10.18	$ 12.98

The fair value of stock grants is calculated using the Black-Scholes option valuation model. The Company granted 290,000 stock options valued at $3.1 million in 2011, 243,000 stock options valued at $2.5 million in 2010 and 254,000 stock options, valued at $3.3 million in 2009. 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, 2011, the Company had $6.3 million of unamortized stock compensation cost of which approximately $3.2 million will amortize in 2012, $2.0 million will amortize in 2013, $0.9 million will amortize in 2014 and $0.2 million will amortize in 2015. As of December 31, 2011, the Company had 160 unvested time-based grants totaling 798,300 options, which vest between 2012 and 2015. Vested and expected to vest stock options equal the Company's total outstanding options at December 31, 2011.

A summary of the Company's stock option activity as of and for the year ended December 31, 2011 is as follows:

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2010	2,919,194	$ 29.77
Granted	290,000	$ 43.27
Exercised	(459,266)	$ 17.36
Forfeited or expired	(4,500)	$ 27.48
Outstanding at December 31, 2011	2,745,428	$ 33.28
Exercisable at December 31, 2011	1,765,397	$ 31.97
Available for grant at December 31, 2011:		
2011 Plan	786,700	

The intrinsic value of stock options exercised in the years ended December 31, 2011, 2010 and 2009 was $11.5 million, $4.4 million and $0.3 million, respectively. The intrinsic value of options outstanding and options exercisable at December 31, 2011 was $32.2 million and $23.0 million, respectively, based on the Company's closing stock price of $45.00 on December 31, 2011. The above intrinsic values are before applicable taxes. The weighted average remaining contractual term of options outstanding and options exercisable at December 31, 2011, was 4.5 years and 2.9 years, respectively.

ESPP

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 57,643, 53,739 and 46,401 shares of common stock under the ESPP Plan in the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011 there were 381,853 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 2011, 2010 and 2009 purchase periods were valued using the following weighted average assumptions:

	Year ended December 31,		
	2011	2010	2009
Expected term (in years)	0.5	0.5	0.5
Expected stock price volatility	26.0%	26.5%	48.3%
Risk-free interest rate	0.4%	0.2%	0.4%
Expected dividend yield	—%	—%	—%

As of December 31, 2011, 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 2012. The intrinsic value of ESPP shares at their date of purchase by employees in 2011, 2010 and 2009 was $0.5 million, $0.3 million and $0.4 million, respectively.

Note 6: Fair Value Measurement:

The Company's investment securities consist of certificates of deposit, corporate bonds, federal tax-exempt state and municipal government debt and sovereign bonds. All 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. The Company has $5.5 million of its investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. The Company has $54.9 million of its investment securities as Level 2 assets, which are pre-refunded municipal securities, non-pre-refunded municipal securities, corporate bonds and sovereign bonds and have observable market based inputs such as quoted prices, interest rates and yield curves.

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

	Fair value measurements at December 31, 2011 using			
	Total carrying value	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	$ 60,395	$ 5,459	$ 54,936	$ —
	$ 60,395	$ 5,459	$ 54,936	$ —

	Fair value measurements at December 31, 2010 using			
	Total carrying value	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	$ —

The following table summarizes the change in the fair values for Level 3 items for the years ended December 31, 2011 and 2010:

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

	2011	2010
Beginning balance	$ —	$ 900
Transfer into Level 3	—	—
Sales	—	(900)
Unrealized holding loss, included in other comprehensive income	—	—
Ending balance	$ —	$ —

Note 7: Investment Securities

The Company's investment securities consist of certificates of deposit, corporate bonds, federal-tax-exempt state and municipal government debt and sovereign bonds. All 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. Unrealized gains and losses on available-for-sale securities, net of tax, are included in accumulated other comprehensive income in the shareholders' equity section of the Company's balance sheets. The Company had no gross unrealized gains or losses on available-for-sale securities at December 31, 2011 or 2010. Balances consist of the following at December 31:

	2011	2010
Federal tax-exempt debt securities	$ 39,745	$ 11,687
Corporate bonds	13,263	—
Sovereign bonds	1,928	—
Certificates of deposit	5,459	2,820
	$ 60,395	$ 14,507

The scheduled maturities of the debt securities are between 2012 and 2042 and are all callable within one year.

Investment income consisted of the following for each year:

	2011	2010	2009
Corporate dividends	$ 15	$ —	$ 169
Tax-exempt interest	103	58	721
Other interest	358	77	199
	$ 476	$ 135	$ 1,089

Note 8: Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2011	2010
Salaries and benefits	$ 7,642	$ 6,029
Incentive compensation	3,627	2,990
Value Added Tax accrual	1,114	2,322
Other	3,676	3,288
	$ 16,059	$ 14,629

Note 9: Asset Purchase

In 2009, the Company purchased the commercial rights and physical assets of Hospira's critical care product line for $29.4 million in cash.

