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, 2012 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, 2012, the last business day of registrant's most recently completed second fiscal quarter, was $674,123,796*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2013 was 14,467,594.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2013 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2012, are incorporated by reference into Part III of this Report.

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

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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 to prevent bloodstream infections and protect healthcare workers and patients from exposure to infectious diseases or hazardous drugs and monitoring 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
  - MicroClave/ MicroClave Clear
  - Anti-Microbial MicroClave
  - Neutron
  - Clave
  - NanoClave
  - Y-Clave
  - Anti-Microbial Clave
- Custom infusion sets

Critical Care

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

Oncology

- ChemoClave closed system transfer device including:
  - Genie closed vial access device
  - Spiros closed male luer
  - Vial and bag access devices
- Custom preparation and administration sets and accessories
- Diana hazardous drug compounding system

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 2012, 2011 and 2010 were $316.9 million, $302.2 million and $283.0 million, respectively. Hospira, our largest customer, accounted for 42%, 42% and 44% of our worldwide revenues in 2012, 2011 and 2010, respectively. Income from operations was $61.3 million, $65.2 million and $47.7 million in 2012, 2011 and 2010, respectively. Total assets were $428.5 million, $361.1 million and $309.6 million in 2012, 2011 and 2010, 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.

In 2001, 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 covering all of 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 on its website (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 Bloodstream Infection ("BSI") and has a high rate of patient morbidity and mortality. The Centers for Medicare Services discontinued payment for HAI that are a result of BSI in late 2008. The reported cost for treatment of a single BSI 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 BSI. Additionally, we believe that these important design features are not available in competitive products.

Clave Needlefree I.V. Technology

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 technology, instead of attaching a hollow-bore needle to the male luer, a needlefree connector with Clave technology 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 pre-slit 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 fluid path 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.

The NanoClave® is smaller than the MicroClave and is designed for use on neonatal and pediatric patients. The device has a clear housing and incorporates Clave technology into a smaller connector, allowing clinicians to flush the connector clear of blood with minimal flush volumes.

These Clave products are our largest selling product line, and accounted for $116.2 million, or 37%, of our revenue in 2012, $109.2 million, or 36%, of our revenue in 2011 and $98.2 million, or 35%, of our revenue in 2010. Additional information regarding Clave product sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

The Neutron™ catheter patency device also features Clave technology, but includes a bi-directional silicone valve that helps prevent blood reflux into a catheter to minimize the incidence of occlusion, or blocking of the catheter due to a blood clot. The Neutron was specifically designed to be used on patients receiving longer indwelling central I.V. lines.

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 $85.6 million, or 27%, of our revenue in 2012, $76.6 million, or 25%, of our revenue in 2011 and $75.6 million, or 27%, of our revenue in 2010. 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 oxygen levels 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, reduce the risk of I.V. line contamination and reduce blood waste for the patient.

CardioFlo Hemodynamic Monitoring Sensor System: CardioFlo is a minimally invasive monitoring sensor for use on critical care patients to deliver accurate and reliable hemodynamic monitoring data. CardioFlo can be used in conjunction with the SafeSet system.

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 of 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.

Central Venous Oximetry Catheters: Catheters used to measure central venous blood oxygen levels using fiber-optics. They may also permit administration of fluids and drugs, monitoring patient temperature and pressures and blood sampling.

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 $55.5 million, or 17%, of our revenue in 2012, $61.4 million, or 20%, of our revenue in 2011 and $63.6 million, or 23%, of our revenue in 2010. 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:

ChemoClave™ Needlefree Closed System Transfer Device: ChemoClave is a needlefree closed system transfer device for the safe handling of hazardous drugs. The components that make up the system include:

- *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.

Diana™ Hazardous Drug Compounding System: Diana is an automated sterile compounding system for the accurate, safe, and efficient preparation of hazardous drugs. It is a user-controlled automated system that provides repeatable accuracy of drug mixes, minimizes clinician exposure to hazardous drugs and reduces the risk of repetitive motion stresses for the clinician while helping to maintain the sterility of the drugs being mixed.

Additional oncology product offerings include:

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 a 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 $30.3 million, or 10%, of our revenue in 2012, $24.4 million, or 8%, of our revenue in 2011 and $18.3 million, or 6%, of our revenue in 2010. 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 $9.5 million, or 3%, of our revenue in 2012, $8.0 million, or 3%, of our revenue in 2011 and $4.3 million, or 2%, of our revenue in 2010. 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 2013 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, 2012, we employed 196 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 OEMs. 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. Our shipments from the United States are invoiced in U.S. dollars and our shipments in Europe are invoiced in Euros.

Domestic Sales

Domestic sales include U.S. sales to Hospira, other medical product manufacturers, domestic distributors and sales directly to the end customer. Domestic sales do not include Canada sales, which were previously classified as domestic sales but have been reclassified as international sales. Total domestic sales were $237.0 million, $224.5 million and $214.1 million in 2012, 2011 and 2010, 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 38% of our revenue in 2012. 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, 2012, we had 54 independent distributors in the United States which accounted for approximately 26% of our revenues in 2012. Distributors purchase and stock our products for resale to healthcare providers.

One distributor accounted for 6% of revenue in 2012. All other independent distributors accounted for less than 5% of revenue in 2012. Although the loss of one or more of our larger distributors could have an adverse effect 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 $79.9 million, $77.7 million and $68.9 million in 2012, 2011 and 2010, respectively.

International sales are primarily concentrated in Europe, Canada, Asia Pacific, Southeast Asia, Latin America, Africa and the Middle East. As of December 31, 2012, we had approximately 189 international distributors. Customers in Europe are served by our facilities in Slovakia, Italy and Germany. We serve the rest of the world from our facilities in the U.S. and Mexico. We have 26 business development personnel serving Europe and 14 serving Asia Pacific, Southeast Asia, Latin America, Africa, the Middle East and Canada.

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, 2012, 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 250,000 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.

Medicare has mandated that dialysis catheter use over the next several years be in the 10-12%% range or less in all dialysis units. This mandate has resulted in catheter use declining in dialysis units nationwide and may cause a decrease in sales of TEGO, our needlefree hemodialysis connector that creates a mechanically and microbiologically closed system when attached to the hub of a catheter.

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.

In the infusion therapy market, our present products compete with and our currently contemplated new products will likely 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 and B Braun. 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 with 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	12/2024-05/2028
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.

Research and Development

Our research and development costs include personnel costs and expenses related to the development of new products. Research and development costs were $10.6 million in 2012, $8.6 million in 2011 and $4.7 million in 2010.

Employees

At December 31, 2012, we had 2,239 full-time employees, consisting of 303 engaged in sales, marketing and administration and 1,913 in manufacturing, molding, product development and quality control, including 1,299 in Mexico and 169 in Slovakia.

Long-lived Assets

As of December 31, 2012, approximately $129.9 million of our gross long-lived assets were located in the United States. As of December 31, 2012, approximately $68.9 million of our gross long-lived assets, principally property and equipment, were located outside the United States: approximately $47.5 million in Mexico, $16.2 million in Slovakia, $5.0 million in Italy and $0.2 million in Germany. As of December 31, 2011, approximately $116.1 million of our gross long-lived assets were located in the United States. As of December 31, 2011, approximately $66.8 million of our gross 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 gross long-lived assets were located in the United States. As of December 31, 2010, approximately $64.9 million of the Company's gross 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.

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%, 42% and 44% of revenue for the years ended December 31, 2012, 2011 and 2010, 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 2012, production costs were approximately $101.8 million in Mexico and approximately $11.3 million in Slovakia. 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, 2012, we employed 1,299 people in operations in our plant in Ensenada, Mexico and 169 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 that became effective January 1, 2013 and is now being imposed on medical device manufacturers for the sale of certain medical devices to United States customers. 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 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. Our patents 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. 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, and 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 2013, we plan to convert existing warehouse space into manufacturing space and a new clean room at our Salt Lake City plant.

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 2012, Clave products accounted for approximately 37% of our revenue. We depend heavily on sales of Clave products, especially sales of Clave products to Hospira. Most of our 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 effect 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 2013. 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. We do not have "key person" life insurance policies on any of our 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 2010 through December 2012, our trading price ranged from a high of $63.32 per share to a low of $30.55 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 49% of our outstanding shares at the end of 2012. If one or more of the institutions or our other large stockholders 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, 2012 was 1,458,387 shares, or approximately 10% 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 250,000 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.

On May 11, 2012, a bench trial was held on RyMed's prosecution history estoppel defense. The parties have completed a post-trial briefing. Once the court rules on this defense, a further trial will be scheduled to determine the damages, if any, owed by RyMed to ICU Medical.

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:

2012	High	Low
First quarter	$ 49.57	$ 44.41
Second quarter	54.08	47.56
Third quarter	61.94	51.20
Fourth quarter	62.61	57.10

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

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, 2013, we had 80 stockholders of record and we believe we have approximately 9,000 beneficial owners of our common stock.

