ICU MEDICAL INC/DE
Form 10-K
March 01, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018 or

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

For the transition period from to

Commission File No. 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	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. ý Yes o No

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ý No o

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

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

Large accelerated filer x Accelerated filer o

Non-accelerated filer o Small reporting company o
Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2018, the last business day of registrant's most recently completed second fiscal quarter, was $5,575,024,829*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2019 was 20,498,949.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2019 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2018, 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, 2018
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.

Company Background

ICU was founded in 1984 and our initial public offering was in 1992. Our headquarters are in San Clemente, California. In 1993, we launched the Clave™, an innovative one-piece needlefree intravenous ("IV") connection device. Since the late 1990's, we have expanded our product offerings by introducing internally developed products and systems. Key developments have included the MicroClave Clear™ connector as an update to the Clave, Tego™ needlefree connector for use in hemodialysis, products for handling hazardous drugs including the ChemoClave™ and ChemoLock™ CSTDs (“closed-system transfer devices”, the Diana™ hazardous drug compounding system, and the Neutron®, a catheter patency device.

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.

In February 2017, we acquired Pfizer Inc.'s ("Pfizer") Hospira Infusion Systems ("HIS") business. The HIS acquisition complements our legacy non-dedicated infusion sets and oncology business by expanding our product portfolio to include a complete intravenous infusion therapy product-line from IV solutions to IV pumps to non-dedicated infusion sets.

General Overview of Business

We develop, manufacture and sell innovative medical products used in infusion therapy and critical care applications. Our product portfolio includes IV smart pumps, sets, connectors, closed system transfer devices for hazardous drugs, sterile IV solutions, cardiac monitoring systems, along with pain management and safety software technology designed to help meet clinical, safety and workflow goals.

Our primary customers are acute care hospitals, wholesalers, ambulatory clinics and alternate site facilities, such as clinics, home health care providers and long-term care facilities. We sell our products in more than 90 countries throughout the world.

Products

Our primary product offerings are listed below, which we present in four product lines as follows:

Infusion Consumables

Infusion therapy sets, 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, that may or may not be used with an IV pump. Our primary IV Consumable products are:

Clave™ needlefree products, including the MicroClave, MicroClave Clear, and NanoClave™ brand of connectors, accessories, extension and administration sets used for the administration of IV fluids and medications and the Neutron catheter patency device, used to help maintain patency of central venous catheters;

SwabCap disinfecting cap, used to protect and disinfect any needlefree connector, including competitive brands of connectors;

Tego hemodialysis connector used to cap and protect hemodialysis central venous catheter hubs; and

NovaCath™ and SuperCath™ peripheral IV catheters(PIV).

Closed System Transfer Devices (CSTD) and hazardous drug compounding systems are used to prepare and deliver hazardous IV medications such as those used in chemotherapy, which, if released, can have harmful effects to the healthcare worker and environment. Our products are:

ChemoLock, is a pharmacy-preferred CSTD used for the preparation and administration of hazardous drugs. ChemoLock limits 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, is an ISO standard and universally compatible CSTD used for the preparation and administration of hazardous drugs. ChemoClave utilizes standard ISO luer locking connections, making it compatible with all brands of needlefree connectors and pump delivery systems. ChemoClave also limits the escape of hazardous drug or vapor concentrations, blocks the transfer of environmental contaminants into the system, and eliminates the risk of needlestick injury; and

Diana hazardous drug compounding system is an automated sterile compounding system that incorporates ChemoClave and ChemoLock CSTD consumables and IV workflow technology for the accurate, safe, and efficient preparation of hazardous drugs. It is a user-controlled automated system that provides repeatable accuracy of drug mixes and minimizes clinician exposure to hazardous drugs while helping to maintain the sterility of the drugs being mixed.

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 pharmacies and on the nursing floors for the preparation and administration of hazardous drugs.

IV Solutions

We provide a broad portfolio of IV solutions to meet our customers’ clinical needs, providing a consistent supply of IV solutions, irrigation, and nutritionals to help provide safe and effective patient care. Our primary IV Solutions products are:

IV Therapy and Diluents:

- Including Sodium Chloride, Dextrose, Balanced Electrolyte Solutions, Lactated Ringer's, Ringer's, Mannitol, Sodium Chloride/Dextrose, Sterile Water

Irrigation/Urologics:

- Including Sodium Chloride Irrigation, Sterile Water Irrigation, Physiologic Solutions, Ringer's Irrigation, Ringer's Irrigation, Acetic Acid Irrigation, Glycine Irrigation, Sorbitol-Mannitol Irrigation, Flexible Containers and Pour Bottle Options, 250 mL

Infusion Systems

We offer a wide range of infusion pumps, dedicated IV sets and software. Our primary Infusion System products are dedicated IV sets and the following:

Infusion Pump Hardware:

- Plum 360™: The Plum 360™ infusion pump is an ICU Medical MedNet™ ready large volume infusion pump with an extensive drug library and wireless capability. Plum 360 was named the 2018 Best in KLAS winner as top-performing IV smart pump and is the first medical device to be awarded UL Cybersecurity Assurance Program Certification; and

- LifeCare PCA™: The LifeCare PCA infusion pump is an ICU Medical MedNet™ ready patient-controlled analgesia pump ("PCA"), providing complete IV-EHR interoperability since 2016.

IV Mediation Safety Software:

- ICU Medical MedNet™: ICU Medical MedNet is an enterprise-class medication management platform for any sized healthcare system that can help reduce medication errors, improve quality of care, streamline workflows and maximize revenue capture. ICU Medical MedNet connects our industry-leading smart pumps

to a hospital's Electronic Health Records (EHR), asset tracking systems, and alarm notification platforms with the largest array of integration partners.

Professional Services:

- In addition to the products above, our teams of clinical, information technology, and professional services experts work with customers to develop and deliver safe and efficient infusion systems, providing customized and personalized configuration, implementation, and data analytics services to complement our infusion hardware and software.

Critical Care

Our critical care products help clinicians get accurate real-time access to patients' hemodynamic and cardiac status with an extensive portfolio of monitoring systems and advanced sensors & catheters. Measurements provided by our systems help clinicians determine how well the heart is pumping blood and how efficiently oxygen from the blood is being used by the tissues. Our primary Critical Care products are:

- Cogent™ 2-in-1 hemodynamic monitoring system
- CardioFlo™ hemodynamic monitoring system
- TDQ™ and OptiQ™ cardiac output monitoring catheters
- Transpac™ blood pressure transducers
- SafeSet™ closed blood sampling and conservation system

Financial information relating to our reporting segment and primary product lines is set forth in Part I, Item 6. "Selected Financial Data" and Item 7. "Management Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K, and is incorporated herein by reference.