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 10: Income Taxes

Income from continuing operations before taxes for the years ended December 31, 2011, 2010 and 2009 is as follows:

	2011	2010	2009
United States	$ 63,575	$ 46,669	$ 33,672
Foreign	2,847	1,116	2,935
	$ 66,422	$ 47,785	$ 36,607

The provision (benefit) for income taxes for the years ended December 31, 2011, 2010 and 2009 is as follows:

	2011	2010	2009
Current:			
Federal	$ 19,246	$ 15,331	$ 9,533
State	1,246	1,200	692
Foreign	785	1,109	1,126
	21,277	17,640	11,351
Deferred:			
Federal	$ 169	$ (781)	$ 1,056
State	326	439	(1,002)
Foreign	(19)	564	221
	476	222	275
	$ 21,753	$ 17,862	$ 11,626

Current income taxes payable were reduced from the amounts in the above table by $4.3 million, $1.7 million and $0.1 million in 2011, 2010 and 2009, 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 2011 has recognized a $0.1 million net decrease of accruals most of which relates to state tax reserves.

Reconciliations of the provision for income taxes at the statutory rate to the Company's effective tax rate for the years ended December 31, 2011, 2010 and 2009 are as follows:

	2011		2010		2009	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ 23,247	35.0 %	$ 16,724	35.0 %	$ 12,812	35.0 %
State income tax, net of federal effect	1,460	2.2 %	1,007	2.1 %	818	2.2 %
Tax credits	(1,171)	(1.8)%	(121)	(0.3)%	(1,690)	(4.6)%
Tax-exempt interest and dividends	(45)	(0.1)%	(33)	(0.1)%	(283)	(0.8)%
Domestic production activities/other	(1,508)	(2.3)%	(997)	(2.0)%	(351)	(0.9)%
Foreign income tax	(230)	(0.3)%	1,282	2.7 %	320	0.9 %
	$ 21,753	32.7 %	$ 17,862	37.4 %	$ 11,626	31.8 %

Tax credits in 2011, 2010 and 2009 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, 2011, 2010 and 2009 are as follows:

	2011	2010	2009
Allowance for doubtful accounts	$ (24)	$ (66)	$ (17)
Inventory reserves	1,147	(1,137)	(297)
Accruals	(464)	(1,792)	(114)
State income taxes	(7)	(290)	(52)
Acquired future tax deductions	293	300	300
Depreciation and amortization	(205)	2,820	1,571
Tax credits	(264)	387	(1,116)
	$ 476	$ 222	$ 275

The components of the Company's deferred income tax assets (liabilities) at December 31, 2011 and 2010 are as follows:

	2011	2010
Current deferred tax assets:		
State income taxes	$ 343	$ 549
Foreign	$ 429	$ 444
Accruals/other	$ 1,377	$ 1,827
Tax credits	$ 452	$ —
Allowance for doubtful accounts	$ 102	$ 105
Inventory reserves	1,378	2,128
	$ 4,081	$ 5,053
Non-current deferred tax asset:		
State income taxes	$ —	$ (33)
Foreign	526	—
Accruals/other	347	—
Depreciation and amortization	(523)	—
Tax credits state	4,409	4,597
	$ 4,759	$ 4,564
Non-current deferred tax liability:		
State income taxes	$ (1,481)	$ (1,661)
Foreign	$ (2,633)	$ (2,140)
Accruals/other	$ (186)	$ —
Depreciation and amortization	$ (6,862)	$ (7,193)
Acquired future tax deductions	(460)	(28)
Stock-based compensation	3,843	2,943
Foreign currency translation adjustments	635	56
	$ (7,144)	$ (8,023)

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 and (b) by the tax benefited portion of Bio-Plexus's NOL carry-forward which will be realized in approximately equal amounts over the next 12 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 Company's Mexican subsidiary has a deferred tax liability of $2.6 million at December 31, 2011, as a result of 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.

