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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015 or

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

For the transition period from to

Commission File No. 0-19974

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 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.

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

ICU Medical, Inc.
Form 10-K
For the Year Ended December 31, 2015
TABLE OF CONTENTS

		Page
PART I		
Item 1	Business	3
Item 1A	Risk Factors	12
Item 1B	Unresolved Staff Comments	20
Item 2	Properties	20
Item 3	Legal Proceedings	20
Item 4	Mine Safety Disclosures	21
PART II		
Item 5	Market for the Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	21
Item 6	Selected Financial Data	23
Item 7	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 7A	Quantitative and Qualitative Disclosures about Market Risk	33
Item 8	Financial Statements and Supplementary Data	34
	Report of Independent Registered Public Accounting Firm	35
Item 9	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	60
Item 9A	Controls and Procedures	60
Item 9B	Other Information	62
PART III		
Item 10	Directors, Executive Officers and Corporate Governance	62
Item 11	Executive Compensation	63
Item 12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	63
Item 13	Certain Relationships and Related Transactions, and Director Independence	63
Item 14	Principal Accounting Fees and Services	63
PART IV		
Item 15	Exhibits and Financial Statement Schedules	64
	Signatures	70

Table of Contents

PART I

Item 1. Business.

Overview

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion therapy, oncology and critical care applications. Our 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
  - MicroClave® and MicroClave Clear®
  - Neutron®
  - NanoClave®
  - Clave®
  - SwabCap®
- Custom infusion sets
- Tego® 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
- ChemoClave® 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.

Table of Contents

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.

Table of Contents

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/SvO_2 (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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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 are 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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

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

Table of Contents

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.

Table of Contents

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					
Basic	15,848	15,282	14,688	14,223	13,835
Diluted	16,496	15,647	15,274	14,725	14,161
Cash dividends per share	$—	$—	$—	$—	$—
CASH FLOW DATA:					
Total cash flows from operations	$54,865	$60,640	$65,726	$66,271	$64,487

	As of December 31, (in thousands)				
	2015	2014	2013	2012	2011
BALANCE SHEET DATA:					
Cash, cash equivalents and investment securities	$377,397	$346,764	$296,891	$226,159	$159,985
Working capital	$462,389	$403,801	$367,410	$296,385	$231,098
Total assets	$626,825	$541,102	$499,643	$428,512	$361,112
Stockholders' equity	$579,871	$508,252	$464,725	$390,857	$320,577

23

Table of Contents

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

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 include needlefree connection devices, custom infusion sets, CSTD for the handling of hazardous drugs, advanced sensor catheters, closed blood sampling systems and innovative hemodynamic monitoring systems.

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
  - MicroClave® and MicroClave Clear®
  - Neutron®
  - NanoClave®
  - Clave®
  - SwabCap®
- Custom infusion sets
- Tego® 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
- ChemoClave CSTD and components
- Diana hazardous drug compounding system

Revenues for 2015, 2014 and 2013 were $341.7 million, $309.3 million and $313.7 million, respectively. We currently sell our products through direct channels, which include distributors and the end users of our products and as an OEM supplier.

Our largest customer is Pfizer due to its acquisition of Hospira in September 2015. Pfizer accounted for 36% of our worldwide revenues in 2015 and 2014 and 39% of our worldwide revenues in 2013. 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.

We believe that as healthcare providers continue to either consolidate or join major buying organizations, the success of our products will depend, in part, on our ability, either independently or through strategic relationships such as our Pfizer relationship, to secure long-term contracts with large healthcare providers and major buying organizations. As

a result of this marketing and distribution strategy we derive most of our revenues from a relatively small number of distributors and manufacturers. The loss of a strategic relationship with a customer or a decline in demand for a manufacturing customer's products could have a material adverse effect on our operating results.

We believe that achievement of our growth objectives worldwide will require increased efforts by us in sales and marketing and product development; however, there is no assurance that we will be successful in implementing our growth strategy. Product development or acquisition efforts may not succeed, and even if we do develop or acquire additional products, there is no assurance that we will achieve profitable sales of such products. An adverse change in our relationship with Pfizer, or a deterioration of Pfizer's position in the market, could have an adverse effect on us. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have

Table of Contents

taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

The following table sets forth, for the periods indicated, total revenues by market segment and its major product groups as a percentage of total revenues:

Product line	2015		2014		2013	
Infusion therapy	72	%	70	%	71	%
Critical care	16	%	18	%	17	%
Oncology	12	%	12	%	12	%
	100	%	100	%	100	%

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.

SwabCap Acquisition

On October 6, 2015, we acquired all of the outstanding shares of EXC Holding Corp. ("EXC"), for approximately $59.5 million in cash. Immediately following the completion of the acquisition of EXC we sold certain assets to Excelsior Medical, LLC for a final purchase price including working capital adjustments of $29.0 million in cash. We retained all of the assets related to the business of manufacturing and selling the needleless connector disinfection SwabCap. The SwabCap product enhances our infusion therapy product offering across our existing direct and OEM business lines, as well as, open new customer opportunities globally. In 2015, we signed an exclusive agreement with Medline to supply them with SwabCaps for their SwabFlush syringe product used in infusion therapy. The SwabCap product is expected to have a minimal impact on earnings per share for the first year, however after one year we expect to see a greater return on invested capital.

Table of Contents

Year-to-Year Comparisons

We present summarized income statement data in Item 6. Selected Financial Data. The following table shows, for the three most recent years, the percentages of each income statement caption in relation to revenues.

	Percentage of Revenues		
	2015	2014	2013
Revenue			
Net sales	100 %	100 %	100 %
Other	— %	— %	— %
Total revenues	100 %	100 %	100 %
Gross margin	53 %	49 %	49 %
Selling, general and administrative expenses	24 %	29 %	28 %
Research and development expenses	5 %	6 %	4 %
Restructuring and transaction expense	2 %	1 %	— %
Gain on sale of building	— %	— %	— %
Legal settlements	1 %	— %	— %
Impairment of assets held for sale	1 %	— %	— %
Total operating expenses	33 %	36 %	32 %
Income from operations	20 %	13 %	17 %
Other income	— %	— %	— %
Income before income taxes	20 %	13 %	17 %
Income taxes	7 %	4 %	4 %
Net income	13 %	9 %	13 %

A portion of our sales is conducted in currencies other than the U.S. dollar, particularly the Euro. In 2015, approximately 13% of our total revenue was denominated in the Euro and translated to the U.S. dollar. Significant fluctuations in foreign currency exchange rates, particularly the Euro, impact the comparability of our total revenues. In addition to comparing changes in revenue on a U.S. GAAP basis, we also compare the changes in revenue from one period to another using constant currency. We provide constant currency information to enhance the visibility of underlying business trends, excluding the effects of changes in foreign currency translation rates. To calculate our constant currency results, we apply the average exchange rate for revenues from the prior year to the current year results. These results should be considered in addition to, not as a substitute for, results reported in accordance with GAAP. Results on a constant currency basis, as we present them, may not be comparable to similarly titled measures used by other companies and are not measures of performance presented in accordance with GAAP.

Comparison of 2015 to 2014

Revenues were $341.7 million in 2015, compared to $309.3 million in 2014. On a constant currency basis, revenues would have been $350.6 million in 2015, an increase of $41.3 million from 2014.

Infusion Therapy: Net infusion therapy sales were $244.8 million in 2015, an increase of $28.5 million, or 13%, from 2014. On a constant currency basis, net infusion therapy sales would have been $249.9 million in 2015, an increase of $33.6 million, or 16%, from 2014. The increase in infusion therapy sales is primarily due to new customers and higher volume to existing customers. Domestic infusion therapy sales were $181.8 million in 2015, an increase of $26.4 million, or 17%, from 2014. The increase in domestic infusion therapy sales was from $12.2 million in higher sales to Pfizer, and $14.2 million in higher direct domestic sales, both due to increased unit sales related to increased utilization and new customers. International infusion therapy sales were $63.0 million in 2015, an increase of $2.1 million, or 3%, from 2014. International infusion therapy sales outside of Europe increased $3.7 million and were

offset by $1.6 million in lower European sales due to the decline in the exchange rate of the Euro to the U.S. dollar. On a constant currency basis, international infusion therapy sales would have increased $7.2 million in 2015, compared to 2014.

Critical Care: Net critical care sales were $54.3 million in 2015, a decrease of $0.8 million, or 1.4%, from 2014. On a constant currency basis, net critical care sales would have been $55.2 million in 2015, an increase of $0.2 million from 2014.

Table of Contents

The decrease in critical care sales is primarily due the decline in the exchange rate of the Euro to the U.S. dollar and lower domestic unit sales. Domestic critical care sales were $39.2 million in 2015, a decrease of $1.4 million from 2014. International critical care sales were $15.1 million in 2015, an increase of $0.6 million, or 4%, from 2014 primarily due to increased sales outside of Europe, partially offset by the effect of the decline in the exchange rate of the Euro to the U.S. dollar. On a constant currency basis, international critical care sales would have increased $1.6 million in 2015, compared to 2014.

Oncology: Net oncology sales were $41.4 million in 2015, an increase of $4.7 million from 2014. On a constant currency basis, net oncology sales would have been $44.2 million in 2015, an increase of $7.5 million, or 21%, from 2014. Domestic oncology sales were $20.0 million in 2015, an increase of $4.2 million, or 27%, from 2014. The increase in domestic oncology was from $1.4 million in higher sales to Pfizer and $2.8 million in higher direct domestic sales, both due to increased unit sales. International oncology sales were $21.5 million in 2015, an increase of $0.6 million, or 3%, from 2014. On a constant currency basis, international oncology sales would have increased $3.4 million in 2015, compared to 2014.

Gross margins for 2015 and 2014 were 52.9% and 49.0%, respectively. The increase in gross margin was due to favorable customer and product mix, operational efficiencies and favorable foreign exchange rates on our operations expenses due to the decline in the average exchange rate of the Mexican Peso to the U.S. dollar.

Selling, general and administrative (SG&A) expenses were $83.2 million, or 24% of revenues, in 2015 compared with $88.9 million, or 29% of revenues, in 2014. The decrease in SG&A expense is primarily due to $5.8 million in lower sales and marketing compensation and benefits, promotion expenses and travel expenses and $1.8 million lower legal fees, partially offset by $3.0 million in higher stock compensation expenses. The lower sales and marketing expenses are primarily due to the restructuring of the U.S. sales organization in the third quarter of 2014 and the decline in the average exchange rate of the Euro to the U.S. dollar.

Research and development (R&D) expenses were $15.7 million, or 5% of revenues, in 2015 compared to $18.3 million, or 6%, of revenues in 2014. The decrease in R&D expenses was primarily from lower R&D project expenses related to the development of a new hemodynamic monitor for our Critical Care market.

Restructuring and strategic transaction expenses were $8.5 million, or 2% of revenues, in 2015 compared to $5.1 million, or 1% of revenues, in 2014.

In 2015, we incurred $4.2 million in restructuring charges, primarily related to the authorized closure of our Vrable, Slovakia facilities. We incurred $2.5 million in restructuring charges primarily related to an agreement with Dr. Lopez, a member of our Board of Directors and a former employee in our research and development department, pursuant to which we bought out Dr. Lopez's right to employment under his then-existing employment agreement. We also incurred $1.8 million in strategic transaction expenses, primarily related to the acquisition of EXC, which closed in October 2015.

In 2014, we reorganized our selling and corporate infrastructure, resulting in a reduction in workforce of 69 employees. The $3.5 million restructuring charge related to the reorganization is comprised of employee termination benefits and other associated costs. Additionally, in 2014, we incurred $1.6 million in charges associated with a strategic transaction that did not go forward.

Gain on sale of building was $1.1 million in 2015 from the sale of one of our buildings in San Clemente to Dr. Lopez.

Legal settlement awards were $1.8 million, less than 1% of revenues, in 2015. During 2015, an arbitrator ruled on a breach of contract claim between us and a customer, Hospira, awarding Hospira a settlement and that we pay 75% of

Hospira's legal fees and expenses, resulting in a $7.1 million legal settlement charge. Additionally during 2015, an arbitrator ruled on a breach of contract claim between us and a service provider, awarding us $8.8 million. Our legal counsel for this mater represented us under a contingency fee agreement. We recorded a settlement award, net of legal fees and costs, of $5.3 million.