Recent Significant Acquisitions

On February 3, 2017, we completed the acquisition of Pfizer's HIS business, a leading global provider of IV infusion therapy products to hospitals and alternate site providers, such as clinics, home health care providers and long-term care facilities. Our acquisition of the HIS business was strategic and provides us with an increase in scale and product portfolio that we believe will result in a stronger competitive position within the industry. We believe the HIS business acquisition was the natural evolution for us based on a long-term successful and productive partnership with HIS for over 20 years.

Manufacturing

As of December 31, 2018, we operate four primary manufacturing facilities globally, which are detailed in Part I, Item 2 of this report. We operate four main service centers globally. We also rely on certain outside manufacturers for certain product lines in Infusion Systems and IV Solutions.

Our four primary manufacturing sites are:

- La Aurora de Heredia, Costa Rica, which manufactures most of our infusion pumps and dedicated disposables, as well as a portion of our non-dedicated infusion consumables products;

- Ensenada, Mexico, which manufactures infusion consumables products;

Salt Lake City, Utah, which produces primarily our proprietary brands of connector and CSTD components, and sends those products to Costa Rica or Mexico for finished goods assembly; and

Austin, Texas, which produces our IV Solutions products.

Additionally, we leverage a long-term supply agreement with Pfizer (described below) to provide additional IV Solution products to us.

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

During 2017, we closed our manufacturing facility in San Cristobal, Dominican Republic, which was part of the HIS acquisition, and transferred the assets and the production of Infusion Consumables to our plants in Costa Rica and Mexico.

We have four main regional device service centers in San Jose, California; Sligo, Ireland; San Laurent, Quebec, Canada; and Rydalmere, Australia.

As part of our 2017 HIS business acquisition, we entered into two Manufacturing and Supply Agreements ("MSAs") under which, (i) Pfizer manufactures and supplies us with certain agreed upon products for an initial five-year term with a one-time two-year option to extend and (ii) we manufacture and supply Pfizer certain agreed upon products for a term of five or ten years depending on the product, with a one-time two-year option to extend. The initial supply price will be annually updated and is in full consideration for all costs associated with the manufacture, documentation, packaging and certification of the products.

We purchase many of the components and raw materials used in manufacturing our products from numerous suppliers in various countries. Certain components and raw materials are available only from a sole supplier. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. We have generally been able to obtain adequate supplies of such raw materials and components.

Sales, Marketing and Administration

We ship around the world with the majority of our sales denominated in U.S. dollars, Euro and Canadian dollars. We are not dependent on any single customer and no single customer accounted for 10% or more of our net sales in 2018.

Distribution

Our products are marketed to medical product manufacturers, independent distributors and directly to end users.

The U.S. distribution of solutions, IV sets and accessories is supported by a network of three owned distribution centers acquired in the HIS business acquisition, which include King of Prussia, Pennsylvania; Los Angeles, California; and Dallas, Texas. We also acquired the contracts to a number of public warehouses as part of the HIS acquisition.

Internationally, we manage our operations through the Netherlands, which utilizes international regional hubs and we also manage operations through independent distributors.

Government Regulation

Our products and operations are subject to extensive and rigorous regulation by the Food and Drug Administration ("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 U.S. 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 U.S. 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.

Under the 510(k) process, applicants must demonstrate to the FDA that the device is as safe and effective as, or substantially equivalent to, a legally marketed device, the “predicate” device. Applicants must submit performance data to establish substantial equivalence. In some instances, data from human clinical trials must also be submitted in support of a 510(k) premarket notification. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption ("IDE") regulations. The FDA must issue a decision finding substantial equivalence before commercial distribution can occur. Changes to cleared devices that could not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) premarket notifications; otherwise, a new 510(k) is required.

In the PMA application process, the applicant must demonstrate to the satisfaction of the FDA that the device is safe and effective for its intended use. This approval process applies to most Class III devices, and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with IDE requirements. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose, and that the proposed manufacturing is in compliance with the Quality System Regulation ("QSR"). For novel technologies, the FDA will generally seek input from an advisory panel of medical experts and seek their views on the safety, effectiveness and benefit-risk of the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process, though 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.

Drug Regulation in the U.S.

In the U.S., IV solutions are considered pharmaceutical products and subject to the same extensive pre- and post-market regulations by the FDA, as indicated above.

The pre-market approval process is a time-intensive multi-phased process. When successfully completed an application may be submitted to the FDA that includes detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things. This application process may be subject to substantial fees.

FDA approval is typically required before any new drug can be marketed. A New Drug Application ("NDA"), or an Abbreviated New Drug Application ("ANDA"), is typically required to be submitted to the FDA to obtain approval of pharmaceutical products.

Before approval, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practices ("cGMP") requirements and are adequate to assure consistent production of the product within required specifications. Additionally, the FDA may inspect one or more clinical trial sites to assure compliance with Good Clinical Practice, or GCP, requirements.

Post-Approval Regulation

After the FDA permits a drug or device to enter commercial distribution, numerous regulatory requirements continue to apply. The FDA actively monitors regulations through review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA can take action against a company that promotes "off-label" uses. The FDA may also enjoin and restrain a company for certain violations of the FDC Act and regulations pertaining to medical devices, or initiate action for criminal prosecution of such violations. Any adverse regulatory action, depending on its magnitude, may restrict a company from effectively marketing and selling its products, may limit a company's ability to obtain future premarket clearances or approvals, and could results in a substantial modification to the company's business practices and operations.

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 cGMPs. The FDA and regulatory agencies outside the U.S. monitor compliance with these requirements through inspections of manufacturing facilities. If an 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 international 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. 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.

To market our products in the EC, 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 U.S., 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

Our industry is highly competitive. We believe our ability to effectively compete in this industry will be determined by our ability to provide a wide breadth of cost-effective, high quality products. We believe the added breadth of our HIS business product portfolio has increased our competitiveness as we can now provide a one-stop shop for customers and offer more flexible competitive pricing. We believe the infusion pump will also enable us to pull through a larger volume of higher margin infusion consumables. In addition, we now have unified distribution channels after the HIS acquisition.

