UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016 or

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

For the transition period from to

Commission File No. 001-34634

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

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

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

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

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

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

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

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

Indicate by check mark whether registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2016, the last business day of registrant's most recently completed second fiscal quarter, was $1,643,877,298*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2017 was 16,338,132.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2017 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2016, 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, 2016
TABLE OF CONTENTS

PART I

Item 1. Business.

First person pronouns used in this Report, such as “we,” “us,” and “our,” refer to ICU Medical, Inc. ("ICU") and its subsidiaries unless context requires otherwise.

Overview

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion therapy, critical care and oncology 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 65 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
- Consumable Blood Pressure Transducers
- 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.

Total revenues for 2016, 2015 and 2014 were $379.4 million, $341.7 million and $309.3 million, respectively. Income from operations was $82.9 million, $68.6 million and $39.0 million in 2016, 2015 and 2014, respectively. Total assets were $704.7 million, $626.8 million and $541.1 million in 2016, 2015 and 2014, respectively.

Our largest OEM customer has historically been Hospira, Inc., a subsidiary of Pfizer, Inc. ("Pfizer"). We began our relationship with Pfizer and its predecessor companies in 1995. Sales to Pfizer accounted for 30%, 36% and 36% of our worldwide revenues in 2016, 2015 and 2014, respectively.

In October 2016, we entered into a Stock and Asset Purchase Agreement to acquire Pfizer’s Hospira Infusion Systems ("HIS") business. The original purchase agreement was subsequently amended and restated on January 5, 2017 and the acquisition closed on February 3, 2017 for a purchase price of 3.2 million newly issued shares of common stock of the Company and approximately $275.0 million in cash. We believe combining HIS with our current infusion therapy business will create a pure-play infusion business enabling us to offer customers a full suite of intravenous ("IV") therapy devices and solutions. The combination unifies a split distribution channel which we believe in the long-term will reduce costs and improve efficiencies. We believe that the acquisition significantly expands our footprint allowing us to potentially compete more successfully on a global scale and eliminates our single customer concentration risk that clouded our strategic value. Following the acquisition, we will report the combined revenue of ICU and HIS by the following four market segments: (1) pumps, which

includes the infusion pump hardware, service revenue, dedicated consumable pump sets and software; (2) consumables, which includes our legacy IV therapy and oncology segments, non-dedicated sets, oncology and accessories; (3) IV solutions; and (4) Critical Care.

Company Background

ICU was founded in 1984 and our initial public offering was in 1992. In 1993, we launched the Clave, an innovative one-piece needlefree IV 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 IV connectors to enhance our direct and OEM infusion therapy product offerings and to open new customer opportunities globally.

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 IV administration of medications, fluids and nutrients, and to allow instantaneous IV 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.

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 consumable 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 IV 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 IV products that are sold by a subsidiary of Pfizer. These products are promoted under the name SetSource.

Infusion Therapy sales accounted for $272.6 million, or 72%, of our revenue in 2016, $244.7 million, or 72%, of our revenue in 2015 and $216.3 million, or 70%, of our revenue in 2014. 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. In addition, we are the exclusive United States distributor of the LiDCO® LXi noninvasive hemodynamic monitoring system under license from LiDCO Group Plc.

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 IV 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 IV line contamination and reduce blood waste for the patient.

Transpac® Consumable Blood Pressure Transducers: Transpac transducers provide clinicians with accurate real-time access to their patient's blood pressure status in surgical and intensive care settings.

Other Critical Care Products: Venous oximetry and advanced sensing catheters, Lopez Valve® and cables and accessories for hemodynamic monitoring.

Critical care sales accounted for $53.6 million, or 14%, of our revenue in 2016, $54.3 million, or 16%, of our revenue in 2015 and $55.0 million, or 18%, of our revenue in 2014. Additional information regarding critical care sales over the last three years is discussed in Part II, Item 7 of this Annual Report on Form 10-K.

Oncology

Oncology products, 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 Food and Drug Administration ("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 consumables 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 $52.3 million, or 14%, of our revenue in 2016, $41.5 million, or 12%, of our revenue in 2015 and $36.7 million, or 12%, of our revenue in 2014. 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, 2016, we employed 153 people worldwide in sales, marketing and customer support. Our sales administrative operations are in San Clemente, California, Roncanova, Italy, Houten, 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 $266.0 million, $241.9 million and $212.7 million in 2016, 2015 and 2014, respectively.

Direct

Direct domestic sales includes sales both to our distributors and directly to the end user of our products. Direct domestic sales accounted for 43%, 39%, and 38% of our worldwide revenue in 2016, 2015, and 2014, respectively. Distributors purchase and stock our products for resale to healthcare providers. One distributor accounted for 8% and two distributors accounted for 7% each of revenue in 2016. All other distributors accounted for less than 5% of revenue in 2016. 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 also distribute our products on an OEM basis to other medical device manufacturers. OEM domestic sales accounted for 28%, 32%, and 31% of our worldwide revenue in 2016, 2015, and 2014, respectively. Pfizer has been a major supplier of infusion pumps and IV solutions, and has helped us achieve market share where they have multiple products under contract with a customer or broader international distribution channels than we would have been able to have on our own. Our agreements with Pfizer, which terminated upon acquisition of Pfizer's HIS business, provided 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 have been exclusive or nonexclusive. We also served as the exclusive manufacturer for certain custom IV products that are sold by a subsidiary of Pfizer. These products are promoted under the name SetSource®. The loss of Pfizer as a customer would have had a significant adverse effect on our business and operating results; as such our decision to acquire HIS was in part to protect against this significant earnings exposure, accordingly this concentration risk will be eliminated going forward.

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

In 2016, we started to report our revenue based on distribution channel within our market segments with both Terumo-related geographies in Asia and sales to Medline in our OEM business, and no longer in Direct. As such, prior year results have been reported in the same manner for comparative purposes.

In 2015, we had entered into a long-term supply agreement with Terumo Corporation of Japan for Japan and certain smaller Asian countries. In accordance with the agreement, Terumo distributes our entire product portfolio, including IV therapy and CSTD product lines. Japan and Asia remains a valuable growth market.

International sales were $113.4 million, $99.8 million and $96.6 million in 2016, 2015 and 2014, respectively.

International sales through our direct channels, including distributors and directly to the end customer, were $92.8 million, $81.3 million and $76.9 million in 2016, 2015, and 2014, respectively. International sales as an OEM supplier were $20.6 million, $18.5 million and 19.7 million in 2015, 2014 and 2013, respectively.

In 2016, customers in Europe were served by our facilities in Slovakia, Netherlands, Italy, France 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 completed the closure of those facilities in the second half of 2016. As of December 31, 2016, we had 20 sales and sales support personnel serving Europe and 27 serving Asia Pacific, Southeast Asia, Latin America, South Africa, the Middle East and Canada.

Manufacturing

Manufacturing of our products involves injection molding of plastic and silicone parts, manual and automated assembly of the molded plastic parts 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.

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 during 2016 was done at our facilities in Ensenada, Mexico. Our Vrable, Slovakia facilities were closed during 2016. Our Mexico facilities were recently expanded to approximately 308,000 square feet, which has an electron beam ("e-beam") sterilizer and has approximately 125,000 square feet and 62,000 square feet, respectively, of space for production and warehousing. Principal products assembled manually in Mexico are used in conjunction with infusion therapy systems (which includes oncology) and critical care systems.

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 plant in Mexico which is used to sterilize most of the products assembled in that plant. 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

Our products and operations are subject to extensive and rigorous regulation by the FDA and other federal, state and local authorities, as well as foreign regulatory authorities. The FDA regulates, among other things, the research, development, testing, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting and import and export of medical devices and combination drug/device products in the United States to assure the safety and effectiveness of medical products for their intended use. The Federal Trade Commission also regulates the advertising of our products. Further, we are subject to laws directed at preventing fraud and abuse, which subject our sales and marketing, training and other practices to government scrutiny.

U.S. Device Classification and Clearance

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FDC Act") also referred to as a 510(k) clearance, or approval from the FDA of a pre-market approval ("PMA") application. Both the 510(k) clearance and PMA processes can be expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Under the FDC Act, medical devices are classified into one of three classes-Class I, Class II or Class III-depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation ("QSR") facility registration and product listing, reporting of adverse events and malfunctions, and

appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls, which can include performance standards, guidelines and postmarket surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed "predicate" device.

To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. Such devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction reasonable assurance of the safety and effectiveness of the device for its intended use.

Post-Approval Regulation

Even after a device has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug or device. After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include, but are not limited to:

- the registration and listing regulation, which requires manufacturers to register all manufacturing facilities and list all medical devices placed into commercial distribution;
- the FDA’s current QSR, which requires manufacturers, including third-party manufacturers, to follow elaborate design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations and unique device identification requirements;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- annual reporting requirements;
- the FDA's general prohibition against promoting products for unapproved or "off-label" uses;
- the Medical Device Reporting, or MDR, regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur;

- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDC Act that may present a risk to health;

- recall requirements, including a mandatory recall if there is a reasonable probability that the drug or device would cause serious adverse health consequences or death;

- an order of repair, replacement or refund;

- device tracking requirements; and

- post-approval study and postmarket surveillance requirements.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Manufacturing Regulation

We must also 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 QSR and current Good Manufacturing Practices ("cGMPs"). Under these regulations, the manufacturing process must be regulated and controlled by the use of written procedures and the ability to produce devices that meet the manufacturer's specifications must be validated by extensive and detailed testing of every critical aspect of the process. They also require investigation of any deficiencies in the manufacturing process or in the products produced and detailed record keeping. Further, the FDA and ISO's interpretation and enforcement of these requirements has been increasingly strict in recent years and seems likely to be even more stringent in the future. Failure to adhere to QSR, applicable cGMPs 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.

Other Healthcare Laws

We are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and ownership and investment interests held by the physicians described above and their immediate family members, and payments or other "transfers of value" to such physician owners; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to track and report information related to payments and other "transfers of value" to physicians and other healthcare providers or pricing, marketing expenditures and information; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Due to the breadth of these laws, the absence of guidance in the form of regulations or court decisions, and the potential for additional legal or regulatory change in this area, it is possible that our sales and marketing practices and/or our relationships with physicians and other healthcare providers might be challenged under such laws. If our operations are found to violate any of the laws described above or any other laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from our participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and materially adversely affect our business, results of operations and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Coverage and Reimbursement; Cost Containment

Our profitability and operations are subject to changes in legislative, regulatory and reimbursement policies and decisions as well as changes in private payer reimbursement coverage and payment decisions and policies. Our products are purchased by hospitals, physicians and other healthcare providers that typically bill various third-party payors, such as

governmental programs, private insurance plans and managed care plans, for the healthcare services and products provided to their patients. The ability of our customers to obtain appropriate coverage and reimbursement for healthcare services and products from third-party payors is critical because it affects which products customer purchase and the prices they are willing to pay. Third-party payors are increasingly reducing coverage and reimbursement for certain healthcare services and products and challenging prices charged for healthcare services and products.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on reimbursement and coverage. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. In the United States, there has been an increase in political support for controlling significant price increases of drug products, in particular due to high-profile cases that have gained national attention and triggered Congressional inquiries. Implementation of further legislative or administrative reforms in the reimbursement system in the U.S. and abroad or adverse decisions relating to coverage or reimbursement could have an impact on acceptance of and demand for our products and the prices that our customers are willing to pay for them.

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 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 2016, we received FDA 510(k) clearance for 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 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.

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 $13.0 million in 2016, $15.7 million in 2015 and $18.3 million in 2014.

Employees

At December 31, 2016, we had 2,803 full-time employees, consisting of 317 engaged in sales, marketing and administration and 2,486 in manufacturing, molding, product development and quality control, including 1,954 in Mexico.

Geographic Data

Information regarding financial data by geography is set forth in Part II, Item 8 of this Form 10-K in the Notes to Consolidated Financial Statements in Note 12.

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.

We may not realize the anticipated benefits of the HIS acquisition, which could adversely impact our business and our operating results.

The HIS acquisition that closed on February 3, 2017 was a significant transaction for us and the HIS business was one in which we did not operate directly prior to the closing of the transaction. The success of our business will depend, in part, on our ability to realize our anticipated benefits, opportunities and synergies from combining the businesses of our company and the HIS business. We can provide no assurance that the anticipated benefits of the HIS transaction will be fully realized in the time frame anticipated or at all. We have limited prior history of integrating acquired companies or businesses into our operations, much less one of this size and complexity. Integrating the operations of the HIS business with that of our own will be a complex, costly and time-consuming process and the nature of a carve out acquisition makes it inherently more difficult to assume operations on closing day as well as to integrate activities, as certain systems, processes and people may not all have transferred with the acquired business to support such activities. In connection with the consummation of the acquisition, we entered into a number of arrangements with Pfizer, including a transitional services agreement, pursuant to which Pfizer agreed to provide us with certain significant and essential human resource, commercial, regulatory, finance, research and development and operational services on an interim basis, for a duration generally not to exceed eighteen (18) months from the date of the closing of the transaction, with respect to our operation of the HIS business. The integration process may disrupt the businesses and, if implemented ineffectively, would restrict the realization of the full expected benefits. The failure to meet the challenges involved in integrating the two businesses could cause an interruption of, or a loss of momentum in, the activities of the combined businesses and could adversely affect the results of operations of the combined businesses. Potential difficulties that may be encountered in the integration process include the following:

- challenges in preserving important strategic customer and other third-party relationships of both businesses;
- the diversion of management's attention to integration matters;
- challenges in maintaining employee morale and retaining or attracting key employees;
- potential incompatibility of corporate cultures;
- costs, delays and other difficulties (i) consolidating corporate and administrative infrastructures and information systems, (ii) implementing common systems and procedures including, in particular, our internal controls over financial reporting, and (iii) implementing the transitional services, manufacturing and other arrangements with Pfizer entered into at the closing of the HIS transaction; and
- coordinating and integrating a geographically dispersed organization, including operations in jurisdictions we did not operate in prior to the HIS transaction.

