UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2019 or

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

For the transition period from to

Commission File No. 001-34634

ICU MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

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

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

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

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

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

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

Indicate by check mark whether registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes 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 ☒ No 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, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company," in Rule 12b-2 of the Exchange Act:

Large Accelerated Filer	x	Accelerated filer	o
Non-accelerated filer	o	Small reporting company	☐
		Emerging growth company	☐

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). ☐ Yes ☒ No

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 28, 2019, the last business day of registrant's most recently completed second fiscal quarter, was $4,836,397,922*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2020 was 20,774,907.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2020 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Report.

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

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PART I

ITEM 1. BUSINESS

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 and Overview of Business

ICU is one of the world's leading pure-play infusion therapy companies with global operations and a wide-ranging product portfolio that includes IV solutions, IV smart pumps, dedicated and nondedicated IV sets and needlefree connectors, along with pain management and safety software technology designed to help meet clinical, safety and workflow goals. In addition, ICU manufactures automated pharmacy IV compounding systems with workflow technology, closed system transfer devices for hazardous IV drugs and cardiac monitoring systems to optimize patient fluid levels.

Headquartered in San Clemente, California, ICU was founded in 1984. In 1992, we had our initial public offering and reincorporated under Delaware law. Our primary customers are acute care hospitals, wholesalers, ambulatory clinics and alternate site facilities, such as outpatient clinics, home health care providers, and long-term care facilities. Since our inception we have grown organically and through acquisition, and we currently serve customers in more than 90 countries around the world.

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 complemented 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.

In November 2019, we acquired Pursuit Vascular, Inc. ("Pursuit"). Pursuit was a privately-held medical device company with a primary focus on innovative catheter disinfecting products and technologies to reduce costly bloodstream infections and lower healthcare costs. Pursuit’s primary product is the ClearGuard® HD cap, which is used for the maintenance of hemodialysis catheters.

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;
- *NovaCath™ and SuperCath™* peripheral IV catheters(PIV); and
- *ClearGuard HD* antimicrobial barrier caps for hemodialysis catheters.

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™* CSTD which utilizes a proprietary needlefree connection method, is used for the preparation and administration of hazardous drugs. ChemoLock is used to limit the escape of hazardous drug or vapor concentrations, block the transfer of environmental contaminants into the system, and eliminates the risk of needlestick injury;

- *ChemoClave™*, an ISO Connection 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 is used to limit the escape of hazardous drug or vapor concentrations, block the transfer of environmental contaminants into the system, and eliminate the risk of needlestick injury; and

- *Diana™* hazardous drug compounding system, 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 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.

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, 2019 and 2020 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.

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:

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

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;
- *TriOx™* venous oximetry catheters;
- Transpac™ blood pressure transducers; and
- 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.

Manufacturing

As of December 31, 2019, we operate four primary manufacturing facilities globally, which are discussed 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.

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

In 2017, we entered into two Manufacturing and Supply Agreements ("MSAs") with Pfizer 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 2019.

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 distribution by utilizing international regional hubs and 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 Community ("EC") Directives and regulations such as the Council Directive 93/42/EEC (the "Medical Device Directive") and Regulation 2017/745 (the "Medical Device Regulation") 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 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 and regulations such as the Medical Device Directive and the Medical Device Regulation 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;

- 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. 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;

- 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), certain health care professionals beginning in 2022, 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.

Violations of any of the laws described above include civil and criminal penalties, damages, fines, the curtailment or restructuring of an entity's operations, the debarment, suspension or exclusion from federal and state healthcare programs and/or imprisonment.

Coverage and Reimbursement

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 since our products are not separately reimbursed by any third-party payor. Third-party payors are increasingly reducing coverage and reimbursement for certain healthcare services and products and challenging prices charged for healthcare services and products.

Health Care Reform

In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments by governmental payors for medical devices, and the procedures in which medical devices are used. For example, in March 2010, comprehensive healthcare reform legislation was enacted through the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education and Reconciliation Act (the "Affordable Care Act"), which, among other things, imposed, among other things, 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, the Tax Cuts and Jobs Act, among other things, removes penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate 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. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the Affordable Care Act will impact the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will stay in effect through 2029 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, further reduced Medicare payments to several providers, including hospitals. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or internationally, or the effect any future legislation or regulation will have on us. Such legislation and regulation of healthcare costs may, however, result in decreased lower reimbursements by governmental and private payors to our customers, which may adversely affect our business, financial condition and results of operations.

Data Privacy and Security

Medical device companies may be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health

care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act (the "CCPA"), which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context.

In Europe, the General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes stringent data protection requirements for controllers and processors of personal data of persons within the EU. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

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"), and B. Braun Medical, Inc. ("B. Braun"). There is no assurance that we will be able to compete successfully with these larger competitors. 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, ongoing innovation in this market space will be required, and there is no assurance that these innovations will be able to sustain continued growth.

Infusion Systems

We face strong global competitors in the Infusion Systems market. In the United States ("U.S.") our competitors include BD, Baxter, and to a lesser extent B. Braun. Outside of the U.S., our primary competitors are BD, B. Braun, Fresenius Kabi, a division of Fresenius Group and a large number of local market pump manufacturers. 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.

IV Solutions

We participate in the IV solutions market only in the U.S. and Canada. Our primary competitors in the U.S. include Baxter, and B. Braun. 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.

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, SwabCap, Custom Set Design and Manufacturing Methods, Diana Hazardous Drug Compounding System and ClearGuard. 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, Diana Hazardous Drug Compounding System and ClearGuard.

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 the 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 $48.6 million in 2019, $52.9 million in 2018 and $51.3 million in 2017.

Employees

At December 31, 2019, we had approximately 8,000 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 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

We have may continue to acquire businesses, form strategic alliances or make investments in businesses or technologies that could adversely impact our business and our operating results and such transactions could result in unforeseen operating difficulties, expenditures and require significant management resources, charges or write-downs.

We have and may continue to seek to supplement our internal growth through acquisitions of complementary businesses, technologies, services, or products, as well as investments and strategic alliances. We compete for those opportunities with others including our competitors, some of which have greater financial or operational resources than we do. We may not be able to identify suitable acquisition candidates or strategic partners, we may have inadequate access to information or insufficient time to complete due diligence, and we may not be able to complete such transactions on favorable terms, if at all. 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. Difficulties in assimilating acquired businesses include 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. Integration of an acquired business also may disrupt our ongoing operations and require management resources that we would otherwise focus on developing our existing business. For example, 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. In addition, in connection with the HIS business acquisition, we also entered into two manufacturing and supply agreements (the "MSAs") with Pfizer 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. Our facility in Austin, Texas manufactures and supplies these products to Pfizer under the MSAs, which, for certain products, could expire as early as 2022. The expiration of these MSAs may adversely impact our production capacity utilization of our Austin facility, which could result in unforeseen operating difficulties and may impact our profitability.

In addition, any acquisition could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We may also experience losses related to investments in other companies, which could have an adverse effect on our results of operations and financial condition. As such, there can be no assurance that any past or future transactions will be successful.