Infusion Consumables

We believe that our ability to effectively compete in the Infusion Consumables market depends upon our ability to differentiate our products based on continued innovation, safety, quality, convenience, reliability, patent protection, ease of use and the pricing of our products, in addition to access to distribution channels. We encounter significant competition in this market both from global, large, established medical device manufacturers and from smaller companies. We compete with products and systems marketed by Becton Dickinson ("BD"), Baxter International ("Baxter"), B. Braun Medical, Inc. ("B. Braun"), and Fresenius Kabi a division of Fresenius Group ("Fresenius"). 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. Our CSTD used for the preparation and safe handling of oncology drugs, compete with similar products from BD, and B. Braun. We believe that our current CSTD product offering provides benefits over these competing systems in several areas related to safety, ease of use, quality, 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.

IV Solutions

We participate in the IV solutions only in the United States and Canada. Our primary competitors in the United States include Baxter, B. Braun and Fresenius. Demand for IV solutions is typically high and raw materials required to produce IV solutions are readily available. Our ability to compete will depend on our ability to maximize production, develop innovations in our product line, focus on cost-effectiveness and our ability to maintain the appropriate quality infrastructure.

Infusion Systems

We face strong global competitors including BD, Baxter, B. Braun and Fresenius. These competitors benefit from greater financial, research and development and marketing resources than we have. The smart pump market in recent years has been troubled with security concerns, and product recalls. We believe our ability to effectively compete in this market segment will be determined by our ability to build our brand strength using the development of technological advancements aimed at increasing the quality, reliability and safety of our pumps while at the same time focusing on manufacturing efficiency and cost-effectiveness, which are operationally challenging with evolving product lines.

Critical Care

Our primary competitor in Critical Care is Edwards Lifesciences.

Patents

We have U.S. 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 U.S. and/or foreign patents on MicroClave Connector, Neutron Connector, Tego Connector, Y-Clave Connector with Integral Check Valve, ChemoClave Technologies, ChemoLock Technologies, Swabcaps, and Diana Hazardous Drug Compounding System.

With the acquisition of HIS, we acquired rights, title and interest to a substantial number of patents and patent applications and related provisionals, divisionals, continuations, continuations-in-part, reissues, reexaminations, extensions, and substitutions of any of the foregoing (“Patent Rights”), that were primarily used or held for use by Pfizer in the HIS business. There is however, no single patent or group of patents that we acquired that we believe is material in relation to our business as a whole.

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 U.S. 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, Tego Connector, Swabcap, ChemoClave and ChemoLock technologies, 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

There are no significant seasonal aspects to our business. 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 $52.9 million in 2018, $51.3 million in 2017 and $13.0 million in 2016.

Employees

At December 31, 2018, we had 8,100 employees.

Geographic Data

Information regarding financial data by geography is set forth in Part II, Item 8. "Financial Statements and Supplementary Data" of this Form 10-K in Note 4 and 13 to the Consolidated Financial Statements, and is incorporated herein by reference.

Available Information

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).

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.

Risks Related to our Strategic Transactions

Failure to integrate acquired businesses into our operations successfully could adversely impact our business and our operating results and such acquisitions could result in unforeseen operating difficulties and expenditures, require significant management resources, and require significant charges or write-downs.

We may seek to supplement our internal growth through acquisitions of complementary businesses, technologies, services, or products, as well as investments and strategic alliances. Such transactions are inherently risky, and the integration of any newly-acquired business requires significant effort and management attention that otherwise would be available for ongoing development of our other businesses. The success of any acquisition, investment or alliance may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity or to successfully integrate any business we may acquire into our existing business. There can be no assurance that any past or future transactions will be successful.

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. Integrating the operations of the HIS business with that of our own is 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. The failure to meet the challenges involved in integrating the two businesses could adversely affect the results of operations of the combined businesses. Potential difficulties that may be encountered in the integration of the HIS business or in the process of integrating other businesses we acquire 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 and (ii) implementing common systems and procedures including, in particular, our internal controls over financial reporting; and
- coordinating and integrating a geographically dispersed organization, including operations in jurisdictions we did not operate in prior to the transaction.

Any one or all of these factors may increase operating costs or lower anticipated financial performance. 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.

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 U.S. 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 acquired the HIS business in February 2017, which includes IV pumps, solutions, and devices in order to create a leading pure-play infusion therapy company, but we continue to make significant integration efforts in order to achieve the anticipated benefits of the transaction.

We have additional production facilities outside the U.S. 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.

Business and Operating Risks

We are dependent on single and limited source third-party suppliers, which subjects our business and results of operations to risks of supplier business interruptions, and a loss or degradation in performance in our suppliers could

have an adverse effect on our business and financial condition.

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 on a timely basis or at all. 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. Furthermore, our contract manufacturers could require us to move to another one of their production facilities. An interruption in our commercial operations could occur

if we encounter delays or difficulties in securing these components, materials or services and if we cannot then obtain an acceptable substitute. 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.

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 and Costa Rica rely. Our IV Solutions are manufactured at our manufacturing facility in Austin, Texas and by a third party manufacturer Pfizer in Rocky Mount, North Carolina.

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.

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.

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.

Market and Other External Risks

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 Infusion Consumables products in 2019. We also are adding additional IV Solutions capacity at our IV Solutions manufacturing facility. 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.

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.

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, both domestic and international, 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. Because there is often no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our products exists among third-party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. There can be no assurance that third-party payor policies will provide coverage for procedures in which our products are used. If we are not successful in reversing existing non-coverage policies, or if third-party payors that currently cover or reimburse our products and related procedures reverse or limit their coverage in the future, or if other third-party payors issue similar policies, this could have a material adverse effect on our business.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the U.S. and in international markets. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory approval may not be available or adequate in either the U.S. or international markets, which could have an adverse effect on our business, financial condition and results of operations and impair our ability to grow our

business.

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.

We are subject to foreign, federal, and state data privacy and security laws, and 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.

We are also subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), in the U.S. HIPAA established uniform standards governing the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information ("PHI"). HIPAA also requires business associates, such as independent contractors or agents of covered entities that have access to PHI in connection with providing a service to or on behalf of a covered entity, of covered entities to enter into business associate agreements with the covered entity and to safeguard the covered entity’s PHI against improper use and disclosure.

The HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose PHI is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal “floor” and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI as defined under HIPAA. Similarly, we may be subject to additional federal privacy laws such as Section 5 of the Federal Trade Commission Act.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured PHI. If notification to patients of a breach is required, such notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, we would be required to report the improper use or disclosure to the U.S. Department of Health and Human Services ("HHS") which would post the violation on its website, and to the media.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

The new EU-wide General Data Protection Regulation ("GDPR") became applicable on May 25, 2018, replacing the prior data protection laws issued by each EU member state based on the Directive 95/46/EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to

demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR are significant-the greater of EUR 20 million or 4% of global turnover. The GDPR provides that EU member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.
The California legislature passed the California Consumer Privacy Act of 2018 (the "CCPA") on June 28, 2018. The CCPA applies to certain businesses that collect personal information from California residents, whether directly or indirectly. The CCPA establishes several consumer rights including a right to know what personal information is being collected about them and whether and to whom it is sold, a right to access their personal information and have it deleted, a right to opt out of the sale of their personal information, and a right to equal service and price regardless of exercise of these rights. Violation of the CCPA can result in civil penalties through enforcement by the California Attorney General (effective July 1, 2020) or a private right of action by consumers following a data breach (effective January 1, 2020). The law includes specific exemptions for entities and information covered by HIPAA or the Confidentiality of Medical Information Act (CMIA). However, not all personal information maintained by entities covered by HIPAA or CMIA is exempt from the CCPA. California legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. The U.S. Congress may also pass a law to pre-empt all or part of the CCPA. As passed, the effects of the CCPA potentially are significant, however, and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply. Implementing regulations from the Attorney General that may clarify the CCPA are not due until July 1, 2020 and additional amendments to the CCPA may be signed into law before then.
Failure to comply with any of these laws or to protect our information systems against security breaches, service interruptions, or misappropriation of data could disrupt operations, compromise sensitive data, and expose us to fines, penalties, other liability, and reputational harm, any of which could adversely affect our ability to operate our business and our financial results.

Expiring patents may affect our future sales.

Some of our products are covered by patents that, if valid, give us a degree of market exclusivity during the term of the patent. 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.

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. New laws or regulations adopted in response to climate change could also increase energy costs as well as the costs of certain raw materials and components. Any such regulations or interruptions 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.

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 2016 through December 2018, our trading price ranged from a high of $321.70 per share to a low of $85.56 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 approximately 55% of our outstanding shares at the end of 2018. 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Legal, Compliance, and Regulatory Risks

We are subject to certain federal, state and foreign fraud and abuse and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, 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 federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, 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 healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- 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;
- the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program ("CHIP") to report annually to the US Department of Health and Human Services Centers for Medicare and Medicaid Services ("CMS") information related to payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties of $11,278 per failure up to an aggregate of $169,170 per year (or up to an aggregate of $1.128 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;
- HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, HIPAA, as amended by HITECH and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $57,051 per violation, not to exceed $1.71 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or

to obtain statutory damages on behalf of residents of his or her state; 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 or patients; state laws that require 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 report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace

activities and activities that potentially harm customers; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.
To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

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 and certain other healthcare professionals 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 U.S. 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 U.S. customers. The excise tax, which became effective January 1, 2013, resulted in additional expense of $2.0 million in 2015 recorded in Selling, General and Administrative expenses. Congress has temporarily suspended this medical device excise tax for two years commencing January 2018. Unless Congress changes the current law, we expect this tax to resume beginning in 2020. The Affordable Care Act also provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business.

We expect that the current Presidential Administration and U.S. Congress will continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. For example, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance, beginning in 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the Affordable Care Act's individual mandate to carry insurance coverage is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services, or CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

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 U.S. since the Affordable Care Act was enacted that reduced payments to Medicare providers. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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 U.S., or in other jurisdictions, may have an adverse effect on our financial condition and results of operations.

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 U.S., 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.

Our ability to market our products in the U.S. 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.

We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

In the U.S., our device products are subject to clearance or approval by the U.S. FDA under the Food, Drug and Cosmetics Act ("FDC Act"). 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 tended to 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. The FDA enforces these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. 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 U.S. 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. 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.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our future products under development. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDC Act. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers using the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. These proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

Modifications to our products may require us to obtain new clearances or approvals, and if we market modified products without obtaining necessary clearances or approvals, we may be required to cease marketing or recall the modified products until required approvals are obtained.

Certain modifications to a cleared or approved device may require a new clearance or approval, or alternatively a notification or other submission to FDA. The FDA may not agree with our decisions regarding whether a new regulatory submission is necessary. We may make modifications to our approved devices in the future that we believe do not require a new clearance or approval. If the FDA disagrees with our determination and requires us to submit a new submission for modifications to our previously approved products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not clear or approve our products for the indications that are necessary or desirable for successful commercialization, or could require

clinical trials to support any modifications. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

If we or our component manufacturers fail to comply with the FDA's Quality System Regulation or Good Manufacturing Practice regulations or other requirements, 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, a complex regulatory scheme 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.

In May 2017, the Medical Device Regulation entered into force to replace the Medical Device Directive, as amended. The Medical Device Regulation will apply after a three-year transition period and imposes stricter requirements for the marketing and sale of medical devices and grants EU Notified Bodies increased post-market surveillance authority. We may be subject to risks associated with additional testing, modification, certification, or amendment of

our existing market authorizations, or we may be required to modify products already installed at our customers' facilities to comply with the official interpretations of these revised regulations.

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.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our products have been cleared or approved by the FDA for specific indications. We train our marketing personnel and direct sales force to not promote our products for uses outside of the FDA-cleared or approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those cleared or approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

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. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. Patients, healthcare workers, healthcare providers or others 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, and result in substantial liabilities and reputational harm. Furthermore, there is no assurance that product liability insurance will continue to be available to us on acceptable terms.

In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our existing or new products;
- decreased demand for our products or, if cleared or approved, products in development;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or

loss of revenue.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations.

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 judgments 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.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances or approvals, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and

financial results.

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.

Geographic Risks

We are subject to risks associated with doing business outside of the U.S.

We operate in a global market and global operations are subject to a number of risks. Sales to customers outside of the U.S. made up approximately 25% of our revenue in 2018 and as our operations and sales located in Europe and other areas outside the U.S. increase, we may face new challenges and uncertainties, although we can give no assurance that such operations and sales will increase. In June 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union (the "EU"), commonly referred to as "Brexit." Until the terms of the UK's exit from the EU are determined, including any transition period, it is difficult to predict its impact. It is possible that the withdrawal could, among other things, affect the legal and regulatory environments to which our businesses are subject, impact trade between the United Kingdom and the EU and other parties and create economic and political uncertainty in the region.

The risks associated with our operations outside the U.S. also include:

- healthcare reform legislation;
- changes in medical reimbursement policies and programs;
- changes in non-U.S. government programs;
- multiple non-U.S. 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-U.S. 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 U.S.;
- 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 U.S. In 2018, the U.S. imposed tariffs on steel and aluminum as well as on goods imported from China and certain other countries, which has resulted in retaliatory tariffs by China and other countries. Additional tariffs imposed by the U.S. on a broader range of imports, or further retaliatory trade measures taken by other countries in response, 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. 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 U.S. 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 U.S.. 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 U.S., Costa Rica 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.