Table of Contents

Impairment of assets held for sale

In 2015, our Board of Directors authorized us to close our Vrable, Slovakia manufacturing facility. The closure is to enable for greater efficiency of our Ensenada, Mexico facility. The expected completion date for the closure will be during the third quarter of 2016. In connection with the Board of Director's authorization, we reclassified the assets related to the Slovakia facility as held for sale, recording the value of those assets at the lower of their carrying value or their estimated fair value, less costs to sell. A third party fair market valuation on the held-for-sale assets resulted in an impairment charge of $4.1 million.

Other income was $1.1 million in 2015 and $0.8 million in 2014.

Income taxes were accrued at an estimated annual effective tax rate of 35% in 2015 compared to 34% in 2014. Included in the 2015 estimated annual effective tax rate are the effects of foreign and state income taxes, tax credits, deductions for domestic production activities and discrete tax items related to the conclusion of state tax examinations, one-time tax effects related to the acquisition of EXC, and tax impact related to the proposed shut down of our Slovakia plant.

Comparison of 2014 to 2013

Revenues were $309.3 million in 2014, compared to $313.7 million in 2013.

Infusion Therapy: Net infusion therapy sales were $216.3 million in 2014, a decrease of $4.9 million, or 2%, from 2013. Domestic infusion therapy sales were $155.4 million in 2014, a decrease of $9.8 million, or 6%, from 2013. The decrease in domestic infusion therapy sales was from $11.2 million in lower sales to Pfizer, due to lower unit sales, partially offset by $1.4 million in higher domestic direct sales. International infusion therapy sales were $60.9 million in 2014, an increase of $4.9 million, or 9%, from 2013. The increase in international infusion therapy was primarily from higher unit sales and higher ASPs due to change in product mix outside of Europe.

Critical Care: Net critical care sales were $55.1 million in 2014, an increase of $0.8 million, or 1%, from 2013. Domestic critical care sales were $40.5 million in 2014, an increase of $0.1 million from 2013. International critical care sales were $14.5 million in 2014, an increase of $0.6 million, or 4%, from 2013 primarily due to higher unit sales and higher ASPs due to change in product mix outside of Europe.

Oncology: Net oncology sales were $36.7 million in 2014, a decrease of $0.2 million from 2013. Domestic oncology sales were $15.7 million in 2014, a decrease of $0.6 million, or 4%, from 2013. The decrease in domestic oncology sales was from $2.2 million in lower sales to Pfizer in the United States, partially offset by $1.6 million in increased direct sales from higher unit sales. International oncology sales were $20.9 million in 2014, an increase of $0.4 million, or 2%, from 2013, due to a $1.2 million increase in European oncology sales due to higher unit sales, partially offset by $0.8 million in lower international oncology sales outside of Europe due to lower unit sales.

Gross margins for 2014 and 2013 were 49.0% and 49.3%, respectively. The decrease in gross margin was due to unfavorable change in product mix and temporary rework of one of our product lines, partially offset by lower logistic expenses.

SG&A expenses were $88.9 million, or 29% of revenues, in 2014 compared with $89.0 million, or 28%, of revenues in 2013. The $3.8 million increase in stock compensation expense was offset by lower sales and marketing compensation and benefits and travel expenses. The lower sales and marketing expenses are primarily due to the restructuring of the U.S. sales organization in the third quarter of 2014.

R&D expenses were $18.3 million, or 6% of revenues, in 2014 compared to $12.4 million, or 4%, of revenues in 2013. The increase in R&D expenses was primarily from increased compensation and benefit expenses from an increase in R&D employees and increased external R&D project expenses.

Restructuring and strategic transaction expenses were $5.1 million, or 1% of revenues, in 2014 compared to $1.4 million in 2013. In 2014, we reorganized our selling and corporate infrastructure, resulting in a reduction in workforce of 69 employees. The $3.5 million restructuring charge is comprised of employee termination benefits and other associated costs.

In 2014, we incurred $1.6 million in charges associated with a strategic transaction that did not go forward. In 2013, we incurred $1.4 million in charges associated with a strategic transaction that did not go forward.

Table of Contents

Other income was $0.8 million in 2014 and in 2013.

Income taxes were accrued at an estimated annual effective tax rate of 34% in 2014 compared to 23% in 2013. The rate differed from the statutory corporate rate of 35% principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities and discrete tax items related to the conclusion of state tax examinations.

Liquidity and Capital Resources

During 2015, our cash, cash equivalents and investment securities increased by $30.6 million from $346.8 million at December 31, 2014 to $377.4 million at December 31, 2015.

Operating Activities: Our cash provided by operations was $54.9 million in 2015. Net income plus adjustments for non-cash net expenses contributed $80.7 million to cash provided by operations. Net cash used by operations as a result of changes in operating assets and liabilities was $25.8 million. The changes in operating assets and liabilities included a $20.5 million increase in accounts receivable, an $8.3 million increase in inventories, a $7.7 million net change in prepaid and deferred income taxes and $1.8 million increase in prepaid expenses and other assets, partially offset by a $9.4 million increase in accrued liabilities and a $3.1 million increase in accounts payable. The increase in accounts receivable was primarily due to higher revenue in the fourth quarter of 2015 compared to the fourth quarter of 2014 and an increase in days sales outstanding. The increase in inventory was primarily due to an increase in forecasted sales and inventory from South Africa. The net changes in prepaid and deferred income taxes was primarily due to a loss on the sale of assets to Medline and the utilization of an Excelsior net operating loss carryover. The $9.4 million increase in accrued liabilities was primarily due to restructuring charges accruals, acquisition accruals and accrued compensation and benefits. The increase in accounts payable and increase in prepaid expenses and other assets were a result of timing.

Investing Activities: Our cash used by investing activities was $11.2 million in 2015, which was primarily comprised of $56.8 million related to the acquisition of EXC and $13.0 million in capital purchases, partially offset by $29.0 million in proceeds from the sale of a business, net investment sales of $26.9 million and $3.6 million in proceeds from the sale of our building. Our property, plant and equipment purchases were primarily for additional investments in molds, machinery and equipment in our manufacturing operations in the United States and Mexico and in IT to benefit world-wide operations.

While we can provide no assurances, we estimate that our capital expenditures in 2016 will approximate $18 million to $20 million. We anticipate making additional investments in molds, machinery and equipment in our manufacturing operations in the United States and Mexico to support new and existing products and in IT to benefit world-wide operations. Additionally, we expect to expand our Mexico manufacturing plant for the anticipated increase in operations as a result of the Slovakian plant closure. We expect to use our cash and investments to fund our capital purchases. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

Financing Activities: Our cash provided by financing activities was $25.0 million in 2015. Cash provided by the exercise of stock options and shares purchased by our employees under the employee stock purchase plan was $17.2 million, resulting in 469,445 shares issued to our employees and directors. The tax benefits from share awards was $9.3 million in 2015, which fluctuates based principally on when employees choose to exercise their vested stock options. In 2015, we withheld 17,299 shares of our common stock from vested restricted stock units as consideration for making $1.5 million in payments for the employee's share award tax withholding obligations.

In July 2010, our Board of Directors approved a new share purchase plan to purchase up to $40.0 million of our common stock. We had no purchases of our common stock during 2015. To date, we have purchased $17.5 million of

our stock from this plan, leaving a balance of $22.5 million available for future purchases. This plan has no expiration date.

We have a substantial cash and investment security position generated from profitable operations and stock sales, principally from the exercise of employee stock options. We maintain this position to fund our growth, meet increasing working capital requirements, fund capital expenditures, buy back our common stock on an opportunistic basis and to take advantage of acquisition opportunities that may arise. Our primary investment goal is capital preservation.

As of December 31, 2015, we have $32.6 million of cash and cash equivalents held in local currency by our foreign subsidiaries. If these funds were needed for our operations in the U.S., we would be required to accrue and pay U.S. taxes for a portion of any repatriated funds. However, we expect to permanently reinvest these funds outside of the U.S. and, based on our current plans, we do not presently anticipate a need to repatriate them to fund our U.S. operations.

Table of Contents

We believe that our existing cash, cash equivalents and investment securities along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months. In the event that we experience illiquidity in our investment securities, downturns or cyclical fluctuations in our business that are more severe or longer than anticipated or if we fail to achieve anticipated revenue and expense levels, we may need to obtain or seek alternative sources of capital or financing, and we can provide no assurances that the terms of such capital or financing will be available to us on favorable terms, if at all.

Critical Accounting Policies

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements. In preparing our financial statements, we make estimates and assumptions that affect the expected amounts of assets and liabilities and disclosure of contingent assets and liabilities. We apply our accounting policies on a consistent basis. As circumstances change, they are considered in our estimates and judgments, and future changes in circumstances could result in changes in amounts at which assets and liabilities are recorded.

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

Revenue recognition: We record sales and related costs when ownership of the product transfers to the customer, persuasive evidence of an arrangement exists, collectability is reasonably assured and the sales price is determinable. Under the terms of all our purchase orders, ownership transfers on shipment. If there are significant doubts at the time of shipment as to the collectability of the receivable, we defer recognition of the sale in revenue until the receivable is collected. Our customers are medical product manufacturers, distributors and end-users. Our only post-sale obligations are warranty and certain rebates. We warrant products against defects and have a policy permitting the return of defective products. We accrue for warranty and product returns based on historical experience. We accrue rebates as a reduction in revenue based on agreements and historical experience.

Accounts receivable: Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on the age of the receivable or on specific past due accounts for which we consider collection to be doubtful. We rely on prior payment trends, financial status and other factors to estimate the cash which ultimately will be received. Such amounts cannot be known with certainty at the financial statement date. We regularly review individual past due balances for collectability. Loss exposure is principally with international customers for whom normal payment terms are long in comparison to those of our other customers and, to a lesser extent, domestic distributors. Many of these distributors are relatively small and we are vulnerable to adverse developments in their businesses that can hinder our collection of amounts due. If actual collection losses exceed expectations, we could be required to accrue additional bad debt expense, which could have an adverse effect on our operating results in the period in which the accrual occurs.

Inventories: Inventories are stated at the lower of cost (first in, first out) or market. We need to carry many components to accommodate our rapid product delivery, and if we mis-estimate demand or if customer requirements change, we may have components in inventory that we may not be able to use. Most finished products are made only after we receive orders except for certain standard (non-custom) products which we will carry in inventory in expectation of future orders. For finished products in inventory, we need to estimate what may not be saleable. We regularly review inventory and reserve for slow moving items, and write off all items that we do not expect to use in manufacturing, and finished products that we do not expect to sell. If actual usage of components or sales of finished

goods inventory is less than our estimates, we could be required to write off additional inventory, which could have an adverse effect on our operating results in the period in which the write-off occurs.

Property and equipment/depreciation: Property and equipment is carried at cost and depreciated on the straight-line method over the estimated useful lives. The estimates of useful lives are significant judgments in accounting for property and equipment, particularly for molds and automated assembly machines that are custom made for us. We may retire them on an accelerated basis if we replace them with larger or more technologically advanced tooling. The remaining useful lives of all property and equipment are reviewed regularly and lives are adjusted or assets written off based on current estimates of future use. As part of that review, property and equipment is reviewed for other indicators of impairment. An unexpected shortening of useful lives of property and equipment that significantly increases depreciation provisions, or other circumstances causing us to

Table of Contents

record an impairment loss on such assets, could have an adverse effect on our operating results in the period in which the related charges are recorded.

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

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

New Accounting Pronouncements

See Note 1 of the Consolidated Financial Statements in this Annual Report on Form 10-K.

Off Balance Sheet Arrangements

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. Although we can provide no assurances, we have never incurred, nor do we expect to incur, any liability for indemnification.