Any one or all of these factors may increase operating costs or lower anticipated financial performance. Additionally, any failure by Pfizer to deliver the services to be provided under our arrangements with Pfizer could have a material adverse effect on our business, financial condition and results of operations. Achieving the anticipated benefits and the potential benefits underlying our reasons for the HIS business acquisition will depend on successful integration of the businesses. Because of the significance of the HIS business acquisition to us, our failure to successfully integrate the HIS business with that of our own could have a material adverse impact on our business, financial condition and results of operations.

The actual impact of the HIS acquisition on our financial results may be worse than the assumptions we have used.

We have made certain assumptions relating to the impact on our financial results of the HIS acquisition. These assumptions relate to numerous matters, including the acquisition costs, including transaction and integration costs, and other financial and strategic risks of the acquisition. If one or more of these assumptions are incorrect, it could have an adverse effect on our business and operating results, and the perceived benefits from the acquisition may not be realized.

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

We continue to expand our production in Mexico. Most of the material we use in manufacturing is imported into Mexico, and substantially all of the products we manufacture in Mexico are exported.

As of December 31, 2016, we employed 1,954 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.

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 measures 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 and jurisdictions in which we 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 and the relative costs associated with doing business. The laws and regulations that may affect our ability to operate include, without limitation, anti-kickback laws that prohibit payments or other remuneration that could be considered to induce hospitals, physicians or other potential purchasers of our products either to refer patients or to purchase, lease or order, or arrange for or recommend the purchase, lease or order, of healthcare products or services for which payment may be made under federal and state healthcare programs as well as false claims laws that prohibit filing of false or improper claims for payment. Federal laws apply to federal and state healthcare programs, such as Medicare and Medicaid, and several states have similar laws that may apply more broadly to all payors. Although we would not submit claims directly to government payors, manufacturers can be held liable under the federal and state false claim act if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, price reporting, or promoting a product off-label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this federal and state false claims laws. As a manufacturer of U.S. FDA-approved products reimbursable by federal healthcare programs, we are subject to the Physician Payments Sunshine Act, which requires us to annually report certain payments and other transfers of value we make to U.S.-licensed physicians or U.S. teaching hospitals and any ownership or investment interests held by physicians and their immediate family members. These laws may affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians and other potential purchasers of our products. These laws are broadly written and are subject to evolving interpretations, and it is often difficult to determine how these laws will be applied to specific circumstances. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, imprisonment, or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Our profitability and operations are subject to risks relating to changes in government and private reimbursement programs and policies and changes in legal requirements in the U.S. and in the world. There have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenues and profitability in the U.S. and abroad. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act ("Affordable Care 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 and $1.9 million in 2014 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.

We expect that the new Presidential Administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. The House and Senate have recently passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump has also recently issued an executive order in which he stated that it is his Administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of burdensome provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted that reduced payments to Medicare providers. Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The ultimate implementation of any healthcare reform legislation and any new laws and regulations, 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 and inadequate coverage and reimbursement 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. Our products are purchased by hospitals, physicians and other healthcare providers that typically bill various third-party payors, such as governmental programs, private insurance plans and managed care plans, for the healthcare services and products provided to their patients. The ability of our customers to obtain appropriate coverage and reimbursement for healthcare services and products from third-party payors is critical because it affects which products customers purchase and the prices they are willing to pay. Implementation of further legislative or administrative reforms in the reimbursement system in the U.S. and abroad or adverse decisions relating to coverage or reimbursement could have an impact on acceptance of and demand for our products and the prices that our customers are willing to pay for them. 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.

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. We recently acquired the HIS business, which includes IV pumps, solutions, and devices in order to create a leading pure-play infusion therapy company, but we have significant integration efforts to achieve the anticipated benefits. See "*—We may not realize the anticipated benefits of the HIS transaction, which could adversely impact our business and our operating results."*

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.

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.

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 significant 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, 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.

We are subject to risks associated with doing business outside of the United States.

We operate in a global market and global operations are subject to a number of risks. Sales to customers outside of the United States made up approximately 30% of our revenue in 2016 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. The risks associated with our operations outside the United States include:

- healthcare reform legislation;
- changes in medical reimbursement policies and programs;
- changes in non-United States government programs;
- multiple non-United States regulatory requirements that are subject to change and that could restrict our ability to manufacture and sell our products;
- possible failure to comply with anti-bribery laws such as the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;
- different local medical practices, product preferences and product requirements;
- possible failure to comply with trade protection and restriction measures and import or export licensing requirements;
- difficulty in establishing, staffing and managing non-United States operations;
- different labor regulations or work stoppages or strikes;
- changes in environmental, health and safety laws;
- potentially negative consequences from changes in or interpretations of tax laws, including changes regarding taxation of income earned outside the United States;
- political instability and actual or anticipated military or political conflicts;
- economic instability, including the European financial crisis or other economic instability in other parts of the world and the impact on interest rates, inflation and the credit worthiness of our customers;
- uncertainties regarding judicial systems and procedures;
- minimal or diminished protection of intellectual property in some countries;
- imposition of government controls; and
- regulatory changes that may place our products at a disadvantage.

These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition. The occurrence or allegation of these types of risks may adversely affect our business, performance, prospects, value, financial condition, and results of operations.

Any significant changes in U.S trade, tax or other policies that restrict imports or increase import tariffs could have a material adverse effect on our results of operations.

A significant amount of our products are manufactured outside of the United States. The new Presidential administration has called for substantial changes to U.S. trade and tax policies, which may include import restrictions or increased import tariffs. Restrictions on imports could prevent or make it difficult for us to obtain the components needed for new products which would affect our sales. Increased tariffs would require us to increase our prices which likely would decrease customer and consumer demand for our products. Other countries might retaliate through the imposition of their own restrictions and or increased tariffs which would affect our ability to export products and therefore adversely affect our sales. Any significant changes in current U.S. trade, tax or other policies could have a material adverse effect upon our results of operations.

International sales pose additional risks related to competition with larger international companies and established local companies and 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.

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 consumable 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 companies have introduced competitive products with 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 in 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 ("GPOs") or integrated delivery networks ("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. While having a contract with a GPO or IDN can facilitate sales to members of that GPO or IDN, it is no assurance that sales volume of those products will be maintained. The members of such groups may choose to purchase from our competitors due to the price or quality offered by such competitors, which could result in a decline in our sales and profitability. In addition, distributors of our products may begin to negotiate terms of sale more aggressively in an effort to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing or other terms of sale could adversely affect our results of operations and financial condition. In addition, if we fail to implement distribution arrangements successfully, it could cause us to lose market share to our competitors. Moreover, 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.

Product development requires substantial investment that may be difficult for us to fund and may be challenging to recover through commercial product sales.

Innovations generally require a substantial investment in product development before we can determine their commercial viability, and we may not have the financial resources necessary to fund these innovations. Even if we succeed in creating new product candidates from these innovations, those innovations still may fail to result in commercially successful products. The success of new product offerings for device products depends on several factors, including our ability to anticipate and meet customers'/patients' needs, obtain timely regulatory approvals or clearances, and manufacture quality products in an economic and timely manner. Even if we are able to develop successfully new products or enhancements, we may not produce sales exceeding the costs of development, and we may not avoid infringing the proprietary rights of third parties. Further, those new or enhanced products may be quickly rendered obsolete by changing customer preferences or the introduction by competitors of products embodying new technologies or features. Moreover, innovations may not be successful due to difficulties encountered in achieving positive clinical outcomes, meeting safety, efficacy or other regulatory requirements of government
agencies, or obtaining favorable pricing on those products. Finally, innovations may not be accepted quickly in the marketplace because of, among other things, entrenched patterns of clinical practice and uncertainty over third-party reimbursement.

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 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 2017. 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 fail to comply with the 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. For example, our device 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”). In the United States, before we can market a new medical device, or a new use of, new claim for, or significant modification to, an existing product, we must first receive either clearance under Section 510(k) of the FDC Act or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. If the manufacturer is unable to demonstrate substantial equivalence to FDA’s satisfaction, or if there is no available predicate device, then the manufacturer may be required to seek approval through the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies.

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.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future 510(k) clearances, PMA approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirement will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If we or our component manufacturers fail to comply with the FDA's Quality System Regulation or Good Manufacturing Practice regulations, our manufacturing operations could be interrupted, and our product sales and operating results could suffer.

We and some of our component manufacturers are required to comply with regulatory requirements known as the FDA's Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, inspection, complaint handling, recordkeeping, management review, labeling, packaging, sterilization, storage and shipping of our device products. The FDA's current Good Manufacturing Practices, or cGMPs apply to the manufacture of medical device components and finished medical devices. The FDA audits compliance with these

regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time, and we and some of our component suppliers are subject to such inspections. Although we believe our manufacturing facilities and those of our critical component suppliers are in compliance with the QSR requirements, and with applicable cGMPs for our products, we cannot provide assurance that any future inspection will not result in adverse findings. If our manufacturing facilities or those of any of our component suppliers are found to be in violation of applicable laws and regulations, or we or our suppliers have significant noncompliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for clearance or approval of new products or modified products;
- withdrawing clearances or approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could adversely affect our business, financial conditions and operating results.

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.

We may be unable to realize any benefit from our cost reduction and restructuring efforts and our profitability may be hurt or our business otherwise might be adversely affected.

We have engaged in restructuring activities in the past and may engage in other restructuring activities in the future. These types of cost reduction and restructuring activities are complex. If we do not successfully manage our current restructuring activities, or any other restructuring activities that we may take in the future, any expected efficiencies and benefits might be delayed or not realized, and our operations and business could be disrupted. In addition, the costs associated with implementing restructuring activities might exceed expectations, which could result in additional future charges.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and other worldwide anti-bribery laws.

The Foreign Corrupt Practices Act and anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business or other commercial advantage. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties, including criminal and civil fines, potential loss of export licenses, possible suspension of the ability to do business with the federal government, denial of government reimbursement for products and exclusion from participation in government healthcare programs. We operate in jurisdictions that have experienced governmental and private sector corruption to some degree, and, in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. We cannot assure that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees, distributors or other agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations.

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 2014 through December 2016, our trading price ranged from a high of $154.80 per share to a low of $54.00 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, acquisitions or divestitures, 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 41% of our outstanding shares at the end of 2016. 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 308,000 square foot building on approximately 94 acres of land in Ensenada, Baja California, Mexico; and a 23,000 square foot building in Roncanova, Italy. We lease a building in San Clemente, California, San Diego, California; Houten, Netherlands; Ludenscheid, Germany; 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.

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 sales prices for our common stock quoted by NASDAQ:

2016	High	Low
First quarter	$ 110.89	$ 85.56
Second quarter	113.24	98.10
Third quarter	128.93	108.51
Fourth quarter	154.80	124.85

2015	High	Low
First quarter	$ 94.00	$ 79.44
Second quarter	98.95	84.02
Third quarter	124.69	95.13
Fourth quarter	122.98	102.06

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, 2017, we had 65 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

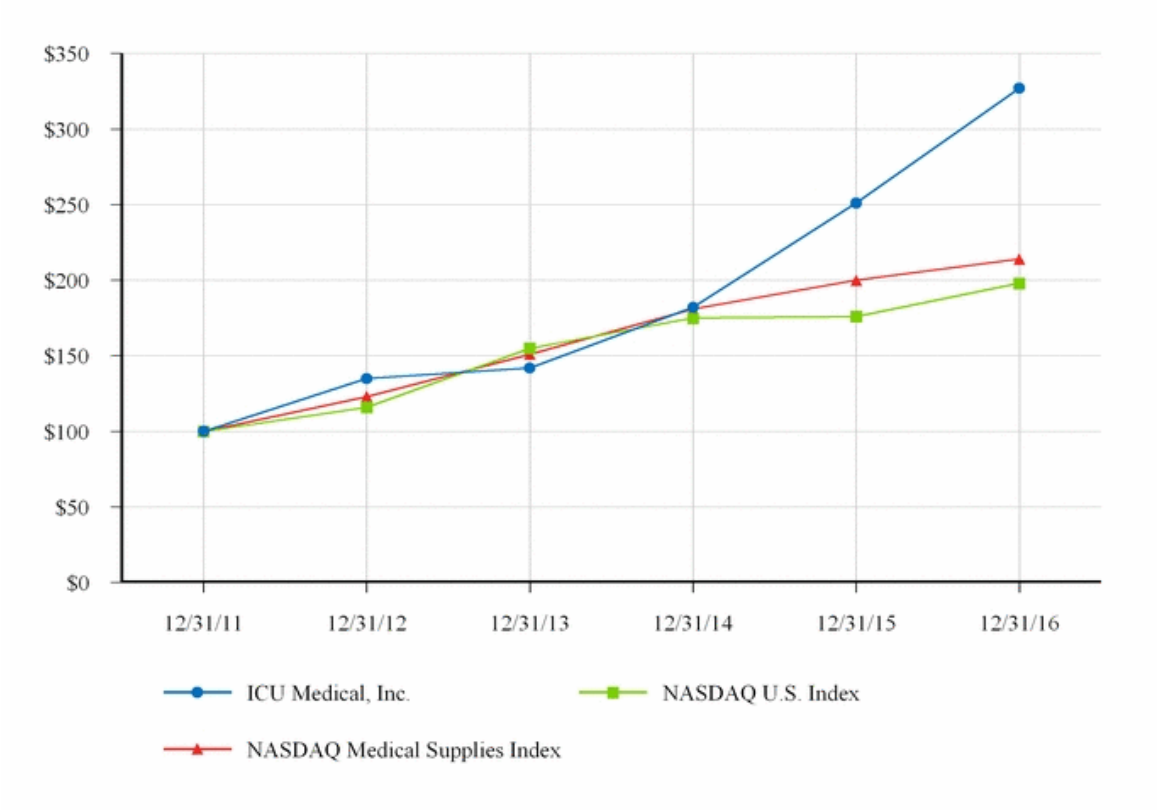
The following is a summary of our stock repurchasing activity during the fourth quarter of 2016:

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[1]
10/01/2016 - 10/31/2016	—	$ —	—	$ 7,169,000
11/01/2016 - 11/30/2016	—	$ —	—	7,169,000
12/01/2016 - 12/31/2016	—	$ —	—	7,169,000
Fourth quarter 2016 total	—	$ —	—	$ 7,169,000

(1) Our common stock purchase plan, which authorized the repurchase of up to $40.0 million of our common stock, was authorized by our Board of Directors and publicly announced on July 19, 2010. This plan has no expiration date. We are not obligated to make any purchases under our stock purchase program. Subject to applicable state and federal corporate and securities laws, purchases under a stock purchase program may be made at such times and in such amounts as we deem appropriate. Purchases made under our stock purchase program can be discontinued at any time we feel additional purchases are not warranted.