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.

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 U.S. rather than Mexico, which may negatively impact our operations and result in higher costs and inefficiencies.

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, Mexican Peso, Costa Rican Colón, and the Canadian Dollar against the U.S. dollar. The withdrawal of the UK from the EU could also, among other things, create volatility in currency exchange rates.

We currently do not hedge against our foreign currency exchange rate risks, other than the Mexican Peso 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.

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.

Changes in tax laws and unanticipated tax liabilities could adversely affect the Company's effective income tax rate and profitability.

The Company is subject to income taxes in the United States and numerous foreign jurisdictions. Although comprehensive U.S. tax legislation commonly referred to as the Tax Cuts and Jobs Act (“the Tax Act”) enacted in December 2017 lowered the U.S. corporate income tax rate to 21%, the Company's effective income tax rate in the future could be adversely affected by a number of factors, including: changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and the outcome of income tax audits in various jurisdictions around the world. The Company regularly assesses all of these matters to determine the adequacy of its tax provision, which is subject to significant discretion.

The Tax Act is unclear in certain respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (IRS), any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. While some of the changes made by the tax legislation may adversely affect the Company in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

Our corporate headquarters and the locations and uses of our principal manufacturing and other properties as of December 31, 2018, are as follows:

Location	Approximate Square Footage	Primary Use	Owned/Leased
San Clemente, California, U.S.	39,000	Corporate Headquarters and R&D	Owned
San Clemente, California, U.S.	28,108	Corporate Headquarters	Leased
San Diego, California, U.S.	44,779	Corporate Offices and R&D	Leased
Lake Forest, Illinois, U.S.	137,498	Corporate Offices	Leased
Montreal, Canada	48,065	Corporate Offices	Leased
Chennai, India	36,879	Corporate Offices	Leased
Rydalmere, NSW Australia	14,735	Corporate Offices/Device service center	Leased
Austin, Texas, U.S.	594,602	Manufacturing	Owned
Ensenada, Baja California, Mexico	265,021	Manufacturing	Owned
La Aurora, Costa Rica	626,869	Manufacturing	Owned
Salt Lake City, Utah, U.S.	450,000	Manufacturing	Owned
Farmers Branch, Texas, U.S.	66,060	Distribution Warehouse	Owned
King of Prussia, Pennsylvania, U.S.	105,571	Distribution Warehouse	Owned
Round Rock, Texas, U.S.	71,960	Distribution Warehouse	Owned
Santa Fe Springs, California, U.S.	76,794	Distribution Warehouse	Owned
San Jose, California, U.S.	78,119	Device service center	Leased
Sligo, Ireland	26,000	Device service center	Leased

In addition to the above, we own and lease additional office and building space, research and development, and sales and support offices primarily in North America, Europe, South America, and Asia. We believe our existing facilities, both owned and leased, are in good condition and suitable for the conduct of our business.

ITEM 3. LEGAL PROCEEDINGS

Certain legal proceedings in which we are involved are discussed in Part II, Item 8. "Financial Statements and Supplementary Data" of this Form 10-K in Note 15. Commitments and Contingencies to the Consolidated Financial Statements, and is incorporated herein by reference.

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

Market Information for Common Stock

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 price per share for our common stock quoted by NASDAQ:

2018	High	Low
First quarter	$265.27	$211.25
Second quarter	$313.20	$241.05
Third quarter	$321.70	$263.26
Fourth quarter	$286.28	$210.94

2017	High	Low
First quarter	$159.95	$127.00
Second quarter	$175.73	$144.25
Third quarter	$188.85	$164.00
Fourth quarter	$225.38	$180.45

Dividends

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.

Stockholders

As of January 31, 2019, we had 128 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 2018:

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)]
10/01/2018 - 10/31/2018	—	$ ——	——	$ 7,169,000
11/01/2018 - 11/30/2018	—	$ ——	——	7,169,000
12/01/2018 - 12/31/2018	—	$ ——	——	7,169,000
Fourth quarter 2018 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 DECEMBER 31, 2013 TO DECEMBER 31, 2018 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, 2013 to December 31, 2018 and the total returns of the NASDAQ U.S. Index and NASDAQ Medical Supplies Index for the same period.

	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
ICU Medical, Inc.	$ 100.00	$ 128.55	$ 177.02	$ 231.28	$ 339.04	$ 360.43
NASDAQ U.S. Index	$ 100.00	$ 112.46	$ 113.00	$ 127.70	$ 155.01	$ 146.57
NASDAQ Medical Supplies Index	$ 100.00	$ 120.17	$ 132.87	$ 141.93	$ 198.67	$ 213.25

Assumes $100 invested on December 31, 2013 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

The following selected consolidated financial data (presented in thousands, except per share amounts) is derived from our Consolidated Financial Statements. During 2017, we acquired HIS (see Note 2 to the consolidated financial statements in Part II, Item 8 of this Form 10-K). During 2018, we adopted Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers, using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. The adoption of this standard did not have a material impact on our consolidated financial statements (see Note 4 to the consolidated financial statements in Part II, Item 8 of this Form 10-K). Our historical operating results are not necessarily indicative of future operating results and should be read in conjunction with the Consolidated Financial Statements and notes thereto, and with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

	Year ended December 31, (in thousands, except per share data)				
	2018	2017	2016	2015	2014
INCOME DATA:					
REVENUE					
Net sales	$1,400,040	$1,292,166	$379,339	$341,254	$308,770
Other	—	447	33	414	490
TOTAL REVENUE	1,400,040	1,292,613	379,372	341,668	309,260
COST OF GOODS SOLD	830,012	866,518	177,974	160,871	157,859
GROSS PROFIT	570,028	426,095	201,398	180,797	151,401
Selling, general and administrative expenses	328,146	303,953	89,426	83,216	88,939
Research and development expenses	52,867	51,253	12,955	15,714	18,332
Restructuring and strategic transaction	105,390	77,967	15,348	8,451	5,093
Contract settlement	41,613	—	—	—	—
Change in fair value of contingent earn-out	20,400	8,000	—	—	—
Gain on sale of assets	—	—	—	(1,086)	—
Legal settlements	—	—	—	1,798	—
Impairment of assets held for sale	—	—	728	4,139	—
TOTAL OPERATING EXPENSES	548,416	441,173	118,457	112,232	112,364
INCOME (LOSS) FROM OPERATIONS	21,612	(15,078)	82,941	68,565	39,037
BARGAIN PURCHASE GAIN	—	70,890	1,456	—	—
INTEREST EXPENSE	(709)	(2,047)	(118)	(39)	—
OTHER INCOME (EXPENSE), net	1,471	(2,482)	885	1,173	755
INCOME BEFORE INCOME TAXES	22,374	51,283	85,164	69,699	39,792
BENEFIT (PROVISION) FOR INCOME TAXES	6,419	17,361	(22,080)	(24,714)	(13,457)
NET INCOME	$28,793	$68,644	$63,084	$44,985	$26,335
NET INCOME PER SHARE					
Basic	$1.41	$3.50	$3.90	$2.84	$1.72
Diluted	$1.33	$3.29	$3.66	$2.73	$1.68
WEIGHTED AVERAGE NUMBER OF SHARES					
Basic	20,394	19,614	16,168	15,848	15,282
Diluted	21,601	20,858	17,254	16,496	15,647
Cash dividends per share	$—	$—	$—	$—	$—
CASH FLOW DATA:					
Total cash flows from operations	$160,215	$154,423	$89,941	$64,195	$66,340

