

ICU MEDICAL INC/DE
Form 10-K
February 26, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015 or

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

For the transition period from _____ to _____

Commission File No. 0-19974

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

Delaware	33-0022692
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

951 Calle Amanecer	
San Clemente, California	92673
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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

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

Indicate by check mark whether registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrant was

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required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

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

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

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

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Small reporting company ☐

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2015, the last business day of registrant's most recently completed second fiscal quarter, was \$1,362,886,674*.

The number of shares outstanding of registrant's common stock, \$.10 par value, as of January 31, 2016 was 16,119,568.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2016 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2015, are incorporated by reference into Part III of this Report.

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

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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 product line includes needlefree connection devices, custom infusion sets, closed system transfer devices ("CSTD") for the handling of hazardous drugs, advanced sensor catheters, closed blood sampling systems, and hemodynamic monitoring systems. Our headquarters are in San Clemente, California.

Our products are used in acute care hospitals and ambulatory clinics in more than 60 countries throughout the world. We categorize our products into three main market segments: Infusion Therapy, Critical Care and Oncology. Our primary products include:

Infusion Therapy

- Needlefree connector products
 - MicroClav[®] and MicroClave Clear[®]
 - Neutron[®]
 - NanoClav[®]
 - Clav[®]
 - SwabCap[®]
- Custom infusion sets
- Teg[®] needlefree hemodialysis connector

Critical Care

- Hemodynamic Monitoring Systems
- Closed Blood Sampling and Conservation Systems
- Other Critical Care Products and Accessories

Oncology

- ChemoLock[™] CSTD and components
- ChemoClav[®] CSTD and components
- Diana[®] hazardous drug compounding system

We sell the majority of our products through our direct sales force and through independent distributors. Additionally, we sell our products on an original equipment manufacturer ("OEM") basis to other medical device manufacturers. Revenues for 2015, 2014 and 2013 were \$341.7 million, \$309.3 million and \$313.7 million, respectively. Our largest OEM customer is a subsidiary of Pfizer, which acquired Hospira in September 2015 and accounted for 36%, 36% and 39% of our worldwide revenues in 2015, 2014 and 2013, respectively. Income from operations was \$68.6 million, \$39.0 million and \$51.9 million in 2015, 2014 and 2013, respectively. Total assets were \$626.8 million, \$541.1 million and \$499.6 million in 2015, 2014 and 2013, respectively.

Company Background

ICU Medical, Inc. was founded in 1984 and our initial public offering was in 1992. In 1993, we launched the Clave, an innovative one-piece needlefree intravenous ("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 from acquisitions. Key developments have included the Tego needlefree connector for use in hemodialysis, products for handling hazardous drugs including the ChemoClave and ChemoLock CSTDs, the Diana hazardous drug compounding system, the Neutron, a catheter patency device and NanoClave, a series of MicroClave Clear derivatives which are uniquely designed for incorporation into custom manifolds and sets. 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 October 2015, we acquired Excelsior Medical Corporation's SwabCap disinfecting cap for needlefree I.V. connectors to enhance our direct and OEM infusion therapy product offerings and to open new customer opportunities globally.

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We began our relationship with Pfizer and its predecessor companies in 1995. In 2011, our agreements were extended through December 2018. All of our existing Hospira agreements survived the September 2015 acquisition by Pfizer.

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

Infusion therapy lines, used in hospitals and ambulatory clinics, consist of a tube running from a bottle or plastic bag containing a 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 infusion line can be connected to permit constant I.V. administration of medications, fluids and nutrients, and to allow instantaneous I.V. administration of medication.

Clave Needlefree Technology

Prior to the introduction of needle-safe connectors, a conventional infusion line terminated with a male luer connector to which a hollow-bore needle would be attached to penetrate an injection port to make a primary or secondary connection. With the Clave technology, instead of attaching a hollow-bore needle to the male luer, the male luer without a needle is simply attached directly to the needlefree Clave port.

All types of medications can be administered through the Clave by using a standard syringe or various types of administration sets. The Clave can be used with any conventional peripheral or central vascular access device, both for venous and arterial applications. The resilience of the silicone compression seal permits repeated connections and disconnections without replacing the Clave. The Clave contains no natural rubber latex.

The MicroClave is smaller than the standard Clave but is functionally similar. The MicroClave has a feature where upon disconnection of an infusion 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. 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 Clear is functionally identical to the MicroClave, and has a clear housing so that clinicians can visualize the fluid path.