Issuer Repurchase of Equity Securities

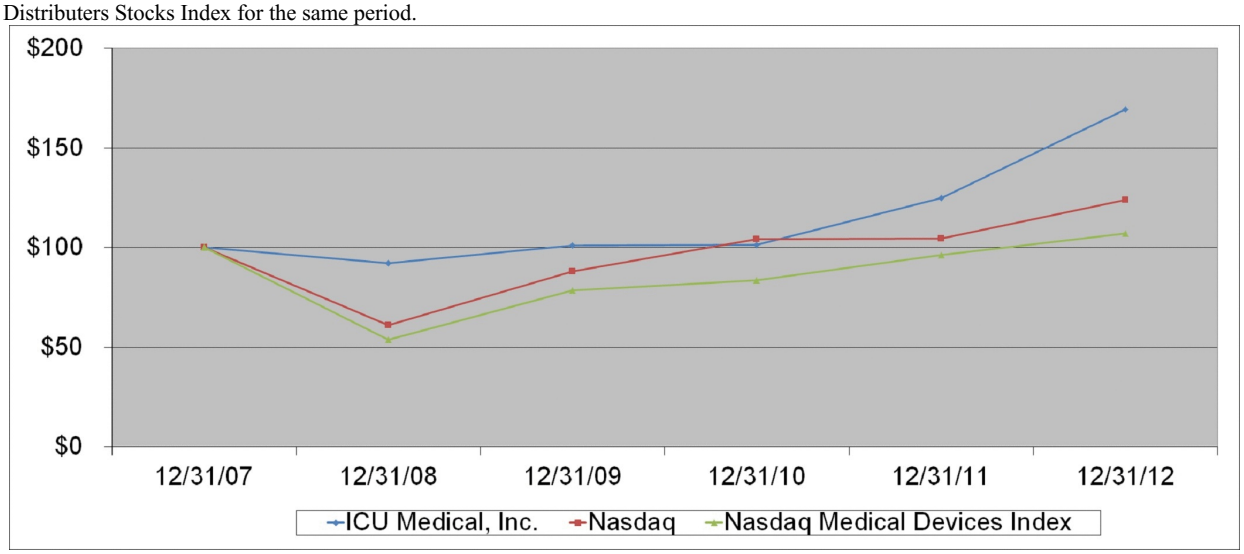
In July 2010, our Board of Directors approved a common stock purchase plan to purchase $40.0 million of our common stock. This plan has no expiration date.

The following is a summary of our stock repurchasing activity during the fourth quarter of 2012:

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
10/01/2012 - 10/31/2012	—	$ —	—	$ 28,089,000
11/01/2012 - 11/30/2012	—	$ —	—	28,089,000
12/01/2012 - 12/31/2012	—	$ —	—	28,089,000
Fourth quarter 2012 total	—	$ —	—	$ 28,089,000

COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1,2008 TO DECEMBER 31, 2012 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, 2007 to December 31, 2012 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.



	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012
ICU Medical, Inc.	$ 100.00	$ 92.03	$ 101.19	$ 101.36	$ 124.97	$ 169.20
Nasdaq	$ 100.00	$ 61.17	$ 87.93	$ 104.13	$ 104.69	$ 123.85
Nasdaq Medical Devices Index	$ 100.00	$ 53.85	$ 78.53	$ 83.75	$ 96.21	$ 107.11

Assumes $100 invested on December 31, 2007 in ICU Medical Inc.'s common stock, the NASDAQ U.S. Index and the Nasdaq Medical Devices, Instruments and Supplies, Manufacturers and Distributers Stocks Index and that all dividends, if any, were reinvested.

Item 6. Selected Financial Data.

ICU MEDICAL, INC.
SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2012	2011	2010	2009	2008
INCOME DATA:					
Revenue					
Net sales	$ 316,322	$ 301,642	$ 282,357	$ 228,431	$ 203,026
Other	547	553	602	540	1,700
Total revenue	316,869	302,195	282,959	228,971	204,726
Cost of goods sold	160,359	159,841	153,989	122,695	114,910
Gross profit	156,510	142,354	128,970	106,276	89,816
Selling, general and administrative expenses	84,604	85,287	76,636	68,205	53,611
Research and development expenses	10,630	8,588	4,678	2,645	4,822
Legal settlement	—	(2,500)	—	—	—
Gain on sale of assets	—	(14,242)	—	—	—
Total operating expenses	95,234	77,133	81,314	70,850	58,433
Income from operations	61,276	65,221	47,656	35,426	31,383
Other income	563	1,201	129	1,181	4,695
Income before income taxes	61,839	66,422	47,785	36,607	36,078
Provision for income taxes	(20,558)	(21,753)	(17,862)	(11,626)	(11,778)
Net income	$ 41,281	$ 44,669	$ 29,923	$ 24,981	$ 24,300
Net income per common share					
Basic	$ 2.90	$ 3.23	$ 2.20	$ 1.70	$ 1.72
Diluted	$ 2.80	$ 3.15	$ 2.16	$ 1.67	$ 1.67
Weighted average number of shares					
Basic	14,223	13,835	13,611	14,720	14,144
Diluted	14,725	14,161	13,855	14,984	14,565
Cash dividends per share	$ —	$ —	$ —	$ —	$ —
CASH FLOW DATA:					
Total cash flows from operations	$ 66,271	$ 64,487	$ 33,095	$ 51,139	$ 30,322

	As of December 31, (in thousands)				
	2012	2011	2010	2009	2008
BALANCE SHEET DATA:					
Cash, cash equivalents, restricted cash and current and long-term investment securities	$ 226,159	$ 159,985	$ 93,357	$ 108,135	$ 129,153
Working capital	$ 296,385	$ 231,098	$ 179,489	$ 172,666	$ 157,428
Total assets	$ 428,512	$ 361,112	$ 309,644	$ 307,577	$ 283,434
Stockholders' equity	$ 390,857	$ 320,577	$ 271,704	$ 263,429	$ 253,031

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

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion therapy, oncology and critical care applications. Our products improve patient outcomes by helping to prevent bloodstream infections and protect healthcare workers and patients from exposure to infectious diseases or hazardous drugs and monitoring 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 37% of our revenues in 2012.

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. We recently introduced the Neutron, a catheter patency device using Clave technology, the NanoClave, a smaller Clave product designed for neonatal and pediatric patients, CardioFlo Hemodynamic Monitoring Sensor System, a minimally invasive monitoring sensor for use on critical care patients and the Diana Hazardous Drug Compounding System, an automated sterile compounding system for preparing hazardous drugs. 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 covering 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
  - MicroClave/ MicroClave Clear
  - Anti-Microbial MicroClave
  - Neutron
  - Clave
  - NanoClave
  - Y-Clave
  - Anti-Microbial Clave
- Custom infusion sets

Critical Care

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

Oncology

- ChemoClave closed system transfer device including:
  - Genie closed vial access device
  - Spiros closed male luer
  - Vial and bag access devices
- Custom preparation and administration sets and accessories
- Diana hazardous drug compounding system

Other

- TEGO needlefree hemodialysis connector
- Lopez enteral valve

Our largest customer is Hospira. Hospira accounted for 42%, 42% and 44% of our worldwide revenues in 2012, 2011 and 2010, 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 to Hospira of Clave products, custom infusion sets, oncology products and new products 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, oncology products and our other products worldwide.

Revenues for 2012, 2011 and 2010 were $316.9 million, $302.2 million and $283.0 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 and oncology products. 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	**2012**	**2011**	**2010**
Clave products	37%	36%	35%
Custom infusion therapy	27%	25%	27%
Other infusion therapy	4%	5%	4%
Infusion therapy	**68%**	**66%**	**66%**
Critical care	**17%**	**20%**	**23%**
Oncology	**10%**	**8%**	**6%**
TEGO	3%	3%	2%
Other products/other revenue	2%	3%	3%
Other	**5%**	**6%**	**5%**
	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. In 2013, we plan to convert existing warehouse space into manufacturing space and a new clean room in our Salt Lake City plant. 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. We have reclassified 2011 and 2010 Canada sales as international, which were previously reported as domestic sales in both domestic medical product manufacturers and domestic distributors/direct channels. Product revenues for each distribution channel as a percentage of total channel product revenue were as follows:

Channel	**2012**	**2011**	**2010**
Medical product manufacturers	40%	39%	42%
Domestic distributors/direct sales	35%	35%	34%
International customers	25%	26%	24%
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.

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		
	2012	**2011**	**2010**
Revenue			
Net sales	100%	100 %	100%
Other	—%	— %	—%
Total revenues	100%	100 %	100%
Gross margin	49%	47 %	46%
Selling, general and administrative expenses	27%	28 %	27%
Research and development expenses	3%	3 %	2%
Legal settlement	—%	(1)%	—%
Gain on sale of assets	—%	(5)%	—%
Total operating expenses	30%	25 %	29%
Income from operations	19%	22 %	17%
Other income	—%	— %	—%
Income before income taxes	19%	22 %	17%
Income taxes	6%	7 %	6%
Net income	13%	15 %	11%

Comparison of 2012 to 2011

Revenues were $316.9 million in 2012, compared to $302.2 million in 2011.