	As of December 31, (in thousands)				
	2018	2017	2016	2015	2014
BALANCE SHEET DATA:					
Cash, cash equivalents and short-term investment securities	$382,110	$300,133	$445,082	$377,397	$346,764
Working capital	$677,747	$654,370	$528,560	$462,389	$403,801
Total assets	$1,585,391	$1,496,951	$704,688	$626,825	$541,102
Stockholders’ equity	$1,263,655	$1,198,254	$660,155	$579,871	$508,252

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our Consolidated Financial Statements and Notes thereto.

Business Overview and Highlights

During 2018, we continued to integrate Pfizer's HIS business, which we acquired on February 3, 2017. See "Acquisitions" below for additional detail regarding the acquisition. We are now one of the world's leading pure-play infusion therapy companies. We develop, manufacture and sell innovative medical products used in infusion therapy and critical care applications. Our product portfolio includes IV smart pumps, sets, connectors, closed system transfer devices for hazardous drugs, sterile IV solutions, cardiac monitoring systems, along with pain management and safety software technology designed to help meet clinical, safety and workflow goals.

Consolidated Results of Operations

The following table summarizes our total worldwide revenue by domestic and international markets by amount and as a percentage of total revenue (in millions, except percentages):

	Year Ended December 31,								
	2018			2017			2016		
	$	% of Revenue		$	% of Revenue		$	% of Revenue	
Domestic	$1,054.7	75	%	$980.0	76	%	$261.7	69	%
International	345.3	25	%	312.6	24	%	117.7	31	%
Total Revenue	$1,400.0	100	%	$1,292.6	100	%	$379.4	100	%

The following table sets forth, for the periods indicated, total revenue by product line as a percentage of total revenue:

Product line	2018		2017		2016	
Infusion Consumables	35	%	28	%	86	%
IV Solutions	36	%	40	%	—	%
Infusion Systems	25	%	23	%	—	%
Critical Care	4	%	4	%	14	%
Other	—	%	5	%	—	%
	100	%	100	%	100	%

We manage our product distribution in the U.S. through a network of four owned distribution facilities, as well as, through direct channels, which include independent distributors and the end users of our products, and as original equipment manufacturer suppliers. Most of our independent distributors handle the full line of our products.

Internationally, we manage our operations through the Netherlands, which utilizes international regional hubs and we also manage our operations through independent distributors.

A substantial amount of our products are sold to group purchasing organization ("GPO") member hospitals. 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 revenue from a relatively small number of distributors and manufacturers. Although we believe that we are not dependent on any single distributor for distribution of our products, the loss of a strategic relationship with a customer or a decline in demand for our 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 acquisition and 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

There are no significant seasonal aspects to our business. 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.

Significant Acquisitions

On February 3, 2017, we acquired 100% interest in Pfizer's HIS business for total consideration of approximately $260.0 million in cash (net of estimated working capital adjustments paid at closing) and the issuance of 3.2 million shares of our common stock. As of December, 31, 2018, Pfizer has sold all of their shares of our common stock. We partially funded the cash portion of the consideration paid with a $75 million three-year interest-only seller note. The fair value of the common shares issued to Pfizer was determined based on the closing price of our common shares on the issuance date, discounted to reflect a contractual lock-up period whereby Pfizer cannot transfer the shares, subject to certain exceptions, until the earlier of (i) the expiration of Pfizer’s services to us in the related transitional services agreement or (ii) eighteen months. Pfizer also may be entitled up to an additional $225 million in cash contingent consideration based on the achievement of performance targets for the combined company for the three years ending December 31, 2019.

See Note 2 to the consolidated financial statements in Part II, Item 8 of this Form 10-K for further details of our acquisitions.

Five-year Revolving Credit Facility ("Credit Facility")

On November 8, 2017, we entered into a five-year Revolving Credit Facility ("Credit Facility") with various lenders for $150 million, with Wells Fargo Bank, N.A. as the administrative agent. The Credit Facility has an accordion feature that would enable us to increase the borrowing capacity of the credit facility by the greater of (i) $100 million and (ii) 2.00x Total Leverage (as defined in our Credit Facility). Under the terms of the facility we will be subject to certain financial covenants pertaining to leverage and fixed charge coverage ratios, see below under "Liquidity and Capital Resources" for further details. Borrowings under the Credit Facility will bear interest, at our option, based on the Base Rate plus applicable margin or LIBOR plus an applicable margin, both tied to the leverage ratio in effect. The unused portion of the Credit Facility will be subject to a per annum commitment fee which is also calculated

using the leverage ratio in effect. The Credit Facility was entered into in order to provide us with flexible funding for future acquisition and operational needs.

In connection with the Credit Facility, during 2017, we incurred $1.4 million in financing costs, which are being amortized to interest expense over the remaining term of the Credit Facility.

See Note 11 to the consolidated financial statements in Part II, Item 8 of this Form 10-K for further information regarding the Credit Facility.

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		
	2018	2017	2016
Revenue			
Net sales	100 %	100 %	100 %
Other	— %	— %	— %
Total revenues	100 %	100 %	100 %
Gross margin	41 %	33 %	53 %
Selling, general and administrative expenses	23 %	24 %	24 %
Research and development expenses	4 %	4 %	3 %
Restructuring and transaction expense	8 %	6 %	4 %
Change in fair value of contingent earn-out	1 %	1 %	— %
Contract settlement	3 %	— %	— %
Impairment of assets held for sale	— %	— %	— %
Total operating expenses	39 %	35 %	31 %
Income (loss) from operations	2 %	(2)%	22 %
Bargain Purchase Gain	— %	5 %	— %
Interest expense	— %	— %	— %
Other (expense) income, net	— %	— %	— %
Income before income taxes	2 %	3 %	22 %
(Benefit) Provision For Income taxes	— %	(1)%	6 %
Net income	2 %	4 %	16 %

Total revenues for 2018, 2017 and 2016 were $1.4 billion, $1.3 billion and $379.4 million, respectively.