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 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. Failure to manage this growth could adverse effect our operations through higher manufacturing costs, declining product quality, slower responses to competitive challenges, among other things. A failure in any one of these areas could make it difficult for us to meet market expectations for our products, and could damage our reputation and our financial performance may be adversely affected.

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 or supply chain network could impair our ability to produce our products.

A severe weather event, other natural or man-made disaster, or any other significant disruption, such as outbreak of disease (including the recent coronavirus outbreak), affecting our manufacturing facilities or our suppliers and logistics partners could materially and adversely impact our business, financial condition and results of operations. Certain of our key product components are manufactured in China and the extent to which our ability to produce products is affected by the coronavirus will largely depend on future developments, which are highly uncertain and cannot be accurately predicted.

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 or our suppliers' facilities. If our facilities are inoperable, for even a short period of time, it could adversely affect our ability to manufacture and distribute our products in a timely or cost-effective manner, and our ability to make product sales. Furthermore, our facilities and the equipment we use to perform our manufacturing processes could be unavailable or costly and time-consuming to repair or replace.

Damage to any of our facilities could render us unable to manufacture our products or require us to reduce the output of products at the damaged facility. We carry insurance for damage to our property and disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our facilities and business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

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 with our competitors, 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 numerous factors including, among other things, 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 these factors, 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' or 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 2020. 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.

In Europe the 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. In addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

The California legislature passed the California Consumer Privacy Act of 2018 (the "CCPA") on June 28, 2018, which went into effect on January 1, 2020. 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. 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.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology systems, which support our operations. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from, among others, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization or similar disruptive problems. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and often are not foreseeable or recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. If an actual or perceived breach of our security occurs, public perception of the effectiveness of our security measures and brand could be harmed and our results of operations could be negatively affected. Data security breaches and other incidents may also result from non-technical means (e.g., actions by employees or contractors). Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of personally identifiable information. Any compromise of our security could result in a violation of applicable security, privacy or data protection, consumer and other laws, regulatory or other governmental investigations, enforcement actions, and legal and financial exposure, including potential contractual liability. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors or other organizations with which we expect to form strategic relationships. Any such compromise could also result in damage to our reputation and a loss of confidence in our security and privacy or data protection measures. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenue, regulatory actions or litigations. Any of these effects could materially and adversely affect our business, financial condition and results of operations.

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.

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.

Cost volatility or loss of supply of our raw materials 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 2017 through December 2019, our trading price ranged from a high of $321.70 per share to a low of $127.00 per share. We believe that factors such as quarter-to-quarter fluctuations in financial results, differences between stock analysts' expectations and actual quarterly and annual results, new product introductions by us or our competitors, acquisitions or divestitures, changing regulatory environments, litigation, changes in healthcare reimbursement policies, sales or the perception in the market of possible sales of common stock by insiders, market rumors and substantial product orders could contribute to the volatility in the price of our common stock. General economic trends unrelated to our performance such as recessionary cycles, changing interest and tax 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 59% of our outstanding shares at the end of 2019. 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 significant civil monetary penalties, 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 additional fines and/or 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, 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 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 beginning in 2022, 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 significant civil monetary penalties for any 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; 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.

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 was a 2.3% excise tax imposed on medical device manufacturers for the sale of certain medical devices to U.S. customers, which, due to subsequent legislative amendments, was suspended, effective January 1, 2016, and subsequently repealed altogether, effective January 1, 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.

Since its enactment, there have been efforts to challenge, repeal or replace 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. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the Affordable Care Act will impact the Affordable Care Act and our business.

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 2029 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.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payers to reduce costs while expanding individual healthcare benefits. 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 or other proprietary rights, if our products are found to infringe patents or other proprietary rights owned by others or if the cost to protect our patent or other proprietary rights becomes excessive or as our 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 identical or similar to ours, which could adversely affect our business.

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.

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 our Clave products, the CLC2000 Connector and Tego Connector. 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 (Regulation 2017/745) entered into force to replace the Medical Device Directive, as amended. Unlike directives, which must be implemented into the national laws of the European Economic Area member States (the "EEA member States"), the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation will become applicable three years after publication (in May 2020). Once applicable, the Medical Devices Regulation will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance, and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals, and the public with comprehensive information on products available in the EU;
- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

As a result of these new requirements, 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 $40,000,000 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 27% of our revenue in 2019 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. Additionally, following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the EU on January 31, 2020 and entered into a transition period during which it will continue its ongoing and complex negotiations with the EU relating to the future trading relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital. In addition, 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;
- natural disasters or outbreak of diseases;
- 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. The U.S. government has recently initiated substantial changes in U.S. trade policy and U.S. trade agreements, including the initiation of tariffs on certain foreign goods. In response to these tariffs, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U.S. goods. For example, 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. Additionally, we are subject to income taxes in the United States and numerous foreign jurisdictions. 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 dependent on manufacturing in Mexico, and could be adversely affected by increased labor costs and any economic, social or political disruptions.

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. Disruptions in the financial markets, including the impact of the United Kingdom's withdrawal 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 limitations and difficulty forecasting future activity. 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.

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, 2019, 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	16,414	Corporate Offices	Leased
Chennai, India	36,879	R&D	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
Round Rock, Texas, U.S.	71,960	Warehouse/Manufacturing	Owned
Farmers Branch, Texas, U.S.	66,060	Distribution Warehouse	Owned
King of Prussia, Pennsylvania, U.S.	105,571	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.

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, 2020, we had 54 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 2019:

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]
10/01/2019 - 10/31/2019	—	$ —	—	$ 100,000,000
11/01/2019 - 11/30/2019	—	$ —	—	$ 100,000,000
12/01/2019 - 12/31/2019	—	$ —	—	$ 100,000,000
Fourth quarter 2019 total	—	$ —	—	$ 100,000,000

(1) Our common stock purchase plan, which authorized the repurchase of up to $100.0 million of our common stock, was authorized by our Board of Directors and publicly announced in August, 2019. 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.

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. 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)				
	2019	2018	2017	2016	2015
INCOME DATA:					
REVENUE					
Net sales	$ 1,266,208	$ 1,400,040	$ 1,292,166	$ 379,339	$ 341,254
Other	—	—	447	33	414
TOTAL REVENUE	1,266,208	1,400,040	1,292,613	379,372	341,668
COST OF GOODS SOLD	794,344	830,012	866,518	177,974	160,871
GROSS PROFIT	471,864	570,028	426,095	201,398	180,797
Selling, general and administrative expenses[1]	276,982	320,002	302,169	89,426	83,216
Research and development expenses	48,611	52,867	51,253	12,955	15,714
Restructuring and strategic transaction	80,574	105,390	77,967	15,348	8,451
Contract settlement	5,737	41,613	—	—	—
Change in fair value of contingent earn-out	(47,400)	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	364,504	540,272	439,389	118,457	112,232
INCOME (LOSS) FROM OPERATIONS	107,360	29,756	(13,294)	82,941	68,565
BARGAIN PURCHASE GAIN	—	—	70,890	1,456	—
INTEREST EXPENSE	(549)	(709)	(2,047)	(118)	(39)
OTHER INCOME (EXPENSE), net[1]	7,896	(6,673)	(4,266)	885	1,173
INCOME BEFORE INCOME TAXES	114,707	22,374	51,283	85,164	69,699
(PROVISION) BENEFIT FOR INCOME TAXES	(13,672)	6,419	17,361	(22,080)	(24,714)
NET INCOME	$ 101,035	$ 28,793	$ 68,644	$ 63,084	$ 44,985
NET INCOME PER SHARE					
Basic	$ 4.90	$ 1.41	$ 3.50	$ 3.90	$ 2.84
Diluted	$ 4.69	$ 1.33	$ 3.29	$ 3.66	$ 2.73
WEIGHTED AVERAGE NUMBER OF SHARES					
Basic	20,629	20,394	19,614	16,168	15,848
Diluted	21,545	21,601	20,858	17,254	16,496
Cash dividends per share	$ —	$ —	$ —	$ —	$ —
CASH FLOW DATA:					
Total cash flows from operations	$ 101,918	$ 160,215	$ 154,423	$ 89,941	$ 64,195

