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