Infusion Consumables

The following table summarizes our total Infusion Consumables revenue (in millions, except percentages):

	Year Ended December 31,			$ change 2018 over 2017	% change 2018 over 2017	$ change 2017 over 2016	% change 2017 over 2016
	2018	2017	2016				
Infusion Consumables	$483.0	$365.6	$324.9	$117.4	32.1 %	$40.7	12.5 %

The increase in Infusion Consumables revenue in 2018, as compared to 2017 was primarily driven by three factors, (i) the classification of revenue related to certain foreign jurisdiction HIS entities with deferred closes during 2017 as "Other Revenue" for 2017, due to the fact that we were unable to allocate the revenue to a specific product line, (ii) the addition of new customers in Infusion for IV therapy and oncology products in 2018, and (iii) the completion of acquisitions in 2018. In addition, 2017 includes approximately eleven months of revenue from the point of closing of the HIS transaction to the end of the year.

In 2017, our Infusion Consumables revenue included our acquired revenue from the HIS business, which included approximately eleven months of revenue from the point of closing of the transaction to the end of 2017, as well as our legacy Infusion Therapy and Oncology businesses. In 2016, our Infusion Consumables revenue as presented above consisted of our legacy Infusion Therapy and Oncology businesses.

IV Solutions

The following table summarizes our total IV Solutions revenue (in millions, except percentages):

	Year Ended December 31,			$ change 2018 over 2017	% change 2018 over 2017	$ change 2017 over 2016	% change 2017 over 2016
	2018	2017	2016				
IV Solutions	$508.0	$522.0	$ —	$(14.0)	(2.7)%	$522.0	*

* Not Applicable

In 2017, competitor supply constraints were significantly reduced in the second half of the year. We temporarily benefited from those supply constraints. Beginning in 2018, supply normalized, which eventually normalized customers demand. IV Solutions revenue for 2017 also includes approximately eleven months of revenue from the point of closing of the HIS transaction to the end of the year.

Infusion Systems

The following table summarizes our total Infusion Systems revenue (in millions, except percentages):

	Year Ended December 31,			$ change 2018 over 2017	% change 2018 over 2017	$ change 2017 over 2016	% change 2017 over 2016
	2018	2017	2016				
Infusion Systems	$355.5	$290.2	$ —	$65.3	22.5%	$290.2	*

* Not Applicable

Infusion Systems revenue increased in 2018, as compared to 2017, primarily due to the revenue related to certain foreign jurisdiction HIS entities that had deferred closes during 2017. The revenue related to these deferred close entities in 2017 was included in "Other Revenue", as we were unable to allocate the revenue to a specific product line. In addition, 2017 includes approximately eleven months of revenue from the point of closing of the HIS transaction to the end of the year.

Critical Care

The following table summarizes our total Critical Care revenue (in millions, except percentages):

	Year Ended December 31,			$ change 2018 over 2017	% change 2018 over 2017	$ change 2017 over 2016	% change 2017 over 2016
	2018	2017	2016				
Critical Care	$53.5	$50.0	$53.6	$3.5	7.0 %	$(3.6)	(6.7)%

In 2018, Critical Care revenue increased, as compared to 2017, primarily due to new product shipments of the Cogent patient monitor and due to timing of orders. In 2017, Critical Care revenue slightly decreased, as compared to 2016, due to timing of orders.

Revenue from Deferred Close Entities

As part of the HIS business acquisition, the closing of certain foreign jurisdictions were deferred, as such, we entered into a Net Economic Benefit agreement with Pfizer (see Note 2 to the consolidated financial statements in Part II, Item 8 of this Form 10-K for additional information). The revenue data related to these deferred closing entities was not available by product line, therefore our revenue by product line for 2017 described above did not include amounts

related to these entities. All of the deferred closing entities were effectively closed in 2018, which allowed for allocation of all of the revenue to a specific product line for 2018.

The following table summarizes our revenue from our deferred close entities (in millions):

	Year Ended December 31,			$ change	% change	$ change	% change
	2018	2017	2016	2018 over 2017		2017 over 2016	
Revenue from Deferred Close Entities	$—	$64.4	$—	$(64.4)	*	$64.4	*

* Not meaningful.

Gross Margins

Gross margins for 2018, 2017 and 2016 were 40.7%, 33.0%, and 53.1%, respectively.

The increase in gross margin in 2018, as compared to 2017, was primarily due to a change in product mix related to increased Infusion Consumables and increased factory efficiencies. 2017 was negatively impacted by the step-up of inventory from the purchase accounting related to the HIS acquisition.

The decrease in gross margin in 2017, as compared to 2016, was primarily due to the integration of HIS, which has historically had lower gross margins than our legacy business. Additionally, there was an impact of approximately five percentage points related to the step-up of inventory from our purchase accounting and also a temporary negative impact on absorption due to our planned inventory reduction.

Selling, General and Administrative ("SG&A") Expenses

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2018	2017	2016	2018 over 2017		2017 over 2016	
SG&A	$328.1	$304.0	$89.4	$24.1	7.9 %	$214.6	240.0%

Consolidated SG&A expense increased in 2018, as compared to 2017, primarily attributable to the impact of the integration of HIS as we incurred duplicative costs as we added resources to stand up the business that will replace the services provided under the transitional services agreement with Pfizer. Compensation expense increased $19.5 million, information technology expense increased $7.7 million, realized foreign exchange losses increased $5.7 million, marketing expenses increased $4.5 million, legal expenses increased $3.5 million, travel expenses increased $3.3 million and dealer fees increased $2.2 million. Offsetting these increases was a $23.9 million decrease in consulting expenses and decreases in other miscellaneous expenses. Compensation increased due to an increase in headcount from new employees hired to support the company post-acquisition of HIS. Information technology expense increases were due to the HIS post-acquisition needs to stand up the company. Realized foreign exchange losses increased due to changes in the rate and increased foreign monetary account balances. Marketing expenses increased primarily due to the continued integration of HIS and the post-acquisition operational activity. Legal expenses increased due to the continued integration of HIS and legal services needed to support a larger business. Travel expense increased as a result of the operational needs of the company. Dealer fees increased due to the increase in revenue.