The NanoClave is a derivative of the MicroClave, where it is incorporated into custom manifolds and components to be used in highly customized applications generally found in neonatal and pediatric patient populations. The NanoClave is also a neutral displacement connector with a clear housing, allowing clinicians to flush the connector clear of medications and blood with minimal flush volumes.

Neutron

The Neutron catheter patency device also features Clave technology, but includes a bi-directional silicone bellows 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 venous catheters.

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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 bacterial contamination and infection.

SwabCap

SwabCap is a disposable cap designed to disinfect needlefree connectors with 70% isopropyl alcohol. The SwabCap product line complements the Clave family of needlefree connectors, as both work together to deliver the critical elements of safety, protection and maintenance of I.V. catheters.

Custom Infusion Sets

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 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.

We serve as the exclusive manufacturer for certain custom I.V. products that are sold by a subsidiary of Pfizer. These products are promoted under the name SetSource.

Infusion Therapy sales accounted for \$244.8 million, or 72%, of our revenue in 2015, \$216.3 million, or 70%, of our revenue in 2014 and \$221.2 million, or 71%, of our revenue in 2013. Additional information regarding infusion therapy 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. 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. Most of our critical care products can be sold in custom systems containing specific components to meet the individual needs of the customer, and in some cases, custom made or acquired components.

The primary critical care products we manufacture are the following:

Hemodynamic Monitoring Systems: Q2 Plus™ CCO/SvO₂ (continuous cardiac output/oximetry) computer providing advanced hemodynamic monitoring with unparalleled accuracy and reliability; and Cogent™ 2-in-1 hemodynamic monitoring system providing minimally invasive and invasive hemodynamic monitoring technologies in a single, lightweight system with wireless communication (pending USFDA 510(k) clearance, not available for commercial sale).

SafeSet® Closed Blood Sampling and Conservation System: 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 blood borne pathogens, reduce the risk of I.V. line contamination and reduce blood waste for the patient.

Other Critical Care Products: Catheters, Lopez Valve® and cables and accessories for hemodynamic monitoring.

Critical care sales accounted for \$54.3 million, or 16%, of our revenue in 2015, \$55.1 million, or 18%, of our revenue in 2014 and \$54.3 million, or 17%, of our revenue in 2013. 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.

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Oncology

Oncology products, known as CSTDs 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 the ChemoClave CSTD, which incorporates Clave technology, and in 2013, we introduced the ChemoLock CSTD.

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 an infusion pump set to a patient. Components of the ChemoClave and ChemoLock product lines are used both in Pharmacy and on the nursing floors for the preparation and administration of hazardous drugs. Custom design capability allows for a specialized product mix within the ChemoClave and ChemoLock systems to best adapt to the existing hazardous drug handling workflow.

The primary oncology products we manufacture are the following:

ChemoLock Needlefree CSTD: ChemoLock was the first CSTD to receive FDA 510(k) clearance for both pharmacy (ONB) and patient administration (FPA) applications. ChemoLock prevents the escape of hazardous drug or vapor concentrations, blocks the transfer of environmental contaminants into the system, and eliminates the risk of needlestick injury.

ChemoClave Needlefree CSTD: ChemoClave utilizes standard ISO luer locking connections, making it compatible with all brands of needlefree connectors and pump delivery systems. ChemoClave also prevents the escape of hazardous drug or vapor concentrations, blocks the transfer of environmental contaminants into the system, and eliminates the risk of needlestick injury.

Diana Hazardous Drug Compounding System: Diana is an automated sterile compounding system that incorporates ChemoClave and ChemoLock disposables 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.

Oncology sales accounted for \$41.4 million, or 12%, of our revenue in 2015, \$36.7 million, or 12%, of our revenue in 2014 and \$36.9 million, or 12%, of our revenue in 2013. 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 Revenues

We have a significant number of patents on the technology in our products and methods used to manufacture them. We have continuing royalty and revenue share income from our technology and from time to time may receive license fees or royalties from other entities for the use of our technology.

Sales, Marketing and Customer Support

As of December 31, 2015, we employed 148 people worldwide in sales, marketing and customer support. Our sales administrative operations are in San Clemente, California, Roncanova, Italy, Utrecht, Netherlands, Bella Vista, NSW Australia, Ludenscheid, Germany and Johannesburg, South Africa. We ship around the world with the majority of our sales denominated in U.S. dollars and Euro.

Domestic Sales

Domestic sales include direct and OEM U.S. sales. Total domestic sales were \$241.9 million, \$212.7 million and \$223.1 million in 2015, 2014 and 2013, respectively.