Contractual Obligations

We have contractual obligations, at December 31, 2015, of approximately the amount set forth in the table below. This amount excludes inventory-related purchase orders for goods and services for current delivery. The majority of our inventory purchase orders are blanket purchase orders that represent an estimated forecast of goods and services. We do not have a commitment liability on the blanket purchase orders. Since we do not have the ability to separate out blanket purchase orders from non-blanket purchase orders for inventory-related goods and services for current delivery, amounts related to such purchase orders are excluded from the table below. We have excluded from the table below pursuant to ASC 740-10-25 (formerly FIN 48), an interpretation of ASC 740-10 (formerly SFAS 109), a non-current income tax liability of $1.5 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)					
Contractual Obligations	Total	2016	2017	2018	2019	2020
Operating leases	$1,040	$492	$213	$136	$132	$67
Warehouse service agreements	823	619	204	—	—	—
Purchase obligations	4,700	4,700	—	—	—	—
Other contractual obligations	16	13	3	—	—	—

$6,579	$5,824	$420	$136	$132	$67

Forward Looking Statements

Various portions of this Annual Report on Form 10-K, including this Management's Discussion and Analysis of Financial Condition and Results of Operations, describe trends in our business and finances that we perceive and state some of our expectations and beliefs about our future. These statements about the future are "forward looking statements," within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we identify them by using words such as "anticipate," "believe," "expect," "estimate," "intend," "plan," "will," "continue," "could," "may," and by similar expressions and statements about ain and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, without limitation, statements about:

Table of Contents

- future growth; future operating results and various elements of operating results, including future expenditures and effects with respect to sales and marketing and product development and acquisition efforts; future sales and unit volumes of products; expected increases and decreases in sales; deferred revenue; accruals for restructuring charges, future license, royalty and revenue share income; production costs; gross margins; litigation expense; future SG&A and R&D expenses; manufacturing expenses; future costs of expanding our business; income; losses; cash flow; amortization; source of funds for capital purchases and operations; future tax rates; alternative sources of capital or financing; changes in working capital items such as receivables and inventory; selling prices; and income taxes;

- factors affecting operating results, such as shipments to specific customers; reduced dependence on current proprietary products; loss of a strategic relationship; change in demand; domestic and international sales; expansion in international markets, selling prices; future increases or decreases in sales of certain products and in certain markets and distribution channels; maintaining strategic relationships and securing long-term and multi-product contracts with large healthcare providers and major buying organizations; increases in systems capabilities; introduction, development and sales of new products, including SwabCap and integration of EXC; benefits of our products over competing systems; qualification of our new products for the expedited Section 510(k) clearance procedure; possibility of lengthier clearance process for new products; planned increases in marketing; warranty claims; rebates; product returns; bad debt expense; amortization expense; inventory requirements; lives of property and equipment; manufacturing efficiencies and cost savings; unit manufacturing costs; establishment or expansion of production facilities inside or outside of the United States; planned new orders for semi-automated or fully automated assembly machines for new products; adequacy of production capacity; results of R&D; our plans to repurchase shares of our common stock; asset impairment losses; relocation of manufacturing facilities and personnel; effect of expansion of manufacturing facilities on production efficiencies and resolution of production inefficiencies; the effect of costs to customers and delivery times; business seasonality and fluctuations in quarterly results; customer ordering patterns and the effects of new accounting pronouncements; and

- new or extended contracts with manufacturers and buying organizations; dependence on a small number of customers; loss of larger distributors and the ability to locate other distributors; future sales to and revenues from Pfizer and the importance of Pfizer to our growth; effect of the current relationship with Pfizer, including its effect on future revenues and our positioning with respect to new product introductions and market share; and the impact of the Pfizer acquisition; growth of our Clave products in future years; design features of Clave products; the outcome of our strategic initiatives; regulatory approvals and compliance; outcome of litigation; patent protection and intellectual property landscape; patent infringement claims and the impact of newly issued patents on other medical devices; competitive and market factors, including continuing development of competing products by other manufacturers; improved production processes and higher volume production; innovation requirements; consolidation of the healthcare provider market and downward pressure on selling prices; distribution or financial capabilities of competitors; healthcare reform legislation; use of treasury stock; working capital requirements; liquidity and realizable value of our investment securities; future investment alternatives; foreign currency denominated financial instruments; foreign exchange risk; commodity price risk; our expectations regarding liquidity and capital resources over the next twelve months; capital expenditures; plans to convert existing space; acquisitions of other businesses or product lines, indemnification liabilities and contractual liabilities.

Forward looking statements involve certain risks and uncertainties, which may cause actual results to differ materially from those discussed in each such statement. First, one should consider the factors and risks described in the statements themselves or otherwise discussed herein. Those factors are uncertain, and if one or more of them turn out differently than we currently expect, our operating results may differ materially from our current expectations.

Second, investors should read the forward looking statements in conjunction with the Risk Factors discussed in Item 1A of this Annual Report on Form 10-K. Also, actual future operating results are subject to other important factors and risks that we cannot predict or control, including without limitation, the following:

- general economic and business conditions, both in the United States and internationally;
- unexpected changes in our arrangements with Pfizer or our other large customers;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- increases in costs or availability of the raw materials need to manufacture our products;
- the effect of price and safety considerations on the healthcare industry;

Table of Contents

- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- the successful development and marketing of new products;
- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- the effects of additional governmental regulations;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

The forward looking statements in this report are subject to additional risks and uncertainties, including those detailed from time to time in our other filings with the Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof and, except as required by law, we undertake no obligation to update or revise any of them, whether as a result of new information, future events or otherwise.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Financial Market Risk

We had a portfolio of government bonds, corporate bonds, commercial paper and certificates of deposit of $41.2 million as of December 31, 2015. The securities are all “investment grade,” comprised of $5.0 million of pre-refunded municipal securities, $25.4 million in corporate bonds, $2.1 million in commercial paper, $7.5 million in U.S. Treasury securities and $1.2 million of certificates of deposit. The pre-refunded municipal securities are fully escrowed by U.S. government Treasury bills with low market risk.

Our future earnings are subject to potential increase or decrease because of changes in short-term interest rates. Generally, each one-percentage point change in the interest rate will cause our overall yield to change by two-thirds to three-quarters of a percentage point, depending upon the relative mix of our portfolio and market conditions specific to the securities in which we invest. Two-thirds to three-quarters of a percentage point change in our earnings on investment securities would create a change of approximately $0.4 million to investment income based on the average investment securities balance for the year ended December 31, 2015.

Foreign Exchange Risk

We have foreign currency exchange risk related to foreign-denominated cash, short-term investments, accounts receivable and accounts payable. In our European operations, our net Euro asset position at December 31, 2015 was approximately €20.7 million. We also have approximately €66.9 million in Euro denominated cash and investment accounts held by our corporate entity. A 10% change in the conversion of the Euro to the U.S. dollar for our cash and investments, accounts receivable, accounts payable and accrued liabilities from the December 31, 2015 spot rate would impact our consolidated amounts on these balance sheet items by approximately $9.6 million, or 2.5% of these net assets. We expect that in the future, with the growth of our European distribution operation, that net Euro denominated instruments will continue to increase. We currently do not hedge our foreign currency exposures.

Sales from the United States to foreign distributors are denominated in U.S. dollars. We have manufacturing, sales and distribution facilities in several countries and we conduct business transactions denominated in various foreign currencies, although principally the Euro and Mexican Peso. A 10% change in the conversion of the Mexican Peso to the U.S. dollar from the average exchange rate we experienced in 2015 and our manufacturing spending from 2015

would have impacted our cost of goods sold by approximately $2.3 million. To date, the change in the conversion of the Euro to U.S. dollar has not had a material impact to our operating earnings.

Table of Contents

Item 8. Financial Statements and Supplementary Data.

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Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of ICU Medical, Inc. and subsidiaries (the “Company”) as of December 31, 2015 and 2014, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. Our audits also included the financial statement schedule listed in the Index at Item 15. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2015, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2016 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Costa Mesa, California
February 26, 2016

Table of Contents

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except par value data)

	December 31, 2015	2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$336,164	$275,812
Investment securities	41,233	70,952
Cash, cash equivalents and investment securities	377,397	346,764
Accounts receivable, net of allowance for doubtful accounts of $1,101 and $1,127 at December 31, 2015 and 2014, respectively	57,847	39,051
Inventories	43,632	36,933
Prepaid income taxes	14,366	3,963
Prepaid expenses and other current assets	7,631	5,818
Assets held for sale	4,134	—
Total current assets	505,007	432,529
PROPERTY AND EQUIPMENT, net	74,320	86,091
GOODWILL	6,463	1,478
INTANGIBLE ASSETS, net	23,936	7,063
DEFERRED INCOME TAXES	17,099	13,941
	$626,825	$541,102
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$13,670	$11,378
Accrued liabilities	28,948	17,350
Total current liabilities	42,618	28,728
LONG-TERM LIABILITIES	1,476	—
DEFERRED INCOME TAXES	1,372	1,376
INCOME TAX LIABILITY	1,488	2,746
COMMITMENTS AND CONTINGENCIES	—	—
STOCKHOLDERS' EQUITY:		
Convertible preferred stock, $1.00 par value Authorized—500 shares; Issued and outstanding— none	—	—
Common stock, $0.10 par value — Authorized—80,000 shares; Issued and outstanding, 16,086 shares at December 31, 2015 and 15,595 shares at December 31, 2014	1,608	1,559
Additional paid-in capital	145,125	107,336
Retained earnings	453,896	408,911
Accumulated other comprehensive loss	(20,758)	(9,554)
Total stockholders' equity	579,871	508,252
	$626,825	$541,102

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

Table of Contents

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME
(Amounts in thousands, except per share data)

	Year ended December 31,		
	2015	2014	2013
REVENUES:			
Net sales	$341,254	$308,770	$313,056
Other	414	490	660
TOTAL REVENUE	341,668	309,260	313,716
COST OF GOODS SOLD	160,871	157,859	158,984
Gross profit	180,797	151,401	154,732
OPERATING EXPENSES:			
Selling, general and administrative	83,216	88,939	89,006
Research and development	15,714	18,332	12,407
Restructuring and strategic transaction	8,451	5,093	1,370
Gain on sale of building	(1,086)	—	—
Legal settlements, net	1,798	—	—
Impairment of assets held for sale	4,139	—	—
Total operating expenses	112,232	112,364	102,783
Income from operations	68,565	39,037	51,949
OTHER INCOME, NET	1,134	755	765
Income before income taxes	69,699	39,792	52,714
PROVISION FOR INCOME TAXES	(24,714)	(13,457)	(12,296)
NET INCOME	$44,985	$26,335	$40,418
NET INCOME PER SHARE			
Basic	$2.84	$1.72	$2.75
Diluted	$2.73	$1.68	$2.65
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	15,848	15,282	14,688
Diluted	16,496	15,647	15,274

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

Table of Contents

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Amounts in thousands)

	Year ended December 31,		
	2015	2014	2013
Net income	$44,985	$26,335	$40,418
Other comprehensive (loss) income, net of tax of ($2,680), ($3,129) and $803 for the years ended December 31, 2015, 2014 and 2013, respectively:			
Foreign currency translation adjustment	(11,204)	(11,747)	3,622
Comprehensive income	$33,781	$14,588	$44,040

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

Table of Contents

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands)

	Common Stock		Additional			Accumulated Other Comprehensive	
	Shares	Amount	Paid-In Capital	Treasury Stock	Retained Earnings	Income (Loss)	Total
Balance, December 31, 2012	14,458	$1,486	$63,770	$(15,128)	$342,158	$ (1,429)	$390,857
Issuance of restricted stock and exercise of stock options, including excess income tax benefits of $6,966	733	24	2,030	22,916	—	—	24,970
Treasury stock acquired in lieu of cash payment on stock option exercises and income tax withholding obligations	(140)	—	6,678	(9,711)	—	—	(3,033)
Proceeds from employee stock purchase plan	51	—	583	1,874	—	—	2,457
Stock compensation	—	—	5,434	—	—	—	5,434
Foreign currency translation adjustment	—	—	—	—	—	3,622	3,622
Net income	—	—	—	—	40,418	—	40,418
Balance, December 31, 2013	15,102	1,510	78,495	(49)	382,576	2,193	464,725
Issuance of restricted stock and exercise of stock options, including excess income tax benefits of $5,700	544	48	18,528	4,122	—	—	22,698
Purchase of treasury stock, treasury stock acquired in lieu of cash payment on stock option exercises and income tax withholding obligations	(98)	—	285	(6,121)	—	—	(5,836)
Proceeds from employee stock purchase plan	47	1	436	2,048	—	—	2,485
Stock compensation	—	—	9,592	—	—	—	9,592
Foreign currency translation adjustment	—	—	—	—	—	(11,747)	(11,747)
Net income	—	—	—	—	26,335	—	26,335
Balance, December 31, 2014	15,595	1,559	107,336	—	408,911	(9,554)	508,252
Issuance of restricted stock and exercise of stock options, including excess income tax benefits of $9,330	475	46	22,715	1,611	—	—	24,372
Purchase of treasury stock, treasury stock acquired in lieu of cash payment on stock option exercises and income tax withholding obligations	(18)	—	88	(1,611)			(1,523)
Proceeds from employee stock purchase plan	34	3	2,159	—	—	—	2,162

Stock compensation	—	—	12,827	—	—	—	12,827
Foreign currency translation adjustment	—	—	—	—	—	(11,204)	(11,204)
Net income	—	—	—	—	44,985	—	44,985
Balance, December 31, 2015	16,086	$1,608	$145,125	$—	$453,896	$ (20,758)	$579,871