COMPARISON OF CUMULATIVE TOTAL RETURN FROM JANUARY 1, 2012 TO DECEMBER 31, 2016 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, 2011 to December 31, 2016 and the total returns of the NASDAQ U.S. Index and NASDAQ Medical Supplies Index for the same period.



	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016
ICU Medical, Inc.	$ 100.00	$ 135.40	$ 141.58	$ 182.00	$ 250.62	$ 327.44
NASDAQ U.S. Index	$ 100.00	$ 116.43	$ 155.41	$ 174.78	$ 175.62	$ 198.47
NASDAQ Medical Supplies Index	$ 100.00	$ 123.05	$ 150.66	$ 181.04	$ 200.19	$ 213.83

Assumes $100 invested on December 31, 2011 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.

Item 6. Selected Financial Data.

ICU MEDICAL, INC.
SELECTED FINANCIAL DATA

	Year ended December 31, (in thousands, except per share data)				
	2016	2015	2014	2013	2012
INCOME DATA:					
REVENUE					
Net sales	$ 379,339	$ 341,254	$ 308,770	$ 313,056	$ 316,322
Other	33	414	490	660	547
TOTAL REVENUE	379,372	341,668	309,260	313,716	316,869
COST OF GOODS SOLD	177,974	160,871	157,859	158,984	160,359
GROSS PROFIT	201,398	180,797	151,401	154,732	156,510
Selling, general and administrative expenses	89,426	83,216	88,939	89,006	84,604
Research and development expenses	12,955	15,714	18,332	12,407	10,630
Restructuring and strategic transaction	15,348	8,451	5,093	1,370	—
Gain on sale of assets	—	(1,086)	—	—	—
Legal settlements	—	1,798	—	—	—
Impairment of assets held for sale	728	4,139	—	—	—
TOTAL OPERATING EXPENSES	118,457	112,232	112,364	102,783	95,234
INCOME FROM OPERATIONS	82,941	68,565	39,037	51,949	61,276
BARGAIN PURCHASE GAIN	1,456	—	—	—	—
OTHER INCOME, net	767	1,134	755	765	563
INCOME BEFORE INCOME TAXES	85,164	69,699	39,792	52,714	61,839
PROVISION FOR INCOME TAXES	(22,080)	(24,714)	(13,457)	(12,296)	(20,558)
NET INCOME	$ 63,084	$ 44,985	$ 26,335	$ 40,418	$ 41,281
NET INCOME PER SHARE					
Basic	$ 3.90	$ 2.84	$ 1.72	$ 2.75	$ 2.90
Diluted	$ 3.66	$ 2.73	$ 1.68	$ 2.65	$ 2.80
WEIGHTED AVERAGE NUMBER OF SHARES					
Basic	16,168	15,848	15,282	14,688	14,223
Diluted	17,254	16,496	15,647	15,274	14,725
Cash dividends per share	$ —	$ —	$ —	$ —	$ —
CASH FLOW DATA:					
Total cash flows from operations[1]	$ 89,941	$ 64,195	$ 66,340	$ 72,692	$ 70,838

[1] Total cash flows from operations for Years 2012 through 2015 have been retrospectively adjusted to reflect the reclassification of the tax benefits from exercise of stock options from financing activities to operating activities as permitted by Accounting Standard Update ("ASU") 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which was adopted early during 2016 (see Note 1 of the Consolidated Financial Statements in this Annual Report on Form 10-K for additional detail).

	As of December 31, (in thousands)				
	2016	2015	2014	2013	2012
BALANCE SHEET DATA:					
Cash, cash equivalents and investment securities	$ 445,082	$ 377,397	$ 346,764	$ 296,891	$ 226,159
Working capital	$ 528,560	$ 462,389	$ 403,801	$ 367,410	$ 296,385
Total assets	$ 704,688	$ 626,825	$ 541,102	$ 499,643	$ 428,512
Stockholders' equity	$ 660,155	$ 579,871	$ 508,252	$ 464,725	$ 390,857

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

Business Overview and Highlights

We are a leader in the development, manufacture and sale of innovative medical devices used in infusion therapy, critical care and oncology 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 65 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
- Consumable Blood Pressure Transducers
- Other Critical Care Products and Accessories

Oncology

- ChemoLock® CSTD and components
- ChemoClave® CSTD and components
- Diana® Hazardous Drug Compounding System

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	2016	2015	2014
Infusion therapy	72%	72%	70%
Critical care	14%	16%	18%
Oncology	14%	12%	12%
	100%	100%	100%

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 has been Hospira, Inc., a subsidiary of Pfizer, to which we distributed our products as an OEM supplier. Pfizer accounted for 30% of our worldwide revenues in 2016 and 36% of our worldwide revenues in both 2015 and 2014. Pfizer has been a major supplier of infusion pumps and IV solutions, and has helped us achieve market share where they have multiple products under contract with a customer or broader international distribution channels than we would have been able to have on our own. Our agreements with Pfizer, which were terminated upon our acquisition of Pfizer's HIS business, provided 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 have been exclusive or nonexclusive. Our relationship with Pfizer has been important for our growth but we have had significant earnings exposure to a single customer. Eliminating this concentration risk was an important factor in making the decision to acquire Pfizer's HIS business, see "Acquisitions."

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, 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. Increased expenditures for sales and marketing and product acquisition and development may not yield desired results when expected, or at all. While we have taken steps to control these risks, there are certain risks that may be outside of our control, and there is no assurance that steps we have taken will succeed.

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.

Acquisitions

On October 6, 2016, we entered into a Stock and Asset Purchase Agreement (the "Purchase Agreement") to acquire Pfizer's HIS business. On January 5, 2017, we amended and restated the original purchase agreement to modify the terms of the agreement as a result of changes in the performance of HIS that affect expectations for the transaction. The transaction closed on February 3, 2017. Under the terms of the restated and amended agreement we paid $275 million in cash, which was financed with existing cash balances and a three-year interest-only seller note of $75 million and we delivered 3.2 million shares of our common stock to Pfizer. Additionally, Pfizer may be entitled up to an additional $225 million based on achievement of performance targets for the combined company through December 31, 2019. The aggregate purchase consideration is subject to certain adjustments, based on working capital, cash and indebtedness of the HIS business at closing. We believe that the acquisition of the HIS business complements our existing business by creating a leading pure-play infusion company. Strategically the transaction eliminates our reliance on Pfizer, increases our scale and unifies our distribution channel, which we believe will improve efficiency and allow us to compete more successfully both domestically and globally.

On April 4, 2016, we acquired all of the outstanding shares of Tangent Medical Technologies, Inc. ("Tangent") for $2.6 million in cash. Tangent designs, develops, and commercializes intravenous catheters and associated products for the improvement of infusion therapy. We believe that Tangent's products enhance our infusion therapy product offering. We do not expect any significant commercial results from this product line over the next twelve to eighteen months while we make changes to this product.

Consolidated Results of Operations

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 total revenues.

	Percentage of Revenues		
	2016	2015	2014
Revenue			
Net sales	100%	100%	100%
Other	—%	—%	—%
Total revenues	100%	100%	100%
Gross margin	53%	53%	49%
Selling, general and administrative expenses	24%	24%	29%
Research and development expenses	3%	5%	6%
Restructuring and transaction expense	4%	2%	1%
Gain on sale of building	—%	—%	—%
Legal settlements	—%	1%	—%
Impairment of assets held for sale	—%	1%	—%
Total operating expenses	31%	33%	36%
Income from operations	22%	20%	13%
Bargain Purchase Gain	—%	—%	—%
Other income, net	—%	—%	—%
Income before income taxes	22%	20%	13%
Income taxes	6%	7%	4%
Net income	16%	13%	9%

A portion of our sales is conducted in currencies other than the U.S. dollar, particularly the Euro. Significant fluctuations in foreign currency exchange rates can impact the comparability of our total revenues. When exchange rate changes significantly impact our 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. If significant, 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.

Foreign currency exchange rate changes did not significantly impact our revenue results for 2016, as compared to 2015, however, they did have significant impact when comparing 2015 revenue results to the comparable 2014 period. As such, the constant currency comparison is discussed below for 2015, as compared to 2014 period results.

Total revenues for 2016, 2015 and 2014 were $379.4 million, $341.7 million and $309.3 million, respectively.

Beginning in 2016, we reported our revenue based on distribution channel within our market segments with both Terumo-related geographies in Asia and sales to Medline in our OEM business, and no longer in Direct. As such, prior year results have been reported in the same manner for comparative purposes.

Infusion Therapy Revenue

The following table summarizes our total infusion therapy revenue by direct and OEM distribution channels (in millions, except percentages):

	Year Ended December 31,			% increase (decrease) 2016 over 2015	% increase 2015 over 2014
	2016	2015	2014		
Direct	$ 162.5	$ 132.6	$ 114.7	22.5 %	15.6%
OEM	110.1	112.1	101.6	(1.8)%	10.3%
Total Infusion Therapy Revenue	$ 272.6	$ 244.7	$ 216.3	11.4 %	13.1%

Direct infusion therapy revenue increased $29.9 million in 2016, as compared to 2015, primarily due to sales of our SwabCap product-line, which was acquired through an acquisition in October 2015, and our Clave product-lines as a result of new customer sales and an increase in sales to existing customers.

OEM infusion therapy sales decreased $2.0 million in 2016, as compared to 2015, due to a decrease in sales of our Clave product lines to Pfizer partially offset by sales of our OEM SwabCap product.

Direct infusion therapy revenue increased $17.9 million in 2015, as compared to 2014, primarily due to increased unit sales related to increased utilization and new customers. On a constant currency basis direct infusion therapy revenue would have increased $22.2 million in 2015, compared to 2014, a $4.3 million unfavorable foreign exchange rate change impact.

OEM infusion therapy sales increased $10.5 million in 2015, as compared to 2014, primarily due to increased unit sales and increased utilization. On a constant currency basis OEM infusion therapy revenue would have increased $11.3 million in 2015, compared to 2014, a $0.8 million unfavorable foreign exchange rate change impact.

Critical Care Revenue

The following table summarizes our total critical care revenue by direct and OEM distribution channels (in millions, except percentages):

	Year Ended December 31,			% (decrease) increase 2016 over 2015	% decrease 2015 over 2014
	2016	2015	2014		
Direct	$ 53.5	$ 54.3	$ 55.0	(1.5)%	(1.3)%
OEM	0.1	—	—	100.0 %	— %
Total Critical Care Revenue	$ 53.6	$ 54.3	$ 55.0	(1.3)%	(1.3)%

Direct critical care revenue decreased $0.8 million in 2016, as compared to 2015, primarily due to an overall decline of both international and U.S. sales as a result of temporary production constraints in the first part of the year.

Direct critical care revenue decreased $0.7 million in 2015, as compared to 2014, primarily due to the decline in the exchange rate of the Euro to the U.S. dollar. On a constant currency basis direct critical care revenue would have increased $0.2 million in 2015, compared to 2014, a $0.9 million unfavorable foreign exchange rate change impact.

OEM critical care sales were flat in 2016, as compared to 2015.

Oncology Revenue

The following table summarizes our total oncology revenue by direct and OEM distribution channels (in millions, except percentages):

	Year Ended December 31,			% increase 2016 over 2015	% increase 2015 over 2014
	2016	2015	2014		
Direct	$ 37.6	$ 26.9	$ 24.0	39.8%	12.1%
OEM	14.7	14.6	12.7	0.7%	15.0%
Total Oncology Revenue	$ 52.3	$ 41.5	$ 36.7	26.0%	13.1%

Direct oncology revenue increased $10.7 million in 2016, as compared to 2015, primarily due to increased U.S. sales. These increases were a result of new customer sales and an increase in sales to existing customers of our ChemoClave and ChemoLock products.

OEM oncology sales slightly increased to $0.1 million in 2016, as compared to 2015. Sales growth to Pfizer has been steadily declining over the last several years.

Direct oncology revenue increased $2.9 million in 2015, as compared to 2014, primarily due to a higher volume of sales to existing customers. On a constant currency basis direct oncology revenue would have increased $5.0 million in 2015, compared to 2014, a $2.1 million unfavorable foreign exchange rate change impact.

OEM oncology sales increased $1.9 million in 2015, as compared to 2014, primarily due to a higher volume of sales. On a constant currency basis OEM oncology revenue would have increased $2.6 million in 2015, compared to 2014, a $0.7 million unfavorable foreign exchange rate change impact.

Gross Margins

Gross margins for 2016, 2015 and 2014 were 53.1%, 52.9%, and 49.0%, respectively.

The 20 basis point increase in gross margin in 2016, as compared to 2015, was primarily due to favorable foreign exchange rates on our operations expenses due to the decline in the Mexican Peso and favorable product mix partially offset by the impact of certain manufacturing constraints in the earlier part of the year.