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Direct

Direct domestic sales includes sales both to our distributors and directly to the end user of our products. Direct domestic sales accounted for 39% of our worldwide revenue in 2015. Distributors purchase and stock our products for resale to healthcare providers. One distributor accounted for 7% and one distributor accounted for 5% of revenue in 2015. All other distributors accounted for less than 5% of revenue in 2015. 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.

OEM

We distribute our products as an OEM supplier to Pfizer. We began this relationship in 1995. In 2011, our agreements were extended through December 2018. Pfizer is a major supplier of infusion pumps and I.V. solutions, and helps us achieve market share where they have multiple products under contract with a customer or broader international distribution channels than we can have on our own. Our agreement with Pfizer provides them 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. Domestic sales to Pfizer accounted for approximately 32% of our worldwide revenue in 2015. The loss of Pfizer as a customer would have a significant adverse effect on our business and operating results.

Pfizer purchases Clave products both as finished goods end-products for distribution to healthcare providers and in bulk for assembly into Pfizer infusion disposable products. The MicroClave, MicroClave Clear, ChemoClave CSTD and pre-pierced connector products are purchased and packaged separately as finished good end products. We also serve as the exclusive manufacturer for certain custom I.V. products that are sold by a subsidiary of Pfizer. These products are promoted under the name SetSource.

In 2015, we signed an exclusive agreement with Medline to supply them with SwabCaps for their SwabFlush syringe product used in infusion therapy.

International Sales

International sales were \$99.8 million, \$96.6 million and \$90.6 million in 2015, 2014 and 2013, respectively.

International sales through our direct channels, including distributors and directly to the end customer, were \$86.1 million, \$81.2 million and \$75.1 million in 2015, 2014, and 2013, respectively. International sales as an OEM supplier to Pfizer were \$13.7 million, \$15.4 million and \$15.5 million in 2015, 2014 and 2013, respectively.

In 2015, customers in Europe were served by our facilities in Slovakia, Netherlands, Italy and Germany. We serve the rest of the world from our facilities in the United States and Mexico. In 2015, we made the decision to begin shutting down our manufacturing facility in Slovakia and to move those products to our facility in Mexico. We expect to finish that process in the second half of 2016. As of December 31, 2015, we had 24 sales and sales support personnel serving Europe and 29 serving Asia Pacific, Southeast Asia, Latin America, Africa, the Middle East and Canada.

During 2015, we entered into a long-term supply agreement with Terumo Corporation of Japan for Japan and certain smaller Asian countries. Under the agreement, we have agreed that Terumo will distribute our entire product portfolio, including I.V. therapy products, Oncology products, Diana and our SwapCap product line. We see Japan and Asia as a valuable growth market.

Manufacturing

Manufacturing of our products involves injection molding of plastic and silicone parts, manual and automated assembly of the molded plastic parts and other components, quality control inspection, packaging and sterilization. We mold most 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 109,500 square feet of class 100,000 clean room area, approximately 36,000 square feet of other manufacturing space, approximately 77,000 square feet of warehouse space and approximately 155,000 square feet of office space.

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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 the majority of our proprietary molded components. The raw materials for our molding operation are principally resins and silicones, and these materials are available from several sources. 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.

Most of our manual assembly is done at our facilities in Ensenada, Mexico and Vrable, Slovakia, each of which has an electron beam ("e-beam") sterilizer and which have approximately 250,000 square feet and 77,000 square feet, respectively, of space for production and warehousing. Principal products assembled manually in Mexico and Slovakia are used in conjunction with infusion therapy systems (which includes oncology) and critical care systems. In 2015, we made the decision to begin shutting down our manufacturing facility in Slovakia and to move those products to our facility in Mexico. We expect to finish that process in the second half of 2016.

The majority of the infusion and oncology 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 products assembled in the respective plants. All other sterilization is done by independent contractors.

We also assemble compounders in our leased facility in Ludenscheid, Germany and Salt Lake City, Utah.

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. The FDA classifies all of the regulated products that we currently manufacture as Class II medical devices. Class II medical devices are subject to performance standards relating to one or more aspects of the design, manufacturing, testing and performance or other characteristics of the product in addition to general controls involving compliance with labeling and record keeping requirements.