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

Table of Contents

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year ended December 31,		
	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$44,985	$26,335	$40,418
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	18,073	19,447	19,506
Provision for doubtful accounts	54	34	185
Provision for warranty and returns	52	(360)	671
Stock compensation	12,827	9,592	5,434
(Gain) loss on disposal of property and equipment	(1,106)	8	(36)
Bond premium amortization	1,670	2,188	2,715
Impairment of assets held for sale	4,139	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(20,515)	4,912	3,556
Inventories	(8,337)	(3,836)	2,319
Prepaid expenses and other assets	(1,832)	1,970	(383)
Accounts payable	3,118	(621)	(31)
Accrued liabilities	9,454	2,344	(2,215)
Income taxes, including excess tax benefits and deferred income taxes	(7,717)	(1,373)	(6,413)
Net cash provided by operating activities	54,865	60,640	65,726
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(12,984)	(16,604)	(18,415)
Proceeds from sale of assets	3,592	5	49
Intangible asset additions	(951)	(989)	(1,080)
Business acquisitions, net of cash acquired	(56,786)	—	—
Proceeds from sale of assets acquired in a business acquisition	28,970	—	—
Purchases of investment securities	(56,137)	(93,588)	(86,022)
Proceeds from sale of investment securities	83,054	89,426	92,348
Net cash used by investing activities	(11,242)	(21,750)	(13,120)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	15,042	16,998	18,004
Proceeds from employee stock purchase plan	2,162	2,485	2,457
Tax benefits from exercise of stock options	9,330	5,700	6,966
Purchase of treasury stock	(1,523)	(5,836)	(3,033)
Net cash provided by financing activities	25,011	19,347	24,394
Effect of exchange rate changes on cash	(8,282)	(8,447)	2,122
NET INCREASE IN CASH AND CASH EQUIVALENTS	60,352	49,790	79,122
CASH AND CASH EQUIVALENTS, beginning of period	275,812	226,022	146,900
CASH AND CASH EQUIVALENTS, end of period	$336,164	$275,812	$226,022
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the year for income taxes	$22,998	$8,668	$12,172

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

Table of Contents

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS - CONTINUED
(Amounts in thousands)

	Year ended December 31,		
	2015	2014	2013
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:			
Accrued liabilities for property and equipment	$182	$789	$212
Detail of acquisitions:			
Fair value of assets acquired	$60,693	$—	$—
Cash paid for acquisitions, net of cash acquired	(56,786)	—	—
Liabilities assumed	(3,907)	$—	$—

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

Table of Contents

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2015, 2014 and 2013
(Amounts in tables in thousands, except share and per share data)

Note 1: General and Summary of Significant Accounting Policies

a. Description of Business/Basis of Presentation

ICU Medical, Inc., a Delaware corporation, operates in one business segment engaged in the development, manufacturing and sale of innovative medical technologies used in infusion therapy, critical care and oncology applications. Our devices are sold directly or to distributors and medical product manufacturers throughout the United States and internationally. The manufacturing for all product groups occurs in Salt Lake City, Slovakia and Mexico. Assets and operating expenses are not allocated to individual product groups. 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.

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

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

b. Cash and Cash Equivalents

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

c. Accounts Receivable

Accounts receivable are stated at net realizable value. An allowance is provided for estimated collection losses based on an assessment of various factors. We consider prior payment trends, the age of the accounts receivable balances, financial status and other factors to estimate the cash which ultimately will be received. Such amounts cannot be known with certainty at the financial statement date. We regularly review individual past due balances for collectability.

d. Inventories

Inventories are stated at the lower of cost or market with cost determined using the first-in, first-out method. Inventory costs include material, labor and overhead related to the manufacturing of medical devices.

Inventories consist of the following at December 31:

	2015	2014
Raw material	$24,681	$23,006
Work in process	4,282	3,546
Finished goods	14,669	10,381
Total	$43,632	$36,933

Table of Contents

e. Property and Equipment

Property and equipment consist of the following at December 31:

	2015	2014
Machinery and equipment	$96,909	$90,744
Land, building and building improvements	56,716	71,415
Molds	36,436	33,166
Computer equipment and software	23,346	23,228
Furniture and fixtures	3,638	3,571
Construction in progress	6,003	2,590
Total property and equipment, cost	223,048	224,714
Accumulated depreciation	(148,728)	(138,623)
Net property and equipment	$74,320	$86,091

All property and equipment are stated at cost. We use the straight-line method for depreciating property and equipment over their estimated useful lives. Estimated useful lives are:

Buildings	15 - 30 years
Building improvements	15 years
Machinery and equipment	2 - 10 years
Furniture, fixtures and molds	2 - 5 years
Computer equipment and software	3 - 5 years

We capitalize expenditures that materially increase the life of the related assets; maintenance and repairs are expensed as incurred. The costs and related accumulated depreciation applicable to property and equipment sold or retired are removed from the accounts and any gain or loss is reflected in the statements of income at the time of disposal. Depreciation expense was $15.9 million, $17.0 million and $17.0 million in the years ended December 31, 2015, 2014 and 2013, respectively.

The cost of property and equipment are presented net of government incentive reimbursements we received from the Slovakian government for building a manufacturing plant in their country. Government incentives recorded in property and equipment were $2.2 million at December 31, 2015 and $3.3 million December 31, 2014.

f. Goodwill

We test goodwill for impairment on an annual basis in the month of November. If the carrying amount of goodwill exceeds the implied estimated fair value, an impairment charge to current operations is recorded to reduce the carrying value to the implied estimated fair value. There were no accumulated impairment losses as of December 31, 2015 and 2014. During 2015, we acquired EXC Holding Corp. ("EXC"), as a result of the acquisition $5.0 million was added as acquired goodwill, see Note 3, Acquisitions and Strategic Expenses.

Table of Contents

g. Intangible Assets

Intangible assets, carried at cost less accumulated amortization and amortized on a straight-lined basis, were as follows:

	Weighted Average Amortization Life in Years	December 31, 2015		
		Cost	Accumulated Amortization	Net
Patents	10	$13,308	$8,302	$5,006
MCDA contract *	10	8,571	8,571	—
Customer contracts	9	5,319	4,133	1,186
Non-contractual customer relationships	15	7,080	118	6,962
Trademarks	4	425	425	—
Trade name	15	7,310	122	7,188
Developed technology	10	3,686	92	3,594
Total		$45,699	$21,763	$23,936

	Weighted Average Amortization Life in Years	December 31, 2014		
		Cost	Accumulated Amortization	Net
Patents	9	$12,357	$7,315	$5,042
MCDA contract *	10	8,571	8,285	286
Customer contracts	9	5,319	3,584	1,735
Trademarks	4	425	425	—
Total		$26,672	$19,609	$7,063

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

Amortization expense in 2015, 2014 and 2013 was $2.2 million, $2.4 million and $2.5 million, respectively. Estimated annual amortization for each of the next five years is approximately $2.7 million for 2016, $2.5 million for 2017, $2.4 million for 2018, $2.0 million for 2019 and $1.9 million for 2020.

h. Long-Lived Assets

We periodically evaluate the recoverability of long-lived assets whenever events and changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. When indicators of impairment are present, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of the underlying business. The net book value of the underlying asset is adjusted to fair value if the sum of the expected discounted cash flows is less than book value. Fair values are based on estimates of market prices and assumptions concerning the amount and timing of estimated future cash flows and discount rates, reflecting varying degrees of perceived risk.

i. Investment Securities

Our investment securities, which are carried at fair market value and are considered available-for-sale, consist principally of certificates of deposits, corporate bonds, U.S. Treasury securities, commercial paper and federal tax-exempt state and municipal government debt. Available-for-sale securities are recorded at fair value, and

unrealized holding gains and losses are recorded, net of tax, as a component of accumulated other comprehensive income. Unrealized losses on available-for-sale securities are charged against net earnings when a decline in fair value is determined to be other than temporary. Our management reviews several factors to determine whether a loss is other than temporary, such as the length and extent of the fair value decline, the financial condition and near term prospects of the issuer, and for equity investments, our intent and ability to hold the security for a period of time sufficient to allow for any anticipated recovery in fair value. For debt securities, management also evaluates whether we have the intent to sell or will likely be required to sell before its anticipated recovery. Realized gains and losses are accounted for on the specific identification method.

Table of Contents

j. Income Taxes

Deferred taxes are determined based on the differences between the financial statements and the tax bases using rates as enacted in the laws. A valuation allowance is established if it is “more likely than not” that all or a portion of the deferred tax assets will not be realized.

We recognize interest and penalties related to unrecognized tax benefits in the tax provision. We recognize liabilities for uncertain tax positions when it is more likely than not that a tax position will not be sustained upon examination and settlement with various taxing authorities. Liabilities for uncertain tax positions are measured based upon the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. We have not recorded any material interest or penalties during any of the years presented.

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

k. Foreign Currency

We have operations in Europe where the functional currency is the Euro and operations in Australia where the functional currency is the Australian dollar. Assets and liabilities are translated to U.S. dollars at the exchange rate in effect at the balance sheet date and revenues and expenses are translated at the average monthly exchange rates during the year. Translation adjustments are recorded as a component of accumulated other comprehensive income, a separate component of stockholders' equity on our consolidated balance sheets and the effect of exchange rate changes on cash and cash equivalents are reflected on our consolidated statements of cash flows. Gains and losses for transactions denominated in a currency other than the functional currency of the entity are included in our statements of operations. Foreign currency transaction gains and losses were $0.2 million in 2015, $0.1 million in 2014 and less than $0.1 million in 2013.

l. Revenue Recognition

Most of our product sales are free on board shipping point and ownership of the product transfers to the customer on shipment. We record sales and related costs when ownership of the product transfers to the customer, persuasive evidence of an arrangement exists, collectability is reasonably assured and the sales price is determinable. Our customers are distributors, medical product manufacturers and end-users. Our only post-sale obligations are warranty and certain rebates. We warrant products against defects and have a policy permitting the return of defective products. We reserve for warranty and returns based on historical experience. We accrue rebates based on agreements and on historical experience as a reduction in revenue at the time of sale.

Other revenue consists of license, royalty and revenue sharing payments. Payments expected to be received are estimated and recorded in the period earned, and adjusted to actual amounts when reports are received from payers; if there is insufficient data to make such estimates, payments are not recorded until reported by the payers.

m. Shipping Costs

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

n. Advertising Expenses

Advertising expenses are expensed as incurred and reflected in selling, general and administrative expenses in our consolidated statements of income and were $0.2 million in 2015, $0.1 million in 2014 and $0.3 million in 2013.

o. Post-retirement and Post-employment Benefits

We do not provide retirement or post-employment benefits to employees other than our Section 401(k) retirement plan ("plan") for employees. Our contributions to the plan were approximately $1.3 million in 2015, $1.3 million in 2014 and $1.1 million in 2013.

Table of Contents

p. Research and Development

Research and development costs are expensed as incurred.

q. Net Income Per Share

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities are outstanding common stock options (excluding stock options with an exercise price in excess of the average market value for the period), less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method. Options that are anti-dilutive because their exercise price exceeded the average market price of the common stock for the period approximated 16,000 shares in 2014 and 10,000 shares in 2013. There were no anti-dilutive options in 2015.

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

	Year ended December 31, (in thousands, except per share data)		
	2015	2014	2013
Net income	$44,985	$26,335	$40,418
Weighted average number of common shares outstanding (basic)	15,848	15,282	14,688
Dilutive securities	648	365	586
Weighted average common and common equivalent shares outstanding (diluted)	16,496	15,647	15,274
EPS - basic	$2.84	$1.72	$2.75
EPS - diluted	$2.73	$1.68	$2.65

r. Accounting Estimates

Preparing financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

s. New Accounting Pronouncements

In November 2015, the FASB issued ASU No. 2015-17 Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments are effective prospectively or retrospectively for annual periods beginning after December 15, 2016 and interim periods within those annual periods. We early adopted ASU 2015-17 retrospectively as of the year ended December 31, 2015. The adoption of this standard resulted in the reclassification of $4.7 million from current deferred income tax assets in the consolidated balance sheet as of December 31, 2014 resulting in adjusted total noncurrent deferred income tax assets $13.9 million. Adoption of this standard did not impact results of operations, retained earnings, or cash flows in the current or previous annual reporting periods.
In September 2015, the Financial Accounting Standards Board ("FASB") issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. ASU 2015-16 requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined, including the cumulative effect of the change in provisional amount as if the accounting had been completed at the acquisition date. The adjustments related to

previous reporting periods since the acquisition date must be disclosed by income statement line item either on the face of the income statement or in the notes. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on or after December 15, 2015 (early adoption is permitted only for financial statements that have not been issued). We do not anticipate a material impact on our consolidated financial statements from adoption of this ASU.