The 390 basis point increase in gross margin in 2015, as compared to 2014, 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

The following table summarizes our SG&A expenses (in millions, except percentages):

	Year Ended December 31,			% increase 2016 over 2015	% decrease 2015 over 2014
	2016	2015	2014		
SG&A	$ 89.4	$ 83.2	$ 88.9	7.5%	(6.4)%

Consolidated SG&A expense increased $6.2 million in 2016, as compared to 2015, primarily due to an increase of $3.6 million in compensation, $1.5 million in higher dealer fees, $1.3 million in commissions and $0.7 million in depreciation and amortization partially offset by $1.9 million in lower medical device excise taxes and a $0.6 million decrease in legal fees. The increase in compensation was in part due to filling positions that were open during 2015, additional employees retained as part of the acquired SwabCap product line, the general hiring and recruitment of new employees and increases in stock-based compensation issued to attract these employees. The increases in dealer fees and commissions were related to an increase in revenue on which they are calculated. The increase in depreciation and amortization was primarily driven by amortization of acquired intangible assets related to our 2015 acquisition of EXC Holding Corp ("EXC"). The decrease in medical device excise tax expense was due to the elimination of the tax in the current period due to Congress temporarily suspending this tax for the 2016-2017 two-year period and the decrease in legal expenses were a result of fewer litigations.

Consolidated SG&A expense decreased $5.7 million in 2015, as compared to 2014 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

	Year Ended December 31,			% decrease 2016 over 2015	% decrease 2015 over 2014
	2016	2015	2014		
R&D	$ 13.0	$ 15.7	$ 18.3	(17.2)%	(14.2)%

In 2016, as compared to 2015, and in 2015, as compared to 2014, R&D expenses declined primarily from decreasing R&D project expenses related to the development of our Cogent™ 2-in-1 hemodynamic monitoring system, which received FDA 510(k) clearance during 2016.

Restructuring and Strategic Transaction Expenses

Restructuring and strategic transaction expenses were $15.3 million, $8.5 million and $5.1 million in 2016, 2015 and 2014, respectively.

Restructuring Charges

In 2016, restructuring charges were $1.0 million. These charges were primarily related to residual expenses for the closure of our Slovakian manufacturing facility and we incurred $0.2 million related to other restructuring activities.

In 2015, restructuring charges were $6.7 million. These charges were related to: (i) 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; (ii) the reorganization of our corporate infrastructure, resulting in one-time employee termination benefits and other associated costs; and (iii) a commitment to a plan to sell our Slovakia manufacturing facility.

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.

Strategic Transaction Expenses

In 2016, we incurred $14.3 million in strategic transaction expenses related to our acquisition of the HIS business, our second quarter 2016 acquisition of Tangent and expenses related to our acquisition of EXC.

In 2015, we incurred $1.8 million in strategic transaction expenses related to the acquisition of EXC.

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

Gain on sale of building

We recognized a gain of $1.1 million in 2015 from the sale of one of our buildings in San Clemente to Dr. Lopez, a member of our Board of Directors.

Legal Settlements

During 2015, we recorded a net settlement charge of $1.8 million, less than 1% of revenues, due to the following claims:

An arbitrator ruled on a breach of contract claim between us and a service provider, awarding us a gross settlement of $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; and

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.

Impairment of Assets Held-for-Sale

During 2015, our Board of Directors authorized us to close our Vrable, Slovakia manufacturing facility. The closure was to enable for greater efficiency of our Ensenada, Mexico facility. After receiving the Board of Director's authorization, we reclassified the assets related to the Slovakia facility as held-for-sale, and recorded the value of those assets at the lower of their carrying value or their estimated fair value, less costs to sell, which was based on a third party fair market valuation. As the estimated fair value, less cost to sell was lower than the carrying value of the assets held-for-sale we recorded an impairment charge of $4.1 million.

During 2016, we completed the closure of our Slovakia manufacturing facility and sold the land and building held-for-sale for $3.3 million, net of costs to sell, resulting in an additional impairment loss of $0.7 million.

Bargain Purchase Gain

In 2016, we recognized a bargain purchase gain of $1.5 million in connection with the Tangent acquisition. The bargain purchase gain represented the excess of the estimated fair market value of the identifiable tangible and intangible assets acquired and liabilities assumed, net of deferred tax assets over the total purchase consideration. The bargain purchase was driven by our ability to realize acquired deferred tax assets.

Other income

Other income was $0.8 million, $1.1 million and $0.8 million in 2016, 2015 and 2014, respectively.

Income taxes

Income taxes were accrued at an estimated annual effective tax rate of 26%, 35% and 34% in 2016, 2015 and 2014, respectively.

The effective tax rate for 2016 differs from the federal statutory rate principally because of the effect of foreign and state income taxes, tax credits, deductions for domestic production activities, and included material discrete tax benefits related to the adoption of ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (see Note 1 of the Consolidated Financial Statements in this Annual Report on Form 10-K).

The 2016 material discrete tax benefit related to the impact of ASU 2016-09, adopted during the second quarter of 2016 was $7.6 million. The income tax benefit was treated as a discrete item when determining the annual estimated effective tax rate.

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.

Liquidity and Capital Resources

During 2016, our cash, cash equivalents and investment securities increased by $67.7 million from $377.4 million at December 31, 2015 to $445.1 million at December 31, 2016. As of December 31, 2016, we had liquidated all of our short-term and long-term investment securities to fund the pending acquisition of HIS.

Cash Flows from Operating Activities*:*

Our cash provided by operations was $89.9 million in 2016. Net income plus adjustments for non-cash net expenses contributed $98.7 million to cash provided by operations. Net cash used by operations as a result of changes in operating assets and liabilities was $8.8 million. The changes in operating assets and liabilities included a $5.5 million increase in inventories, a $3.0 million increase in prepaid expenses and other assets, a $1.2 million decrease in accrued liabilities, and a $0.5 million decrease in accounts payable, partially offset by a $0.7 million decrease in accounts receivable and a $0.7 million net change in prepaid and deferred income taxes. The increase in inventories was primarily due to building finished good safety stock, to support better customer deliveries, raw materials related to our Slovakia plant closure, and related transfer to our Mexico plant, and inventory associated with the acquired SwabCap product-line. The increase in prepaid expenses and other assets was primarily due to repayment of state aid and interest related to the closure of our Slovakian manufacturing facilities. The

decrease in accrued liabilities was primarily due to the payment of accrued restructuring charges related to the closure of our Slovakian manufacturing facility and the payment of acquisition-related accruals from our 2015 EXC acquisition. The decrease in accounts payable was a result of the timing of disbursements. The decrease in accounts receivable was due to collection efforts on our past due accounts. The net changes in income taxes was a result of the timing of payments for cash tax purposes, which includes true-ups for 2015 overpayment and 2016 estimated taxes.

Our cash provided by operations was $64.2 million in 2015, which includes a retrospective adjustment to include $9.3 million in excess tax benefits as an operating item due to the implementation of ASU 2016-09 in 2016 (see Note 1 of the Consolidated Financial Statements in this Annual Report on Form 10-K for additional detail). 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 $16.5 million, retrospectively adjusted for the impact of the aforementioned ASU. The changes in operating assets and liabilities included a $20.5 million increase in accounts receivable, an $8.3 million increase in inventories, and $1.8 million increase in prepaid expenses and other assets, partially offset by a $9.4 million increase in accrued liabilities, a $3.1 million increase in accounts payable and a $1.6 million net change in prepaid and deferred income taxes. 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 $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 of disbursements. The net changes in prepaid and deferred income taxes was primarily due to the $9.3 million retrospective reclass of excess tax benefits in accordance with the aforementioned ASU mostly offset by a loss on the sale of assets to Medline and the utilization of an Excelsior net operating loss carryover.

Cash Flows from Investing Activities

The following table summarizes the changes in our investing cash flows (in thousands):

	For the Years Ended December 31,			Variance		
	2016	2015	2014	2016	2015	
Investing Cash Flows:						
Purchases of property and equipment	$ (23,361)	$ (12,984)	$ (16,604)	$ (10,377)	$ 3,620	(1)
Proceeds from sale of assets	—	3,592	5	(3,592)	3,587	(2)
Proceeds from the disposal of assets held-for-sale, net	3,268	—	—	3,268	—	(3)
Intangible asset additions	(1,192)	(951)	(989)	(241)	38	
Business acquisitions, net of cash acquired	(2,584)	(56,786)	—	54,202	(56,786)	(4)
Proceeds from sale of assets acquired in a business combination	—	28,970	—	(28,970)	28,970	(5)
Purchases of investment securities	(118,384)	(56,137)	(93,588)	(62,247)	37,451	(6)
Proceeds from sale of investment securities	158,534	83,054	89,426	75,480	(6,372)	(7)
Net cash provided by (used in) investing activities	$ 16,281	$ (11,242)	$ (21,750)	$ 27,523	$ 10,508	

(1) Our purchases of property and equipment will vary from period to period based on additional investments needed to support new and existing products and expansion of our manufacturing facilities. During 2016, we expanded our Mexico manufacturing facilities to absorb the production capacity from the closed Slovakian facilities.

(2) In 2015, we sold an office building for $3.6 million.

(3) In 2016, we sold our Slovakian manufacturing facilities for $3.3 million, net of costs to sell of $0.1 million.

(4) Our business acquisitions will vary from period to period based upon our current growth strategy and our ability to execute on desirable target companies. In 2016, we acquired Tangent for $2.6 million in cash. In 2015, we acquired EXC for $56.8 million in cash.

(5) In 2015, we sold certain assets from the EXC acquisition for $29.0 million in cash to Excelsior Medical, LLC.

(6) Our purchases of investment securities will vary from period to period based on current cash needs, planning for known future transactions and due to changes in our investment strategy. In 2016, we amended our investment policy to allow for the purchase of securities with final maturities in excess of one year. Accordingly, we adjusted our investment strategy to take advantage of the higher yields available on these longer term securities. Our longer term securities have maturities up to three years.

(7) The proceeds from the sale of our investment securities increased significantly during in 2016, as compared to the comparable prior year periods, due to the liquidation of all of our short-term and long-term investment securities, which were used to fund the 2017 acquisition of HIS.

While we can provide no assurances, we estimate that our capital expenditures in 2017 related to our legacy business, not including HIS, will approximate $18 million to $20 million. In January 2017, we completed an expansion of our Mexico manufacturing plant. 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. 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.

Cash Flows from Financing Activities

The following table summarizes the changes in our financing cash flows (in thousands):

	For the Years Ended December 31,			Variance		
	2016	2015	2014	2016	2015	
Financing Cash Flows:						
Proceeds from exercise of stock options	$ 17,346	$ 15,042	$ 16,998	$ 2,304	$ (1,956)	(1)
Proceeds from employee stock purchase plan	2,361	2,162	2,485	199	(323)	
Purchase of treasury stock	(17,235)	(1,523)	(5,836)	(15,712)	4,313	(2)
Net cash provided by financing activities	$ 2,472	$ 15,681	$ 13,647	$ (13,209)	$ 2,034	

(1) Proceeds from the exercise of stock options will vary from period to period based on the volume of options exercised and the exercise price of the specific options exercised.

(2) In 2016, we purchased 174,885 shares of our common stock under our share purchase plan on the open market for $15.3 million. Additionally in 2016, our employees surrendered 20,261 shares of our common stock from vested restricted stock awards as consideration for approximately $1.9 million in minimum statutory withholding obligations paid on their behalf.

In 2015, our employees surrendered 17,299 shares of our common stock from vested restricted stock awards as consideration for approximately $1.5 million in minimum statutory withholding obligations paid on their behalf.

In 2014, we purchased 88,792 shares of our common stock under our share purchase plan on the open market for $ 5.6 million and our employees surrendered 4,232 shares of our common stock from vested restricted stock awards as consideration for approximately $0.2 million in minimum statutory withholding obligations paid on their behalf.

Our common stock purchase plan, which authorized the repurchase of up to $40.0 million of our common stock, was authorized by our Board of Directors and publicly announced on July 19, 2010. To date, we have purchased a total of $32.8 million of our stock from this plan, leaving a balance of $7.2 million available for future purchases. This plan has no expiration date.

We have a substantial cash 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. In line with the above policy, as of December 31, 2016 we had liquidated all of our short-term and long-term investment securities to fund the acquisition of HIS.

As of December 31, 2016, we have $28.5 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.

Post year end Uses of Capital and Financing

On February 3, 2017 we paid $275 million in cash to acquire HIS, which was financed with existing cash balances and a three-year interest-only seller note of $75 million. The seller note bears interest at the London interbank offered rate plus (a) 2.25% per annum for the first twelve months after the closing date and (b) 2.5% per annum thereafter. The seller note matures on February 3, 2020 and the full balance of the note must be paid at that time. Our cash balance after the acquisition was approximately $270 million.

We believe that our existing cash, cash equivalents 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, as well as fund the acquisition of HIS. 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 and Estimates

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

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

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

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

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

slow moving items, and write off all items that we do not expect to use in manufacturing, and finished products that we do not expect to sell. If actual usage of components or sales of finished goods inventory is less than our estimates, we could be required to write off additional inventory, which could have an adverse effect on our operating results in the period in which the write-off occurs.

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

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

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

New Accounting Pronouncements

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

Off Balance Sheet Arrangements

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

Contractual Obligations

We have contractual obligations, at December 31, 2016, 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**	**2017**	**2018**	**2019**	**2020**	**2021**
Operating leases	$ 1,737	$ 554	$ 337	$ 333	$ 338	$ 175
Warehouse service agreements	4,373	1,573	1,568	1,232	—	—
Purchase obligations	4,829	4,829	—	—	—	—
Other contractual obligations	3	3	—	—	—	—
	$ 10,942	$ 6,959	$ 1,905	$ 1,565	$ 338	$ 175

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 aims, goals and plans. The forward looking statements are based on the best information currently available to us and assumptions that we believe are reasonable, but we do not intend the statements to be representations as to future results. They include, without limitation, statements about:

- future growth; future operating results and various elements of operating results, including future expenditures and effects with respect to sales and marketing and product development and acquisition efforts; future sales and unit volumes of products; expected increases and decreases in sales; deferred revenue; 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, acquisition and integration of businesses and product lines, including the HIS business, SwabCap (EXC) and Tangent; 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; the impact of our acquisition of the HIS business; 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 our large customers;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- increases in costs or availability of the raw materials need to manufacture our products;
- the effect of price and safety considerations on the healthcare industry;
- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- the successful development and marketing of new products;
- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- the effects of additional governmental regulations;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

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

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

Foreign Exchange Risk

We have foreign currency exchange risk related to foreign-denominated cash, accounts receivable and accounts payable. In our European operations, our net Euro asset position at December 31, 2016 was approximately €37.7 million. We also have approximately €8.0 million in an Euro denominated cash account held by our corporate entity. A 10% change in the conversion of the Euro to the U.S. dollar for our cash, accounts receivable, accounts payable and accrued liabilities from the December 31, 2016 spot rate would impact our consolidated amounts on these balance sheet items by approximately $4.8 million, or 1.0% of these net assets. We expect that in the future, with the organic growth of our European distribution operation and from our acquisition of HIS, our net Euro denominated instruments will 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 2016 and our manufacturing spending from 2016 would have impacted our cost of goods sold by approximately $2.4 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.