[1] For the years 2018 and 2017, we reclassified foreign currency losses out of selling, general and administrative in to other income (expense), net to be comparative to the current year presentation.

	As of December 31, (in thousands)				
	2019	2018	2017	2016	2015
BALANCE SHEET DATA:					
Cash, cash equivalents and short-term investment securities	$ 292,637	$ 382,110	$ 300,133	$ 445,082	$ 377,397
Working capital	$ 633,729	$ 677,747	$ 654,370	$ 528,560	$ 462,389
Total assets	$ 1,692,382	$ 1,585,391	$ 1,496,951	$ 704,688	$ 626,825
Stockholders' equity	$ 1,377,244	$ 1,263,655	$ 1,198,254	$ 660,155	$ 579,871

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

We are one of the world's leading pure-play infusion therapy companies with global operations and a wide-ranging product portfolio that includes IV solutions, IV smart pumps, dedicated and nondedicated IV sets and needlefree connectors, along with pain management and safety software technology designed to help meet clinical, safety and workflow goals. In addition, we manufacture automated pharmacy IV compounding systems with workflow technology, closed system transfer devices for hazardous IV drugs and cardiac monitoring systems to optimize patient fluid levels.

The system integration of Pfizer's HIS business that was primarily completed by the end of 2018 resulted in cost improvements and operating efficiencies during 2019. These cost improvements and operating efficiencies partially offset the revenue decrease for the current period as compared to the prior year, which was driven in part by our competitive commercial environment, primarily in our IV Solutions product line.

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,					
	2019		2018		2017	
	$	% of Revenue	$	% of Revenue	$	% of Revenue
Domestic	$ 923.3	73%	$ 1,054.7	75%	$ 980.0	76%
International	342.9	27%	345.3	25%	312.6	24%
Total Revenue	$ 1,266.2	100%	$ 1,400.0	100%	$ 1,292.6	100%

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

Product line	2019	2018	2017
Infusion Consumables	37%	35%	28%
Infusion Systems	26%	25%	23%
IV Solutions	33%	36%	40%
Critical Care	4%	4%	4%
Other	—%	—%	5%
	100%	100%	100%

We manage our product distribution in the U.S. through a network of three 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 distribution utilizing international regional hubs and through independent distributors.

In the U.S. 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. Although we believe that we are not dependent on any single distributor, large healthcare provider or major buying organization for distribution of our products, the loss of a strategic relationship with any one of these 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.

Acquisitions

On November 2, 2019, we acquired 100% interest in Pursuit for total consideration of approximately $75.0 million in cash and a potential contingent earn-out of up to $50.0 million payable in 2021. See Note 2 to the consolidated financial statements in Part II, Item 8 of this Form 10-K for further details of our acquisitions.

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		
	2019	**2018**	**2017**
Revenue			
Net sales	100 %	100 %	100 %
Other	— %	— %	— %
Total revenues	100 %	100 %	100 %
Gross margin	37 %	41 %	33 %
Selling, general and administrative expenses	22 %	23 %	24 %
Research and development expenses	4 %	4 %	4 %
Restructuring and transaction expense	6 %	8 %	6 %
Change in fair value of contingent earn-out	(4)%	1 %	1 %
Contract settlement	— %	3 %	— %
Total operating expenses	28 %	39 %	35 %
Income (loss) from operations	9 %	2 %	(2)%
Bargain Purchase Gain	— %	— %	5 %
Interest expense	— %	— %	— %
Other income (expense), net	1 %	— %	— %
Income before income taxes	10 %	2 %	3 %
Provision (Benefit) For Income taxes	1 %	— %	(1)%
Net income	9 %	2 %	4 %

Total revenues for 2019, 2018 and 2017 were $1.3 billion, $1.4 billion and $1.3 billion, respectively.

Infusion Consumables

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2019	2018	2017	2019 over 2018		2018 over 2017	
Infusion Consumables	$ 477.6	$ 483.0	$ 365.6	$ (5.4)	(1.1)%	$ 117.4	32.1%

Infusion Consumables revenue decreased in 2019, as compared to 2018. The decrease was mostly driven by foreign exchange rates. On a constant currency basis, Infusion Consumables revenue would have been $485.8 million for 2019, an increase of $2.8 million or 0.6%, as compared to 2018.

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.

Infusion Systems

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2019	2018	2017	2019 over 2018		2018 over 2017	
Infusion Systems	$ 328.3	$ 355.5	$ 290.2	$ (27.2)	(7.7)%	$ 65.3	22.5%

Infusion Systems revenue decreased in 2019, as compared to 2018. The decrease in revenue was primarily due to the impact of exchange rates and losses of our non-core ambulatory and patient controlled analgesia pumps business. On a constant currency basis Infusion Systems revenue in 2019 would have been $338.6 million, a decrease of $16.9 million or 4.8%, as compared to 2018.

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.

IV Solutions

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2019	2018	2017	2019 over 2018		2018 over 2017	
IV Solutions	$ 415.0	$ 508.0	$ 522.0	$ (93.0)	(18.3)%	$ (14.0)	(2.7)%

IV Solutions sales decreased in 2019, as compared to 2018. Supply constraints at our competitors beginning in the second quarter of 2017 and continuing through 2018 caused some temporary customer purchases and stock-up of IV Solutions in 2018. These market shortages temporarily drove up the demand for our product during the latter part of 2017, in 2018 and during the first part of 2019. In addition, the temporary increase in IV Solutions sales that we had as a result of competitor supply constraints has generally normalized as customers have returned to their original contract supplier.

IV Solutions sales decreased in 2018, as compared to 2017. In 2017, the supply constraints at our competitors, mentioned above, temporarily drove up the demand for our products. During 2018, supply normalized, which started to normalize customer demand. IV Solutions revenue for 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	% change	$ change	% change
	2019	2018	2017	2019 over 2018		2018 over 2017	
Critical Care	$ 45.3	$ 53.5	$ 50.0	$ (8.2)	(15.3)%	$ 3.5	7.0%

Critical Care revenue decreased in 2019, as compared to 2018, primarily due to manufacturing constraints.

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.

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 and beyond.