Domestic sales: Net domestic sales in 2012 were $237.0 million, compared to net domestic sales of $224.5 million in 2011, an increase of 6%.

Net domestic sales to Hospira in 2012 were $121.1 million, an increase of $5.5 million, or 5%, from 2011. Infusion therapy sales increased $2.7 million, or 2%, from 2011 and oncology sales increased $2.7 million, or 46%, from 2011. Infusion therapy sales included a $0.9 million increase in sales of Clave products and a $1.7 million increase in sales of custom infusion sets. The increase in Clave product, custom infusion product and oncology sales was from higher unit sales due to conversion of products sold for needlefree connectors and increased market share through Hospira. We expect U.S. sales to Hospira in 2013 to be comparable to or slightly lower than 2012 due to Hospira's planned reduction in orders in the first quarter of 2013, with orders expected to resume to normal levels in the remaining three quarters of 2013, although there is no assurance that these expectations will be realized.

Net other domestic sales (excluding Hospira) in 2012 were $115.9 million, an increase of $7.0 million, or 6%, from 2011. Infusion therapy sales increased $8.7 million, or 18%, from 2011, which was primarily from a $4.5 million increase in Clave product sales and a $3.9 million increase in custom infusion set sales. Oncology sales increased $2.0 million, or 44% from 2011. Critical care sales decreased $4.4 million, or 10%, from 2011. The increased Clave, custom infusion set and oncology sales were primarily due to increased unit sales. The decrease in critical care sales was primarily from increased competition 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 2013 compared to 2012, primarily from higher infusion therapy and oncology sales, although there is no assurance that these expectations will be realized.

International sales: Net international sales in 2012 were $79.9 million, compared to net international sales of $77.7 million in 2011, an increase of 3%. Infusion therapy sales increased $5.0 million, or 12%, from 2011, which was primarily from a $3.4 million increase in custom infusion set sales and a $1.6 million increase in Clave product sales. Oncology sales increased $1.2 million, or 8%, from 2011. Critical care sales decreased by $1.4 million, or 9%, from 2011. Other product sales decreased by $2.6 million, or 39%, from 2011. The increases in infusion therapy and oncology were from increased unit sales from increased market share and demographic growth. The decrease in critical care sales was primarily due to increased competition and the decline of the Euro to U.S. dollar. The decrease in other product sales was primarily from the sale of the Orbit diabetes product line in 2011.

Geographically, our 2012 international sales were primarily in Europe, the Pacific Rim, Latin America, Canada and Africa. Sales in the Pacific Rim, Canada and Africa increased by $5.5 million and were offset by $3.3 million in lower European sales. The lower European sales in 2012 were impacted by a weak Euro. Our 2012 international sales were negatively impacted by approximately $3.6 million due to the decrease in the average exchange rate of the Euro to the U.S. dollar compared to 2011. We expect modest increases in international sales in 2013 compared to 2012 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 $215.3 million in 2012, an increase of $16.4 million, or 8%, from 2011. The increase from 2011 was primarily from $7.0 million in increased Clave product sales and $9.0 million in increased custom infusion set sales. 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 increased in all channels from higher unit sales. We expect modest increases in infusion therapy sales in 2013 compared to 2012, primarily from higher sales in Clave products and custom infusion set sales. There is no assurance, however, that these expectations will be realized.

Net critical care sales were $55.5 million in 2012, a decrease of $5.9 million, or 10%, from 2011. 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 2013 compared to 2012 from increased competition, although there is no assurance that these expectations will be realized.

Net oncology sales were $30.3 million in 2012, an increase of $5.9 million, or 24%, from 2011. The increase was from higher sales in all channels. The increased sales was from increased market share and demographic growth. We expect significant growth in oncology sales in 2013 compared to 2012, although there is no assurance that these expectations will be realized.

Other product sales were $15.3 million, a decrease of $1.6 million, or 10%, from 2011. The largest contributor to this change from 2011 was $2.1 million in lower Orbit sales, a product line that we sold in 2011, partially offset by $1.5 million in higher TEGO sales.

Other revenue consists of license, royalty and revenue share income and was approximately $0.5 million in 2012 and $0.6 million in 2011.

Gross margins for 2012 and 2011 were 49% and 47%, respectively. Our favorable product mix contributed to approximately one percentage point of the gross margin increase. Favorable exchange rates on the Mexican Peso contributed to approximately one-half of a percentage point of the gross margin increase. The remaining increase in the gross margin was due to plant efficiencies.

Selling, general and administrative expenses **("SG&A")** were $84.6 million, or 27%, of revenues in 2012, compared with $85.3 million, or 28%, of revenues in 2011. SG&A expenses for 2011 include one-time expenses for the Long-Term Retention Plan ("LTRP") of $2.0 million and compensation expense related to the sale of our Orbit diabetes infusion set

product line of $1.6 million. Our stock compensation expense increased $1.4 million, promotion costs increased $0.7 million, sales and marketing compensation and benefits increased $0.5 million and information technology ("IT") outside services and consulting costs increased by $1.1 million. Our legal expenses decreased $0.8 million. In January 2011, our Compensation Committee approved the pay out of the 2005 LTRP grants, determined to not make any future payments for the 2006 and 2007 awards, and determined that no additional awards would be made under the LTRP in the future, thus effectively cancelling the plan. The increase in sales and marketing compensation and benefits is primarily the result of the expansion of our sales and marketing workforce and compensation increases. The decrease in legal expenses is due to lower legal costs for patent litigation. We expect SG&A expenses in 2013 to be approximately 27% of revenue, although there is no assurance that these expectations will be realized.

Research and development expenses **("R&D")** were $10.6 million, or 3%, of revenue in 2012 compared to $8.6 million, or 3%, of revenue in 2011. The increase in R&D expenses was primarily from $1.7 million of higher project related R&D expenses supporting our infusion therapy, critical care and oncology market segments and $0.6 million in increased compensation and benefits from an expanded workforce, partially offset by the $0.3 million one-time expense for the LTRP payout in 2011. 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 2013 to be approximately 3% 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 $0.6 million in 2012 compared to $1.2 million in 2011. The decrease is primarily due to lower interest income and a small loss on disposal of assets in 2012 versus a gain on disposal of assets in 2011.

Income taxes were accrued at an estimated annual effective tax rate of 33.2% in 2012 compared to 32.7% in 2011. 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 34% in 2013.

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 $224.5 million, compared to net domestic sales of $214.1 million in 2010, an increase of $10.4 million, or 5%.

Net domestic sales to Hospira in 2011 were $115.6 million, an increase of $2.7 million, or 2%, from 2010. Infusion therapy sales increased $1.0 million from 2010, and oncology sales increased $2.2 million from 2010. Infusion therapy sales included a $6.3 million, or 9%, increase in sales of Clave products and a $5.7 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 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.

Net other domestic sales (excluding Hospira) in 2011 were $108.9 million, an increase of $7.7 million, or 8%, from 2010. Infusion therapy sales increased $5.5 million, or 13%, from 2010, which was primarily from a $3.7 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 $1.8 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. TEGO sales increased $3.2 million, or 133%, from 2010 from increased unit sales.

International sales: Net international sales were $77.7 million in 2011, compared to net international sales of $68.9 million in 2010, an increase of 13%. Infusion therapy sales increased $4.2 million, or 11%, from 2010, which was primarily

from a $3.4 million increase in custom infusion set sales and a $1.0 million increase in Clave product sales. Oncology sales increased $3.5 million, or 34%, from 2010. The increases in infusion therapy and oncology were from increased unit sales from increased market share and demographic growth.

Geographically, our 2011 and 2010 international sales were primarily in Europe, the Pacific Rim and Latin America. Our 2011 international sales were favorably impacted by a stronger Euro compared to 2010. This resulted in approximately $1.9 million increase in sales because the average exchange rate of the Euro to the U.S. dollar was higher in 2011 compared to 2010.

Sales by market segment and other revenue: Net infusion therapy sales were $198.9 million in 2011, 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.

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.

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.

Other product sales were $16.9 million, an increase of $4.6 million, or 37%, from 2010. The increase was primarily from $3.7 million in higher TEGO sales.

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 two percentage points 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.

***S*G&A** expenses 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 LTRP of $2.0 million, $1.6 million in compensation expense related to the sale of our Orbit diabetes infusion set product line, increases in 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 IT costs of $0.9 million, partially offset by $1.1 million in lower legal costs. 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.

R&D expenses 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 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.

Legal settlement income of $2.5 million was received in 2011. 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.

Liquidity and Capital Resources

During 2012, our cash, cash equivalents and investment securities increased by $66.2 million from $160.0 million at December 31, 2011 to $226.2 million at December 31, 2012.

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 changes in net income, accounts receivable, inventories and the timing of tax payments.