Item 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders 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, 2016 and 2015, 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, 2016. 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, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, 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, 2016, 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 March 1, 2017 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Costa Mesa, California
March 1, 2017

ICU MEDICAL, INC. AND SUBSIDIARIES

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

	December 31,	
	2016	2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 445,082	$ 336,164
Short-term investment securities	—	41,233
TOTAL CASH, CASH EQUIVALENTS AND INVESTMENT SECURITIES	445,082	377,397
Accounts receivable, net of allowance for doubtful accounts of $1,073 and $1,101 at December 31, 2016 and 2015, respectively	56,161	57,847
Inventories	49,264	43,632
Prepaid income taxes	11,235	14,366
Prepaid expenses and other current assets	7,355	7,631
Assets held-for-sale	—	4,134
TOTAL CURRENT ASSETS	569,097	505,007
PROPERTY AND EQUIPMENT, net	85,696	74,320
GOODWILL	5,577	6,463
INTANGIBLE ASSETS, net	22,383	23,936
DEFERRED INCOME TAXES	21,935	17,099
TOTAL ASSETS	$ 704,688	$ 626,825
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 14,641	$ 13,670
Accrued liabilities	25,896	28,948
TOTAL CURRENT LIABILITIES	40,537	42,618
LONG-TERM LIABILITIES	1,107	1,476
DEFERRED INCOME TAXES	1,370	1,372
INCOME TAX LIABILITY	1,519	1,488
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, 16,338 shares at December 31, 2016 and 16,086 shares at December 31, 2015	1,633	1,608
Additional paid-in capital	162,828	145,125
Treasury stock, at cost	(14)	—
Retained earnings	516,980	453,896
Accumulated other comprehensive loss	(21,272)	(20,758)
TOTAL STOCKHOLDERS' EQUITY	660,155	579,871
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 704,688	$ 626,825

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

ICU MEDICAL, INC. AND SUBSIDIARIES

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

	Year ended December 31,		
	2016	**2015**	**2014**
REVENUES:			
Net sales	$ 379,339	$ 341,254	$ 308,770
Other	33	414	490
TOTAL REVENUE	379,372	341,668	309,260
COST OF GOODS SOLD	177,974	160,871	157,859
GROSS PROFIT	201,398	180,797	151,401
OPERATING EXPENSES:			
Selling, general and administrative	89,426	83,216	88,939
Research and development	12,955	15,714	18,332
Restructuring and strategic transaction	15,348	8,451	5,093
Gain on sale of building	—	(1,086)	—
Legal settlements, net	—	1,798	—
Impairment of assets held for sale	728	4,139	—
TOTAL OPERATING EXPENSES	118,457	112,232	112,364
INCOME FROM OPERATIONS	82,941	68,565	39,037
BARGAIN PURCHASE GAIN	1,456	—	—
OTHER INCOME, NET	767	1,134	755
INCOME BEFORE INCOME TAXES	85,164	69,699	39,792
PROVISION FOR INCOME TAXES	(22,080)	(24,714)	(13,457)
NET INCOME	$ 63,084	$ 44,985	$ 26,335
NET INCOME PER SHARE			
Basic	$ 3.90	$ 2.84	$ 1.72
Diluted	$ 3.66	$ 2.73	$ 1.68
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	16,168	15,848	15,282
Diluted	17,254	16,496	15,647

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Amounts in thousands)

	Year ended December 31,		
	2016	2015	2014
Net income	$ 63,084	$ 44,985	$ 26,335
Other comprehensive loss, net of tax of $185, ($2,680) and ($3,129) for the years ended December 31, 2016, 2015 and 2014, respectively:			
Foreign currency translation adjustment	(514)	(11,204)	(11,747)
Comprehensive income	$ 62,570	$ 33,781	$ 14,588

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount					
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**
Issuance of restricted stock and exercise of stock options	416	22	103	17,221	—	—	17,346
Purchase of treasury stock, treasury stock acquired in lieu of cash payment on stock option exercises and income tax withholding obligations	(195)	—	—	(17,235)			(17,235)
Proceeds from employee stock purchase plan	31	3	2,358	—	—	—	2,361
Stock compensation	—	—	15,242	—	—	—	15,242
Foreign currency translation adjustment	—	—	—	—	—	(514)	(514)
Net income	—	—	—	—	63,084	—	63,084
Balance, December 31, 2016	**16,338**	**$1,633**	**$ 162,828**	**$ (14)**	**$516,980**	**$ (21,272)**	**$660,155**

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

ICU MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year ended December 31,		
	2016	**2015**	**2014**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 63,084	$ 44,985	$ 26,335
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	19,050	18,073	19,447
Provision for doubtful accounts	—	54	34
Provision for warranty and returns	559	52	(360)
Stock compensation	15,242	12,827	9,592
Loss (gain) on disposal of property and equipment	59	(1,106)	8
Bond premium amortization	1,355	1,670	2,188
Impairment of assets held-for-sale	728	4,139	—
Bargain purchase gain	(1,456)	—	—
Other	75	—	—
Changes in operating assets and liabilities:			
Accounts receivable	744	(20,515)	4,912
Inventories	(5,501)	(8,337)	(3,836)
Prepaid expenses and other assets	(3,028)	(1,832)	1,970
Accounts payable	(463)	3,118	(621)
Accrued liabilities	(1,221)	9,454	2,344
Income taxes, including excess tax benefits and deferred income taxes	714	1,613	4,327
Net cash provided by operating activities	89,941	64,195	66,340
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(23,361)	(12,984)	(16,604)
Proceeds from sale of assets	—	3,592	5
Proceeds from the disposal of assets held-for-sale, net	3,268	—	—
Intangible asset additions	(1,192)	(951)	(989)
Business acquisitions, net of cash acquired	(2,584)	(56,786)	—
Proceeds from sale of assets acquired in a business acquisition	—	28,970	—
Purchases of investment securities	(118,384)	(56,137)	(93,588)
Proceeds from sale of investment securities	158,534	83,054	89,426
Net cash provided by (used in) investing activities	16,281	(11,242)	(21,750)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	17,346	15,042	16,998
Proceeds from employee stock purchase plan	2,361	2,162	2,485
Purchase of treasury stock	(17,235)	(1,523)	(5,836)
Net cash provided by financing activities	2,472	15,681	13,647
Effect of exchange rate changes on cash	224	(8,282)	(8,447)
NET INCREASE IN CASH AND CASH EQUIVALENTS	108,918	60,352	49,790
CASH AND CASH EQUIVALENTS, beginning of period	336,164	275,812	226,022
CASH AND CASH EQUIVALENTS, end of period	$ 445,082	$ 336,164	$ 275,812
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the year for income taxes	$ 21,101	$ 22,998	$ 8,668

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

ICU MEDICAL, INC. AND SUBSIDIARIES

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

	Year ended December 31,		
	2016	2015	2014
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:			
Accrued liabilities for property and equipment	$ 1,566	$ 182	$ 789
Detail of acquisitions:			
Fair value of assets acquired	$ 3,306	$ 60,693	$ —
Cash paid for acquisitions, net of cash acquired	(2,584)	(56,786)	—
Bargain purchase gain	(1,456)	—	—
Liabilities assumed	$ 734	$ (3,907)	$ —

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

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1: General and Summary of Significant Accounting Policies

Basis of Presentation and Preparation

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 and Mexico. Our Slovakian manufacturing facilities were closed during the second half of 2016. Assets and operating expenses are not allocated to individual product groups.

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

In our opinion, the consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. These consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Preparing financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount 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.

In the second quarter of 2016, we adopted Accounting Standard Update ("ASU") No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This update requires excess tax benefits or deficiencies to be recognized in income tax expense instead of to additional paid in capital. Also, the assumed proceeds from applying the treasury stock method when computing earnings per share no longer includes the amount of excess tax benefits or deficiencies. The update also requires that the excess tax benefits or deficiencies be classified as an operating cash flow line item instead of a financing cash flow line item in our consolidated statement of cash flows. The requirements of the update were to be reflected as of the beginning of the fiscal year regardless of in which interim period it was actually adopted. Accordingly certain line-items in our Note 17: Quarterly Financial Data for the three months ended March 31, 2016 have been adjusted from previously reported amounts. March 31, 2016 net income was adjusted to $18.2 million, basic earnings per share was adjusted to $1.13 and diluted earnings per share was adjusted to $1.08. Additionally, the update gave the option to retroactively reclassify the excess tax benefits from a financing cash flow to an operating cash flow in the prior year's consolidated cash flow statements presented; accordingly, the presentation of $9.3 million and $5.7 million, respectively, in excess tax benefits in the December 31, 2015 and 2014 consolidated statement of cash flows were reclassified from financing cash flows to operating cash flows to conform to the new accounting standard.

Cash and Cash Equivalents

Cash equivalents are short-term, highly liquid investments with an original maturity of three months or less.

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.

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 (in thousands):

	2016	2015
Raw material	$ 28,435	$ 24,681
Work in process	4,415	4,282
Finished goods	16,414	14,669
Total	$ 49,264	$ 43,632

Property and Equipment

Property and equipment consist of the following at December 31 (in thousands):

	2016	2015
Machinery and equipment	$ 96,536	$ 96,909
Land, building and building improvements	63,524	56,716
Molds	39,014	36,436
Computer equipment and software	26,458	23,346
Furniture and fixtures	3,243	3,638
Construction in progress	15,180	6,003
Total property and equipment, cost	243,955	223,048
Accumulated depreciation	(158,259)	(148,728)
Net property and equipment	$ 85,696	$ 74,320

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

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

We capitalize expenditures that materially increase the life of the related assets; maintenance and repairs are expensed as incurred. The costs and related accumulated depreciation applicable to property and equipment sold or retired are removed from the accounts and any gain or loss is reflected in the statements of income at the time of disposal. Depreciation expense was $16.3 million, $15.9 million and $17.0 million in the years ended December 31, 2016, 2015 and 2014, respectively.

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, 2016 and 2015.

The following table presents the changes in the carrying amount of our goodwill for 2016 and 2015 (in thousands):

	Total
Balance as of December 31, 2014	$ 1,478
Goodwill acquired	4,985
Other	—
Balance as of December 31, 2015	6,463
Goodwill acquired	—
Other [1]	(886)
Balance as of December 31, 2016	$ 5,577

[1] In 2016, "other" relates to measurement period adjustments on the net assets of our 2015 acquisition of EXC Holding Corp. ("EXC").

Intangible Assets

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

	Weighted Average Amortization Life in Years	December 31, 2016		
		Cost	Accumulated Amortization	Net
Patents	10	$ 14,423	$ 9,326	$ 5,097
MCDA contract *	10	8,571	8,571	—
Customer contracts	9	5,319	4,512	807
Non-contractual customer relationships	15	7,080	590	6,490
Trademarks	4	425	425	—
Trade name	15	7,310	609	6,701
Developed technology	10	3,797	509	3,288
Total		$ 46,925	$ 24,542	$ 22,383

	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

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

Amortization expense in 2016, 2015 and 2014 was $2.8 million, $2.2 million and $2.4 million, respectively.

As of December 31, 2016 estimated annual amortization for our intangible assets for each of the next five years is approximately (in thousands):

2017	$	2,719
2018		2,560
2019		2,147
2020		2,008
2021		1,925
Thereafter		11,024
Total	$	22,383

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.

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.

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. With the adoption of a new accounting standard during 2016 (see Note 1: General and Summary of Significant Accounting Policies), the direct tax benefits of share based compensation are also recorded as a reduction to the tax provision and not through additional paid in capital as in the prior years.

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Foreign Currency

We have operations in Europe where the functional currency is the Euro, operations in Australia where the functional currency is the Australian dollar and operations in South Africa where the functional currency is the Rand. 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 $0.3 million in 2016, $0.2 million in 2015 and less than $0.1 million in 2014.

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.

Shipping Costs

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

Advertising Expenses

Advertising expenses are expensed as incurred and reflected in selling, general and administrative expenses in our consolidated statements of income and were $0.1 million in 2016, $0.2 million in 2015 and $0.1 million in 2014.

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 $1.5 million in 2016, $1.3 million in 2015 and $1.3 million in 2014.

Research and Development

Research and development costs are expensed as incurred. Research and development costs include salaries and related benefits, consulting fees, production supplies, samples, travel costs, utilities and other miscellaneous administrative costs.

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. There were no anti-dilutive options in 2016 or 2015.

The following table presents the calculation of net earnings per common share ("EPS") — basic and diluted (in thousands except per share data):

	Year ended December 31, (in thousands, except per share data)		
	2016	2015	2014
Net income	$ 63,084	$ 44,985	$ 26,335
Weighted average number of common shares outstanding (basic)	16,168	15,848	15,282
Dilutive securities [1]	1,086	648	365
Weighted average common and common equivalent shares outstanding (diluted)	17,254	16,496	15,647
EPS - basic	$ 3.90	$ 2.84	$ 1.72
EPS - diluted	$ 3.66	$ 2.73	$ 1.68

[1] During the second quarter of 2016, we early adopted ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. Under this ASU, the change to the treasury stock method impacted weighted average common and common equivalent shares outstanding by 413,000 shares for the year ended December 31, 2016 (see other sections of this note for further information on the changes required by ASU 2016-09).