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

	Year Ended December 31,			$ change	% change
	2019	2018	2017	2018 over 2017	
Revenue from Deferred Close Entities	$ —	$ —	$ 64.4	$ (64.4)	*

* Not meaningful.

Gross Margins

Gross margins for 2019, 2018 and 2017 were 37.3%, 40.7%, and 33.0%, respectively.

The decrease in gross margin in 2019, as compared to 2018 was primarily due to the slowdown in manufacturing of IV Solutions and additional supply chain costs related to higher than optimal inventory levels. In 2019, we also recorded a one-time supply chain inventory optimization charge of $16.3 million for the initial ramp down of IV Solution production to align supply to market demand.

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.

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
	2019	2018	2017	2019 over 2018		2018 over 2017	
SG&A	$ 277.0	$ 320.0	$ 302.2	$ (43.0)	(13.4)%	$ 17.8	5.9%

Consolidated SG&A expenses decreased in 2019, as compared to 2018. Consulting expenses decreased $33.9 million, compensation expense decreased $17.9 million, legal expense decreased $3.8 million, marketing expenses decreased $3.4 million, information technology decreased $3.3 million, stock based compensation decreased $3.2 million and travel expenses decreased $2.8 million. Partially offsetting these decreases was a $10.6 million increase in depreciation and amortization and a

$7.9 million increase in bad debt and warranty expense. Consulting expenses decreased as our transitional services agreement with Pfizer ended in the fourth quarter of 2018. Compensation expense decreased in the current period as incentive bonuses were higher in the prior year due to company performance. Legal expenses were higher in the prior year due to expenses incurred related to the contract settlement, discussed below. Marketing expenses decreased in the current period as the prior period included additional expenses related to post-acquisition branding efforts. Information technology expenses decreased as software maintenance costs decreased in the current period. Stock based compensation decreased due to an adjustment for changes in the number of performance shares estimated to vest. Depreciation expense increased due to an increase in the depreciable asset base related to the HIS integration. Bad debt expense increased as a result of the quarterly assessment of our reserves related to our accounts receivable.

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, 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. 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.

We reclassified $8.1 million and $1.8 million of foreign exchange losses for 2018 and 2017, respectively, from SG&A to other income (expense), net to conform to our current year reporting of those gains and losses.

Research and Development ("R&D") Expenses

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2019	2018	2017	2019 over 2018		2018 over 2017	
R&D	$ 48.6	$ 52.9	$ 51.3	$ (4.3)	(8.1)%	$ 1.6	3.1%

R&D expenses decreased slightly in 2019, as compared to 2018. The current year expense is primarily related to compensation and benefit expenses incurred on our current R&D projects.

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.

Restructuring, Strategic Transaction and Integration Expenses

Restructuring, strategic transaction and integration expenses were $80.6 million, $105.4 million and $78.0 million in 2019, 2018 and 2017, respectively.

Restructuring Charges

In 2019, restructuring charges were $8.4 million. These charges were primarily related to a one-time charge to move our U.S. pump service depot to our existing Salt Lake City facility and other plant restructuring. We expect to pay unpaid restructuring charges as of December 31, 2019, in 2020.

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, 2019.

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.

Strategic Transaction and Integration Expenses

In 2019, we incurred $72.2 million in strategic transaction and integration expenses primarily related to the integration of the HIS business. Integration expenses included a one-time strategic supply chain restructuring charge of $22.1 million, which reduces our contracted commitments to our third party manufacturer and we incurred charges related to our final Pfizer separation costs and clean-up, which included a $12.7 million non-cash write-off of related assets.

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.

Change in fair value of contingent earn-out

In 2019, the fair value revaluation of our HIS contingent earn-out liability resulted in a change in value of $47.4 million reducing the liability balance to zero. The earn-out period ended on December 31, 2019 and we did not meet the required performance targets in order to pay out any of the 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 2019 and 2018, we incurred a $5.7 million and $41.6 million charge, respectively, 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.

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.

Interest Expense

Interest expense was $0.5 million, $0.7 million and $2.0 million in 2019, 2018 and 2017, respectively.

In 2019 and 2018, the interest expense was related to amortization of the financing cost incurred in 2017 in connection with the five-year Revolving Credit Facility ("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 Income (Expense), net

Other income (expense), net was $7.9 million, $(6.7) million and $(4.3) million in 2019, 2018 and 2017, respectively. In 2019, other income (expense), net was primarily due to interest income of $6.8 million related to our banking and investment accounts. In 2018, other income (expense), net included $5.4 million of interest income offset by $3.9 million loss on disposal of or write-off of property, plant and equipment and an $8.1 million reclassification of foreign exchange losses, net from SG&A to conform to the current year's presentation. In 2017, we reclassified $1.8 million of foreign exchange losses to other income (expense), net from SG&A.

Income taxes

Income taxes were accrued at an estimated annual effective tax rate of 12%, (29%) and (34%) in 2019, 2018 and 2017, respectively.

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.

The effective tax rate in 2019 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign incomes, state income taxes, global intangible low-taxed income ("GILTI") and tax credits. The effective tax rate for 2019 included a tax benefit of $9.6 million related to the excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the period. The effective tax rate for 2019 was also impacted by the repatriation of certain intellectual property and assets from a liquidation of one of our foreign subsidiaries to the U.S. parent. In accordance with the changes to the accounting for income tax effects of such intra-entity transfers of assets, we recorded a net tax benefit of $3.8 million related to the liquidation. Lastly, the effective tax rate during 2019 included a tax expense of $2.2 million related to return-to-provision adjustments for the year ended December 31, 2018 primarily due to changes in estimates for our U.S. GILTI inclusion.

The effective tax rate in 2018 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign incomes, state income taxes and tax credits. The effective tax rate for 2018 included a 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.

The effective tax rate for 2017 differs from the federal statutory rate of 35% because of the effect of the mix of foreign and state incomes, state taxes, tax credits, and impact of the gain on bargain purchase. The tax effect of the gain on bargain purchase is treated as a part of purchase accounting and is not a component of the income tax provision. The effective tax rate during 2017 also included a tax benefit of $20.8 million related to the excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the period. In 2017, after the enactment of the Tax Act, 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 related to the Tax Act. In 2017, we recorded income tax expense of $3.1 million as a result of the Tax Act, which is comprised of $1.1 million of income tax expense as a result of the re-measurement of deferred tax assets and liabilities at the new lower statutory tax rate of 21%, and a net tax expense of $2.0 million as a result of the mandatory deemed repatriation on earnings and profits of U.S.-owned foreign subsidiaries.

Liquidity and Capital Resources

Introduction

Our primary sources of cash are cash flows from operating activities, proceeds from the exercise of employee options and available borrowings under our Credit Facility (as defined above). Our primary uses of cash are to meet working capital requirements, finance capital expenditures and acquisitions along with acquisition-related incremental transaction and integration costs.

During 2019, our cash, cash equivalents and short-term investment securities decreased by $89.5 million from $382.1 million at December 31, 2018 to $292.6 million at December 31, 2019. Our cash provided by operations was offset primarily

by acquisitions, the purchases of property and equipment and cash taxes paid by us on the employees behalf related to net share settlement of their equity awards.