Our estimate of undistributed earnings of the Company's foreign subsidiaries for which no federal or state liability has been recorded cumulatively totaled $14.0 million and $9.7 million at December 31, 2011 and December 31, 2010, respectively. These undistributed 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 2009 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, 2011 was $5.0 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 for 2011, 2010 and 2009 :

	2011	2010	2009
Beginning balance	$ 4,411	$ 5,306	$ 4,887
Increases (decreases) to prior year tax positions	494	(649)	(29)
Increases to current year tax positions	764	518	536
Decrease related to settlements	(392)	(764)	(88)
Decrease related to lapse of statute of limitations	(299)	—	—
Ending balance	$ 4,978	$ 4,411	$ 5,306

Note 11: Products, Major Customers and Concentrations of Credit Risks

The Company's primary product groups are infusion therapy, critical care and oncology. Infusion therapy products accounted for $198.9 million, $188.1 million and $152.6 million of revenues in 2011, 2010 and 2009, respectively. Critical care products accounted for $61.4 million, $63.6 million and $51.9 million of revenues in 2011, 2010 and 2009, respectively. Oncology products accounted for $24.4 million, $18.3 million and $14.7 million of revenues in 2011, 2010 and 2009, respectively.

The Company sells products worldwide, which are sold on credit terms on an unsecured basis, to medical product manufacturers, independent medical supply distributors, and directly to the end customer. The manufacturers and distributors, in turn, sell the Company's products to healthcare providers. For the years ended December 31, 2011, 2010 and 2009, the Company had worldwide sales to one manufacturer, Hospira, of 42%, 44% and 54%, respectively, of consolidated revenue. As of December 31, 2011, and 2010, the Company had accounts receivable from Hospira of 36% and 46%, respectively, of consolidated accounts receivable.

Domestic sales, which include sales in the United States and Canada, accounted for 76%, 77% and 79% of total revenue in 2011, 2010 and 2009, respectively. International sales, which are determined by the destination of the product shipment, accounted for 24%, 23% and 21% of total revenue in 2011, 2010 and 2009, respectively.

As of December 31, 2011, approximately $116.1 million of the Company's long-lived assets were located in the United States. As of December 31, 2011, approximately $66.8 million of the Company's long-lived assets, principally property and equipment, were located outside the United States: approximately $46.4 million in Mexico, $15.2 million in Slovakia, $5.0 million in Italy and $0.2 million in Germany. As of December 31, 2010, approximately $104.7 million of the Company's long-lived assets were located in the United States. 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.

Note 12: Treasury Stock

In July 2010, the Company's board of directors approved a common stock purchase plan to purchase up to $40.0 million of its common stock. This plan has no expiration date. The Company purchased $12.0 million of its common stock in the year ended December 31, 2011, of which $11.9 million was attributed to the July 2010 purchase plan and $0.1 million was attributed to the July 2008 purchase plan. The Company expects to use the treasury stock to issue shares for stock option exercises, restricted stock grants and employee stock purchase plan stock purchases.

Note 13: 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 14: Operating Leases

The Company leases its building in Ludenscheid, Germany which expires December 31, 2013 and has an option to extend the term. The Company also leases various office equipment with expiration dates ranging from 2012 to 2016. The 2011 lease expense was $0.2 million. Our annual minimum future lease payments are $0.3 million in 2012, $0.3 million in 2013, $0.2 million in 2014, $0.2 million in 2015 and $0.1 million in 2016.

Note 15: 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.

Note 16: Restatement of Previously Issued Consolidated Financial Statements

Subsequent to the issuance of the consolidated financial statements the Company discovered an underestimation in the rebate reserves that amounted to an increase to the reserves and a reduction to net sales of $2.6 million for the year ended December 31, 2009. For the year ended December 31, 2010 the Company made an additional reserve adjustment and a reduction of revenues of $1.6 million. The total reserve adjustment as of December 31, 2010 was $4.2 million. The following tables show the effects of these adjustments:

	December 31, 2010		
	As previously reported	Adjustment	As re-stated
Consolidated balance sheet			
Accounts receivable	$ 55,106	$ (4,165)	$ 50,941
Prepaid income taxes	$ 687	$ 1,583	$ 2,270
Total current assets	$ 207,833	$ (2,582)	$ 205,251
Total assets	$ 312,226	$ (2,582)	$ 309,644
Retained earnings	$ 258,790	$ (2,582)	$ 256,208
Total stockholders' equity	$ 274,286	$ (2,582)	$ 271,704
Total liabilities and stockholders' equity	$ 312,226	$ (2,582)	$ 309,644