On February 3, 2017, as part of the purchase price for the acquisition of Pfizer Inc.'s ("Pfizer") Hospira Infusion Systems ("HIS") business, we delivered to Pfizer 3.2 million newly issued common shares (see Note 3: Acquisitions and Strategic Transaction Expenses).

New Accounting Pronouncements

Recently Adopted Accounting Standards

In December 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-19, Technical Corrections and Improvements. The amendments in this Update represent changes to clarify, correct errors, or make minor improvements to the Accounting Standards Codification. The amendments make the Accounting Standards Codification easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. Most of the amendments in this Update do not require transition guidance and are effective upon issuance of this Update. Six amendments in this Update clarify guidance or correct references in the Accounting Standards Codification that could potentially result in changes in current practice because of either misapplication or misunderstanding of current guidance, these include: an amendment to Subtopic 350-40, Intangibles—Goodwill and Other— Internal-Use Software; an amendment to Subtopic 360-20, Property, Plant, and Equipment— Real Estate Sales; an amendment to Topic 820, Fair Value Measurement; an amendment to Subtopic 405-40, Liabilities—Obligations Resulting from Joint and Several Liability Arrangements; an amendment to Subtopic 860-20, Transfers and Servicing—Sales of Financial Assets; and an amendment to Subtopic 860-50, Transfers and Servicing—Servicing Assets and Liabilities. Early adoption is permitted for the six amendment topics listed above that require transition guidance. In December 2016, we early adopted this ASU, which did not have a material impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The amendments address several aspects of the accounting for share-based payment award transactions, including income tax accounting consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The amendments in this update are effective for annual periods beginning after December 15, 2016. Early adoption is permitted for an entity in any interim or annual period. An entity that elects early adoption must adopt all of the amendments in the same period and any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. We early adopted this standard during the second quarter ended June 30, 2016. During 2016, in accordance with the changes required by this ASU, we have recognized $7.6 million in tax benefits as a discrete item. We elect to account for forfeitures as they occur.

In September 2015, the 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. We adopted this ASU on January 1, 2016 and the adoption did not have a material impact on our consolidated financial statements.

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. 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. On January 1, 2016, we adopted this ASU on a prospective basis. The adoption did not have a material impact on our consolidated financial statements.

Recently Issued Accounting Standards

In October 2016, the FASB issued No. ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory. Current generally accepted accounting principles prohibits the recognition of current and deferred income taxes for an intra-entity asset transfer until after the asset has been sold to an outside party. The amendments in ASU 2016-16 eliminates this prohibition. Accordingly, an entity should recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. Amendments in this update are effective for annual reporting periods beginning after December 15, 2017. Early adoption is permitted in the first interim period of an annual reporting period. The amendments should be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In August 2016, the FASB issued No. ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 provides specific guidance on eight cash flow issues where current guidance is unclear or does not include any specifics on classification. The eight specific cash flow issues are: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments or other debt instruments with zero coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies, including bank-owned policies; distributions received from equity method investees; beneficial interests in securitization transactions; and separately identifiable cash flows and application of the predominance principle. The amendments in ASU 2016-15 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2017. Early adoption is permitted. If adopted in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes the interim period. Amendments should be applied using a retrospective transition method to each period presented. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued No. ASU 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This update amends the FASB's guidance on the impairment of financial instruments by requiring timelier recording of credit losses on loans and other financial instruments. The ASU adds an impairment model that is based on expected losses rather than incurred losses. The ASU also amends the accounting for credit losses on available-
for-sale debt securities and purchased financial assets with credit deterioration. The amendments in this update will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted as of the fiscal years beginning after December

15, 2018. The updated guidance requires a modified retrospective adoption. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In February 2016, the FASB issued No. ASU 2016-02, Leases (Topic 842). The amendments in this update require an entity to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Recognition, measurement and presentation of expenses will depend on classification as finance or operating lease. The amendments also require certain quantitative and qualitative disclosures about leasing arrangements. The amendments in this update will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. The updated guidance requires a modified retrospective adoption. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In January 2016, the FASB issued No. ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which amends certain aspects of recognition, measurement, presentation and disclosure of financial instruments. This amendment requires all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under the equity method of accounting or those that result in the consolidation of the investee). The amendments in this update will be effective for fiscal years beginning after December 15, 2017. Early adoption of the amendments is not permitted with the exception of the provision requiring the recognition in other comprehensive income the fair value change from instrument-specific credit risk measured using the fair value option for financial instruments. We are currently evaluating the impact of this ASU on the consolidated financial statements and related disclosures.

In July 2015, the FASB issued No. 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 or after December 15, 2016. We do not anticipate a material impact on our consolidated financial statements from the 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 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. Subsequent to the issuance of this ASU, the FASB issued three amendments: ASU No. 2016-08 which clarifies principal versus agent considerations; ASU 2016-10 which clarifies guidance related to identifying performance obligations and licensing implementation; and ASU 2016-12 which provides narrow-scope improvements and practical expedients. All of the amendments have the same effective dates mentioned above. We previously disclosed that we did not anticipate a material impact on our consolidated financial statements from adoption of any of the above ASUs related to Topic 606; we will reassess these ASUs with consideration to their impact on Hospira Infusion Systems ("HIS"). We expect to adopt the full retrospective transition method when adopting this ASU.

Note 2: Restructuring Charges

In 2016, we incurred an additional $0.8 million related to the closure of the Slovakian manufacturing facility, described below. Additionally, we incurred $0.2 million related to a one-time charge unrelated to the events disclosed in the table below.

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, which was sold during 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 and 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 and corporate restructuring actions resulted in a total charge of $0.6 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.

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

	Accrued Balance December 31, 2014	Charges incurred	Payments	Accrued Balance December 31, 2015	Charges incurred	Payments	Currency Translation	Other Adjustments	Accrued Balance December 31, 2016
Severance pay and benefits	$ 1,358	$ 2,582	$ (1,435)	$ 2,505	$ 25	$ (2,683)	$ 77	$ 129	$ 53
Government incentive repayment	—	1,884	—	1,884	—	(1,769)	57	(172)	—
Employment agreement buyout	—	1,905	(60)	1,845	—	(368)	—	—	1,477
Other corporate restructuring	11	305	(11)	305	168	(468)	—	(5)	—
Retention and closure expenses	—	—	—	—	581	(581)	—	—	—
	$ 1,369	$ 6,676	$ (1,506)	$ 6,539	$ 774	$ (5,869)	$ 134	$ (48)	$ 1,530

Note 3: Acquisitions and Strategic Transaction Expenses

Acquisition of Hospira Infusion Systems

On October 6, 2016, we entered into a Stock and Asset Purchase Agreement to acquire Pfizer's HIS business. On January 5, 2017, we amended and restated the original purchase agreement to modify the terms of the agreement as a result of changes in the performance of HIS that affect expectations for the transaction ("the "Purchase Agreement"). The transaction closed on February 3, 2017. Under the terms of the Purchase Agreement, we paid $275 million in cash, which was financed with existing cash balances and a three-year interest-only seller note of $75 million and we delivered 3.2 million shares of our common stock to Pfizer. Additionally, Pfizer also may be entitled up to an additional $225 million in cash based on achievement of performance targets for the combined company for the three years ending December 31, 2019 ("Earnout Periodt"). In the event that the sum of our Adjusted EBITDA (as defined by the Purchase Agreement) for each of the three years in the Earnout Period (the "Cumulative Adjusted EBITDA") is equal to or exceeds approximately $1.0 billion ("the "Earnout Target"), then Pfizer will be entitled to receive the full amount of the earnout. In the event that the Cumulative Adjusted EBITDA is equal to or greater than 85% of the Earnout Target (but less than the Earnout Target), Pfizer will be entitled to receive the corresponding percentage of the earnout. In the event that the Cumulative Adjusted EBITDA is less than 85% of the Earnout Target, then no earnout amount will be earned by Pfizer. The aggregate purchase consideration is subject to certain adjustments, based on working capital, cash and indebtedness of the HIS business at closing.

Due to the close proximity of the acquisition date and the filing of this annual report on Form 10-K for the year ended December 31, 2016, the initial accounting for the business combination is incomplete, and therefore we are unable to fully
disclose the information required by ASC 805, Business Combinations. Such information will be included in our subsequent Form 10-Q (see Note 18: Subsequent Events).

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We believe that the acquisition of the HIS business complements our existing business by creating a company that has a complete intravenous therapy product portfolio. We also believe that the acquisition also significantly enhances our global footprint and platform for continued competitiveness and growth.

Other Acquisitions During the Reporting Period

On April 4, 2016, we acquired all of the outstanding shares of Tangent Medical Technologies, Inc. ("Tangent") for $2.6 million in cash. Tangent designs, develops, and commercializes intravenous catheters and associated products for the improvement of infusion therapy. Tangent's products enhance our infusion therapy product offering. For the year ended December 31, 2016, we recognized a $1.5 million bargain purchase gain related to the acquisition, which is separately stated in our consolidated statements of income. The bargain purchase gain represents the excess of the estimated fair market value of the identifiable tangible and intangible assets acquired, liabilities assumed and deferred tax assets over the total purchase consideration. The bargain purchase was driven by our ability to realize acquired deferred tax assets. The purchase price allocation is final.

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 included $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 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 2016, we incurred $14.3 million in transaction costs related to our pending acquisition of HIS, our acquisition of Tangent and our acquisition of EXC. In 2015, we incurred $1.8 million in charges primarily associated with the acquisition of EXC. In 2014, we incurred $1.6 million 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

During 2015, we sold an office building in our San Clemente location to George A. Lopez, M.D., a member of our Board of Directors. 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, we recorded a net settlement charge of $1.8 million due to the following claims:

An arbitrator ruled on a breach of contract claim between us and a service provider, awarding us a gross settlement of $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; and

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.

Note 6: Impairment on Asset Held-for-Sale

During 2015, our Board of Directors authorized us to close our Vrable, Slovakia manufacturing facility. The closure was to enable for greater efficiency of our Ensenada, Mexico facility. After receiving the Board of Director's authorization, we reclassified the land and building related to the Slovakia facility as held-for-sale, and recorded the value of those assets at the lower of their carrying value or their estimated fair value less costs to sell, which was based on a third party fair market valuation. As the estimated fair value less cost to sell was lower than the carrying value of the assets held-for-sale, we recorded an impairment charge of $4.1 million in 2015.

During 2016, we completed the closure of our Slovakia manufacturing facility and sold the land and building held-for- sale for $3.3 million, net of costs to sell, resulting in an additional $0.7 million impairment charge on those assets.

The impairment charges are separately stated in our consolidated statements of income above income from operations.

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 and direct tax benefits from the exercise of stock options, which with the implementation of ASU 2016-09 during 2016, those benefits are prospectively recorded as a reduction of income tax expense (see Note 1: General and Summary of Significant Accounting Policies). We also have indirect tax benefits upon exercise of stock options related to
research and development tax credits which are also recorded as a reduction of income tax expense. The table below summarizes compensation costs and related tax benefits (in thousands):

	Year ended December 31,		
(In thousands)	2016	2015	2014
Stock compensation expense	$ 15,242	$ 12,827	$ 9,592
Tax benefit from stock-based compensation cost	$ 5,682	$ 4,922	$ 3,567
Indirect tax benefit	$ —	$ 1,997	$ 209

As of December 31, 2016, we had $16.8 million of unamortized stock compensation cost which we will recognize as an expense over approximately 0.7 years.

Stock Incentive and Stock Option Plans

Our 2011 Stock Incentive Plan ("2011 Plan") replaced our 2003 Stock Option Plan (“2003 Plan”). Our 2011 Plan initially had 650,000 shares available for issuance, plus the remaining available shares for grant from the 2003 Plan. In 2012 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, 2016, 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 (dollars in thousands):

	Year ended December 31,		
	2016	2015	2014
Number of time-based options granted	13,405	22,816	492,935
Grant date fair value of options granted (in thousands)	$ 413	$ 590	$ 7,311
Weighted average assumptions for stock option valuation:			
Expected term (years)	5.5	5.6	4.7
Expected stock price volatility	31.8%	25.9%	26.7%
Risk-free interest rate	0.7%	1.7%	1.4%
Expected dividend yield	—%	—%	—%
Weighted average grant price per option	$ 101.32	$ 93.30	$ 58.92
Weighted average grant date fair value per option	$ 30.78	$ 25.86	$ 14.83

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 became exercisable when the closing price of our common stock was 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. All of the 2015 and 2014 performance stock option grant's stock price conditions have been met.

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, the total valuation and the weighted average assumptions (dollars in thousands). There were no performance option grants in 2016.

	Year ended December 31,		
	2016	2015	2014
Number of performance options granted		244,825	699,625
Number of performance options earned	244,825	349,812	349,813
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, 2016 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	2,379,407	$ 56.90		
Granted	13,405	$ 101.32		
Exercised	(366,065)	$ 47.38		
Forfeited or expired	(8,457)	$ 62.57		
Outstanding at December 31, 2016	2,018,290	$ 58.90	6.4	$ 178,521
Exercisable at December 31, 2016	1,354,853	$ 54.44	5.8	$ 125,878
Vested and expected to vest, December 31, 2016	2,018,290	$ 58.90	6.4	$ 178,521

The intrinsic values for options exercisable, outstanding and vested or expected to vest at December 31, 2016 is based on our closing stock price of $147.35 at December 31, 2016 and are before applicable taxes.