Future Cash Flows

Short-term

Our five-year $150 million Credit Facility provides us with fast, flexible funding for future acquisition and operational needs.

Our short-term investment portfolio is invested in corporate bonds and our primary investment goal is capital preservation.

While we can provide no assurances, we estimate that our capital expenditures in 2020 will approximate $85 million to $90 million. We anticipate making additional investments in machinery and equipment in our manufacturing operations in Costa Rica, the U.S. and Mexico to support new and existing products, in infusion devices that get placed with customers outside the U.S., and in IT to benefit world-wide operations. We expect to use our cash and cash equivalents to fund our capital purchases. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

We believe that our existing cash, cash equivalents along with funds expected to be generated from future operations will provide us with sufficient funds to finance our current operations for the next twelve months.

Long-term

Our long-term liquidity needs include capital expenditures related to the expansion and maintenance of our business and potential acquisitions in accordance with our growth strategy.

We are unable to project with certainty whether our long-term cash flow from operations and amounts available to us under our Credit Facility will be sufficient to fund our future capital expenditures and acquisitions as they arise. In the event that we experience illiquidity in our investment securities, downturns or cyclical fluctuations in our business that are more severe or longer than anticipated or if we fail to achieve anticipated revenue and expense levels, we may need to obtain or seek alternative sources of capital or financing, and we can provide no assurances that the terms of such capital or financing will be available to us on favorable terms, if at all.

Credit Facility

On November 8, 2017, we entered into a five year revolving Credit Facility with various lenders which includes $150 million in borrowing capacity available for revolving credit loans and may also be used to borrow, on same-day notice under a swingline, the lesser of $10 million and the aggregate unused amount of the revolving credit available. As of December 31, 2019, we had no borrowings and $150 million of availability under the revolving credit facility.

All of our obligations under the Credit Facility are guaranteed by ICU Medical, Inc. and certain of our existing subsidiaries. The obligations under the Credit Facility are secured by a pledge of 100% of the capital stock of certain subsidiaries owned by us and a security interest in substantially all of our tangible and intangible assets and the tangible and intangible assets of each guarantor.

The Credit Facility contains certain financial covenants pertaining to Consolidated Fixed Charge Coverage and Consolidated Total Leverage ratios, see below under "Financial Covenants". In addition, the Credit Facility has restrictions pertaining to limitations on debt, liens, negative pledges, loans, advances, acquisitions, other investments, dividends, distributions, redemptions, repurchases of equity interests, fundamental changes and asset sales and other dispositions, prepayments, redemptions and purchases of subordinated debt and other junior debt, transactions with affiliates, dividend and payment restrictions affecting subsidiaries, changes in line of business, fiscal year and accounting practices and amendment of organizational documents and junior debt documents.

Financial Covenants

The Credit Facility contains certain negative financial covenants, including, Consolidated Total Leverage and Consolidated Fixed Charge Coverage Ratios.

The Consolidated Leverage Ratio is defined as the ratio of Consolidated Total Funded Indebtedness on such date, to Consolidated Adjusted EBITDA, as defined under the Credit Facility Agreement, for the most recently completed four fiscal quarters. The maximum Consolidated Leverage Ratio is not more than 3.00 to 1.00.

The Consolidated Fixed Charge Coverage Ratio is defined as the ratio of: (a) Consolidated Adjusted EBITDA less the sum of (i) capital expenditures, (ii) federal, state, local and foreign income taxes paid in cash and (iii) cash restricted payments made after the closing date, to (b) Consolidated Fixed Charges for the most recently completed four fiscal quarters, calculated on a pro forma basis. The minimum Consolidated Fixed Charge Coverage Ratio is 2.00 to 1.00.

We were in compliance with all financial covenants as of December 31, 2019.

Historical Cash Flows

***Cash Flows from Operating Activities**:*

Our cash provided by operations was $101.9 million in 2019. Net income plus adjustments for non-cash net expenses contributed $213.6 million to cash provided by operations. Net cash used in operations as a result of changes in operating assets and liabilities was $111.6 million. The changes in operating assets and liabilities included a $43.7 million decrease in accrued liabilities, a $29.8 million increase in other assets, a $25.0 million increase in inventories, a $23.7 million increase in accounts receivable, and a $2.7 million decrease in accounts payable. Offsetting these amounts was a $8.6 million decrease in prepaid expenses and other current assets and $4.7 million in net changes in income taxes, including excess tax benefits and deferred income taxes. The decrease in accrued liabilities was primarily a result of the payout of accrued compensation, partially offset by an increase in certain accruals including $22.1 million in accrued costs related to the initial ramp down of IV Solution production. The increase in other assets was primarily related to the purchase of spare parts. The increase in inventory was primarily due to an increase in our finished goods safety stock. The increase in accounts receivable is mainly due to the current year reclassification of receivables from Pfizer and the timing of revenue and collections. In the current year, receivables from Pfizer are included in accounts receivable and not in a separate related-party receivable line item as in the prior year. As of December 31, 2018, Pfizer had sold all of its shares of our common stock thereby ending its related-party relationship with us. The decrease in accounts payable was due to the timing of payments. The decrease in prepaid expenses and other current assets was primarily due to the collection of receivable amounts owed from Pfizer. The net changes in income taxes was a result of the timing of payments.

Our cash provided by operations was $160.2 million in 2018. Net income plus adjustments for non-cash net expenses contributed $192.9 million to cash provided by operations. Net cash provided by operations as a result of changes in operating assets and liabilities was $32.7 million. The changes in operating assets and liabilities included a $76.7 million increase in accounts receivable, a $29.6 million decrease in accrued liabilities, a $21.8 million increase in inventories, a $20.0 million in net changes in income taxes, including excess tax benefits and deferred income taxes and a $9.1 million increase in other assets. Offsetting these amounts was a $97.4 million decrease in related party receivables and a $23.3 million increase in accounts payable. The increase in accounts receivable is due to the increase in revenue and timing of collections. The decrease in accrued liabilities was primarily a result of the settlement of contract liabilities. The increase in inventory was primarily due to efforts to build-up the inventory level of certain products. The net changes in income taxes was a result of the timing of payments. The increase in other assets was primarily due to the purchase of spare parts. The decrease in related-party receivables was a result of the transition services agreement with Pfizer nearing its end. The increase in accounts payable was due to the timing of payments.

Cash Flows from Investing Activities

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

	For the Years Ended December 31,			Variance		
	2019	2018	2017	2019	2018	
Investing Cash Flows:						
Purchases of property, plant and equipment	$ (97,312)	$ (92,720)	$ (74,479)	$ (4,592)	$ (18,241)	(1)
Proceeds from sale of assets	33	765	2	(732)	763	
Proceeds from the disposal of assets held-for-sale, net	—	13,000	—	(13,000)	13,000	(2)
Intangible asset additions	(8,728)	(8,059)	(5,203)	(669)	(2,856)	
Business acquisitions, net of cash acquired	(76,133)	(1,300)	(162,448)	(74,833)	161,148	(3)
Purchases of investment securities	(26,040)	(30,496)	(24,743)	4,456	(5,753)	(4)
Proceeds from sale of investment securities	41,292	15,440	—	25,852	15,440	(5)
Net cash (used in) provided by investing activities	$ (166,888)	$ (103,370)	$ (266,871)	$ (63,518)	$ 163,501	

(1) Our purchases of property, plant and equipment will vary from period to period based on additional investments needed to support new and existing products and expansion of our manufacturing facilities.