We must comply with FDA, International Organization for Standardization (“ISO”) and European Council Directive 93/42/EEC (“Medical Device Directive”) regulations governing medical device manufacturing practices. The FDA, state, foreign agencies and ISO require manufacturers to register and subject manufacturers to periodic FDA, state, foreign agencies and ISO inspections of their manufacturing facilities. We are a FDA and ISO registered medical device manufacturer, and must demonstrate that we and our contract manufacturers comply with the FDA’s current Quality System Regulations (“QSR”). Under these regulations, the manufacturing process must be regulated and controlled by the use of written procedures and the ability to produce devices that meet the manufacturer’s specifications must be validated by extensive and detailed testing of every critical aspect of the process. They also require investigation of any deficiencies in the manufacturing process or in the

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products produced and detailed record keeping. Further, the FDA and ISO's interpretation and enforcement of these requirements has been increasingly strict in recent years and seems likely to be even more stringent in the future. Failure to adhere to QSR and ISO standards would cause the products produced to be considered in violation of the applicable law and subject to enforcement action. The FDA and ISO monitor compliance with these requirements by requiring manufacturers to register with the FDA and ISO, and by subjecting them to periodic FDA and ISO inspections of manufacturing facilities. If an FDA or ISO inspector observes conditions that might be violative, the manufacturer must correct those conditions or explain them satisfactorily, or face potential regulatory action that might include physical removal of the product from the marketplace.

We believe that our products and procedures are in compliance with all applicable FDA and ISO regulations. There is no assurance, however, that other products we are developing or products that we may develop in the future will be cleared by the FDA and classified as Class II products, or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the FDA, ISO or agencies in other jurisdictions. In addition, changes in FDA, ISO or other federal or state health, environmental or safety regulations or their applications could adversely affect our business.

To market our products in the European Community ("EC"), we must conform to additional requirements of the EC and demonstrate conformance to established quality standards and applicable directives. As a manufacturer that designs, manufactures and markets its own devices, we must comply with the quality management standards of EN ISO 13485. Those quality standards are similar to the QSR regulations.

Manufacturers of medical devices must also conform to EC Directives such as Council Directive 93/42/EEC and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the "CE" Mark may be affixed to its devices. The CE Mark gives devices unobstructed entry to all the member countries of the EC.

We have demonstrated conformity to the regulation of EN ISO 13485 and the Medical Device Directive and we affix the CE Mark to our device labeling for product sold in member countries of the EC.

We believe our products and systems are in compliance with all EC requirements. There can be no assurance, however, that other products we are developing or products that we may develop in the future will conform or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the EC.

Competition

The market for infusion therapy, critical care and oncology 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 these markets both from global, 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, we currently hold the market leading position for needlefree infusion devices, including the original Clave, the MicroClave and the MicroClave Clear. These products compete with, and currently contemplated new products will likely compete with, needlefree infusion devices and systems marketed by Baxter Healthcare Corporation ("Baxter"), B. Braun Medical, Inc. ("B. Braun"), Becton Dickinson and Company ("Becton

Dickinson"), Fresenius Kabi ("Fresenius"), Pfizer in certain non-exclusive markets and others. Although we believe that our needlefree infusion 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 CSTDs for the safe handling of oncology drugs, most notably Becton Dickinson, 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 has historically been based on competitive pricing, customer service and differentiated product features such as customization. The overall market for

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critical care products has been shifting in recent years from the invasive pulmonary artery catheter segment to less invasive technologies to deliver patient hemodynamic status data. In 2015, we filed with the FDA for 510(k) clearance of the Cogent 2-in-1 Hemodynamic Monitoring System, which will combine invasive and minimally invasive technologies in a single monitor.

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, Becton Dickinson (which acquired CareFusion), Fresenius and B. Braun are leading distributors of infusion and oncology systems, Edwards Life Sciences Corporation has a significant share of the critical care hemodynamic monitoring market, while Navilyst Medical, Inc., and Merit Medical Systems, Inc., are competitors in the angiography kit market. Several of these competitors have broad product lines and have been successful in obtaining 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 OEM customers such as Pfizer, Terumo, and Medline.

We believe the success of our market-leading needlefree connector line has and will continue to motivate others to develop 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 the success of our CSTD products has and will continue to motivate others to develop competing systems. Our ability to compete in the area of oncology will be particularly affected by clinical differentiation and quality of our products. While we believe we have advantages in these areas, there is no assurance that other companies will not be able to compete successfully with our CSTD products.

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 clinical differentiation, quality and delivery times to the customer. While we believe we have advantages in these 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/or certain foreign patents relating to the technologies found in the Clave / MicroClave Connector, MicroClave Clear Connector, Neutron Connector, CLC2000 Connector, Tego Connector, ChemoClave Technologies, ChemoLock Technologies, Click Lock Technology, SwabCaps, Custom Set Design and Manufacturing Methods, and Diana Hazardous Drug Compounding System. We have applications pending for additional United States and/or foreign patents on MicroClave Connector, Neutron Connector, Tego Connector, Y-Clave Connector with Integral Check Valve, ChemoClave Technologies, ChemoLock Technologies, and Diana Hazardous Drug Compounding System.