	Year ended December 31,		
(In thousands)	2016	2015	2014
Intrinsic value of options exercised	$ 25,065	$ 28,071	$ 18,802
Cash received from exercise of stock options	$ 17,346	$ 15,042	$ 16,998
Tax benefit from stock option exercises	$ 7,556	$ 9,330	$ 5,700

Stock Awards

In 2016, we granted performance restricted stock units ("PRSU") to our executive officers. The PRSUs will vest, if at all, upon the achievement of a minimum specified compound annual growth rate ("CAGR") in EBITDA, subject to a three-year cliff vesting ending on December 31, 2018. If at that date, our adjusted EBITDA CAGR is at least 8% but less than 10%, 100% of the awarded units will vest. If our adjusted EBITDA CAGR is at least 10% but less than 12%, 200% of the awarded units will vest. If our adjusted EBITDA CAGR is greater than 12%, 300% of the awarded units will vest.

Restricted stock units ("RSU") are granted annually to our Board of Directors and vest on the first anniversary of the grant date.

In 2016 and 2015, we granted RSUs to certain employees that vest ratably on the anniversary of the grant over three years. Additionally in 2015, we granted RSUs to certain new hire employees that vest ratably on the anniversary of the grant over two 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.

The table below summarizes our restricted stock award activity (dollars in thousands):

	Year ended December 31,		
(In thousands except shares and per share amounts)	2016	2015	2014
PRSU			
Shares granted	36,370	—	—
Shares earned	—	—	—
Grant date fair value per share	$ 86.47	$ —	$ —
Grant date fair value	$ 3,145	$ —	$ —
Intrinsic value vested	$ —	$ 787	$ 659
RSU			
Shares granted	60,377	67,745	76,618
Grant date fair value per share	$ 87.47	$ 93.52	$ 58.89
Grant date fair value	$ 5,281	$ 6,336	$ 4,512
Intrinsic value vested	$ 4,680	$ 2,754	$ 292

The table below provides a summary of our PRSU and RSU activity as of and for the year ended December 31, 2016.

	Number of Units	Grant Date Fair Value Per Share	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Non-vested at December 31, 2015	113,649	$ 78.84		
Granted	96,747	$ 87.09		
Vested	(49,386)	$ 75.71		
Forfeited	(1,571)	$ 92.53		
Non-vested and expected to vest at December 31, 2016	159,439	$ 84.68	1.1	$ 23,493

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, 2016, there were 156,913 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, 2016, we had $0.1 million of unamortized stock compensation expense from the ESPP, which will be recognized in the first quarter of 2017.

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 2016, 2015 and 2014 purchase periods.

	Year ended December 31,		
	2016	2015	2014
ESPP shares purchased by employees	31,227	34,299	47,466
Intrinsic value of ESPP purchases (in thousands)	$ 955	$ 1,382	$ 476
Weighted average assumptions for ESPP valuation:			
Expected term (in years)	0.5	0.5	0.5
Expected stock price volatility	32.5%	27.0%	20.8%
Risk-free interest rate	0.3%	0.6%	1.1%
Expected dividend yield	—%	—%	—%

Note 8: Fair Value Measurement

Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value is estimated by applying the following hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

- Level 1: quoted prices in active markets for identical assets or liabilities;
- Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or
- Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair values of the assets or liabilities.

As of December 31, 2016, we had liquidated all of our short-term and long-term investment securities to fund the 2017 acquisition of HIS (see Note 3: Acquisitions and Strategic Transaction Expenses).

As of December 31, 2015, we had investments measured using quoted prices in active markets or Level 1 inputs, which consisted of certificates of deposits and U.S Treasury securities, and we had investments measured using observable market based inputs such as quoted prices, interest rates and yield curves or Level 2 inputs, which consisted of pre-refunded municipal securities, non-pre-refunded municipal securities, commercial paper and corporate bonds.

There were no transfers between levels in 2015 or 2016.

Our assets measured at fair value for the year ended December 31, 2015 on a recurring basis consisted of the following (Level 1, 2 and 3 inputs as defined above) (in thousands):

	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)
Short-term available for sale securities	$ 41,233	$ 8,785	$ 32,448	$ —
Total available for sale securities	$ 41,233	$ 8,785	$ 32,448	$ —

Our assets-held-for-sale whose fair market value was measured on a nonrecurring basis were sold during 2016 (see Note 6: Impairment on Asset Held-For-Sale).

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2016 or 2015. 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.

As of December 31, 2016, we had liquidated all of our short-term and long-term investment securities to fund the 2017 acquisition of HIS (see Note 3: Acquisitions and Strategic Transaction Expenses).

Our investment securities consist of the following (in thousands):

	December 31,
	2015
Federal and municipal tax-exempt debt securities	$ 4,951
Corporate bonds	25,400
U.S. Treasury securities	7,537
Commercial paper	2,097
Certificates of deposit	1,248
	$ 41,233

During 2016, we amended our investment policy to allow for the purchase of securities whose final maturities are in excess of one year. The amended policy continues to adhere to a low risk tolerance in regard to capital preservation while allowing for the achievement of higher available yields.

Investment income, reflected in other income in our consolidated statements of income, was $0.9 million, $0.5 million and $0.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Note 10: Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2016	2015
Salaries and benefits	$ 5,702	$ 6,875
Incentive compensation	7,912	8,302
Legal accrual	4,177	394
Value Added Tax accrual	1,472	993
Restructuring accrual	423	6,539
Acquisition-related accrual	2,750	1,604
Outside commissions	1,141	1,023
Other	2,319	3,218
	$ 25,896	$ 28,948

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 11: Income Taxes

Income from continuing operations before taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2016	2015	2014
United States	$ 80,714	$ 74,288	$ 33,508
Foreign	4,450	(4,589)	6,284
	$ 85,164	$ 69,699	$ 39,792

The provision (benefit) for income taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Current:			
Federal	$ 21,123	$ 18,601	$ 13,860
State	2,347	745	(1,305)
Foreign	1,118	1,426	2,100
	24,588	20,772	14,655
Deferred:			
Federal	$ (2,045)	$ 4,524	$ (2,325)
State	(767)	(960)	988
Foreign	304	378	139
	(2,508)	3,942	(1,198)
	$ 22,080	$ 24,714	$ 13,457

Current income taxes payable were reduced from the amounts in the above table by $9.3 million and $5.7 million in 2015 and 2014, respectively, equal to the direct tax benefit that we receive upon exercise of stock options by employees and directors. We have accrued for tax contingencies for potential tax assessments, and in 2016 we recognized a $0.2 million net increase, most of which related to various federal and state tax reserves.

A reconciliation of the provision for income taxes at the statutory rate to our effective tax rate is as follows (dollars in thousands):

	Year Ended December 31,					
	2016		2015		2014	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ 29,807	35.0 %	$ 24,395	35.0 %	$ 13,927	35.0 %
State income tax, net of federal effect	1,795	2.1 %	2,661	3.9 %	981	2.5 %
Tax credits	(1,014)	(1.2)%	(5,861)	(8.4)%	(1,591)	(4.0)%
Domestic production activities/other	(653)	(0.8)%	107	0.1 %	101	0.2 %
Foreign income tax	(135)	(0.1)%	3,412	4.9 %	39	0.1 %
Stock compensation - ASU 2016-09	(7,720)	(9.1)%	—	— %	—	— %
	$ 22,080	25.9 %	$ 24,714	35.5 %	$ 13,457	33.8 %

Tax credits in 2016, 2015 and 2014 consist principally of research and developmental tax credits. Prior to the adoption of ASU 2016-09 in 2016, 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 are as follows (in thousands):

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Year Ended December 31,		
	2016	2015	2014
Allowance for doubtful accounts	$ —	$ —	$ 4
Inventory reserves	(162)	284	(488)
Accruals	(2,599)	(2,977)	(1,326)
State income taxes	61	502	(4)
Acquired future tax deductions	1,520	3,139	96
Depreciation and amortization	(2,544)	1,080	(780)
Net operating loss	(2,256)	195	62
Tax credits	(873)	(635)	1,238
Valuation allowance	4,345	2,354	—
	$ (2,508)	$ 3,942	$ (1,198)

The components of our deferred income tax assets (liabilities) are as follows (in thousands):

	December 31,	
	2016	2015
Deferred tax asset:		
State income taxes	$ (1,708)	$ (1,647)
Foreign	1,223	3,881
Accruals/other	857	1,432
Depreciation and amortization	(10,027)	(11,735)
Acquired future tax deductions	6,473	5,778
Stock-based compensation	11,089	8,864
Foreign currency translation adjustments	5,175	5,360
Tax credits state	6,764	5,887
Inventory reserves	1,938	1,633
Allowance for doubtful accounts	151	—
Valuation allowance	—	(2,354)
	$ 21,935	17,099
Deferred tax liability:		
Foreign	$ 1,370	$ 1,372
	$ 1,370	$ 1,372

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 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 of $1.2 million which will be realized in approximately equal amounts over the next 7 years, and (c) the tax benefited portion of EXC's NOL carryforward of $4.1 million which is expected to be realized in approximately 4 years, and will expire in 17 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.

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

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Our estimate of undistributed earnings of our foreign subsidiaries for which no federal or state liability has been recorded cumulatively was $10.8 million at December 31, 2016 and $17.8 million at December 31, 2015. 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 2013 and forward are subject to examination by the Internal Revenue Service. Our principal state income tax returns for tax years 2012 and forward are subject to examination by the state tax authorities. The total gross amount of unrecognized tax benefits as of December 31, 2016 was $2.0 million which, if recognized, would impact the effective tax rate.

The following table summarizes our cumulative gross unrecognized tax benefits (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Beginning balance	$ 1,772	$ 4,115	$ 5,544
Increases to prior year tax positions	77	25	217
Increases to current year tax positions	345	345	661
Decreases to prior year tax positions	(46)	(2,399)	—
Decrease related to settlements	—	(314)	(2,113)
Decrease related to lapse of statute of limitations	(148)	—	(194)
Ending balance	$ 2,000	$ 1,772	$ 4,115

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 are as follows (in millions):

	Year Ended December 31,		
	2016	2015	2014
Infusion therapy	$ 272.6	$ 244.7	$ 216.3
Critical care	53.6	54.3	55.0
Oncology	52.3	41.5	36.7
Other	0.9	1.2	1.3
	$ 379.4	$ 341.7	$ 309.3

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, 2016, 2015 and 2014, we had worldwide sales to one manufacturer, Pfizer, of 30%, 36% and 36%, respectively, of consolidated revenue. As of December 31, 2016, and 2015, we had accounts receivable from Pfizer of 23% and 40%, respectively, of consolidated accounts receivable.

In February 2017, we completed the acquisition of Pfizer's HIS business, which we acquired in part to protect against the significant earnings exposure indicated above (see Note 3: Acquisitions and Strategic Transaction Expenses).

Domestic sales accounted for 70%, 71% and 69% of total revenue in 2016, 2015 and 2014, respectively. International sales, which are determined by the destination of the product shipment, accounted for 30%, 29% and 31% of total revenue in 2016, 2015 and 2014, respectively.

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The table below presents our gross long-lived assets, consisting of property, plant and equipment, by country (in thousands):

	As of December 31,	
	2016	2015
Mexico	$ 57,971	53,462
Slovakia[1]	—	5,480
Italy	4,320	4,418
Germany	686	671
Netherlands	278	49
Australia	41	35
France	2	—
Total foreign	$ 63,298	$ 64,115
United States	180,657	158,933
Worldwide total	$ 243,955	$ 223,048

[1] The decrease in Slovakia long-lived assets relates to the 2016 closure of those facilities and the increase in Mexico is due to expansion to absorb the production capacity of the closed Slovakian facilities.

Note 13: Operating Leases

We lease various facilities including: a building in San Clemente, United States, which expires in May 2021; an office space in Johannesburg, South Africa, which expires in March 2018; a building in Ludenscheid, Germany which expires in December 2017; an office space in Houten, Netherlands, which expires in November 2021; and an office space in Bella Vista, NSW Australia, which expires in December 2017.

We also lease various office equipment, which all expire during 2017.

Our lease expense was $0.6 million in 2016, $0.4 million in 2015 and $0.2 million in 2014.

Future minimum lease payments under our noncancelable operating leases as of December 31, 2016, are as follows (in millions):

2017	$ 554
2018	337
2019	333
2020	338
2021	175
Total	$ 1,737

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 $7.2 million remaining on this purchase plan. During 2016 and 2014, we purchased $15.4 million and $5.6 million, respectively of our common stock. We did not purchase any of our common stock under our purchase plan in 2015. We used the treasury stock to issue shares for stock option exercises, restricted stock grants and employee stock purchase plan stock purchases.

In 2016, we withheld 20,261 shares of our common stock from employee vested restricted stock units in consideration for $1.9 million in payments for the employee's share award income tax withholding obligations. We have 93 shares remaining in treasury at December 31, 2016.

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. 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.

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 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.

ICU MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 17: Quarterly Financial Data - Unaudited

	Quarter Ended			
	Mar. 31 [1]	Jun. 30	Sept. 30	Dec. 31
	(in thousands except per share data)			
2016				
Total revenue	$ 89,855	$ 96,721	$ 97,108	$ 95,688
Gross profit	$ 49,233	$ 50,132	$ 51,273	$ 50,760
Net income	$ 18,160	$ 16,606	$ 18,806	$ 9,512
Net income per share:				
Basic	$ 1.13	$ 1.03	$ 1.16	$ 0.58
Diluted	$ 1.08	$ 0.98	$ 1.09	$ 0.54
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

[1] In the second quarter of 2016, we early adopted ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (see Note 1: General and Summary of Significant Accounting Policies). Based on the adoption of this guidance, net income for the quarter ended March 31, 2016 was restated to reflect a $2.3 million adjustment to the income tax provision impacting net income by the same amount. In addition, for the three months ended March 31, 2016, weighted average common and common equivalent shares outstanding increased by 314,000 shares, which along with the impact of the adjustment to the income tax provision resulted in a net restatement of basic earnings per share to $1.13 from 0.99; and diluted earnings per share to $1.08 from 0.96.