Our cash provided by operations was $66.3 million in 2012. Net income plus adjustments for non-cash net expenses contributed $68.6 million to cash provided by operations and was partially offset by a $2.4 million change in operating assets and liabilities. The $5.4 million increase in accounts receivable and the $4.6 million decrease in inventory were the largest changes in operating assets and liabilities. The increase in accounts receivable is primarily due to increased revenue in the fourth quarter of 2012 compared to the fourth quarter of 2011. The decrease in inventory is primarily from improved global supply chain management.

Investing Activities: Our cash used by investing activities was $41.4 million in 2012, which was primarily comprised of net investment purchases of $21.1 million and $19.2 million in capital purchases. Our property, plant and equipment purchases were primarily comprised of machinery, equipment and mold additions in the United States and investments in IT hardware and software.

While we can provide no assurances, we estimate that our capital expenditures in 2013 will approximate $30.0 million to $35.0 million. The large increase in expected capital expenditures is due to planned building improvements to prepare for anticipated capacity requirements beyond 2013. At our Salt Lake City, Utah plant, we plan to convert existing warehouse space into manufacturing space and a new clean room. We also anticipate making investments in molds, machinery and equipment in our manufacturing operations in the United States and Mexico to support new and existing products and in IT 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 $21.6 million in 2012 from stock option exercises, including tax benefits, and employee stock purchase plan purchases. Our employees purchased 587,044 shares of our common stock in 2012. The tax benefits from the exercise of stock options fluctuates based principally on when employees choose to exercise their vested stock options.

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 did not purchase any of our common stock in 2012. 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 of December 31, 2012, we have $15.6 million of cash and cash equivalents held outside of the United States, the majority of which is available to fund foreign operations and obligations.

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

Revenue recognition: We record sales and related costs when ownership of the product transfers to the customer, persuasive evidence of an arrangement exists, collectability is reasonably assured and the sales price is determinable. Under the terms of all our purchase orders, ownership transfers on shipment. If there are significant doubts at the time of shipment as to the collectability of the receivable, we defer recognition of the sale in revenue until the receivable is collected. Our customers are medical product manufacturers, distributors and end-users. Our only post-sale obligations are warranty and certain rebates. We warrant products against defects and have a policy permitting the return of defective products. We accrue for warranty and product returns based on historical experience. 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 customers 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 and reserve for slow moving items, and write off all items that we do not expect to use in manufacturing, and finished products that 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.

We are subject to income taxes throughout the United States and in numerous foreign jurisdictions. We recognize the financial statement benefits for uncertain tax positions as set forth in ASC 740 only if it is more-likely-than-not to be sustained in the event of challenges by relevant taxing authorities based on the technical merit of each tax position. The amounts of uncertain tax positions recognized are the largest benefits that have a greater than 50 percent likelihood of being realized upon settlement with the relevant tax authorities.

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.

Contractual Obligations

We have contractual obligations, at December 31, 2012, 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 $3.3 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)				
Contractual Obligations	**Total**	**2013**	**2014**	**2015**	**2016**
Operating leases	$ 706	$ 322	$ 170	$ 151	$ 63
Warehouse service agreements	844	553	291	—	—
Purchase obligations	14,574	14,574	—	—	—
	$ 16,124	$ 15,449	$ 461	$ 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; loss of a strategic relationship; change in demand; domestic and international 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 and multi-product contracts with large healthcare providers and major buying organizations; increases in systems capabilities; introduction, development 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; possibility of lengthier clearance process for new products; planned increases in marketing; warranty claims; rebates; product returns; bad debt expense; amortization 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; loss of larger distributors and the ability to locate other distributors; 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; design features of Clave products; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; patent protection and intellectual property landscape; patent infringement claims and the impact of newly issued patents on other medical devices; competitive and market factors, including continuing development of competing products by other manufacturers; improved production processes and higher volume production; innovation requirements; consolidation of the healthcare provider market and downward pressure on selling prices; distribution or financial capabilities of competitors; healthcare reform legislation; use 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; plans to convert existing space; 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.

Financial Market Risk

We had a portfolio of government bonds, corporate bonds and certificates of deposit of $79.3 million as of December 31, 2012. The securities are all "investment grade", comprised of $22.3 million of pre-refunded municipal securities, $1.5 million of non-pre-refunded municipal securities, $47.0 million in corporate bonds and $8.5 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 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 $0.5 million to investment income based on the average investment securities balance for the year ended December 31, 2012.

Foreign Exchange Risk

We have foreign currency exchange risk related to foreign-denominated cash, short-term investments, accounts receivable and accounts payable. In our European operations, our net Euro asset position at December 31, 2012 was approximately €12.8 million. We also have approximately €32.6 million in Euro denominated cash and investment accounts held by our corporate entity. 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, 2012 spot rate would impact our consolidated amounts on these balance sheet items by approximately $6.0 million, or 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.

Sales from the U.S. to foreign distributors are 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, although 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 2012 and our manufacturing spending from 2012 would have impacted our cost of goods sold by approximately $2.2 million.

Commodity Risk

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 2012 , a 10% increase to the price of resin would have resulted in approximately a $1.0 million change in material cost.

Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
ICU Medical, Inc.
San Clemente, CA

We have audited the accompanying consolidated balance sheets of ICU Medical, Inc. and subsidiaries (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. Our audits also included the financial statement schedules listed in the Index at Item 15. These consolidated financial statements and financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements and financial statement schedules 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of ICU Medical, Inc. and subsidiaries as of December 31, 2012 and 2011 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedules, 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.

We have also audited in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2013 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche, LLP

Costa Mesa, California
February 26, 2013

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except per share data)

	December 31,	
	2012	2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 146,900	$ 99,590
Investment securities	79,259	60,395
Cash, cash equivalents and investment securities	226,159	159,985
Accounts receivable, net of allowance for doubtful accounts of $998 and $1,293 at December 31, 2012 and 2011, respectively	49,127	43,571
Inventories	36,333	40,423
Prepaid income taxes	2,320	5,589
Prepaid expenses and other current assets	7,271	6,759
Deferred income taxes	4,293	4,081
Total current assets	325,503	260,408
PROPERTY AND EQUIPMENT, net	85,937	83,048
GOODWILL	1,478	1,478
INTANGIBLE ASSETS, net	9,952	11,419
DEFERRED INCOME TAXES	5,642	4,759
	$ 428,512	$ 361,112
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 11,308	$ 13,251
Accrued liabilities	17,810	16,059
Total current liabilities	29,118	29,310
DEFERRED INCOME TAXES	5,247	7,144
INCOME TAX LIABILITY	3,290	4,081
COMMITMENTS AND CONTINGENCIES	—	—
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, 2012 and 2011, outstanding 14,458 shares at December 31, 2012 and 13,871 shares at December 31, 2011	1,486	1,486
Additional paid-in capital	63,770	56,796
Treasury stock, at cost — 397 shares at December 31, 2012 and 984 shares at December 31, 2011	(15,128)	(35,348)
Retained earnings	342,158	300,877
Accumulated other comprehensive loss	(1,429)	(3,234)
Total stockholders' equity	390,857	320,577
	$ 428,512	$ 361,112

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)

	Year ended December 31,		
	2012	2011	2010
REVENUES:			
Net sales	$ 316,322	$ 301,642	$ 282,357
Other	547	553	602
TOTAL REVENUE	316,869	302,195	282,959
COST OF GOODS SOLD	160,359	159,841	153,989
Gross profit	156,510	142,354	128,970
OPERATING EXPENSES:			
Selling, general and administrative	84,604	85,287	76,636
Research and development	10,630	8,588	4,678
Legal settlement	—	(2,500)	—
Gain on sale of assets	—	(14,242)	—
Total operating expenses	95,234	77,133	81,314
Income from operations	61,276	65,221	47,656
OTHER INCOME	563	1,201	129
Income before income taxes	61,839	66,422	47,785
PROVISION FOR INCOME TAXES	(20,558)	(21,753)	(17,862)
NET INCOME	$ 41,281	$ 44,669	$ 29,923
NET INCOME PER SHARE			
Basic	$ 2.90	$ 3.23	$ 2.20
Diluted	$ 2.80	$ 3.15	$ 2.16
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	14,223	13,835	13,611
Diluted	14,725	14,161	13,855

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Amounts in thousands)

	Year ended December 31,		
	2012	2011	2010
Net income	$ 41,281	$ 44,669	$ 29,923
Other comprehensive income, net of tax of $281, $(578) and $(175) for the years ended December 31, 2012, 2011 and 2010, respectively:			
Foreign currency translation adjustment	1,805	(2,170)	(2,251)
Comprehensive income	$ 43,086	$ 42,499	$ 27,672

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Amounts in thousands)