Within the last two years, ICU has received three U.S. patents covering our MicroClave Clear connector. As customer preference continues to migrate toward clear connectors, these patents will protect the market for our MicroClave Clear connector through 2032. We also have multiple continuation patent applications pending for a number of our products, which may issue in the future.

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. Our patents are important in preventing others from introducing competing products that are as effective as our products. The loss of patent protection on Clave/MicroClave, Neutron, ChemoClave and ChemoLock technologies, Custom Set Design and Manufacturing Systems could adversely affect our ability to exclude other manufacturers from producing effective competitive products and could have an adverse impact on our financial results.

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.

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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. 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. 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 \$15.7 million in 2015, \$18.3 million in 2014 and \$12.4 million in 2013.

Employees

At December 31, 2015, we had 2,446 full-time employees, consisting of 256 engaged in sales, marketing and administration and 2,190 in manufacturing, molding, product development and quality control, including 1,398 in Mexico and 233 in Slovakia.

Long-lived Assets

The table below presents our gross long-lived assets by country (in millions):

	December 31,		
	2015	2014	2013
Mexico	\$53.5	\$51.6	\$49.5
Slovakia	5.5	16.6	18.4
Italy	4.4	4.9	5.4
Other	0.7	0.6	0.5
Total foreign	\$64.1	\$73.7	\$73.8
United States	158.9	151.0	139.2
Worldwide total	\$223.0	\$224.7	\$213.0

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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. Any of the following risks, as well as additional risks and uncertainties not currently known to us or that we currently deem immaterial, could materially and adversely affect our results of operations or financial condition.

Unexpected changes in our arrangements with Pfizer may cause a decline in our sales and could result in a significant reduction in our sales and profits.

We depend on Pfizer for a high percentage of our sales and earnings. Worldwide sales to Pfizer were 36%, 36% and 39% of revenue for the years ended December 31, 2015, 2014 and 2013, respectively.

Under the terms of our agreements with Pfizer, we are dependent on the marketing and sales efforts of Pfizer for a large percentage of our sales, and Pfizer determines the prices at which the products that we sell to Pfizer will be sold to its customers. Pfizer 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 Pfizer is unable to maintain its position in the marketplace, in particular in light of its recent acquisition by Pfizer, our sales and operations could be adversely affected.

In 2015 U.S. Pfizer increased its purchases of our infusion therapy products, thereby increasing 2015 sales compared to 2014. In 2014 and 2013, U. S. Pfizer substantially reduced its purchases of our infusion therapy products, resulting in a reduction in 2014 sales compared to 2013. Although purchases from Pfizer increased in 2015, there is no certainty on purchases from Pfizer going forward.

Our ability to maintain our market penetration depends in significant part on the success of our arrangement with Pfizer and Pfizer's arrangements with major buying organizations and its ability to renew such arrangements. Our business could be materially adversely affected if Pfizer terminates its arrangement with us, negotiates lower prices, sells competing products, whether manufactured by Pfizer or others, or otherwise alters the nature of its relationship with us. Early in 2016, Pfizer announced it would commence promotion of a new needlefree valve that is not produced by us, in foreign markets where they do not sell Clave. Although we believe that our OEM partner has historically viewed us as a source of innovative and profitable products in specific markets where we currently have sales, there is no assurance that our relationship with Pfizer will continue as it has in the past. For example, Pfizer, Hospira's current owner, may view Hospira's relationship with us differently than Hospira's management. We have no assurances from Pfizer, and we can provide no assurances, on the impact (if any) that Pfizer's ownership of Hospira may have on our relationship with Hospira going forward. Further, certain actions Pfizer could take with respect to Hospira could adversely affect Hospira's business, and consequently our financial results.

In contrast to our dependence on Pfizer, 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 direct business, resulting in continued concentration of sales to and dependence on Pfizer.

We are increasingly dependent on manufacturing in Mexico, and could be adversely affected by the transfer of operations from Slovakia, increased labor costs and any economic, social or political disruptions.

We continue to expand our production in Mexico, including as a result of the relocation our Slovakia operations. 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. As we relocate the operations presently occurring in Slovakia to Mexico (as well as the United States), we will need to ensure continuity in production, and we could be adversely impacted by such transition being more difficult, costly or time consuming than expected.

As of December 31, 2015, we employed 1,398 people in operations and product development in our plant in Ensenada, Mexico. 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.