Note 18: Subsequent Events

Acquisition of HIS

On February 3, 2017, we completed the acquisition of Pfizer's HIS business. The acquired HIS business includes IV pumps, solutions, and devices, that we believe when combined with our existing IV business, will create a leading pure-play infusion therapy business. We acquired HIS for consideration of $275 million in cash, which was financed with existing cash balances and a three-year interest-only seller note of $75 million and 3.2 million shares of our common stock. Additionally, Pfizer also may be entitled up to an additional $225 million based on achievement of performance targets for the combined company for the three years ending December 31, 2019 ("Earnout Period"). In the event that the sum of our Adjusted EBITDA (as defined by the Purchase Agreement) for each of the three years in the Earnout Period (the "Cumulative Adjusted EBITDA") is equal to or exceeds approximately $1.0 billion ("the "Earnout Target"), then Pfizer will be entitled to receive the full amount of the earnout. In the event that the Cumulative Adjusted EBITDA is equal to or greater than 85% of the Earnout Target (but less than the Earnout Target), Pfizer will be entitled to receive the corresponding percentage of the earnout. In the event that the Cumulative Adjusted EBITDA is less than 85% of the Earnout Target, then no earnout amount will be earned by Pfizer. The aggregate purchase consideration is subject to certain adjustments, based on working capital, cash and indebtedness of the HIS business at closing.

We expect to account for the HIS acquisition as a business combination, however we have not completed the purchase accounting. We are unable to provide preliminary estimates of asset and liability values as as we have not received a preliminary closing balance sheet and the valuation of the assets acquired and liabilities assumed is in progress. We plan to file

the required historical financial statements and the required pro forma financial statements of the combined results of ICU and HIS in a Form 8-K/A to amend the Current Report on Form 8-K filed on February 9, 2017 by April 21, 2017.

Planned Restructuring

We intend to reduce our workforce in order to optimize our business operations in alignment with current and future market opportunities and to remove duplicative activities created as a result of the acquisition of HIS.

In connection with the restructuring, we estimate that we will incur total charges of approximately $3.8 million to $4.2 million, which will be recorded in the first half of 2017. These charges primarily consist of severance and other benefits to terminated employees, most of which are expected to be paid out by the end of the third quarter of 2017.

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.

Changes in Internal Control Over Financial Reporting

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.

Based on this evaluation, management of the Company has concluded that the Company has maintained effective internal control over its financial reporting as of December 31, 2016 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, 2016 financial statements included in this Annual Report on Form 10-K has independently assessed the effectiveness of our internal control over financial reporting and its report is below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders 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, 2016, 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, 2016, 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, 2016 of the Company and our report dated March 1, 2017 expressed an unqualified opinion on those consolidated financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Costa Mesa, California
March 1, 2017

Item 9B. Other Information.

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is set forth under the captions *Executive Officers, 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 2017 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

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

Item 11. Executive Compensation.

The information required by this item is set forth under the caption *Executive Officer and Director Compensation*, *Compensation Committee* and *Compensation Committee Interlocks and Insider Participation* in our definitive Proxy Statement to be filed in connection with our 2017 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* and *Equity Compensation Plan Information* in our definitive Proxy Statement to be filed in connection with our 2017 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

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 2017 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 *Ratification of Auditors* in our definitive Proxy Statement to be filed in connection with our 2017 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

Exhibit Number	Description
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. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 6, 2015, and incorporated herein by reference.
2.2	Asset Purchase Agreement made as of October 5, 2015, by and among Registrant, Excelsior Medical, LLC and Medline Industries, Inc. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 6, 2015, and incorporated herein by reference.
2.3	Amended and Restated Stock and Asset Purchase Agreement, dated as of January 5, 2017, by and between Pfizer Inc., a Delaware corporation, and ICU Medical, Inc., a Delaware corporation. Filed as Exhibit 2.1 to Registrant's Current Report on Form 8-K filed January 5, 2017, and incorporated herein by reference.
3.1	Registrant's Certificate of Incorporation, as amended and restated. Filed as an exhibit to Registrant's Current Report on Form 8-K filed on June 10, 2014, and incorporated herein by reference.
3.2	Registrant's Bylaws, as amended and restated. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed August 3, 2016, and incorporated herein by reference.
10.1	Form of Indemnification Agreement with Directors and Executive Officers. 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.

10.2	Manufacture and Supply Agreement dated September 13, 1993 between Registrant and B. Braun, Inc. relating to the Protected Needle product. 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.
10.3	Supply and Distribution Agreement dated April 3, 1995 between Registrant and Abbott Laboratories, Inc. relating to the Clave product. 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.
10.4	Amended and Restated Rights Agreement dated October 18, 2007 between Registrant and American Stock Transfer & Trust Company as Rights Agent. Filed as an Exhibit to Registrant's Registration Statement on Form 8-A/A dated October 18, 2007, and incorporated herein by reference.
10.5	SafeLine Agreement effective October 1, 1997 by and between Registrant and B. Braun Medical, Inc. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed June 18, 1998, and incorporated herein by reference.
10.6	Amendment to April 3, 1995 Supply and Distribution Agreement, dated January 1, 1999, between Registrant and Abbott Laboratories. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 23, 1999, and incorporated herein by reference.
10.7	Co-Promotion and Distribution Agreement, dated February 27, 2001 between Registrant and Abbott Laboratories. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed March 7, 2001, and incorporated herein by reference.
10.8	Registrant's 2001 Directors' Stock Option Plan.* Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 3, 2002, and incorporated herein by reference.
10.9	Registrant's 2002 Employee Stock Purchase Plan.* Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 3, 2002, and incorporated herein by reference.
10.10	Registrant's 2003 Stock Option Plan.* Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 25, 2003, and incorporated herein by reference.
10.11	Amendment to April 3, 1995 Supply and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories. Filed as an Exhibit to Registrant's Current Report on Form 8-K dated January 15, 2004, and incorporated herein by reference.
10.12	Amendment to February 27, 2001 Co-Promotion and Distribution Agreement, dated as of January 14, 2004, between Registrant and Abbott Laboratories. Filed as an Exhibit to Registrant's Current Report on Form 8-K dated January 15, 2004, and incorporated herein by reference.
10.13	Manufacturing, Commercialization and Development Agreement between Registrant and Hospira, Inc. effective May 1, 2005. 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.
10.14	Letter Agreement dated July 8, 2005 between Registrant and Hospira, Inc. re: Manufacturing, Commercialization and Development Agreement effective May 1, 2005. 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.
10.15	Settlement and Release Agreement dated as of January 2, 2007 between ICU Medical, Inc. and Fulwider Patton Lee & Utecht, LLP. 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.
10.16	Executive officer compensation.*
10.17	Non-employee director compensation.*
10.18	2008 Performance-Based Incentive Plan, as amended.* Filed as Annex A to Registrant's proxy statement filed April 3, 2013, and incorporated herein by reference.
10.19	Amendment No. 1 to 2001 Directors' Stock Option Plan.* 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.

10.20	Amendment No. 2 to 2001 Directors' Stock Option Plan.* 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.
10.21	Amendment No. 3 to 2001 Directors' Stock Option Plan.* 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.
10.22	Amendment 20 to the Supply and Distribution Agreement, effective as of November 30, 2011, between ICU Medical Sales, Inc. and Hospira, Inc. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed December 22, 2011, and incorporated herein by reference.
10.23	Third Amendment to the Co-Promotion and Distribution Agreement, effective as of November 30, 2011, between ICU Medical Sales, Inc. and Hospira, Inc. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed December 22, 2011, and incorporated herein by reference.
10.24	ICU Medical, Inc. Amended 2011 Stock Incentive Plan.* 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.
10.25	Form of Executive Officer Retention Agreement - Tier 1 Employee.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed November 21, 2013, and incorporated herein by reference.
10.26	Form of Executive Officer Retention Agreement - Tier 2 Employee.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed November 21, 2013, and incorporated herein by reference.
10.27	2014 Inducement Stock Incentive Plan.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 26, 2014 and incorporated herein by reference.
10.28	Executive Employment Agreement, dated as of February 7, 2014, by and between ICU Medical, Inc. and Vivek Jain.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 12, 2014, and incorporated herein by reference.
10.29	Amendment to Executive Employment Agreement, dated as of February 12, 2014, by and between ICU Medical, Inc. and Vivek Jain.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 12, 2014, and incorporated herein by reference.
10.30	Buy-Out Agreement between Registrant and George A. Lopez, M.D. effective September 30, 2015.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 1, 2015, and incorporated herein by reference.
10.31	Form of Shareholder Agreement, by and between a subsidiary of Pfizer Inc. and ICU Medical Inc dated February 3, 2017. Filed as an Exhibit to Registrant’s Current Report on Form 8-K filed October 13, 2016, and incorporated herein by reference.
10.32	ICU Medical, Inc. Executive Severance Plan.* Filed as an Exhibit to Registrant’s Current Report on Form 8-K filed January 6, 2017, and incorporated herein by reference.
10.33	Senior Note issued by ICU Medical, Inc. in favor of Pfizer Inc., dated as of February 3, 2017. Filed as an Exhibit to Registrant’s Current Report on Form 8-K filed February 9, 2017, and incorporated herein by reference.
10.34	Transitional Services Agreement, between ICU Medical, Inc. and Pfizer Inc., dated as of February 3, 2017. Filed as an Exhibit to Registrant’s Current Report on Form 8-K filed February 9, 2017, and incorporated herein by reference.
14.1	Code of Business Conduct and Ethics for Directors and Officers. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 5, 2009, and incorporated herein by reference.
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.

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*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

(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

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands) Description	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Write-off/ Disposals	Balance at End of Period
For the year ended December 31, 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
Deferred tax asset valuation allowance	$ —	$ —	$ —	$ —	$ —
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
For the year ended December 31, 2016:					
Allowance for doubtful accounts	$ 1,101	$ —	$ (24)	$ (4)	$ 1,073
Warranty and return reserve - accounts receivable	$ 583	$ 539	$ —	$ —	$ 1,122
Warranty and return reserve - inventory	$ (35)	$ 20	$ —	$ —	$ (15)
Deferred tax asset valuation allowance	$ 2,354	$ —	$ —	$ (2,354)	$ —

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: March 1, 2017

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)	March 1, 2017
/s/ Scott E. Lamb Scott E. Lamb	Chief Financial Officer (Principal Financial Officer)	March 1, 2017
/s/ Kevin J. McGrody Kevin J. McGrody	Controller (Principal Accounting Officer)	March 1, 2017
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Director	March 1, 2017
/s/ Joseph R. Saucedo Joseph R. Saucedo	Director	March 1, 2017
/s/ Richard H. Sherman, M.D. Richard H. Sherman, M.D.	Director	March 1, 2017
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	March 1, 2017
/s/ David C. Greenberg David C. Greenberg	Director	March 1, 2017
/s/ Elisha W. Finney Elisha W. Finney	Director	March 1, 2017
/s/ Douglas E. Giordano Douglas E. Giordano	Director	March 1, 2017

Exhibit 10.16

Executive Officer Compensation

The annual base salaries for our executive officers as of January 1, 2017 are as follows:

Name	Title		
Vivek Jain	Chairman of the Board and Chief Executive Officer	$	650,000
Scott E. Lamb	Chief Financial Officer	$	395,150
Steven C. Riggs	Vice President of Operations	$	360,582
Alison D. Burcar	Vice President and General Manager of Infusion Systems	$	315,000
Tom McCall	Vice President and General Manager of Critical Care	$	293,550

Exhibit 10.17

Non-Employee Director Compensation

We currently pay our non-employee directors the following:

- annual retainer of $60,000
- annual retainer of $85,000 for the Chairperson of the Audit Committee
- annual retainer of $80,000 for the Chairperson of the Compensation Committee
- annual retainer of $70,000 for the Chairperson of the Nominating and Governance Committee

The equity component of the director's compensation is valued at $150,000. The annual equity package consists of 50% in stock options and 50% in restricted stock units. The options become exercisable one year after the grant date and expire ten years after the grant date. The restricted stock units vest one year from the grant date.

Exhibit 21

Subsidiaries of Registrant

Name	State of Incorporation
ICU Medical Sales, Inc.	Delaware
ICU Medical de Mexico, S. de R. L. de C.V.	Mexico
ICU Medical Europe S.r.l.	Italy
ICU World, Inc.	Delaware
ICU Medical Germany GmbH	Germany
ICU Medical Slovakia S.r.o.	Slovak Republic
ICU Medical, LLC	California
Medical Connections CV	Netherlands
ICU Medical BV	Netherlands
ICU Medical Aust Pty Limited	Australia
ICU Medical SA Pty Ltd	South Africa
EXC Holding Corp.	Delaware
Tangent Medical Technologies, Inc.	Delaware
Excelsior Medical Corporation	Delaware
ICU Medical France S.A.S.	France
ICU Medical Canada Inc.	Canada
ICU Medical HIS LLC	Delaware
ICU Medical Latam LLC	Delaware
ICU UK Medical Limited	United Kingdom
ICU Medical Ireland Limited	Ireland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-04171, 333-58024, 333-90462, 333-90464, 333-115654, 333-115653, 333-04167, 333-175239, and 333-198256 on Form S-8 of our reports relating to the consolidated financial statements and financial statement schedule of ICU Medical, Inc. and subsidiaries, and the effectiveness of ICU Medical, Inc. and subsidiaries' internal control over financial reporting dated March 1, 2017, appearing in this Annual Report on Form 10-K of ICU Medical, Inc. for the year ended December 31, 2016.

/s/ Deloitte & Touche LLP

Costa Mesa, California
March 1, 2017

Exhibit 31.1

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

I, Vivek Jain, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 1, 2017

/s/ Vivek Jain

Chief Executive Officer

Exhibit 31.2

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

I, Scott E. Lamb, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 1, 2017

/s/ Scott E. Lamb

Chief Financial Officer

Exhibit 32

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

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Vivek Jain, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

March 1, 2017

/s/ Vivek Jain
Vivek Jain

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

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott E. Lamb, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

March 1, 2017

/s/ Scott E. Lamb
Scott E. Lamb