In July 2015, the FASB issued ASU No. 2015-11 Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 changes the measurement of inventory from lower of cost or market to lower of cost and net realizable value. The amendments are effective prospectively for the fiscal years, and interim reporting periods within those years, beginning on

Table of Contents

or after December 15, 2016. We do not anticipate a material impact on our consolidated financial statements from adoption of this ASU.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). ASU 2014-09 removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. This guidance requires that an entity depict the consideration by applying a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. On April 1, 2015, the FASB voted for a one-year deferral of the effective date of the new revenue recognition standard, ASU No. 2014-09. On July 15, 2015, the FASB affirmed these changes, which requires public entities to apply the amendments in ASU 2014-09 for annual reporting beginning after December 15, 2017. Early adoption is permitted beginning after December 31, 2016, the original effective date in ASU 2014-09. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In June 2014, the FASB issued ASU No. 2014-12, Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period. ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. This guidance will become effective for us at the beginning of the first quarter of 2016. We do not anticipate a material impact on our consolidated financial statements from adoption of this ASU.

Note 2: Restructuring Charges

In 2015, we incurred $6.7 million in total restructuring charges related to: (i) a commitment to a plan to sell our Slovakia manufacturing facility. The assets of the manufacturing facility are classified as assets held for sale and are included as a separate line item in our consolidated balance sheet. The sale is expected to be completed during the third quarter of 2016. The plan to sell the facility resulted in a pre-tax restructuring charge of $4.2 million for employee termination benefits, government incentive repayments and other associated costs; (ii) an agreement with Dr. Lopez, a member of our Board of Directors and a former employee in our research and development department, pursuant to which we bought out Dr. Lopez's right to employment under his then-existing employment agreement. The $1.9 million buy-out, including payroll taxes, will be paid in equal monthly installments until December 2020. Payments that will exceed one year have been accrued under long-term liabilities in our consolidated balance sheet; and (iii) the reorganization of our corporate infrastructure, resulting in one-time employee termination benefits and other associated costs. The buy-out agreement and corporate restructuring actions resulted in a total charge of $2.5 million.

In 2014, we reorganized our selling and corporate infrastructure, resulting in a reduction in workforce of 69 employees. The $3.5 million restructuring charge, which is presented as a separate line item on our consolidated

statements of income, is combined with strategic transaction expenses. The restructuring charge is comprised of employee termination benefits and other associated costs.

Table of Contents

The following table summarizes the activity for the restructuring-related charges discussed above and related accrual (in thousands):

	Accrued Balance December 31, 2013	Charges incurred	Payments	Accrued Balance December 31, 2014	Charges incurred	Payments	Accrued Balance December 31, 2015
Severance pay and benefits	$—	$3,530	$(2,172)	$1,358	$2,582	$(1,435)	$2,505
Government incentive repayment	—	—	—	—	1,884	—	1,884
Employment agreement buyout	—	—	—	—	1,905	(60)	1,845
Other corporate restructuring	—	11	—	11	305	(11)	305
	$—	3,541	(2,172)	$1,369	6,676	(1,506)	$6,539

Note 3: Acquisitions and Strategic Transaction Expenses

Acquisitions

On October 6, 2015, we acquired 100% of the outstanding shares of EXC, for approximately$59.5 million in cash. Immediately following the completion of the acquisition of EXC, we sold certain assets to Excelsior Medical, LLC for a final purchase price including working capital adjustments of $29.0 million in cash. We retained all of the assets related to the business of manufacturing and selling the needleless connector disinfection cap. The acquisition of EXC's SwabCap business enhances our infusion therapy product offering across our existing direct and original equipment manufacturer ("OEM") business lines. The goodwill recognized for this acquisition is attributable to the benefits expected to be derived from product line expansion, new customers and operational synergies. The goodwill is nondeductible for income tax purposes. The following table summarizes the final purchase price and the allocation of the purchase price related to the assets and liabilities retained (in thousands):

Fair Value of Consideration:	
Cash, net of cash acquired	$56,786
Allocation of the Purchase Price:	
Net assets sold to Excelsior Medical, LLC	$28,970
Prepaid expenses and other current assets	254
Deferred tax asset/liabilities	4,426
Property and equipment	3,982
Identifiable intangible assets[1]	18,076
Goodwill	4,985
Assumed liabilities	(3,907)
Net Assets Acquired	$56,786

[1] Identifiable intangible assets include $7.1 million of non-contractual customer relationships, $3.7 million of developed technology and $7.3 million of trade name. The weighted-average amortization period for the total identifiable intangible assets is approximately fourteen years. The weighted-average amortization period for customer relationships and trade name is fifteen years and the weighted-average amortization period for the developed

technology is ten years.

The identifiable intangible assets and other long-lived assets acquired have been valued as Level 3 assets at fair market value by an independent financial valuation and advisory services firm. The estimated fair value of identifiable intangible assets was developed using the income approach and is based on critical estimates, judgments and assumptions derived from: analysis of market conditions; discount rate; discounted cash flows; royalty rates; customer retention rates; and estimated useful

Table of Contents

lives. The prepaid expenses and other current assets and assumed liabilities were recorded at their carrying values as of the date of the acquisition, as their carrying values approximated their fair values due to their short-term nature.

Strategic Transaction Expenses

In 2015, we incurred $1.8 million in charges primarily associated with the acquisition of EXC. In 2014 and 2013, we incurred $1.6 million and $1.4 million, respectively, in charges associated with strategic transactions that did not go forward. Transaction expenses are presented on a separate line item on our statements of income and are combined with restructuring charges.

Note 4: Gain on Sale of Building

On September 30, 2015, we sold an office building in our San Clemente location to Dr. Lopez. The building was sold for $3.6 million, its fair market value as determined by a third party. The net book value of the land and building was $2.5 million, resulting in a gain on the sale of the land and building of $1.1 million.

Note 5: Legal Settlements

During 2015, an arbitrator ruled on a breach of contract claim between us and a customer, Hospira, Inc., awarding Hospira $8.2 million Canadian dollars ($6.5 million U.S. dollars). The arbitrator also ruled that we pay 75% of Hospira's legal fees and expenses, which were $0.7 million U.S. dollars. We made a $7.5 million U.S. dollars settlement payment during 2015, which includes a foreign exchange transaction adjustment to Canadian dollars at the time of payment.
Also during 2015, an arbitrator ruled on a breach of contract claim between us and a service provider, awarding us $8.8 million. Our legal counsel for this matter represented us under a contingency fee agreement. We recorded a settlement award, net of legal fees and costs, of $5.3 million.

Note 6: Impairment on Assets Held for Sale

On November 16, 2015, our Board of Directors authorized us to close our Vrable, Slovakia manufacturing facility. The closure is to enable for greater efficiency of our Ensenada, Mexico facility. The expected completion date for the closure is during the third quarter of 2016. In correlation with the Board's authorization we reclassified the land and building related to the Slovakia facility as held for sale, as such we record the value of those assets at the lower of their carrying value or their estimated fair value, less costs to sell. A third party fair market valuation on the held for sale assets resulted in an impairment charge of $4.1 million. The impairment charge is separately stated in our consolidated statements of income above income from operations.

Note 7: Share Based Awards

We have a stock incentive plan for employees and directors and an employee stock purchase plan. Shares to be issued under these plans will be issued either from authorized but unissued shares or from treasury shares.

We incur stock compensation expense for stock options, restricted stock units ("RSU"), performance restricted stock units ("PRSU") and stock purchased under our employee stock purchase plan ("ESPP"). We receive a tax benefit on stock compensation expense, excluding the direct tax benefits from exercise of stock options, which is reported separately on the consolidated statements of cash flows. We also have indirect tax benefits upon exercise of stock options related to research and development tax credits which were recorded as a reduction of income tax expense. The table below summarizes compensation costs and related tax benefits for the years ended December 31, 2015, 2014 and 2013.

	Year ended December 31,		
(In thousands)	2015	2014	2013
Stock compensation expense	$12,827	$9,592	$5,434
Tax benefit from stock-based compensation cost	$4,922	$3,567	$2,052
Indirect tax benefit	$1,997	$209	$866

As of December 31, 2015, we had $22.7 million of unamortized stock compensation cost which we will recognize as an expense over approximately 1.0 years.

Table of Contents

Stock Incentive and Stock Option Plans

Our 2011 Stock Incentive Plan ("2011 Plan") replaced our 2003 Stock Option Plan (“2003 Plan”). Our 2011 Plan initially had 650,000 shares available for issuance, plus the remaining available shares for grant from the 2003 Plan. In 2012 and 2014, our stockholders approved amendments to the 2011 plan that increased the shares available for issuance by 1,850,000, bringing the initial shares available for issuance to 2,500,000, plus the remaining 248,700 shares that remained available for grant from the 2003 Plan. In addition, any forfeited, terminated or expired shares that would otherwise return to the 2003 Plan are available under the 2011 Plan. As of December 31, 2015, the 2011 Plan has 2,763,300 shares of common stock reserved for issuance to employees, which includes 263,300 shares that transferred from the 2003 Plan. Shares issued as options or stock appreciation rights ("SARs") are charged against the 2011 Plan's share reserve as one share for one share issued. Shares subject to awards other than options and SARs are charged against the 2011 Plan's share reserve as 2.09 shares for 1 share issued. Options may be granted with exercise prices at no less than fair market value at date of grant. Options granted under the 2011 Plan may be “non-statutory stock options” which expire no more than ten years from date of grant or “incentive stock options” as defined in Section 422 of the Internal Revenue Code of 1986, as amended. Upon exercise of non-statutory stock options, we are generally entitled to a tax deduction on the exercise of the option for an amount equal to the excess over the exercise price of the fair market value of the shares at the date of exercise; we are generally not entitled to any tax deduction on the exercise of an incentive stock option. The 2011 Plan includes conditions whereby unvested options are cancelled if employment is terminated.

In 2014, our Compensation Committee of the Board of Directors awarded our new Chief Executive Officer an employment inducement option to purchase 182,366 shares of our common stock and an employment inducement grant of restricted stock units with respect to 68,039 shares of our common stock. The inducement grants were made out of our 2014 Inducement Incentive Plan ("2014 Plan").

Our 2001 Directors’ Stock Option Plan (the “Directors’ Plan”), initially had 750,000 shares reserved for issuance to members of our Board of Directors, expired in November 2011. Although no new grants may be made under the Director's Plan, grants made under the Director's Plan prior to its expiration continue to remain outstanding. Options not vested terminate if the directorship is terminated.

Stock Options

To date, all options granted under the 2014 Plan, 2011 Plan, 2003 Plan and Directors' Plan have been non-statutory stock options. The majority of the time-based outstanding employee option grants vest 25% after one year from the grant date and the balance vests ratably on a monthly basis over 36 months. The 2015 performance based stock option grants vest ratably at 33% per year over three years. The 2014 performance based stock option grants vest ratably at 25% per year over four years. The majority of the outstanding options granted to non-employee directors vest one year from the grant date. The options generally expire 10 years from the grant date.

The fair value of time-based option grants is calculated using the Black-Scholes option valuation model. The expected term for the option grants was based on historical experience and expected future employee behavior. We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock, based on the average expected exercise term. The table below summarizes the total time-based stock options granted, total valuation and the weighted average assumptions for the years ended December 31, 2015, 2014 and 2013.

	Year ended December 31,		
	2015	2014	2013
Number of time-based options granted	22,816	492,935	244,440
Grant date fair value of options granted (in thousands)	$590	$7,311	$3,934
Weighted average assumptions for stock option valuation:			

Expected term (years)	5.6		4.7		4.6	
Expected stock price volatility	25.9	%	26.7	%	29.2	%
Risk-free interest rate	1.7	%	1.4	%	0.8	%
Expected dividend yield	—	%	—	%	—	%
Weighted average grant price per option	$93.30		$58.92		$62.12	
Weighted average grant date fair value per option	$25.86		$14.83		$16.09	

Table of Contents

The 2015 and 2014 performance stock option grants are exercisable if the common stock price condition and the time-based vesting have been met. For the 2015 grants, the vested performance stock options will be exercisable when the closing price of our common stock is equal to or more than 130% of the exercise price for 30 consecutive trading days during the term of the grant. For the 2014 grants, fifty percent of the vested performance stock options became exercisable when the closing price of our common stock was equal to or more than 125% of the exercise price for 30 consecutive trading days during the term of the grant. The remaining 50% of the vested performance stock options became exercisable when the closing price of our common stock was equal to or more than 150% of the exercise price for 30 consecutive trading days during the term of the grant. Both of the 2014 performance stock option grant's stock price conditions have been met. The 2015 performance stock option grant's stock price conditions have not been met as of December 31, 2015.