	Common Stock					Accumulated	
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Retained Earnings	Other Comprehensive Income (Loss)	Total
Balance, December 31, 2009	**14,239**	**1,481**	**$ 54,357**	**$(19,881)**	**$226,285**	**$ 1,187**	**$263,429**
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
Foreign currency translation adjustment	—	—	—	—	—	(2,251)	(2,251)
Net income	—	—	—	—	29,923	—	29,923
Balance, December 31, 2010	**13,659**	**1,486**	**56,502**	**(41,428)**	**256,208**	**(1,064)**	**271,704**
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	—	—	224	—	—	—	224
Foreign currency translation adjustment	—	—	—	—	—	(2,170)	(2,170)
Net income	—	—	—	—	44,669	—	44,669
Balance, December 31, 2011	**13,871**	**1,486**	**56,796**	**(35,348)**	**300,877**	**(3,234)**	**320,577**
Exercise of stock options, including excess income tax benefits of $4,567	526	—	1,348	18,063	—	—	19,411
Proceeds from employee stock purchase plan	61	—	63	2,157	—	—	2,220
Stock compensation	—	—	5,563	—	—	—	5,563
Foreign currency translation adjustment	—	—	—	—	—	1,805	1,805
Net income	—	—	—	—	41,281	—	41,281
Balance, December 31, 2012	**14,458**	**1,486**	**$ 63,770**	**$(15,128)**	**$342,158**	**$ (1,429)**	**$390,857**

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)

	Year ended December 31,		
	2012	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 41,281	$ 44,669	$ 29,923
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	19,001	18,294	17,345
Provision for doubtful accounts	(237)	648	443
Provision for warranty and returns	220	—	—
Stock compensation	5,563	4,016	3,471
Loss (gain) on disposal of property and equipment	212	(42)	338
Gain on sale of assets	—	(14,242)	—
Bond premium amortization	2,585	1,294	1,092
Changes in operating assets and liabilities:			
Accounts receivable	(5,395)	6,232	(6,378)
Inventories	4,573	3,170	(3,670)
Prepaid expenses and other assets	(415)	(920)	(2,518)
Accounts payable	(1,536)	2,673	(8,222)
Accrued liabilities	1,199	1,684	1,946
Deferred revenue	—	(254)	(2,135)
Income taxes, including excess tax benefits and deferred income taxes	(780)	(2,735)	1,460
Net cash provided by operating activities	66,271	64,487	33,095
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(19,160)	(15,824)	(23,171)
Proceeds from sale of assets	10	16,201	893
Proceeds from insurance	—	2,781	622
Intangible asset additions	(1,145)	—	—
Purchases of investment securities	(98,876)	(90,502)	(23,382)
Proceeds from sale of investment securities	77,798	41,610	64,670
Net cash provided (used) by investing activities	(41,373)	(45,734)	19,632
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	14,844	7,974	2,517
Proceeds from employee stock purchase plan	2,220	1,828	1,576
Tax benefits from exercise of stock options	4,567	4,288	1,680
Purchase of treasury stock	—	(11,956)	(28,648)
Net cash provided (used) by financing activities	21,631	2,134	(22,875)
Effect of exchange rate changes on cash	781	(147)	(2,250)
NET INCREASE IN CASH AND CASH EQUIVALENTS	47,310	20,740	27,602
CASH AND CASH EQUIVALENTS, beginning of period	99,590	78,850	51,248
CASH AND CASH EQUIVALENTS, end of period	$ 146,900	$ 99,590	$ 78,850
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the year for income taxes	$ 16,741	$ 20,110	$ 15,249
NON-CASH INVESTING ACTIVITIES			
Accrued liabilities for property and equipment	$ 427	$ 418	$ 716

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

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2012, 2011 and 2010
(Amounts in tables in thousands, except share and per share data)

Note 1: General and Summary of Significant Accounting Policies

a. Description of Business/Basis of Presentation

ICU Medical, Inc., 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. Our devices are sold directly or to distributors and medical product manufacturers throughout the United States and internationally. The manufacturing for all product groups occurs in Salt Lake City, Slovakia and Mexico. Assets and operating expenses are not allocated to individual product groups.

All subsidiaries are wholly owned and are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated.

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

Certain prior period amounts have been reclassified to conform to the current period presentation. Beginning in 2012, our Canada sales, previously classified as domestic sales, are classified as international sales.

b. Cash and Cash Equivalents

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

c. 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. We consider 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. We regularly review individual past due balances for collectability.

d. 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:

	2012	2011
Raw material	$ 20,808	$ 25,227
Work in process	3,013	2,901
Finished goods	12,512	12,295
Total	$ 36,333	$ 40,423

e. Property and Equipment

Property and equipment consist of the following at December 31:

	2012	2011
Machinery and equipment	$ 78,332	$ 73,390
Land, building and building improvements	61,521	60,334
Molds	27,704	24,133
Computer equipment and software	19,611	17,518
Furniture and fixtures	3,339	2,298
Construction in progress	8,266	5,277
Total property and equipment, cost	198,773	182,950
Accumulated depreciation	(112,836)	(99,902)
Net property and equipment	$ 85,937	$ 83,048

All property and equipment are stated at cost. We use 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

We capitalize 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 $16.4 million, $15.6 million and $14.6 million in the years ended December 31, 2012, 2011 and 2010, respectively.

The cost of property and equipment are presented net of government incentive reimbursements we received from the Slovakian government for building a manufacturing plant in their country. Government incentives recorded in property and equipment were $3.5 million at December 31, 2012 and December 31, 2011.

f. Goodwill

We test 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 were no goodwill additions or impairment charges in the years ended December 31, 2012 and 2011.

g. 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, 2012		
		Cost	Accumulated Amortization	Net
Patents	9	$ 10,287	$ 5,350	$ 4,937
MCDA contract *	10	8,571	6,571	2,000
Customer contracts	9	5,319	2,317	3,002
Trademarks	4	425	412	13
Total		$ 24,602	$ 14,650	$ 9,952

	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

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

Amortization expense in 2012, 2011 and 2010 was $2.6 million, $2.7 million and $2.8 million, respectively. Estimated annual amortization for each of the next five years is approximately $2.5 million for 2013, $2.3 million for 2014, $1.6 million for 2015, $1.0 million for 2016 and $0.9 million for 2017.

h. Long-Lived Assets

We periodically evaluate 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.

i. Investment Securities

Our investment securities, which are carried at fair market value and are considered available-for-sale, consist principally of certificates of deposits, corporate bonds and tax-exempt state and municipal government debt. 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. Our 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, our 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 we have 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.

j. Income Taxes

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.

We recognize interest and penalties related to unrecognized tax benefits in the tax provision. We recognize 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. We have not recorded any material interest or penalties during any of the years presented.

The deduction we receive from indirect tax benefits from the exercise of stock options, such as those recognized for research and development credits and domestic production activities deductions, is recorded as a reduction to the tax provision. The direct tax benefits of share based compensation are recorded through additional-paid-in capital.

k. Foreign Currency

We have operations in Europe where the functional currency is the Euro. Assets and liabilities are translated to U.S. dollars at the exchange rate in effect at the balance sheet date and revenues and expenses are translated at the average monthly exchange rates during the year. Translation adjustments are recorded as a component of accumulated other comprehensive income, a separate component of stockholders' equity on our consolidated balance sheets and the effect of exchange rate changes on cash and cash equivalents are reflected on our consolidated statements of cash flows. Gains and losses for transactions denominated in a currency other than the functional currency of the entity are included in our statements of operations. Foreign currency transaction gains and losses were less than $0.1 million in 2012, 2011 and 2010.

l. Revenue Recognition

All of our product sales are FOB shipping point and ownership of the product transfers to the customer on shipment. 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. Our customers are distributors, medical product manufacturers 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 reserve for warranty and returns based on historical experience. We accrue rebates based on agreements and on historical experience as a reduction in revenue at the time of sale.

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 to ship finished goods to our customers are included in cost of goods sold on the consolidated statements of income.

n. Advertising Expenses

Advertising expenses are expensed as incurred and were $0.2 million in 2012, $0.1 million in 2011 and $0.1 million in 2010.

o. Post-retirement and Post-employment Benefits

We do not provide retirement or post-employment benefits to employees other than our Section 401(k) retirement plan for employees. Our contributions to the plan were approximately $1.3 million in 2012, $1.2 million in 2011 and $1.1 million in 2010.

p. Research and Development

Research and development costs are expensed as incurred.

q. 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 7,000 shares in 2012, 217,000 shares in 2011 and 524,000 shares in 2010.

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

	Year ended December 31, (in thousands, except per share data)		
	2012	2011	2010
Net income	$ 41,281	$ 44,669	$ 29,923
Weighted average number of common shares outstanding (basic)	14,223	13,835	13,611
Dilutive securities	502	326	244
Weighted average common and common equivalent shares outstanding (diluted)	14,725	14,161	13,855
EPS - basic	$ 2.90	$ 3.23	$ 2.20
EPS - diluted	$ 2.80	$ 3.15	$ 2.16

r. Accounting Estimates

Preparing 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.

s. New Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update number 2011-05, Comprehensive Income (Topic 220) — Presentation of Comprehensive Income ("ASU 2011-05"), to require an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of equity. In December 2011, the FASB issued ASU No. 2011-12, Comprehensive Income (Topic 220) – Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU 2011-05 ("ASU 2011-12"), which defers the effective date of those changes in ASU 2011-05 that relate to the presentation of reclassification adjustments. We adopted these ASUs using two consecutive statements beginning in 2012 and have applied prospectively for all periods presented.