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Any political or economic disruption in Mexico or a change in the local economies could have an adverse effect on our operations. We depend on our ability to move goods across borders quickly, and any disruption in the free flow of goods across national borders could have an adverse effect on our business. Additionally, political and social instability resulting from violence in certain areas of Mexico has 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 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 that 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 regulation and reform legislation could adversely affect our revenue and financial condition.

The healthcare industry is highly regulated and in recent years, there have been numerous changes in initiatives, laws and regulations. The federal government and all states in which we are currently operate regulate various aspects of our business. Changes in law or new interpretation of existing laws can have a material effect on our permissible activities, the relative costs associated with doing business. 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 imposed on medical device manufacturers for the sale of certain medical devices to United States customers. The excise tax, which became effective January 1, 2013, resulted in additional expense of \$2.0 million in 2015, \$1.9 million in 2014 and \$1.8 million in 2013 recorded in Selling, General and Administrative expenses. Congress has temporarily suspended this medical device excise tax for two years commencing January 2016. Unless Congress changes the current law, we expect this tax to resume beginning in 2018. 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.

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.

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Failure to protect our information systems against security breaches, service interruptions, or misappropriation of data could disrupt operations, compromise sensitive data, and expose us to liability, possibly causing our business and reputation to suffer.

We depend heavily on information technology infrastructure and systems to achieve our business objectives. Any incident that impairs or compromises this infrastructure, including security breaches, malicious attacks or more general service interruptions, could impede our ability to process orders, manufacture and ship product in a timely manner, protect sensitive data and otherwise carry on business in the normal course. Any such events could result in the loss of customers, revenue, or both, and could require us to incur significant expense to remediate, including legal claims or proceedings. Further, as cyber security related incidents continue to evolve, and regulatory focus on these issues continues to expand, additional investment in protective measures, and vulnerability remediation, may be required.

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. 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. For example, we acquired the Excelsior Medical business of manufacturing and selling the needleless connector disinfection SwapCap in October 2015, but may have difficulties quickly and efficiently integrating the product line, pumps and tubing into our current business, particularly in moving the manufacturing of the SwabCap products to our Salt Lake City facility.

We have built additional production facilities outside the United States, to reduce labor costs. The expansion of our 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 rely on a combination of patents, trademarks, copyrights, trade secrets, business methods, software and nondisclosure agreements to protect our proprietary intellectual property. Our efforts to protect our intellectual proprietary and proprietary rights may not be sufficient. Further, there is no assurance 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 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. In addition, our ability to enforce and protect our intellectual property rights may be limited in certain countries outside of the United States, which could make it easier for competitors to obtain market position in such countries by utilizing technologies that are similar to those developed by us.

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.

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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 our 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 infusion connection systems that have been issued to others. While we believe these patents will not affect our ability to market our products, there is no assurance that these or other issued or pending patents might not interfere with our right or ability to manufacture and sell our products.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Patent infringement litigation, which may be necessary to enforce patents issued to us or to defend ourselves against claimed infringement of the rights of others, can be expensive and may involve a substantial commitment of our resources which may divert resources from other uses. Adverse determinations in litigation or settlements could subject us to significant liabilities to third parties, could require us to seek licenses from third parties, could prevent us from manufacturing and selling our products or could fail to prevent competitors from manufacturing products similar to ours. Any of these results could materially and adversely affect our business.

Expiring patents may affect our future sales.

Most of our products are covered by patents that, if valid, give us a degree of market exclusivity during the term of the patent. Our patents will expire at various dates through 2032. 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.

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, 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 rely.

Damage to any of our facilities could render us unable to manufacture our products or require us to reduce the output of products at the damaged facility.

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

Although we have risk mitigation plans in place with key suppliers, 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. Additionally, we are subject to FDA regulations, which could further delay our ability to obtain a qualified alternative supplier. 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. Due to the highly competitive nature of the healthcare industry and the cost controls of our customers and third party payors, we may be unable to pass along cost increases for any key components or raw materials increases through higher prices to our customers. If the cost of key components or raw materials increases and we are unable fully to recover those increased costs through price increases or offset these increases through other cost reductions, we could experience an adverse effect on our financial condition.

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Expansion of our manufacturing facilities may result in inefficiencies that 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 was unusually high in Mexico, and the additional time spent in classroom training and on the job training could create production inefficiencies in Mexico in the future. The addition of new products will require additional molding in Salt Lake City and manual assembly work in Mexico. 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.

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.

We depend heavily on sales of Clave products, especially sales of Clave products to Pfizer, which have decreased in previous years. Most of our sales of Clave products are in the United States. Future 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 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. 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. Early in 2016, Pfizer announced it would commence promotion of a new needlefree valve that is not produced by ICU, in foreign markets where they do not sell Clave.