	Year ended December 31, 2010			Year ended December 31, 2009		
	As previously reported	Adjustment	As re-stated	As previously reported	Adjustment	As re-stated
Consolidated statements of income						
Net sales	$ 283,980	$ (1,623)	$ 282,357	$ 230,973	$ (2,542)	$ 228,431
Total revenue	$ 284,582	$ (1,623)	$ 282,959	$ 231,513	$ (2,542)	$ 228,971
Gross profit	$ 130,593	$ (1,623)	$ 128,970	$ 108,818	$ (2,542)	$ 106,276
Income from operations	$ 49,279	$ (1,623)	$ 47,656	$ 37,968	$ (2,542)	$ 35,426
Income before income taxes	$ 49,408	$ (1,623)	$ 47,785	$ 39,149	$ (2,542)	$ 36,607
Provision for income taxes	$ (18,479)	$ 617	$ (17,862)	$ (12,592)	$ 966	$ (11,626)
Net income	$ 30,929	$ (1,006)	$ 29,923	$ 26,557	$ (1,576)	$ 24,981
Basic earnings per share	$ 2.27	$ (0.07)	$ 2.20	$ 1.80	$ (0.10)	$ 1.70
Diluted earnings per share	$ 2.23	$ (0.07)	$ 2.16	$ 1.77	$ (0.10)	$ 1.67
Consolidated statements stockholders' equity and comprehensive income						
Retained earnings	$ 258,790	$ (2,582)	$ 256,208	$ 227,861	$ (1,576)	$ 226,285
Total stockholders' equity	$ 274,286	$ (2,582)	$ 271,704	$ 265,005	$ (1,576)	$ 263,429
Net income	$ 30,929	$ (1,006)	$ 29,923	$ 26,557	$ (1,576)	$ 24,981
Comprehensive income	$ 28,678	$ (1,006)	$ 27,672	$ 26,842	$ (1,576)	$ 25,266
Consolidated statements of cash flows						
Net income	$ 30,929	$ (1,006)	$ 29,923	$ 26,557	$ (1,576)	$ 24,981
Accounts receivable change	$ (8,001)	$ 1,623	$ (6,378)	$ (9,043)	$ 2,542	$ (6,501)
Prepaid and deferred income taxes, including excess tax benefits change	$ 2,077	$ (617)	$ 1,460	$ 3,130	$ (966)	$ 2,164

Note 17: Quarterly Financial Data - Unaudited

The following tables present the unaudited financial data for each of the interim periods in 2011 and 2010. Subsequent to the issuance of the unaudited consolidated financial statements for the quarter ended September 30, 2011, the Company discovered an under estimation of the rebate reserves that amounted to an increase to the reserves and a reduction to net sales for the year ended December 31, 2010. The previously presented unaudited consolidated quarterly financial statements for the interim periods in 2010 have been adjusted retrospectively. The Company's management believes the effects of these adjustments are not material to any of its previously issued consolidated financial statements.

	Quarter Ended			
	March 31	June 30	Sept. 30	Dec. 31
2011				
Total revenue	$ 71,471	$ 77,796	$ 76,458	$ 76,470
Gross profit	34,626	36,201	35,574	35,953
Net income	8,073	9,493	9,261	17,842
Net income per share:				
Basic	$ 0.59	$ 0.69	$ 0.66	$ 1.29
Diluted	$ 0.57	$ 0.67	$ 0.65	$ 1.26
2010 (restated)				
Total revenue	$ 63,723	$ 68,625	$ 75,482	$ 75,129
Gross profit	26,287	31,890	33,777	37,016
Net income	3,859	7,566	8,817	9,681
Net income per share:				
Basic	$ 0.28	$ 0.56	$ 0.65	$ 0.71
Diluted	$ 0.27	$ 0.55	$ 0.64	$ 0.70

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, 2011 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, 2011 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, Executive Officers and Corporate Governance.

The following table lists the names, ages, certain positions and offices held by our executive officers as of January 31, 2012.

	Age	Office Held
George A. Lopez, M.D.	64	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	39	Vice President of Product Development
Richard A. Costello	48	Vice President of Sales
Scott E. Lamb	49	Chief Financial Officer
Steven C. Riggs	53	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.

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 2012 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

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 *Executive 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 2012 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 2012 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

We have a 2011 Stock Incentive Plan under which we may grant restricted stock or options to purchase our common stock to our employees, directors and consultants. We had a 2001 Directors' Stock Option Plan under which we granted options to purchase our common stock to our directors, which plan expired in November 2011. We also had a 1993 Stock Incentive Plan and a 2003 Stock Option Plan, under which we granted options to purchase common stock to the employees, which plans expired in January 2005 and May 2011, respectively. We also have an Employee Stock Purchase Plan. All plans were approved by our stockholders. Further information about the plans is in Note 5 to the Consolidated Financial Statements. Certain information about the plans at December 31, 2011, 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)*
2,745,428	$ 33.28	1,168,553

*As of December 31, 2011, there were 381,853 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 2012 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

Item 14. Principal Accounting 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 2012 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