Note 2: Share Based Awards

We have 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.

We incur stock compensation expense for stock options, restricted stock units ("RSU"), performance restricted stock units ("PRSU") and stock purchased under our employee stock purchase plan ("ESPP"). We receive a tax benefit on stock compensation expense, excluding the direct tax benefits from exercise of stock options, which is reported separately on the consolidated statements of cash flows. We also have indirect tax benefits upon exercise of stock options related to research and development tax credits which were recorded as a reduction of income tax expense. The table below summarizes compensation costs and related tax benefits for the years ended December 31, 2012, 2011 and 2010.

	Year ended December 31,		
	2012	2011	2010
Stock compensation expense	$ 5,563	$ 4,016	$ 3,471
Tax benefit from stock-based compensation cost	1,922	1,376	1,153
Indirect tax benefit	209	785	438

As of December 31, 2012, we had $6.5 million of unamortized stock compensation cost which we will recognize as an expense over approximately 1.25 years.

Stock Incentive and Stock Option Plans

Our 2011 Stock Incentive Plan ("2011 Plan") replaced our 2003 Stock Option Plan (“2003 Plan”). Our 2011 Plan initially had 650,000 shares available for issuance, plus the remaining available shares for grant from the 2003 Plan. In 2012, our stockholders approved an amendment to the 2011 plan that increased the shares available for issuance by 750,000, bringing the initial shares available for issuance to 1,400,000, plus the remaining 248,700 shares that remained available 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, 2012, the 2011 Plan has 1,650,363 shares of common stock reserved for issuance to employees, which includes 250,363 shares that transferred from the 2003 Plan. Shares issued as options or stock appreciation rights ("SARs") are charged against the 2011 Plan's share reserve as one share for one share issued. Shares subject to awards other than options and SARs are charged against the 2011 Plan's share reserve as 2.09 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, we are 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; we are generally not entitled to any tax deduction on the exercise of an incentive stock option. The 2011 Plan includes conditions whereby unvested options are cancelled if employment is terminated.

Our 2001 Directors’ Stock Option Plan (the “Directors’ Plan”), initially had 750,000 shares reserved for issuance to members of our 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.

Stock Options

To date, all options granted under the 2011 Plan, 2003 Plan and Directors' Plan have been non-statutory stock options. The majority of the employee option grants become exercisable five years from the grant date or 25% becomes exercisable after one year from the grant date and the balance vests ratably on a monthly basis over 36 months. The options granted to non-employee directors generally vest one to four years from the grant date. The options generally expire 10 years from the grant date.

The fair value of option grants is calculated using the Black-Scholes option valuation model. The expected term for the 2012 and 2011 option grants was based on historical experience, expected future employee behavior and the Staff Accounting Bulletin #107 simplified method. The expected term for the 2010 option grants was based on expected future employee behavior. We refined our assumptions on our 2011 grants. Our revised assumptions are in the table below. We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock, based on the average expected exercise term. The table below summarizes the total stock options granted, total valuation and the weighted average assumptions for the years ended December 31, 2012, 2011 and 2010.

	Year ended December 31,		
	2012	2011	2010
Number of options granted	228,328	290,000	243,000
Grant date fair value of options granted (in thousands)	$ 3,158	$ 4,090	$ 2,474
Weighted average assumptions for stock option valuation:			
Expected term (years)	4.7	5.0	3.4
Expected stock price volatility	33.6%	34.5%	40.2%
Risk-free interest rate	0.7%	1.7%	0.8%
Expected dividend yield	—%	—%	—%
Weighted average grant price per option	$ 47.12	$ 43.27	$ 34.70
Weighted average grant date fair value per option	$ 13.83	$ 14.10	$ 10.18

A summary of our stock option activity as of and for the year ended December 31, 2012 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2011	2,745,428	$ 33.28		
Granted	228,328	$ 47.12		
Exercised	(526,040)	$ 28.22		
Forfeited or expired	(2,963)	$ 34.12		
Outstanding at December 31, 2012	2,444,753	$ 35.66	4.7	$ 61,778
Exercisable at December 31, 2012	1,670,325	$ 34.66	3.5	$ 43,873
Vested or expected to vest, December 31, 2012	2,444,753	$ 35.66	4.7	$ 61,778

The intrinsic value for options exercisable, outstanding and vested or expected to vest at December 31, 2012 is based on our closing stock price of $60.93 at December 31, 2012 and are before applicable taxes.

	Year ended December 31,		
	2012	2011	2010
Intrinsic value of options exercised	$ 12,211	$ 11,451	$ 4,422
Cash received from exercise of stock options	$ 14,844	$ 7,974	$ 2,517
Tax benefit from stock option exercises	$ 4,567	$ 4,288	$ 1,680

Stock Awards

In 2012, we began awarding PRSUs to our executive officers and RSUs to our Board of Directors. PRSUs are awarded to our executive officers to receive shares of common stock if the measurement period goal is met. The executive PRSUs are based on a one-year market condition performance period measured against a total shareholder return metric ("TSR"). If the TSR is less than the 33rd percentile of our peer group index, 0% of the award would be earned. If the TSR is equal or greater than the 33rd percentile and less than the 50th percentile of our peer group companies, 50% of the award would be earned. If the TSR is equal or greater than the 50th percentile and less than the 75th percentile of our peer group companies, 100% of the award will be earned. If the TSR is equal or greater than the 75th percentile of our peer group companies, 200% of the award will be earned. The PRSUs vest in equal yearly installments with one-third of the grant becoming vested on each of the three anniversary dates of the award. Our executive officers earned 200% of their 2012 award because the TSR was above the 75th percentile of our peer companies.

The fair value of the PRSUs is calculated using a Monte Carlo simulation embedded in a lattice model. This calculation used a risk-free interest rate of 0.13%, a closing share price of $46.53, assumed no dividends and assumed no forfeitures. The correlation matrix of stock price returns and volatilities were calculated based on one year preceding January 1, 2012.

In 2012, we granted 15,589 PRSUs in 2012 at a fair value of $43.60 per unit. Our executive officers earned 200% of the PRSUs granted, bringing the total PRSUs granted to 31,178 units. We granted 6,132 RSUs to our Board of Directors which vest on the first anniversary of the grant date. The fair value of the RSUs is based on the stock price on the date of the grant, or $53.81 per unit in 2012.

The table below provides a summary of our PRSU and RSU activity as of and for the year ended December 31, 2012. The number of units granted are adjusted to reflect the PRSUs awards at 200% of their original amounts.

	Number of Units	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Non-vested at December 31, 2011	—		
Granted	37,310		
Vested	—		
Forfeited	—		
Non-vested and expected to vest at December 31, 2012	37,310	1.0	$ 2,273

ESPP

We have 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. As of December 31, 2012, there were 320,849 shares available for future issuance. The ESPP is intended to constitute an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. As of December 31, 2012, we had less than $0.1 million of unamortized stock compensation expense from the ESPP which will be recognized in the first quarter of 2013.

The fair value of rights to purchase shares under the ESPP is calculated using the Black-Scholes option valuation model. The table below summarizes the number and intrinsic value of ESPP share purchases and the weighted average valuation assumptions for the 2012, 2011 and 2010 purchase periods.

	Year ended December 31,		
	2012	2011	2010
ESPP shares purchased by employees	61,004	57,643	53,739
Intrinsic value of ESPP purchases (in thousands)	$ 913	$ 530	$ 278
Weighted average assumptions for ESPP valuation:			
Expected term (in years)	0.5	0.5	0.5
Expected stock price volatility	23.6%	26.0%	26.5%
Risk-free interest rate	0.1%	0.4%	0.2%
Expected dividend yield	—%	—%	—%

Note 3: Fair Value Measurement

Our investment securities consist of certificates of deposit, corporate bonds and federal tax-exempt state and municipal government debt. 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. As of December 31, 2012, we have $8.5 million of investment securities as Level 1 assets, which are certificates of deposit with quoted prices in active markets. As of December 31, 2012, we have $70.8 million of investment securities as Level 2 assets, which are pre-refunded municipal securities, non-pre-refunded municipal securities and corporate 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, 2012 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	$ 79,259	$ 8,490	$ 70,769	$ —
	$ 79,259	$ 8,490	$ 70,769	$ —

	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	$ —

Note 4: Investment Securities

Our investment securities consist of certificates of deposit, corporate bonds and federal-tax-exempt state and municipal government debt. 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 our consolidated balance sheets. We have no gross unrealized gains or losses on available-for-sale securities at December 31, 2012 or 2011. Balances consist of the following at December 31:

	2012	2011
Federal tax-exempt debt securities	$ 23,732	$ 39,745
Corporate bonds	47,037	13,263
Sovereign bonds	—	1,928
Certificates of deposit	8,490	5,459
	$ 79,259	$ 60,395

The scheduled maturities of the debt securities are between 2013 and 2043 and are all callable within one year.