The fair value of performance option grants is calculated using the Monte Carlo Simulation. The expected term of the performance option grants is based on the expected number of years to achieve the exercisable goal trigger and assumes that the vested option will be immediately exercised or cancelled, if underwater. We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock over a 10-year period. The table below summarizes the performance stock options granted, total valuation and the weighted average assumptions for the years ended December 31, 2015 and 2014.

	Year ended December 31,	
	2015	2014
Number of performance options granted	244,825	699,625
Grant date fair value of options granted (in thousands)	$6,087	$13,344
Weighted average assumptions for stock option valuation:		
Expected term (years)	3.0	4.0
Expected stock price volatility	30.86 %	31.7 %
Risk-free interest rate	2.3 %	2.9 %
Expected dividend yield	— %	— %
Weighted average grant price per option	$91.88	$58.90
Weighted average grant date fair value per option	$24.86	$19.07

A summary of our stock option activity as of and for the year ended December 31, 2015 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	2,556,936	$49.46		
Granted	267,641	$92.00		
Exercised	(435,146)	$34.77		
Forfeited or expired	(10,024)	$58.20		
Outstanding at December 31, 2015	2,379,407	$56.90	7.1	$132,963
Exercisable at December 31, 2015	1,287,271	$48.45	5.9	$82,809
Vested and expected to vest, December 31, 2015	2,379,407	$56.90	7.1	$132,963

The intrinsic values for options exercisable, outstanding and vested or expected to vest at December 31, 2015 is based on our closing stock price of $112.78 at December 31, 2015 and are before applicable taxes.

	Year ended December 31,		
(In thousands)	2015	2014	2013

Intrinsic value of options exercised	$28,071	$18,802	$21,847
Cash received from exercise of stock options	$15,042	$16,998	$18,004
Tax benefit from stock option exercises	$9,330	$5,700	$6,966

Table of Contents

Stock Awards

RSUs are granted to our Board of Directors and vest on the first anniversary of the grant date.

In 2015, we granted RSUs to certain new hire employees that vest ratably on the anniversary of the grant over two years and certain other employees that vest ratably on the anniversary of the grant over three years.

In 2014, we granted RSUs to our Chief Executive Officer that vest ratably on the anniversary of the grant over three years and to certain other employees that vest ratably on the anniversary of the grant over two years. The fair value of the RSUs is based on the price of the common stock on the grant date.

In 2013, we awarded PRSUs to our executive officers. PRSUs are awarded to our executive officers to receive shares of common stock if the measurement period goal is met. The executive PRSUs are based on a one-year market condition performance period measured against a total shareholder return metric ("TSR"). If the TSR is less than the 33rd percentile of our peer group index, 0% of the award would be earned. If the TSR is equal or greater than the 33rd percentile and less than the 50th percentile of our peer group companies, 50% of the award would be earned. If the TSR is equal or greater than the 50th percentile and less than the 75th percentile of our peer group companies, 100% of the award will be earned. If the TSR is equal or greater than the 75th percentile of our peer group companies, 200% of the award will be earned. The PRSUs vest in equal yearly installments with one-third of the grant becoming vested on each of the three anniversary dates of the award. Our executive officers earned 0% of their 2013 award because the TSR was below the 33rd percentile of our peer companies.

The fair value of the 2013 PRSUs was calculated using a Monte Carlo simulation embedded in a lattice model. The 2013 calculation used a risk-free interest rate of 0.15%, a closing share price of 61.76, assumed no dividends and assumed no forfeitures. For the 2013 calculation, the correlation matrix of stock price returns and volatilities were calculated based on one year preceding January 1, 2013.

The table below summarizes our restricted stock award activity for the years ended December 31, 2015, 2014 and 2013.

	Year ended December 31,		
(In thousands except shares and per share amounts)	2015	2014	2013
PRSU			
Shares granted	—	—	15,085
Grant date fair value per share	$—	$—	$50.82
Grant date fair value	$—	$—	$767
Intrinsic value vested	$787	$659	$636
RSU			
Shares granted	67,745	76,618	4,908
Grant date fair value per share	$93.52	$58.89	$67.25
Grant date fair value	$6,336	$4,512	$330
Intrinsic value vested	$2,754	$292	$412

The table below provides a summary of our PRSU and RSU activity as of and for the year ended December 31, 2015.

	Number of Units	Grant Date Fair Value Per Share	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value

Non-vested at December 31, 2014	86,032	$57.22		
Granted	67,745	$93.52		
Vested	(39,507)	$56.79		
Forfeited	(621)	$88.76		
Non-vested and expected to vest at December 31, 2015	113,649	$78.84	1.0	$12,817

Table of Contents

ESPP

We have an ESPP under which U.S. employees may purchase up to $25,000 annually of common stock at 85% of its fair market value at the beginning or the end of a six-month offering period, whichever is lower. There are 750,000 shares of common stock reserved for issuance under the ESPP, which is subject to an annual increase of the least of 300,000 shares, two percent of the shares outstanding or such a number as determined by the Board. To date, there have been no increases. As of December 31, 2015, there were 188,140 shares available for future issuance. The ESPP is intended to constitute an “employee stock purchase plan” within the meaning of Section 423 of the Internal Revenue Code. As of December 31, 2015, we had $0.1 million of unamortized stock compensation expense from the ESPP, which will be recognized in the first quarter of 2016.

The fair value of rights to purchase shares under the ESPP is calculated using the Black-Scholes option valuation model. The table below summarizes the number and intrinsic value of ESPP share purchases and the weighted average valuation assumptions for the 2015, 2014 and 2013 purchase periods.

	Year ended December 31,		
	2015	2014	2013
ESPP shares purchased by employees	34,299	47,466	50,944
Intrinsic value of ESPP purchases (in thousands)	$1,382	$476	$840
Weighted average assumptions for ESPP valuation:			
Expected term (in years)	0.5	0.5	0.5
Expected stock price volatility	27.0 %	20.8 %	24.4 %
Risk-free interest rate	0.6 %	1.1 %	0.1 %
Expected dividend yield	— %	— %	— %

Note 8: Fair Value Measurement

Our investment securities consist of certificates of deposit, corporate bonds, U.S. Treasury securities, commercial paper and federal tax-exempt state and municipal government debt. All investment securities are considered available-for-sale and are "investment grade", carried at fair value and there have been no gains or losses on their disposal. As of December 31, 2015, we have $8.8 million of investment securities as Level 1 assets, which are certificates of deposit and U.S. Treasury securities with quoted prices in active markets. As of December 31, 2015, we have $32.4 million of investment securities as Level 2 assets, which are pre-refunded municipal securities, non-pre-refunded municipal securities, commercial paper and corporate bonds and are valued using observable market based inputs such as quoted prices, interest rates and yield curves.

There were no transfers between levels in 2015.

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

	Fair value measurements at December 31, 2015 using			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Available for sale securities	$41,233	$ 8,785	$ 32,448	$ —
	$41,233	$ 8,785	$ 32,448	$ —

	Fair value measurements at December 31, 2014 using			
	Total carrying	Quoted prices	Significant	Significant

	value	in active markets for identical assets (level 1)	other observable inputs (level 2)	unobservable inputs (level 3)
Available for sale securities	$70,952	$5,884	$65,068	$—
	$70,952	$5,884	$65,068	$—

As of December 31, 2015, the carrying amounts of assets held for sale, as Level 3 assets, were written-down to their fair value of $4.1 million based upon the expected sales price less costs to sell, as determined by property appraisal reports

Table of Contents

prepared by an independent real estate appraiser. Our assets held for sale are included as a separate line item in our consolidated balance sheets. The estimated fair value of the assets held for sale was developed using the income approach and is based on critical estimates, judgments and assumptions derived from: analysis of market conditions; building condition; comparable properties; and rental income and expense. As a result of the fair value estimate, during 2015, we incurred a $4.1 million impairment on these assets, included as a separate line item in our consolidated statements of income within income from operations.

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

	Fair value measurements at December 31, 2015 using			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets held for sale	4,134	—	—	4,134
	$4,134	$—	$—	$4,134

Note 9: Investment Securities

Our investment securities consist of certificates of deposit, corporate bonds, U.S. Treasury securities, commercial paper and federal-tax-exempt state and municipal government debt. All investment securities are considered available-for-sale and are “investment grade,” carried at fair value and there have been no gains or losses on their disposal. Unrealized gains and losses on available-for-sale securities, net of tax, are included in accumulated other comprehensive income in the stockholders' equity section of our consolidated balance sheets. We have no gross unrealized gains or losses on available-for-sale securities at December 31, 2015 or 2014. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization is included in investment income in other income on our consolidated statements of income.

Balances consist of the following at December 31:

	2015	2014
Federal and municipal tax-exempt debt securities	$4,951	$15,013
Corporate bonds	25,400	46,209
U.S. Treasury securities	7,537	—
Commercial paper	2,097	3,846
Certificates of deposit	1,248	5,884
	$41,233	$70,952

The scheduled maturities of the debt securities are between 2016 and 2037 and are all callable within one year.

Investment income, reflected in other income in our consolidated statements of income, was $0.5 million, $0.4 million and $0.4 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Table of Contents

Note 10: Accrued Liabilities

Accrued liabilities consist of the following at December 31:

	2015	2014
Salaries and benefits	$6,875	$6,746
Incentive compensation	8,302	5,405
Value Added Tax accrual	993	398
Restructuring accrual	6,539	1,368
Acquisition-related accrual	1,604	—
Outside commissions	1,023	1,146
Other	3,612	2,287
	$28,948	$17,350

Note 11: Income Taxes

Income from continuing operations before taxes for the years ended December 31, 2015, 2014 and 2013 is as follows:

	2015	2014	2013
United States	$74,288	$33,508	$48,964
Foreign	(4,589)	6,284	3,750
	$69,699	$39,792	$52,714

The provision (benefit) for income taxes for the years ended December 31, 2015, 2014 and 2013 is as follows:

	2015	2014	2013
Current:			
Federal	$18,601	$13,860	$14,575
State	745	(1,305)	2,145
Foreign	1,426	2,100	(70)
	20,772	14,655	16,650
Deferred:			
Federal	$4,524	$(2,325)	$164
State	(960)	988	(996)
Foreign	378	139	(3,522)
	3,942	(1,198)	(4,354)
	$24,714	$13,457	$12,296

Current income taxes payable were reduced from the amounts in the above table by $9.3 million, $5.7 million and $7.0 million in 2015, 2014 and 2013, respectively, equal to the direct tax benefit that we receive upon exercise of stock options by employees and directors. The benefit is allocated to stockholders' equity. We have accrued for tax contingencies for potential tax assessments, and in 2015 we recognized a $1.8 million net decrease, most of which related to various federal and state tax reserves.

Reconciliations of the provision for income taxes at the statutory rate to our effective tax rate for the years ended December 31, 2015, 2014 and 2013 are as follows:

Table of Contents

	2015		2014		2013	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$24,395	35.0 %	$13,927	35.0 %	$18,450	35.0 %
State income tax, net of federal effect	2,661	3.9 %	981	2.5 %	1,126	2.1 %
Tax credits	(5,861)	(8.4)%	(1,591)	(4.0)%	(1,974)	(3.7)%
Tax-exempt interest and dividends	—	— %	(3)	— %	—	— %
Domestic production activities/other	107	0.1 %	104	0.2 %	(403)	(0.8)%
Foreign income tax	3,412	4.9 %	39	0.1 %	(4,903)	(9.3)%
	$24,714	35.5 %	$13,457	33.8 %	$12,296	23.3 %

Tax credits in 2015, 2014 and 2013 consist principally of research and developmental tax credits. The indirect effect of non-statutory stock options exercised on research and development tax credits and other tax credits were recorded as reductions of the effective tax provision.