(2) In 2018, we sold the land and building related to our Dominican Republic manufacturing facilities acquired as part of the 2017 HIS acquisition.

(3) Our business acquisitions will vary from period to period based upon our current growth strategy and our ability to execute on desirable target companies. In 2019, we acquired Pursuit for approximately $75.0 million in cash consideration and we acquired a small foreign distributor for approximately $4.6 million. In 2017, we acquired HIS for $256 million in cash consideration (net of working capital adjustments), financed with existing cash balances and a three-year interest-only seller note of $75 million and we delivered 3.2 million shares of our common stock to Pfizer and we acquired two small foreign distributors for $10.5 million in cash consideration.

(4) Our purchases of investment securities will vary from period to period based on current cash needs, planning for known future transactions and due to changes in our investment strategy. In 2016, we amended our investment policy to allow for the purchase of securities with final maturities in excess of one year. If cash is not needed for known future transactions our investment strategy takes advantage of the long-term securities with higher yields. Typically, our longer term securities have maturities up to three years.

(5) Proceeds from the sale of our investment securities will vary based on the maturity dates of the investments. The proceeds from the sale of our investment securities increased in 2018, as compared to 2017, as by the end of 2016, we had liquidated all of our investment securities and used the proceeds to fund the acquisition of HIS. Accordingly, we did not have an investment balance in 2017 until purchases were made in September of that year.

Cash Flows from Financing Activities

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

	For the Years Ended December 31,			Variance		
	2019	2018	2017	2019	2018	
Financing Cash Flows:						
Repayment of long-term obligations	$ —	$ —	$ (75,000)	$ —	$ 75,000	(1)
Proceeds from exercise of stock options	7,732	14,275	32,003	(6,543)	(17,728)	(2)
Proceeds from employee stock purchase plan	—	—	2,705	—	(2,705)	
Purchase of treasury stock/tax withholding payments on net share settlement of equity awards	(18,639)	(6,252)	(4,057)	(12,387)	(2,195)	(3)
Net cash (used in) provided by financing activities	$ (10,907)	$ 8,023	$ (44,349)	$ (18,930)	$ 52,372	

(1) The repayment of long-term obligations is related to the repayment of the $75 million seller note from Pfizer.

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

(3) In 2019, our employees surrendered 80,186 shares of our common stock from vested restricted stock awards as consideration for approximately $18.6 million in minimum statutory withholding obligations paid on their behalf. In 2018, our employees surrendered 26,307 shares of our common stock from vested restricted stock awards as consideration for approximately $6.3 million in minimum statutory withholding obligations paid on their behalf. In 2017, our employees surrendered 27,636 shares of our common stock from vested restricted stock awards as consideration for approximately $4.1 million in minimum statutory withholding obligations paid on their behalf.

Our common stock purchase plan, which authorized the repurchase of up to $100.0 million of our common stock, was authorized by our Board of Directors and publicly announced in August 2019. This plan replaced our existing plan and has no expiration date. As of December 31, 2019, all of the $100.0 million available for purchase was remaining under the plan. We are currently limited on share purchases in accordance with the terms and conditions of our Credit Facility (see Note 11 to the consolidated financial statements in Part II, Item 8 of this Form 10-K).

Effects of Inflation

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

New Accounting Pronouncements

See Note 1 to the consolidated financial statements in Part II, Item 8 of this Form 10-K.

Off Balance Sheet Arrangements

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

Contractual Obligations

We have contractual obligations, at December 31, 2019, of approximately the amount set forth in the table below. This amount excludes inventory-related purchase orders for goods and services for current delivery and other open orders for purchases that support normal operations. The majority of our inventory purchase orders are blanket purchase orders that represent an estimated forecast of goods and services. We do not have a firm commitment liability on the blanket purchase orders. We have excluded from the table below pursuant to ASC 740-10-25 (formerly FIN 48), an interpretation of ASC 740-10 (formerly SFAS 109), a non-current income tax liability of $14.5 million due to the high degree of uncertainty regarding the timing of future cash outflows associated with the liabilities.

	(in thousands)						
Contractual Obligations	**Total**	**2020**	**2021**	**2022**	**2023**	**2024**	**Thereafter**
Operating leases	$ 42,748	$ 8,850	$ 7,412	$ 6,621	$ 6,204	$ 5,896	$ 7,765
Commitment fee on Credit Facility	652	229	228	195	—	—	—
Minimum purchase obligations	2,781	2,306	178	178	119	—	—
Warehouse service agreements	18,677	6,388	5,689	3,363	3,117	120	—
	$ 64,858	$ 17,773	$ 13,507	$ 10,357	$ 9,440	$ 6,016	$ 7,765

Critical Accounting Policies and Estimates

Our significant accounting policies are summarized in Note 1 to the Consolidated Financial Statements. In preparing our consolidated financial statements in accordance with GAAP and pursuant to the rules and regulations of the SEC, we make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. We base our estimates, assumptions and judgments on historical experience and other factors that we believe are reasonable. We evaluate our estimates, assumptions and judgments on a regular basis and apply our accounting policies on a consistent basis. We believe that the estimates, assumptions and judgments involved in the accounting for investment securities, revenue recognition, accounts receivable, inventories, property, plant and equipment and related depreciation, income taxes and business combinations have the most potential impact on our consolidated financial statements. Historically, our estimates, assumptions and judgments relative to our critical accounting policies have not differed materially from actual results.

Revenue recognition

We recognize revenues when we transfer control of promised goods to our customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods. We offer certain volume-based rebates to our distribution customers, which we consider variable consideration when calculating the transaction price. We also provide chargebacks to distributors that sell to end-customers at prices determined under a contract between us and the end-customer.
In estimating the most likely rebate and chargeback amounts for use in determining the transaction price, we use information available at the time and our historical experience. We also warrant products against defects and have a policy permitting the return of defective products, for which we accrue and expense at the time of sale using information available and our historical experience. Our revenues are recorded at the net sales price, which includes an estimate for variable consideration related to rebates, chargebacks and product returns.

The vast majority of our sales of Infusion Consumables, IV Solutions, Infusion Systems and Critical Care products are sold on a standalone basis and control of these products transfers to the customer upon shipment.

Our software license renewals are considered to be transferred to a customer at a point in time at the start of each renewal period, therefore revenue is recognized at that time.

Arrangements with Multiple Deliverables

In certain circumstances, we enter into arrangements in which we provide multiple deliverables to our customers. These bundled arrangements typically consist of the sale of infusion systems equipment, along with annual software licenses and related software implementation services, as well as infusion consumables, IV solutions and extended warranties.
Our most significant judgments related to these arrangements are (i) identifying the various performance obligations and (ii) estimating the relative standalone selling price of each performance obligation, typically using a directly observable method or calculated on a cost plus margin basis method. Revenue related to the bundled equipment, software and software implementation services is recognized upon implementation. The transaction price allocated to the extended service-type warranty is recognized as revenue over the period the warranty service is provided.