Investment income consisted of the following for each year:

	2012	2011	2010
Corporate dividends	$ 4	$ 15	$ —
Tax-exempt interest	74	103	58
Other interest	219	358	77
	$ 297	$ 476	$ 135

Note 5: Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2012	2011
Salaries and benefits	$ 8,444	$ 7,642
Incentive compensation	4,210	3,627
Value Added Tax accrual	1,064	1,114
Other	4,092	3,676
	$ 17,810	$ 16,059

Note 6: Income Taxes

Income from continuing operations before taxes for the years ended December 31, 2012, 2011 and 2010 is as follows:

	2012	2011	2010
United States	$ 62,204	$ 63,575	$ 46,669
Foreign	(365)	2,847	1,116
	$ 61,839	$ 66,422	$ 47,785

The provision (benefit) for income taxes for the years ended December 31, 2012, 2011 and 2010 is as follows:

	2012	2011	2010
Current:			
Federal	$ 21,072	$ 19,246	$ 15,331
State	2,080	1,246	1,200
Foreign	678	785	1,109
	23,830	21,277	17,640
Deferred:			
Federal	$ (2,276)	$ 169	$ (781)
State	(796)	326	439
Foreign	(200)	(19)	564
	(3,272)	476	222
	$ 20,558	$ 21,753	$ 17,862

Current income taxes payable were reduced from the amounts in the above table by $4.6 million, $4.3 million and $1.7 million in 2012, 2011 and 2010, respectively, equal to the direct tax benefit that we receive upon exercise of stock options by employees and directors. That benefit is allocated to stockholders' equity. We have accrued for tax contingencies for potential tax assessments, and in 2012 we recognized a $0.7 million net decrease of accruals most of which relates to various federal, state and foreign tax reserves.

Reconciliations of the provision for income taxes at the statutory rate to our effective tax rate for the years ended December 31, 2012, 2011 and 2010 are as follows:

	2012		2011		2010	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ 21,644	35.0 %	$ 23,247	35.0 %	$ 16,724	35.0 %
State income tax, net of federal effect	1,356	2.2 %	1,460	2.2 %	1,007	2.1 %
Tax credits	(1,465)	(2.4)%	(1,171)	(1.8)%	(121)	(0.3)%
Tax-exempt interest and dividends	(23)	(0.1)%	(45)	(0.1)%	(33)	(0.1)%
Domestic production activities/other	(1,559)	(2.5)%	(1,508)	(2.3)%	(997)	(2.0)%
Foreign income tax	605	1.0 %	(230)	(0.3)%	1,282	2.7 %
	$ 20,558	33.2 %	$ 21,753	32.7 %	$ 17,862	37.4 %

Tax credits in 2012, 2011 and 2010 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 our deferred income tax provision for the years ended December 31, 2012, 2011 and 2010 are as follows:

	2012	2011	2010
Allowance for doubtful accounts	$ (59)	$ (24)	$ (66)
Inventory reserves	143	1,147	(1,137)
Accruals	(2,375)	(464)	(1,792)
State income taxes	177	(7)	(290)
Acquired future tax deductions	50	293	300
Depreciation and amortization	(700)	(205)	2,820
Tax credits	(508)	(264)	387
	$ (3,272)	$ 476	$ 222

The components of our deferred income tax assets (liabilities) at December 31, 2012 and 2011 are as follows:

	2012	2011
Current deferred tax assets:		
State income taxes	$ 437	$ 343
Foreign	400	429
Accruals/other	1,881	1,377
Tax credits	441	452
Allowance for doubtful accounts	101	102
Inventory reserves	1,247	1,378
Current deferred tax asset before valuation allowance	$ 4,507	$ 4,081
Valuation allowance	(214)	—
	4,293	4,081
Non-current deferred tax asset:		
Foreign	$ 983	$ 526
Accruals/other	536	347
Depreciation and amortization	(458)	(523)
Tax credits state	4,927	4,409
Non-current deferred tax asset before valuation allowance	$ 5,988	$ 4,759
Valuation allowance	$ (346)	$ —
	$ 5,642	$ 4,759
Non-current deferred tax liability:		
State income taxes	$ (1,751)	$ (1,481)
Foreign	(2,301)	(2,633)
Accruals/other	(186)	(186)
Depreciation and amortization	(6,429)	(6,862)
Acquired future tax deductions	(515)	(460)
Stock-based compensation	5,581	3,843
Foreign currency translation adjustments	354	635
	$ (5,247)	$ (7,144)

Acquired future tax deductions are the tax benefits included in our consolidated income tax returns originating in Bio-Plexus, Inc., an entity purchased in 2002, prior to when we acquired the entity. They consist of: (a) the net tax benefit of items expensed for financial statement purposes but capitalized and amortized for tax purposes and (b) the tax benefited portion of Bio-Plexus's NOL carry-forward which will be realized in approximately equal amounts over the next 11 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.

We have tax credits that we expect to utilize in future periods that may be carried forward indefinitely.

Our Mexican subsidiary has a deferred tax liability of $2.3 million at December 31, 2012, 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.

The realization of deferred tax assets is dependent on generating sufficient foreign taxable income in the years that the temporary difference becomes deductible. A valuation allowance related to a foreign tax loss carry-forward has been provided for the portion of the deferred tax assets that we determined is more likely than not to remain unrealized based on estimated future taxable income and tax planning strategies. A valuation allowance of $0.6 million was recorded against its gross deferred tax asset balance as of December 31, 2012. For the year ended December 31, 2012, we recorded a net valuation allowance increase of $0.6 million, on the basis of management's reassessment of the amount of its deferred tax assets that are more likely than not to be realized.

Our estimate of undistributed earnings of our foreign subsidiaries for which no federal or state liability has been recorded cumulatively totaled $13.5 million at December 31, 2012 and $14.0 million at December 31, 2011. These undistributed earnings are considered to be indefinitely reinvested. However, if unanticipated distribution of those earnings were to occur 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. In the event that our position in this regard changes, determining 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.

We are subject to taxation in the United States and various states and foreign jurisdictions. Our United States federal income tax returns for tax years since 2010 are subject to examination by the Internal Revenue Service. Our 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, 2012 was $4.2 million that, if recognized, would impact the effective tax rate. We do 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 2012, 2011 and 2010 :

	2012	2011	2010
Beginning balance	$ 4,978	$ 4,411	$ 5,306
Increases (decreases) to prior year tax positions	156	494	(649)
Increases to current year tax positions	490	764	518
Decrease related to settlements	(230)	(392)	(764)
Decrease related to lapse of statute of limitations	(1,158)	(299)	—
Ending balance	$ 4,236	$ 4,978	$ 4,411

Note 7: Products, Major Customers and Concentrations of Credit Risks

Our primary product groups are infusion therapy, critical care, oncology and other. Infusion therapy products accounted for $215.3 million, $198.9 million and $188.1 million of revenues in 2012, 2011 and 2010, respectively. Critical care products accounted for $55.5 million, $61.4 million and $63.6 million of revenues in 2012, 2011 and 2010, respectively. Oncology products accounted for $30.3 million, $24.4 million and $18.3 million of revenues in 2012, 2011 and 2010, respectively. Other products accounted for $15.8 million, $17.5 million and $13.0 million of revenues in 2012, 2011 and 2010, respectively.

We sell products worldwide, 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 our products to healthcare providers. For the years ended December 31, 2012, 2011 and 2010, we had worldwide sales to one manufacturer, Hospira, of 42%, 42% and 44%, respectively, of consolidated revenue. As of December 31, 2012, and 2011, we had accounts receivable from Hospira of 35% and 36%, respectively, of consolidated accounts receivable.

Domestic sales accounted for 75%, 74% and 76% of total revenue in 2012, 2011 and 2010, respectively. International sales, which are determined by the destination of the product shipment, accounted for 25%, 26% and 24% of total revenue in 2012, 2011 and 2010, respectively.

As of December 31, 2012, approximately $129.9 million of our gross long-lived assets were located in the United States. As of December 31, 2012, approximately $68.9 million of our gross long-lived assets, principally property and equipment, were located outside the United States: approximately $47.5 million in Mexico, $16.2 million in Slovakia, $5.0 million in Italy and $0.2 million in Germany. As of December 31, 2011, approximately $116.1 million of our gross long-lived assets were located in the United States. As of December 31, 2011, approximately $66.8 million of our gross 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.

Note 8: Operating Leases

We lease a building in Ludenscheid, Germany which expires December 31, 2013 and have an option to extend the term. We also lease various office equipment with expiration dates ranging from 2013 to 2016. Our lease expense was $0.2 million in 2012, $0.2 million in 2011 and $0.2 million in 2010. Our annual minimum future lease payments are $0.3 million in 2013, $0.2 million in 2014, $0.2 million in 2015 and $0.1 million in 2016.