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. Sales to customers outside of the United States made up approximately 29% of our revenue in 2015 and as our operations and sales located in Europe and other areas outside the United States increase, we may face new challenges and uncertainties, although we can give no assurance that such operations and sales will increase.

International sales pose additional risks related to competition with larger international companies and established local companies, our possibly higher cost structure.

We have undertaken an initiative to increase our international sales, and have distribution arrangements in all the principal countries in Western Europe, the Pacific Rim, Middle East, Latin America, Canada 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 and Mexico. 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.

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. The European hospitals tend to be significantly slower in payment which has resulted in an increase to our days sales outstanding from previous years. Our prices to our international distributors, outside of Europe, for product shipped to the customers from the United States or Mexico are generally denominated in U.S. dollars, but their resale prices are set in their local currency. A decline in the value of the local currency in relation to the U.S. dollar may adversely affect their ability to profitably sell in their market the products they buy from us, and may adversely affect their ability to make payment to us for the products they purchase. Legal recourse for non-payment of indebtedness may be uncertain. These factors all contribute to a potential for credit losses.

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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.

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 disposable medical device segment of the health care industry and in particular the infusion products market is intensely competitive and is experiencing both horizontal and vertical consolidation. 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. Due to the highly competitive nature of the group purchasing organizations or IDNs contracting processes, we may not be able to obtain or maintain contract positions with major GPOs and IDNs across our products portfolio. Furthermore, the increasing leverage of organizing buy-in groups may reduce market prices for our products thereby affecting our profitability. There is no assurance that our competitors will not substantially increase resources devoted to the development, manufacture and marketing of products competitive with our products. The successful implementation of such a strategy by one or more of our competitors could materially and adversely affect us.

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

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success and profit margins depend upon the development and

successful commercialization of new products, new or improved technologies and additional applications of our technology. The research and development process is time-consuming and costly, and may not result in products or applications that we can successfully commercialize. We can give no assurance that any such new products will be successful or that they will be accepted in the marketplace.

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 that 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 to recognize an impairment charge for the value of the

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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 2016. If we do not achieve significant sales of these new products, it might be necessary for us to recognize an impairment charge for the value of the production tooling because its costs may not be recovered through production of saleable product, which could adversely affect our financial condition.

If we cannot obtain additional custom tooling and equipment on a timely basis to enable us to meet demand for our products, we might be unable to increase our sales or might lose customers, in which case our sales could decline.

We expanded our manufacturing capacity substantially in recent years, and we expect that continued expansion may be necessary. Molds and automated assembly machines generally have a long lead-time with vendors, often nine months or longer. Inability to secure such tooling in a timely manner, or unexpected increases in production demands, could cause us to be unable to meet customer orders. Such inability could cause customers to seek alternatives to our products.

Increases in the cost of petroleum-based and natural gas-based products or loss of supply could have an adverse effect on our profitability.

Most of the materials used in our products are resins, plastics and other material that depend upon oil or natural gas as their raw material. Crude oil markets are affected by political uncertainty in the Middle East, and there is no assurance that crude oil supplies will not be interrupted in the future. Any such interruption could have an adverse effect on our ability to produce, or the cost to produce, our products. Also, crude oil and natural gas prices have been volatile in recent years. Our suppliers have historically 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

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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 (2012). Those quality standards are similar to the FDA's Quality System Regulations. Manufacturers of medical devices must also be in conformance with EC Directives such as Council Directive 93/42/EEC ("Medical Device Directive") and their applicable annexes. Those regulations assure that medical devices are both safe and effective and meet all applicable established standards prior to being marketed in the EC. Once a manufacturer and its devices are in conformance with the Medical Device Directive, the "CE" Mark maybe affixed to its devices. The CE Mark gives devices an unobstructed entry to all the member countries of the EC. There is no assurance that we will continue to meet the requirements for distribution of our products in Europe.

Distribution of our products in other countries may be subject to regulation in those countries, and there is no assurance that we will obtain necessary approvals in countries in which we want to introduce our products.

Product liability claims could be costly to defend and could expose us to loss.

The use of our products exposes us to an inherent risk of product liability. Patients, healthcare workers or healthcare providers who claim that our products have resulted in injury could initiate product liability litigation seeking large damage awards against us. Costs of the defense of such litigation, even if successful, could be substantial. We maintain insurance against product liability and defense costs in the amount of \$10,000,000 per occurrence. There is no assurance that we will successfully defend claims, if any, arising with respect to products or that the insurance we carry will be sufficient. A successful claim against us in excess of insurance coverage could materially and adversely affect us. Furthermore, there is no assurance that product liability insurance will continue to be available to us on acceptable terms.