The components of our deferred income tax provision for the years ended December 31, 2015, 2014 and 2013 are as follows:

	2015	2014	2013
Allowance for doubtful accounts	$—	$4	$4
Inventory reserves	284	(488)	341
Accruals	(2,977)	(1,326)	(470)
State income taxes	502	(4)	552
Acquired future tax deductions	3,139	96	40
Depreciation and amortization	1,080	(780)	(3,850)
Net operating loss	195	62	—
Tax credits	(635)	1,238	(971)
Valuation allowance	2,354	—	—
	$3,942	$(1,198)	$(4,354)

The components of our deferred income tax assets (liabilities) at December 31, 2015 and 2014 are as follows:

	2015	2014
Deferred tax asset:		
State income taxes	$(1,647)	$(1,862)
Foreign	3,881	$1,905
Accruals/other	1,432	2,604
Depreciation and amortization	(11,735)	(5,594)
Acquired future tax deductions	5,778	639
Stock-based compensation	8,864	6,778
Foreign currency translation adjustments	5,360	2,680
Tax credits state	5,887	5,102
Inventory reserves	1,633	1,538
Allowance for doubtful accounts	—	151
Valuation allowance	(2,354)	—
	$17,099	13,941
Deferred tax liability:		
Foreign	$1,372	$1,376

	$1,372	$1,376

Acquired future tax deductions are the tax benefits included in our consolidated income tax returns originating in Bio-Plexus, Inc., an entity purchased in 2002, prior to when we acquired the entity, and those originating from EXC Holding Corp.

Table of Contents

("EXC") acquired in 2015. They consist of: (a) the net tax benefit of items expensed for financial statement purposes but capitalized and amortized for tax purposes, (b) the tax benefited portion of Bio-Plexus's federal net operating loss ("NOL") carry-forward which will be realized in approximately equal amounts over the next 8 years, and (c) the tax benefited portion of EXC's NOL carryforward of $4.9 million is expected to be realized in approximately 6 years, and will expire in 18 years. Under Section 382 of the Internal Revenue Code, certain ownership changes limit the utilization of the NOL carry-forwards, and the amount of federal NOL carry-forwards recorded is the net federal benefit available.

A net change in the valuation allowance of $2.4 million was recorded against the deferred tax assets of our Slovakia subsidiary due to a change in realization as a result of the decision to close the manufacturing facility.

Foreign currency translation adjustments, and related tax effects, are an element of "other comprehensive income" and are not included in net income.

Our estimate of undistributed earnings of our foreign subsidiaries for which no federal or state liability has been recorded cumulatively was $17.8 million at December 31, 2015 and $14.5 million at December 31, 2014. These undistributed earnings are considered to be indefinitely reinvested. However, if unanticipated distribution of those earnings were to occur in the form of dividends or otherwise, some portion of the distribution would be subject to both foreign withholding taxes and U.S. income taxes. In the event that our position in this regard changes, determining the potential amount of unrecognized deferred federal and state income tax liability and foreign withholding taxes is not practicable because of the complexities associated with its hypothetical calculation. However, unrecognized foreign tax credits would be available to reduce some portion of the federal liability.

We are subject to taxation in the United States and various states and foreign jurisdictions. Our United States federal income tax returns for tax years 2012 and forward are subject to examination by the Internal Revenue Service. Our principal state income tax returns for tax years 2013 and forward are subject to examination by the state tax authorities. The total gross amount of unrecognized tax benefits as of December 31, 2015 was $1.8 million that, if recognized, would impact the effective tax rate.

The following table summarizes our cumulative gross unrecognized tax benefits for 2015, 2014 and 2013:

	2015	2014	2013
Beginning balance	$4,115	$5,544	$4,236
Increases to prior year tax positions	25	217	391
Increases to current year tax positions	345	661	1,353
Decreases to prior year tax positions	(2,399)	—	—
Decrease related to settlements	(314)	(2,113)	—
Decrease related to lapse of statute of limitations	—	(194)	(436)
Ending balance	$1,772	$4,115	$5,544

Note 12: Products, Major Customers and Concentrations of Credit Risks

Our primary product groups are infusion therapy, critical care and oncology. The breakdown by market segment for the years ended December 31, 2015, 2014 and 2013 are as follows:

	2015	2014	2013
Infusion therapy	$244,746	$216,280	$221,192
Critical care	54,312	55,074	54,328
Oncology	41,447	36,651	36,857
Other	1,163	1,255	1,339
	$341,668	$309,260	$313,716

We sell products worldwide, on credit terms on an unsecured basis, as an OEM supplier, to independent medical supply distributors, and directly to the end customer. The manufacturers and distributors, in turn, sell our products to healthcare providers. For the years ended December 31, 2015, 2014 and 2013, we had worldwide sales to one manufacturer, Pfizer, of 36%, 36% and 39%, respectively, of consolidated revenue. As of December 31, 2015, and 2014, we had accounts receivable from Pfizer of 40% and 27%, respectively, of consolidated accounts receivable.

Table of Contents

Domestic sales accounted for 71%, 69% and 71% of total revenue in 2015, 2014 and 2013, respectively. International sales, which are determined by the destination of the product shipment, accounted for 29%, 31% and 29% of total revenue in 2015, 2014 and 2013, respectively.

The table below presents our gross long-lived assets by country:

	As of December 31,	
	2015	2014
Mexico	$53,462	51,554
Slovakia[1]	5,480	16,643
Italy	4,418	4,855
Germany	671	638
Netherlands	49	—
Australia	35	—
Total foreign	$64,115	$73,690
United States	158,933	151,024
Worldwide total	$223,048	$224,714

[1] The decrease in Slovakia long-lived assets included an $8.2 million reclass of land and building to assets held for sale, which were subsequently impaired, see Note 6, Impairment of assets held for sale.

Note 13: Operating Leases

During 2015, we entered into a building lease in San Clemente, United States, which expires in June 2020, and we entered into an office space lease in Johannesburg, South Africa, which expires in March 2018. We also lease a building in Ludenscheid, Germany which expires in December 2016 and have an option to extend the term. We continue to lease office space in Utrecht, Netherlands and Bella Vista, NSW Australia, both which expire in December 2016, and have options to extend the term. We also lease various office equipment, which all expire during 2016. Our lease expense was $0.4 million in 2015, $0.2 million in 2014 and $0.2 million in 2013. Our annual minimum future lease payments are $1.1 million in 2016, $0.4 million in 2017, $0.1 million in 2018, $0.1 million in 2019 and $0.1 million in 2020.

Note 14: Treasury Stock

In July 2010, our Board of Directors approved a common stock purchase plan to purchase up to $40.0 million of our common stock. This plan has no expiration date and we have $22.5 million remaining on this purchase plan. We did not purchase any of our common stock in 2015. We purchased $5.6 million of our common stock in 2014. We used the treasury stock to issue shares for stock option exercises, restricted stock grants and employee stock purchase plan stock purchases.

In 2015, we withheld 17,299 shares of our common stock from employee vested restricted stock units in consideration for $1.5 million in payments for the employee's share award income tax withholding obligations. In 2015, we also withheld 823 shares of our common stock from option exercises with shares remitted back to us in lieu of $0.1 million in cash payments for the option exercises.

In 2014, we withheld 4,232 shares of our common stock from employee vested restricted stock units in consideration for $0.2 million in payments for the employee's share award income tax withholding obligations. In 2014, we also withheld 4,583 shares of our common stock from option exercises with shares remitted back to us in lieu of $0.3 million in cash payments for the option exercises.

Note 15: Stockholder Rights Plan

In July 1997, our Board of Directors adopted a Stockholder Rights Plan. This plan expired in 2007 and in July 2007, our Board of Directors adopted an Amended and Restated Rights Agreement. We distributed a Preferred Share Purchase Right (a "Right") for each share of our Common Stock outstanding. The Rights generally will not be exercisable until a person or group has acquired 15% or more of our Common Stock in a transaction that is not approved in advance by the Board of

Table of Contents

Directors or ten days after the commencement of a tender offer which could result in a person or group owning 15% or more of our Common Stock.

On exercise, each Right entitles the holder to buy one share of Common Stock at an exercise price of $225. In the event a third party or group were to acquire 15% or more of our outstanding Common Stock without the prior approval of the Board of Directors, each Right will entitle the holder, other than the acquirer, to buy Common Stock with a market value of twice the exercise price, for the Right's then current exercise price. In addition, if we were to be acquired in a merger after such an acquisition, shareholders with unexercised Rights could purchase common stock of the acquirer with a value of twice the exercise price of the Rights.

Our Board of Directors may redeem the Rights for a nominal amount at any time prior to the tenth business day following an event that causes the Rights to become exercisable. The Rights will expire unless previously redeemed or exercised on August 8, 2017.

Note 16: Commitments and Contingencies

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

In the normal course of business, we have agreed to indemnify our officers and directors to the maximum extent permitted under Delaware law and to indemnify customers as to certain intellectual property matters related to sales of our products. There is no maximum limit on the indemnification that may be required under these agreements. We have never incurred, nor do we expect to incur, any liability for indemnification.

Note 17: Quarterly Financial Data - Unaudited

	Quarter Ended			
	Mar. 31	Jun. 30	Sept. 30	Dec. 31
2015				
Total revenue	$81,484	$83,781	$86,016	$90,387
Gross profit	$42,514	$43,761	$46,265	$48,257
Net income	$9,686	$13,570	$16,266	$5,463
Net income per share:				
Basic	$0.62	$0.86	$1.02	$0.34
Diluted	$0.60	$0.83	$0.98	$0.33
2014				
Total revenue	$73,230	$78,677	$77,457	$79,896
Gross profit	$36,027	$37,542	$38,147	$39,685
Net income	$6,657	$5,878	$6,428	$7,372
Net income per share:				
Basic	$0.44	$0.39	$0.42	$0.48
Diluted	$0.43	$0.38	$0.42	$0.46

Table of Contents

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have concluded, based on their evaluation of our disclosure controls and procedures (as defined in Regulations 13a-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Report, that our disclosure controls and procedures are effective to ensure that the information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure and that such information is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities Exchange Commission.

There was no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Management’s Annual Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate control over the Company’s financial reporting.

Management has used the criteria in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its internal control over financial reporting.

Management of the Company has concluded that the Company has maintained effective internal control over its financial reporting as of December 31, 2015 based on the criteria in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Our independent registered public accounting firm that audited the December 31, 2015 financial statements included in this Annual Report on Form 10-K has independently assessed the effectiveness of our internal control over financial reporting and its report is below.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of ICU Medical, Inc. and subsidiaries (the “Company”) as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2015 of the Company and our report dated February 26, 2016 expressed an unqualified opinion on those consolidated financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Costa Mesa, California
February 26, 2016

Table of Contents

Item 9B. Other Information.

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table lists the names, ages, certain positions and offices held by our executive officers as of January 31, 2016.

	Age	Office Held
Vivek Jain	43	Chairman of the Board and Chief Executive Officer
Alison D. Burcar	43	Vice President and General Manager of Infusion Systems
Scott E. Lamb	53	Chief Financial Officer
Tom McCall	58	Vice President and General Manager of Critical Care
Steven C. Riggs	57	Vice President of Operations

Mr. Jain joined the Company in February 2014 as Chairman of the Board and Chief Executive Officer. Mr. Jain served as CareFusion Corporation's ("CareFusion") President of Procedural Solutions from 2011 to February 2014. Mr. Jain served as President, Medical Technologies and Services of CareFusion from 2009 until 2011. Mr. Jain served as the Executive Vice-President-Strategy and Corporate Development of Cardinal Health from 2007 until 2009. Mr. Jain served as Senior Vice President, Business Development and M&A for the Philips Medical Systems business of Koninklijke Philips Electronics N.V., an electronics company from 2006 to August 2007. Mr. Jain served as an investment banker at J.P. Morgan Securities, Inc., an investment banking firm, from 1994 to 2006. Mr. Jain's last position with J.P. Morgan was as Co-Head of Global Healthcare Investment Banking from 2002 to 2006.

Ms. Burcar has served as our Vice President and General Manager of Infusion Systems since July 2014. Ms. Burcar served as Vice President of Product Development from July 2009 to July 2014. Ms. Burcar served as our Vice President of Marketing from 2002 to July 2009, our Marketing Operations Manager from 1998 to 2002 and held research and development project/program management positions from 1995 to 1998.

Mr. Lamb has served as our Chief Financial Officer since February 2008. Mr. Lamb served as our Controller from 2003 to February 2008. Mr. Lamb served as Senior Director of Finance for Vitalcom, Inc. from 2000 to 2003.