Exhibit Number	Description
3.1	Registrant's Certificate of Incorporation, as amended. (1)
3.2	Registrant's Bylaws, as amended and restated. (19)
10.1	Form of Indemnification Agreement with Directors and Executive Officers. (18)
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, 1997 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. (11)
10.15	Employment Agreement between Registrant and George A. Lopez, M.D. effective January 1, 2011. (22)*
10.16	Letter Agreement dated July 8, 2005 between Registrant and Hospira, Inc. re: Manufacturing, Commercialization and Development Agreement effective May 1, 2005. (12)
10.17	Settlement and Release Agreement dated as of January 2, 2007 between ICU Medical, Inc. and Fulwider Patton Lee & Utecht, LLP. (13)
10.18	Executive officer compensation.*
10.19	Non-employee director compensation.*
10.20	2008 Performance-Based Incentive Plan, as amended. (22)*
10.21	Amendment No. 1 to 2001 Director's Stock Plan. (16)*
10.22	Amendment No. 2 to 2001 Director's Stock Plan. (16)*
10.23	Amendment No. 3 to 2001 Director's Stock Plan. (16)*
10.24	Form of Executive Officer Retention Agreement. (17)*
10.25	Amended and Restated Retention Agreement between Registrant and Dr. George A. Lopez, dated November 3, 2010. (20)*
10.26	Schedule identifying parties to agreements with the Registrant substantially identical to the Form of Executive Officer Retention Agreement filed as Exhibit 10.25 hereto. (21)
10.27	Amendment 20 to the Supply and Distribution Agreement, effective as of November 30, 2011, between ICU Medical Sales, Inc. and Hospira, Inc. (24)
10.28	Third Amendment to the Co-Promotion and Distribution Agreement, effective as of November 30, 2011, between ICU Medical Sales, Inc. and Hospira, Inc. (24)
10.29	ICU Medical, Inc. 2011 Stock Incentive Plan. (23)*
14.1	Code of Business Conduct and Ethics for Directors and Officers. (15)
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.

*Executive compensation plan or other arrangement

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 filed June 18, 1998, and incorporated herein by reference.
(6)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 23, 1999, and incorporated herein by reference.
(7)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed 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 3, 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 filed February 5, 2009, and incorporated herein by reference.
(16)	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.
(17)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 4, 2010, and incorporated herein by reference.

(18)	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.
(19)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 19, 2010, and incorporated herein by reference.
(20)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed November 5, 2010, and incorporated herein by reference.
(21)	Filed as an Exhibit to Registrant's Annual Report on Form 10-K dated February 18, 2011, and incorporated herein by reference.
(22)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2011, and incorporated herein by reference.
(23)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed May 16, 2011, and incorporated herein by reference.
(24)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed December 22, 2011, and incorporated herein by reference.

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

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

Exhibit Index

EXHIBIT INDEX

10.18	Executive officer compensation
10.19	Non-employee director compensation
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

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

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands) Description	Balance at Beginning of Period	Additions		Write-off/ Disposals	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
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
For the year ended December 31, 2011:					
Allowance for doubtful accounts	$ 742	$ 551	$ —	$ —	$ 1,293

SIGNATURE

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: March 23, 2012

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)	March 23, 2012
/s/ Scott E. Lamb Scott E. Lamb	Chief Financial Officer (Principal Financial Officer)	March 23, 2012
/s/ Kevin J. McGrody Kevin J. McGrody	Controller (Principal Accounting Officer)	March 23, 2012
/s/ Jack W. Brown Jack W. Brown	Director	March 23, 2012
/s/ John J. Connors John J. Connors	Director	March 23, 2012
/s/ Michael T. Kovalchik, III, M.D. Michael T. Kovalchik, III, M.D.	Director	March 23, 2012
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	March 23, 2012
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	March 23, 2012
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	March 23, 2012

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

Board of Directors

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

Jack W. Brown
Former Chairman of the Board and President of Gish Biomedical, Inc., disposable medical devices for cardiovascular surgery and vascular access devices

John J. Connors
Patent Attorney, founder, Connors & Associates, founder of Connors & Associates PC, a professional law corporation specializing in intellectual property law

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 of Bolsa Resources, Inc., a business management consulting firm that provides both management consulting and financial accounting function support to manufacturing companies

Richard H. Sherman, M.D.
Physician in private practice with privileges in Internal Medicine and Cardiology at Bayhealth Medical Center, Milford, Delaware

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

Executive Management

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*
Chief Financial Officer, Secretary and Treasurer

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

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

icumedical

human connections

Corporate Headquarters:
951 Calle Amanacer
San Clemente, California 92673
T: 800.824.7890 | F: 949-366-8368
www.icumed.com