We may incur costs or losses relating to other litigation.

We may from time to time be involved in litigation. Legal proceedings are inherently unpredictable, and the outcome can result in judgements that affect how we operate our business, or we may enter into settlements of claims for monetary damages that exceed our insurance coverage, if any is available. Any such proceedings, regardless of merits, may result in substantial costs, the diversion of management's attention from other business concerns and additional restrictions on our business, which could disrupt our business and have an adverse effect on our financial condition.

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.

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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 2013 through December 2015, our trading price ranged from a high of \$124.69 per share to a low of \$53.01 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, market rumors 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 44% of our outstanding shares at the end of 2015. If one or more of the institutions or if our other large stockholders should decide to reduce or eliminate their position in our common stock, it could cause a significant decrease in the price of our common stock.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We own a 39,000 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. Our Slovakia facility is currently available for sale. We lease a building in San Clemente, California, San Diego, California and in Ludenscheid, Germany. We also lease office space in Utrecht, Netherlands, Bella Vista, NSW Australia and in Johannesburg, South Africa.

Item 3. Legal Proceedings.

We are from time to time involved in various 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.

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Item 4. Mine Safety Disclosures.

Not applicable

PART II

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

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

2015	High	Low
First quarter	\$93.14	\$80.47
Second quarter	98.36	84.21
Third quarter	123.09	95.24
Fourth quarter	119.03	103.10
2014	High	Low
First quarter	\$66.20	\$56.75
Second quarter	61.56	54.19
Third quarter	65.23	57.07
Fourth quarter	85.71	63.81

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, 2016, we had 67 stockholders of record. This does not include persons whose stock is in nominee or "street name" accounts through brokers.

Securities authorized for issuance under equity compensation plans are discussed in Part III, Item 12 of this Annual Report on Form 10-K.

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 2015:

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
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10/01/2015 - 10/31/2015	—	\$—	—	\$ 22,522,000
11/01/2015 - 11/30/2015	—	\$—	—	22,522,000
12/01/2015 - 12/31/2015	—	\$—	—	22,522,000
Fourth quarter 2015 total	—	\$—	—	\$ 22,522,000

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COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2011 TO DECEMBER 31, 2015 OF ICU MEDICAL, INC., NASDAQ AND NASDAQ MEDICAL SUPPLIES 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, 2010 to December 31, 2015 and the total returns of the NASDAQ U.S. Index and NASDAQ Medical Supplies Index for the same period.

	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
ICU Medical, Inc.	\$100.00	\$123.29	\$166.93	\$174.55	\$224.38	\$308.99
NASDAQ U.S. Index	\$100.00	\$100.31	\$116.79	\$155.90	\$175.33	\$176.17
NASDAQ Medical Supplies Index	\$100.00	\$96.21	\$118.39	\$144.96	\$174.19	\$192.61

Assumes \$100 invested on December 31, 2010 in ICU Medical Inc.'s common stock, the NASDAQ U.S. Index and the NASDAQ Medical Supplies 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)				
	2015	2014	2013	2012	2011
INCOME DATA:					
Revenue					
Net sales	\$341,254	\$308,770	\$313,056	\$316,322	\$301,642
Other	414	490	660	547	553
Total revenue	341,668	309,260	313,716	316,869	302,195
Cost of goods sold	160,871	157,859	158,984	160,359	159,841
Gross profit	180,797	151,401	154,732	156,510	142,354
Selling, general and administrative expenses	83,216	88,939	89,006	84,604	85,287
Research and development expenses	15,714	18,332	12,407	10,630	8,588
Restructuring and strategic transaction	8,451	5,093	1,370	—	—
Gain on sale of assets	(1,086)) —	—	—	(14,242)
Legal settlements	1,798	—	—	—	(2,500)
Impairment of assets held for sale	4,139	—	—	—	—
Total operating expenses	112,232	112,364	102,783	95,234	77,133
Income from operations	68,565	39,037	51,949	61,276	65,221
Other income	1,134	755	765	563	1,201
Income before income taxes	69,699	39,792	52,714	61,839	66,422
Provision for income taxes	(24,714)) (13,457)) (12,296)) (20,558)) (21,753)
Net income	\$44,985	\$26,335	\$40,418	\$41,281	\$44,669
Net income per common share					
Basic	\$2.84	\$1.72	\$2.75	\$2.90	\$3.23
Diluted	\$2.73	\$1.68	\$2.65	\$2.80	\$3.15
Weighted average number of shares					