Note 9: Sale of Assets

Our management and Board of Directors made the decision to sell our Orbit diabetes infusion set product line so that our operations could focus on our 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 Statement of Income for the year ended December 31, 2011.

Note 10: Legal Settlement

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

Note 11: Exit Activity from Italy and Germany Facilities

In 2011, our new plant in Slovakia became our European product distribution facility. Product assembly previously done in our Italy and Germany facilities transferred to our Slovakia plant. As a result of this, we had termination costs to certain manufacturing and operations employees from our Italy facility. The product assembly transition from our Italy plant to the Slovakia plant was completed in March 2011. Our Italy facility continues to support sales in Europe. The product assembly transition from our Germany plant to the Slovakia plant was completed in the third quarter of 2011. Our Germany facility continues 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, we 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. There was $0.1 million accrued for these exit activities at December 31, 2011. There are no exit costs obligations remaining at December 31, 2012.

Note 12: Treasury Stock

In July 2010, our Board of Directors approved a common stock purchase plan to purchase up to $40.0 million of our common stock. This plan has no expiration date and we have $28.1 million remaining on this purchase plan. We did not repurchase any of our common stock in the year ended December 31, 2012. We expect 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, our Board of Directors adopted a Stockholder Rights Plan. This plan expired in 2007 and in July 2007, our Board of Directors adopted an Amended and Restated Rights Agreement. We distributed a Preferred Share Purchase Right (a "Right") for each share of our Common Stock outstanding. The Rights generally will not be exercisable until a person or group has acquired 15% or more of our 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 our 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 our 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 we 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.

Our 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: Commitments and Contingencies

From time to time, we are involved in various other legal proceedings, most of which are routine litigation, in the normal course of business. Our management does not believe that the resolution of the other legal proceedings that we are involved with will have a material adverse impact on our financial position or results of operations.

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. We have never incurred, nor do we expect to incur, any liability for indemnification.

Note 15: Quarterly Financial Data - Unaudited

	Quarter Ended			
	March 31	June 30	Sept. 30	Dec. 31
2012				
Total revenue	$ 75,511	$ 77,281	$ 81,405	$ 82,672
Gross profit	34,965	39,082	40,695	41,768
Net income	7,601	9,149	12,188	12,343
Net income per share:				
Basic	$ 0.54	$ 0.65	$ 0.85	$ 0.86
Diluted	$ 0.53	$ 0.63	$ 0.82	$ 0.82
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

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, 2012 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, 2012 financial statements included in this Annual Report on Form 10-K has independently assessed the effectiveness of our internal control over financial reporting and its report is below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
ICU Medical, Inc.
San Clemente, CA

We have audited the internal control over financial reporting of ICU Medical, Inc. and subsidiaries (the "Company") as of December 31, 2012, 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 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 the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit 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, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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 Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2012 of the Company and our report dated February 26, 2013 expressed an unqualified opinion on those consolidated financial statements and financial statement schedule,

/s/ DELOITTE & TOUCHE, LLP

Costa Mesa, California
February 26, 2013

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, 2013.

	Age	Office Held
George A. Lopez, M.D.	65	Chairman of the Board, President and Chief Executive Officer
Alison D. Burcar	40	Vice President of Product Development
Richard A. Costello	49	Vice President of Sales
Scott E. Lamb	50	Chief Financial Officer
Steven C. Riggs	54	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 *Compliance with Section 16(a) Beneficial Ownership Reporting Compliance* in our definitive Proxy Statement to be filed in connection with our 2013 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 2013 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 2013 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 2 to the Consolidated Financial Statements. Certain information about the plans at December 31, 2012, 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)*
2,444,753	$ 35.66	1,553,456

*As of December 31, 2012, there were 320,849 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 2013 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 2013 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. Amended 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 Quarterly Report on Form 10-Q for the Quarter ended June 30, 2012, 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
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31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
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Exhibit 101.INS	XBRL Instance Document
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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: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Write-off/ Disposals	Balance at End of Period
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
For the year ended December 31, 2012:					
Allowance for doubtful accounts	$ 1,293	$ (237)	$ (58)	$ —	$ 998
Warranty and return reserve - accounts receivable	$ —	$ 386	$ —	$ —	$ 386
Warrant and return reserve - inventory	$ —	$ (166)	$ —	$ —	$ (166)
Deferred tax asset valuation allowance	$ —	$ 560	$ —	$ —	$ 560

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: February 26, 2013

SIGNATURES

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

Signature	Title	Date
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Chairman of the Board, President, and Chief Executive Officer, (Principal Executive Officer)	February 26, 2013
/s/ Scott E. Lamb Scott E. Lamb	Chief Financial Officer (Principal Financial Officer)	February 26, 2013
/s/ Kevin J. McGrody Kevin J. McGrody	Controller (Principal Accounting Officer)	February 26, 2013
/s/ Jack W. Brown Jack W. Brown	Director	February 26, 2013
/s/ John J. Connors John J. Connors	Director	February 26, 2013
/s/ Michael T. Kovalchik, III, M.D. Michael T. Kovalchik, III, M.D.	Director	February 26, 2013
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	February 26, 2013
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	February 26, 2013
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	February 26, 2013

Exhibit 10.18

Executive Officer Compensation

The annual base salaries for our executive officers as of January 1, 2013 are as follows:

Name	Title	Annual Base Salary
George A. Lopez, M.D.	Chairman of the Board, President and Chief Executive Officer	$ 710,803
Scott E. Lamb	Chief Financial Officer	$ 383,621
Steven C. Riggs	Vice President of Operations	$ 350,097
Richard A. Costello	Vice President of Sales	$ 356,462
Alison D. Burcar	Vice President of Product Development	$ 300,000

2012 Performance Bonuses:

In February 2013, the Compensation Committee approved bonuses to each of the above named officers for 2012. The amount of the bonuses for 2012 were previously reported in the Current Report on Form 8-K filed with the SEC on February 5, 2013, each of which reports are incorporated herein by reference.

Exhibit 10.19

Non-Employee Director Compensation

We currently pay our non-employee directors an annual retainer of $35,000, plus $1,000 per day for attendance at meetings of the Board of Directors or $500 if the meeting is telephonic. Our lead director is paid an additional annual retainer of $15,000. Pay for attendance at meetings of the Audit Committee of the Board of Directors by the Chairperson of the Committee is $1,500 per day or $750 if the meeting is telephonic and for other Board of Director attendees is $1,000 per day or $375 if the meeting is telephonic. Pay for attendance at meetings of the Compensation Committee and Nominating Governance Committee of the Board of Directors by the Chairperson of the Committee is $1,500 per day or $750 if the meeting is telephonic and for other Board of Director attendees is $750 per day or $375 if the meeting is telephonic. Each Chairperson of a Committee of the Board of Directors also receives an annual retainer. The annual retainer for the Audit Committee Chairperson, the Compensation Committee Chairperson and the Nominating Governance Committee Chairperson is $18,500, $7,500 and $5,000, respectively.

Starting in 2012, the equity component of the director's compensation is valued at $110,000. Half of the annual equity package consists of restricted stock units and the other half consists of stock options. On February 1, 2012, our non-employee directors received an option grant to purchase 1,875 shares of our common stock. On May 11, 2012, our non-employee directors received an option grant to purchase 1,508 shares of our common stock and 1,022 restricted stock units . The options become exercisable one year after the grant date and expire ten years after the grant date. The restricted stock units vest one year from the grant date.

Exhibit 21

Subsidiaries of Registrant

Name	State of Incorporation
ICU Medical Sales, Inc.	Delaware
ICU Medical de Mexico, S.A. de C.V.	Mexico
ICU Medical Europe S.r.l.	Italy
ICU World, Inc.	Delaware
ICE Rink, Inc.	Delaware
Neo Care GmbH	Germany
ICU Medical Slovakia S.r.o.	Slovak Republic

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-04171, 333-58024, 333 -90462, 333-90464, 333-115654, 333-115653, 333-04167, and 333-175239 on Form S-8 of our reports dated February 26, 2013, relating to the consolidated financial statements and financial statement schedules of ICU Medical, Inc. and subsidiaries, and the effectiveness of ICU Medical, Inc. and subsidiaries' internal control over financial reporting, appearing in this Annual Report on Form 10-K of ICU Medical, Inc. and subsidiaries for the year ended December 31, 2012.

/s/ Deloitte & Touche, LLP

Costa Mesa, California
February 26, 2013

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, George A. Lopez, certify that:

1. I have reviewed this annual report on Form 10-K of ICU Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2013

/s/ George A. Lopez, M.D.

Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott E. Lamb, certify that:

1. I have reviewed this annual report on Form 10-K of ICU Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2013

/s/ Scott E. Lamb

Chief Financial Officer

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George A. Lopez, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 26, 2013

/s/ George A. Lopez, M.D.
George A. Lopez, M.D.

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott E. Lamb, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 26, 2013

/s/ Scott E. Lamb
Scott E. Lamb