Consolidated SG&A expense increased $214.6 million in 2017, as compared to 2016, primarily due to the impact of the HIS acquisition. Compensation increased $83.7 million, accounting and information technology fees increased $72.4 million, depreciation expense increased $16.0 million, computer hardware and software increased $11.5 million, travel and related expenses increased $5.8 million and rent expense increased $3.3 million. Compensation increased

primarily due to an increase in headcount related to the HIS acquisition, and from new employees hired to support the company post-acquisition. Accounting and information technology fees increased due to the expenses incurred under the transition services agreement with Pfizer. Depreciation expense increased due to the depreciation of the HIS assets acquired. Computer hardware and software increases were due to the post-acquisition needs to stand up the company. Travel and related expenses increased primarily due to the integration of the HIS acquisition and the post-acquisition operational activity. Rent expense increased due to the operating leases assumed on acquired HIS properties.

Research and Development ("R&D") Expenses

The following table summarizes our total R&D Expenses (in millions, except percentages):

	Year Ended December 31,			$ change 2018 over 2017	% change 2018 over 2017	$ change 2017 over 2016	% change 2017 over 2016
	2018	2017	2016				
R&D	$52.9	$51.3	$13.0	$1.6	3.1 %	$38.3	294.6%

In 2018, as compared to 2017, R&D expenses increased due to post-acquisition operational activity attributable to a larger business and 2017 includes approximately eleven months of R&D expense from the point of closing of the transaction to the end of the year.

In 2017, as compared to 2016, R&D expenses increased due to the acquisition of HIS.

Restructuring and Strategic Transaction Expenses

Restructuring and strategic transaction expenses were $105.4 million, $78.0 million and $15.3 million in 2018, 2017 and 2016, respectively.

Restructuring Charges

In 2018, restructuring charges were $4.5 million. These charges were related to (i) severance costs from the reduction in our workforce as a result of the continued integration of HIS. All material charges in regard to these restructuring activities have been paid as of December 31, 2018.

In 2017, restructuring charges were $18.8 million. These charges were related to (i) severance costs from the reduction in our workforce needed to eliminate duplicative positions created as a result of the HIS acquisition and (ii) we closed our Dominican Republic manufacturing facility and incurred expenses associated with the closure and transfer of assets and production to our Costa Rica and Mexico manufacturing facilities. We have $0.9 million in unpaid restructuring charges related to the year-ended December 31, 2017.

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.

Strategic Transaction and Integration Expenses

In 2018, we incurred $100.9 million in strategic transaction and integration expenses primarily related to our continued integration of the HIS business and IT systems.

In 2017, we incurred $59.2 million in strategic transaction and integration expenses primarily related to our acquisition of the HIS business.

In 2016, we incurred $14.3 million in strategic transaction expenses related to our acquisitions, primarily the acquisition of the HIS business.

Change in fair value of contingent earn-out

In 2018, the fair value revaluation of our HIS contingent earn-out liability resulted in a change in fair value of $20.4 million.

In 2017, the fair value revaluation of our HIS contingent earn-out liability resulted in a loss of $8.0 million.

Contract Settlement

In 2018, we incurred a $41.6 million charge related to the resolution of a dispute with a product partner, which resulted in a redefinition of our contractual arrangement and in the rights and remedies determined under such arrangement.

Impairment of Assets Held-for-Sale

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 2017, in connection with the HIS acquisition, we recognized a bargain purchase gain of $70.9 million. 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 liabilities over the total purchase consideration. We determined that the bargain purchase gain was primarily attributable to expected restructuring costs as well as a reduction to the initially agreed upon transaction price caused primarily by revenue shortfalls across all market segments of the HIS business, negative manufacturing variance due to the drop in revenue and higher operating and required stand up costs, when compared to forecasts of the HIS business at the time that the purchase price was agreed upon.

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.

Interest Expense

Interest expense was $0.7 million, $2.0 million and $0.1 million in 2018, 2017 and 2016, respectively.

In 2018, the interest expense was related to amortization of the financing cost incurred in 2017 in connection with the five-year Revolving Credit Facility and a related per annum commitment fee charged on the unused portion of the revolver under such Credit Facility (see Note 11: Long-Term Obligations in our accompanying consolidated financial statements for additional information).

In 2017, the interest expense was related to (i) the $75 million seller note from Pfizer as part of the HIS business acquisition and (ii) the per annum commitment fee charged on the unused portion of our revolver under the five-year $150 million Credit Facility.

The three-year interest only seller note bore interest based on the London Interbank Offered Rate ("LIBOR") plus (i) 2.25% per year for the first 12 months, and (ii) 2.50% per annum thereafter. On November 8, 2017, we fully repaid the $75 million in outstanding principal under the senior note payable to Pfizer.

The per annum commitment fee is based on consolidated total leverage ratio in effect and can range between 0.15% to 0.30% on the unused portion of the Credit Facility.

Other (Expense) Income

Other (expense) income was $1.5 million, $(2.5) million and $0.9 million in 2018, 2017 and 2016, respectively. In 2018, other (expense) income included $5.4 million of interest income primarily related to our banking and investment accounts offset by $3.9 million loss on disposal of or write-off of property, plant and equipment.

Income taxes

Income taxes were accrued at an estimated annual effective tax rate of (29%), (34%) and 26% in 2018, 2017 and 2016, respectively.

The effective tax rate in 2018 differs from the federal statutory rate of 21% because of the effect of the mix of foreign and state incomes, state taxes and tax credits. The effective tax rate for 2018 also included a material tax benefit of $12.6 million related to the excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the period.

On December 22, 2017, the Tax Act was enacted into law, which includes a broad range of provisions affecting businesses. The Tax Act significantly revises how companies compute their U.S. corporate tax liability by, among other provisions, reducing the corporate tax rate from 35% to 21% for tax years beginning after December 31, 2017. As of December 31, 2018, our accounting for the Tax Act is complete. As noted at 2017 year-end, we were able to reasonably estimate certain effects and, therefore, recorded provisional adjustments associated with the toll charge on undistributed foreign earnings and profits and revaluation of deferred taxes. Measurement-period adjustments for the toll charge and revaluation of deferred taxes recognized during the year ended December 31, 2018 did not have a material impact on our consolidated financial statements. The effect of the measurement-period adjustments on the 2018 effective tax rate was approximately a three percentage point increase. We continue to evaluate various international provisions included in the Tax Act due to the lack of Treasury Regulations and ongoing guidance. These provisions were effective for us beginning on January 1, 2018, and may materially impact our effective tax rate in future years. For the year ended December 31, 2018, we recorded an income tax expense of $2.4 million for the global intangible low-taxed income (GILTI