Accounts receivable

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

Inventories

Inventories are stated at the lower of cost (first in, first out) or net realizable value. We need to carry many components to accommodate our rapid product delivery, and if we overestimate demand or if customer requirements change, we may have components in inventory that we may not be able to use. For finished products in inventory, we need to estimate what may not be saleable. We regularly review inventory and reserve for slow moving items, and write off all items that we do not expect to

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

If our excess and obsolete reserve changed by 1% our cost of goods sold and gross margin would be impacted by $0.7 million with no impact to our gross margin percentage.

Property, plant and equipment/depreciation

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

Income Taxes

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

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

Business Combinations

The application of the acquisition method of accounting for business combinations requires the use of significant estimates, assumptions and judgments in the determination of the estimated fair value of assets acquired and liabilities assumed in order to properly allocate the purchase price at the acquisition date.

Although we believe the estimates, assumptions and judgments we have made are reasonable, they are based in part on historical experience, industry data, information obtained from the management of the acquired companies and assistance from independent third-party appraisal firms, and are inherently uncertain.

Examples of critical estimates in valuing certain of the tangible and intangible assets we have acquired, and certain liabilities assumed include but are not limited to:

- *Inventories* - we used the comparative sales method, which estimates the selling price of finished goods and work-in-progress inventory, reduced by estimated costs expected to be incurred in selling the inventory and a profit on those costs. The fair value of inventory is recognized in our statements of operations as the inventory is sold. Based on internal forecasts and estimates of inventory turnover, acquisition date inventory is sold and recognized in cost of goods sold over an estimated period of six months after the acquisition date.

- *Property, Plant and Equipment* - the fair value estimate of acquired property, plant and equipment is determined based upon the nature of the asset using either the cost approach, the sales comparison approach or the income capitalization approach. The cost approach measures the value of an asset by estimating the cost to acquire or reproduce comparable assets. The sales comparison approach measures the value of an asset through an analysis of comparable property sales. The income approach values the asset based on its earnings potential. The fair value of land was estimated

using a sales comparison approach. Land and building improvements were valued using the cost approach. Personal property assets, such as, leasehold improvements, tooling, laboratory equipment, furniture and fixtures, and equipment, computer hardware, computer software, dies and molds were all valued using the cost approach. Transportation equipment and major manufacturing and equipment were valued using the sales comparison method. Construction-in-progress assets were valued based on the cost approach less adjustments for the nature of the assets. The fair value of property, plant and equipment will be recognized in our statements of operations over the expected useful life of the individual depreciable assets.

- *Identifiable Intangible Assets* - The fair value of the significant acquired identifiable intangible assets generally is determined using varying methods under the income approach. This method starts with a forecast of all of the expected future net cash flows associated with the asset and then adjusts the forecast to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams.

- *Earn-out Liability* - The fair value of the earn-out liabilities were valued using a Monte Carlo simulation (see Note 8 to the consolidated financial statements in Part II, Item 8 of this Form 10-K for details).

Unanticipated events and circumstances may occur which may affect the accuracy or validity of such assumptions, estimates or actual results.

Forward Looking Statements

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

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

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

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

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

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

- general economic and business conditions, both in the U.S. and internationally;
- unexpected changes in our arrangements with our large customers;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increases in labor costs or competition for skilled workers;
- increases in costs or availability of the raw materials need to manufacture our products;
- the effect of price and safety considerations on the healthcare industry;
- competitive factors, such as product innovation, new technologies, marketing and distribution strength and price erosion;
- the successful development and marketing of new products;
- unanticipated market shifts and trends;
- the impact of legislation affecting government reimbursement of healthcare costs;
- changes by our major customers and independent distributors in their strategies that might affect their efforts to market our products;
- the effects of additional governmental regulations;
- unanticipated production problems; and
- the availability of patent protection and the cost of enforcing and of defending patent claims.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Exchange Risk

We have foreign currency exchange risk related to foreign-denominated cash, accounts receivable and accounts payable. In our European operations, our net Euro asset position at December 31, 2019 was approximately €48.0 million. A 10% change in the conversion of the Euro to the U.S. dollar for our cash, accounts receivable, accounts payable and accrued liabilities from the December 31, 2019 spot rate would impact our consolidated amounts on these balance sheet items by approximately $5.4 million, or 0.7% of these net assets. In our Canadian operations, our net Canadian dollar asset position at December 31, 2019 was approximately $18.8 million. A 10% change in the conversion of the Canadian dollar to the U.S. dollar for our cash, accounts receivable, accounts payable and accrued liabilities from the December 31, 2019 spot rate would impact our consolidated amounts on these balance sheet items by approximately $1.4 million, or 0.2% of these net assets. We currently do not hedge our Canadian dollar or Euro foreign currency exposures.

We have manufacturing facilities and conduct business transactions denominated in the Mexican Peso. During 2017, we began to hedge a portion of our manufacturing spend, which reduced our exposure to the foreign currency exchange risk related to the Mexican Peso (see Note 7, Derivatives and Hedging to the consolidated financial statements in Part II, Item 8 of this Form 10-K).

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SCHEDULE

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of ICU Medical, Inc.

We have audited the accompanying consolidated balance sheets of ICU Medical, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2019, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 2, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition - Chargeback Reserve- Refer to Note 1 and Note 4 to the financial statements

Critical Audit Matter Description

The Company recognizes revenue for product sales net of a reserve for estimated chargebacks. Chargebacks are the difference between prices the Company charges distribution customers and contracted prices the Company has with the end-customer which are processed as credits to the distribution customers.

Chargebacks are accounted for as variable consideration when determining the transaction price for purposes of recognizing revenue. The Company estimates and reserves for chargebacks as a reduction of revenue at the time of sale to its distribution customers using information available at that time, including customer agreements and historical experience. Accounts receivables as of December 31, 2019 of $202 million and net sales for the year ended December 31, 2019 of $1,266 million are recorded net of estimated chargebacks.

Given the subjectivity and complexity of evaluating management’s assumptions used in the determination of the chargeback reserve, including the amount of monthly sales to distribution customers and the time to settle chargeback obligations, auditing the chargeback reserve requires a high degree of auditor judgment and an increased extent of effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the chargeback reserves included the following, among others:

- We tested the effectiveness of controls related to chargeback reserves, management's assessment of assumptions related to estimating the provision for chargeback reserves, and the processing and monitoring of chargeback transactions.
- We tested chargeback estimates for purposes of determining whether net revenue recognized at the time of sale was recorded in the proper period.
- We evaluated the methods and assumptions used by management to estimate the chargeback reserve by:
    - Analyzing trends in chargeback provision as a percent of revenues and the chargeback reserve as a percent of revenues.
    - Testing the underlying data, including historical sales to distributor customers and chargeback settlements with distributor customers, that are utilized as the basis for the chargeback reserve, to test whether the inputs to the estimate were reasonable.
    - Developing an expectation of the chargeback reserve based on our evaluation of the amount of monthly sales to distribution customers and the time to settle chargeback obligations and comparing our expectation to the amount recorded by management.
    - Performing a retrospective review comparing management's estimates of the expected chargeback reserves to actual amounts incurred subsequent to management's estimates to assess management's ability to reasonably estimate these obligations and to identify potential bias in management's assessment of the reserve.

