ICU MEDICAL INC/DE
Form 10-K
February 26, 2013
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ý 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

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

For the transition period from to

Commission File No. 0-19974

ICU MEDICAL, INC.
(Exact name of Registrant as specified in its charter)

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

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

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

Title of each class	Name of each exchange on which registered
Common stock, par value $0.10 per share	The NASDAQ Stock Market LLC
Preferred Stock Purchase Rights	(Global Select Market)

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

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

Indicated by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes ý 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.

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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

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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.

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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.

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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.

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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.

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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

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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.

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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,

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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.

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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.

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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.

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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.

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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.

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Expiring patents may affect our future sales.

Most of our products are covered by patents that, if valid, give us a degree of market exclusivity during the term of the patent. The legal life of a patent in the U.S. is 20 years from application. 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

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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

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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.

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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

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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

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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.

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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

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PART II

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

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

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

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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.

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Item 6. Selected Financial Data.

ICU MEDICAL, INC.
SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	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				