Mr. McCall has served as our Vice President and General Manager of Critical Care since July 2014. Mr. McCall served as our Vice President of Marketing from July 2010 to July 2014. Mr. McCall served as Vice President of Marketing Communications and Brand Strategy for Masimo Corporation from 2006 to 2010 and as Vice President of Corporate Marketing and Brand Development for Welch Allyn, Inc. from 2001 to 2006.

Mr. Riggs has served as our as Vice President of Operations from 2002 to October 2013 and resumed this position in February 2014. Mr. Riggs served as Acting Chief Executive Officer from October 2013 to February 2014. Mr Riggs served as our Director of Operations from 1998 to 2002 and as our Senior Manager of Quality Assurance and Quality Control from 1992 to 1998.

The information required by this item about our Board of Directors, audit committee, including the audit committee’s financial expert, and disclosure of Forms 3, 4 or 5 delinquent filers is set forth under the captions Election of Directors, Audit Committee and Compliance with Section 16(a) Beneficial Ownership Reporting Compliance in our definitive Proxy Statement to be filed in connection with our 2016 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

We have a Code of Business Conduct and Ethics for Directors and Officers. A copy is available on our website, www.icumed.com. We will disclose any future amendments to, or waivers from, the Code of Business Conduct and Ethics for Directors and Officers on our website.

Table of Contents

Item 11. Executive Compensation.

The information required by this item is set forth under the caption Executive Officer and Director Compensation, Compensation Committee and Compensation Committee Interlocks and Insider Participation in our definitive Proxy Statement to be filed in connection with our 2016 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is set forth under the caption Security Ownership of Certain Beneficial Owners and Management in our definitive Proxy Statement to be filed in connection with our 2016 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

We have a 2011 Stock Incentive Plan under which we may grant restricted stock or options to purchase our common stock to our employees, directors and consultants. We also have a 2014 Inducement Stock Incentive Plan under which we granted 250,405 restricted stock units and options to purchase our common stock. We had a 2001 Directors' Stock Option Plan under which we granted options to purchase our common stock to our directors, which plan expired in November 2011. We also had a 1993 Stock Incentive Plan and a 2003 Stock Option Plan, under which we granted options to purchase common stock to the employees, which plans expired in January 2005 and May 2011, respectively. We also have an Employee Stock Purchase Plan. All plans were approved by our stockholders. Further information about the plans is in Note 7, Share Based Awards, to the Consolidated Financial Statements. Certain information about the plans at December 31, 2015, is as follows:

Number of shares to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a))
(a)	(b)	(c)*
2,379,407	$56.90	908,314

*As of December 31, 2015, there were 188,140 shares of common stock available for issuance under our Employee Stock Purchase Plan, which are included in this amount.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is set forth under the caption Transactions with Related Persons, Policies and Procedures Regarding Transactions with Related Persons and Director Independence in our definitive Proxy Statement to be filed in connection with our 2016 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item is set forth under the caption Selection of Auditors in our definitive Proxy Statement to be filed in connection with our 2016 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

63

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules.

		Form 10-K Page No.
(a)	The following documents are filed as part of this report:	
	The financial statements listed below are set forth in Item 8 of this Annual Report.	
	Report of Independent Registered Public Accounting Firm	35
	Consolidated Balance Sheets at December 31, 2015 and 2014	36
	Consolidated Statements of Income for the Years Ended December 31, 2015, 2014 and 2013	37
	Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2015, 2014 and 2013	38
	Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015, 2014 and 2013	39
	Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, 2014 and 2013	40
	Notes to Consolidated Financial Statements	42
(b)	Exhibits	68
(c)	Financial Statement Schedules	
	The Financial Statement Schedules required to be filed as a part of this Report are:	
	Schedule II — Valuation and Qualifying Accounts	68

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

Exhibit Number	Description
2.1	Stock Purchase Agreement dated as of October 5, 2015, by and among Registrant, Medline Industries, Inc., Roundtable Healthcare Partners, L.P., Roundtable Healthcare Investors, L.P. and certain other sellers party thereto. (31)
2.2	Asset Purchase Agreement made as of October 5, 2015, by and among Registrant, Excelsior Medical, LLC and Medline Industries, Inc.(32)
3.1	Registrant's Certificate of Incorporation, as amended and restated. (1)
3.2	Registrant's Bylaws, as amended and restated. (19)
10.1	Form of Indemnification Agreement with Directors and Executive Officers. (18)
10.2	Registrant's Amended and Restated 1993 Incentive Stock Plan. (2)*
10.3	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and B. Braun, Inc. relating to the Protected Needle product. (3)

10.4	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the Clave product. (4)
10.5	Amended and Restated Rights Agreement dated October 18, 2007 between Registrant and American Stock Transfer & Trust Company as Rights Agent. (14)

Table of Contents

10.6	SafeLine Agreement effective October 1, 1997 by and between Registrant and B. Braun Medical, Inc. (5)
10.7	Amendment to April 3, 1995 Supply and Distribution Agreement, dated January 1, 1999, between Registrant and Abbott Laboratories. (6)
10.8	Co-Promotion and Distribution Agreement, dated February 27, 2001 between Registrant and Abbott Laboratories. (7)
10.9	Registrant's 2001 Directors' Stock Option Plan. (8)*
10.10	Registrant's 2002 Employee Stock Purchase Plan. (8)*
10.11	Registrant's 2003 Stock Option Plan. (9)*
10.12	Amendment to April 3, 1995 Supply and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories. (10)
10.13	Amendment to February 27, 2001 Co-Promotion and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories. (10)
10.14	Manufacturing, Commercialization and Development Agreement between Registrant and Hospira, Inc. effective May 1, 2005. (11)
10.15	Employment Agreement between Registrant and George A. Lopez, M.D. effective January 1, 2011. (22)*
10.16	Letter Agreement dated July 8, 2005 between Registrant and Hospira, Inc. re: Manufacturing, Commercialization and Development Agreement effective May 1, 2005. (12)
10.17	Settlement and Release Agreement dated as of January 2, 2007 between ICU Medical, Inc. and Fulwider Patton Lee & Utecht, LLP. (13)
10.18	Executive officer compensation.*
10.19	Non-employee director compensation.*
10.20	2008 Performance-Based Incentive Plan, as amended. (22)*
10.21	Amendment No. 1 to 2001 Directors' Stock Option Plan. (16)*
10.22	Amendment No. 2 to 2001 Directors' Stock Option Plan. (16)*
10.23	Amendment No. 3 to 2001 Directors' Stock Option Plan. (16)*
10.24	Form of Executive Officer Retention Agreement. (17)*
10.25	Amended and Restated Retention Agreement between Registrant and Dr. George A. Lopez, dated November 3, 2010. (20)*
10.26	

	Schedule identifying parties to agreements with the Registrant substantially identical to the Form of Executive Officer Retention Agreement filed as Exhibit 10.24 hereto. (21)*
10.27	Amendment 20 to the Supply and Distribution Agreement, effective as of November 30, 2011, between ICU Medical Sales, Inc. and Hospira, Inc. (24)
10.28	Third Amendment to the Co-Promotion and Distribution Agreement, effective as of November 30, 2011, between ICU Medical Sales, Inc. and Hospira, Inc. (24)
10.29	ICU Medical, Inc. Amended 2011 Stock Incentive Plan. (23)*
10.30	Form of Executive Officer Retention Agreement - Tier 1 Employee. (25)*
10.31	Form of Executive Officer Retention Agreement - Tier 2 Employee. (25)*

Table of Contents

10.32	2014 Inducement Stock Incentive Plan (26)*
10.33	Executive Employment Agreement, dated as of February 7, 2014, by and between ICU Medical, Inc. and Vivek Jain (27)*
10.34	Amendment to Executive Employment Agreement, dated as of February 12, 2014, by and between ICU Medical, Inc. and Vivek Jain (27)*
10.35	Employment Agreement between Registrant and George A. Lopez, M.D. effective October 21, 2013 (28)*
10.36	Amended and Restated Retention Agreement between Registrant and George A. Lopez, M.D. effective October 21, 2013 (29)*
10.37	Buy-Out Agreement between Registrant and George A. Lopez, M.D. effective September 30, 2015. (30)*
14.1	Code of Business Conduct and Ethics for Directors and Officers. (15)
21	Subsidiaries of Registrant.
23.1	Consent of Deloitte & Touche LLP.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

*Executive compensation plan or other arrangement

Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(1)	Filed as an exhibit to Registrant's Current Report on Form 8-K filed on June 10, 2014, an incorporated herein by reference.
(2)	Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on March 4, 1999, and incorporated herein by reference.
(3)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 1993, and incorporated herein by reference.
(4)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 1995, and incorporated herein by reference.

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

Table of Contents

(7)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed March 7, 2001, and incorporated herein by reference.
(8)	Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 3, 2002, and incorporated herein by reference.
(9)	Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 25, 2003, and incorporated herein by reference.
(10)	Filed as an Exhibit to Registrant's Current Report on Form 8-K dated January 15, 2004, and incorporated herein by reference.
(11)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2005, and incorporated herein by reference.
(12)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2005, and incorporated herein by reference.
(13)	Filed as an Exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 2006, and incorporated herein by reference.
(14)	Filed as an Exhibit to Registrant's Registration Statement on Form 8-A/A dated October 18, 2007, and incorporated herein by reference.
(15)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 5, 2009, and incorporated herein by reference.
(16)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2009, and incorporated herein by reference.
(17)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 4, 2010, and incorporated herein by reference.
(18)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2010, and incorporated herein by reference.
(19)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed July 25, 2014, and incorporated herein by reference.
(20)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed November 5, 2010, and incorporated herein by reference.
(21)	Filed as an Exhibit to Registrant's Annual Report on Form 10-K dated February 18, 2011, and incorporated herein by reference.
(22)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2011, and incorporated herein by reference.
(23)	

	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2012, and incorporated herein by reference.
(24)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed December 22, 2011, and incorporated herein by reference.
(25)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed November 21, 2013, and incorporated herein by reference.
(26)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 26, 2014 and incorporated herein by reference.
(27)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 12, 2014, and incorporated herein by reference.

Table of Contents

(28)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2014 and incorporated herein by reference.
(29)	Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2014 and incorporated herein by reference.
(30)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 1, 2015, and incorporated herein by reference.
(31)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 6, 2015, and incorporated herein by reference.
(32)	Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 6, 2015, and incorporated herein by reference.

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

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

Exhibit Index

EXHIBIT INDEX

10.18	Executive officer compensation
10.19	Non-employee director compensation
21	Subsidiaries of Registrant.
23.1	Consent of Deloitte & Touche LLP
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

Table of Contents

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands) Description	Balance at Beginning of Period	Additions Charged to Costs and Expenses	Charged to Other Accounts	Write-off/ Disposals	Balance at End of Period
For the year ended December 31, 2013:					
Allowance for doubtful accounts	$998	$185	$ 25	$—	$1,208
Warranty and return reserve - accounts receivable	$386	$638	$ —	$(35)	$989
Warranty and return reserve - inventory	$(166)	$33	$ —	$—	$(133)
Deferred tax asset valuation allowance	$560	$—	$ —	$(560)	$—
For the year ended December 31, 2014:					
Allowance for doubtful accounts	$1,208	$34	$ (99)	$(16)	$1,127
Warranty and return reserve - accounts receivable	$989	$(508)	$ —	$—	$481
Warranty and return reserve - inventory	$(133)	$148	$ —	$—	$15
For the year ended December 31, 2015:					
Allowance for doubtful accounts	$1,127	$54	$ 55	$(135)	$1,101
Warranty and return reserve - accounts receivable	$481	$102	$ —	$—	$583
Warranty and return reserve - inventory	$15	$(50)	$ —	$—	$(35)
Deferred tax asset valuation allowance	$—	$2,354	$ —	$—	$2,354

Table of Contents

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ICU MEDICAL, INC.

By: /s/ Vivek Jain
Vivek Jain
Chairman of the Board and Chief Executive Officer

Dated: February 26, 2016

SIGNATURES

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

Signature	Title	Date
/s/ Vivek Jain Vivek Jain	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 26, 2016
/s/ Scott E. Lamb Scott E. Lamb	Chief Financial Officer (Principal Financial Officer)	February 26, 2016
/s/ Kevin J. McGrody Kevin J. McGrody	Controller (Principal Accounting Officer)	February 26, 2016
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Director	February 26, 2016
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	February 26, 2016
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	February 26, 2016
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	February 26, 2016
/s/ David C. Greenberg David C. Greenberg	Director	February 26, 2016
/s/ Elisha W. Finney Elisha W. Finney	Director	February 26, 2016

70