/s/ DELOITTE & TOUCHE LLP

Costa Mesa, California
March 2, 2020

We have served as the Company's auditor since 2008

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except par value data)

	December 31,	
	2019	**2018**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 268,670	$ 344,781
Short-term investment securities	23,967	37,329
TOTAL CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENT SECURITIES	292,637	382,110
Accounts receivable, net of allowance for doubtful accounts of $20,219 and $5,768 at December 31, 2019 and 2018, respectively	202,219	176,298
Inventories	337,640	311,163
Prepaid income taxes	15,720	11,348
Prepaid expenses and other current assets	33,981	46,117
TOTAL CURRENT ASSETS	882,197	927,036
PROPERTY, PLANT AND EQUIPMENT, net	456,085	432,641
OPERATING LEASE RIGHT-OF-USE ASSETS	34,465	—
LONG-TERM INVESTMENT SECURITIES	—	2,025
GOODWILL	31,245	11,195
INTANGIBLE ASSETS, net	211,408	133,421
DEFERRED INCOME TAXES	27,998	38,654
OTHER ASSETS	48,984	40,419
TOTAL ASSETS	$ 1,692,382	$ 1,585,391
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 128,629	$ 120,469
Accrued liabilities	117,776	128,820
Income tax payable	2,063	—
TOTAL CURRENT LIABILITIES	248,468	249,289
CONTINGENT EARN-OUT LIABILITY	17,300	47,400
OTHER LONG-TERM LIABILITIES	32,820	20,592
DEFERRED INCOME TAXES	2,091	721
INCOME TAX LIABILITY	14,459	3,734
COMMITMENTS AND CONTINGENCIES (Note 15)	—	—
STOCKHOLDERS' EQUITY:		
Convertible preferred stock, $1.00 par value Authorized—500 shares; Issued and outstanding— none	—	—
Common stock, $0.10 par value — Authorized—80,000 shares; Issued — 20,743 shares at December 31, 2019 and 20,492 at December 31, 2018 and outstanding — 20,742 shares at December 31, 2019 and 20,491 shares at December 31, 2018	2,074	2,049
Additional paid-in capital	668,947	657,899
Treasury stock, at cost	(157)	(95)
Retained earnings	721,782	620,747
Accumulated other comprehensive loss	(15,402)	(16,945)
TOTAL STOCKHOLDERS' EQUITY	1,377,244	1,263,655
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,692,382	$ 1,585,391

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except per share data)

	Year ended December 31,		
	2019	**2018**	**2017**
REVENUES:			
Net sales	$ 1,266,208	$ 1,400,040	$ 1,292,166
Other	—	—	447
TOTAL REVENUES	1,266,208	1,400,040	1,292,613
COST OF GOODS SOLD	794,344	830,012	866,518
GROSS PROFIT	471,864	570,028	426,095
OPERATING EXPENSES:			
Selling, general and administrative	276,982	320,002	302,169
Research and development	48,611	52,867	51,253
Restructuring, strategic transaction and integration expense	80,574	105,390	77,967
Change in fair value of contingent earn-out	(47,400)	20,400	8,000
Contract settlement	5,737	41,613	—
TOTAL OPERATING EXPENSES	364,504	540,272	439,389
INCOME (LOSS) FROM OPERATIONS	107,360	29,756	(13,294)
BARGAIN PURCHASE GAIN	—	—	70,890
INTEREST EXPENSE	(549)	(709)	(2,047)
OTHER INCOME (EXPENSE), NET	7,896	(6,673)	(4,266)
INCOME BEFORE INCOME TAXES	114,707	22,374	51,283
(PROVISION) BENEFIT FOR INCOME TAXES	(13,672)	6,419	17,361
NET INCOME	$ 101,035	$ 28,793	$ 68,644
NET INCOME PER SHARE			
Basic	$ 4.90	$ 1.41	$ 3.50
Diluted	$ 4.69	$ 1.33	$ 3.29
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	20,629	20,394	19,614
Diluted	21,545	21,601	20,858

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Amounts in thousands)

	Year ended December 31,		
	2019	**2018**	**2017**
Net income	$ 101,035	$ 28,793	$ 68,644
Other comprehensive income (loss), net of tax:			
Cash flow hedge adjustments, net of tax of $392, $317 and $224 for the years ended December 31, 2019, 2018 and 2017, respectively	1,242	1,003	(365)
Foreign currency translation adjustment, net of tax of $0 for both the years ended December 31, 2019 and 2018, and $56 for the year ended December 31, 2017	372	(3,104)	6,694
Other adjustments, net of tax of $0 for all periods	(71)	115	(16)
Other comprehensive income (loss), net of tax	1,543	(1,986)	6,313
Comprehensive income	$ 102,578	$ 26,807	$ 74,957

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Total
	Shares	Amount					
Balance, January 1, 2017	**16,338**	**$1,633**	**$ 162,828**	**$ (14)**	**$516,980**	**$ (21,272)**	**$ 660,155**
Issuance of restricted stock and exercise of stock options	676	66	27,866	4,071	—	—	32,003
Tax withholding payments related to net share settlement of equity awards	(27)	—	—	(4,057)	—	—	(4,057)
Issuance of common stock for acquisitions	3,200	320	412,819	—	—	—	413,139
Proceeds from employee stock purchase plan	23	2	2,703	—	—	—	2,705
Stock compensation	—	—	19,352	—	—	—	19,352
Other comprehensive income, net of tax	—	—	—	—	—	6,313	6,313
Net income	—	—	—	—	68,644	—	68,644
Balance, December 31, 2017	**20,210**	**2,021**	**625,568**	**—**	**585,624**	**(14,959)**	**1,198,254**
Cumulative effect of accounting change	—	—	—	—	6,330	—	6,330
Issuance of restricted stock and exercise of stock options	307	28	8,090	6,157	—	—	14,275
Tax withholding payments related to net share settlement of equity awards	(26)	—	—	(6,252)	—	—	(6,252)
Stock compensation	—	—	24,241	—	—	—	24,241
Other comprehensive loss, net of tax	—	—	—	—	—	(1,986)	(1,986)
Net income	—	—	—	—	28,793	—	28,793
Balance, December 31, 2018	**20,491**	**2,049**	**657,899**	**(95)**	**620,747**	**(16,945)**	**1,263,655**
Issuance of restricted stock and exercise of stock options	331	25	(10,870)	18,577	—	—	7,732
Tax withholding payments related to net share settlement of equity awards	(80)	—	—	(18,639)	—	—	(18,639)
Stock compensation	—	—	21,918	—	—	—	21,918
Other comprehensive income, net of tax	—	—	—	—	—	1,543	1,543
Net income	—	—	—	—	101,035	—	101,035
Balance, December 31, 2019	**20,742**	**$2,074**	**$ 668,947**	**$ (157)**	**$721,782**	**$ (15,402)**	**$1,377,244**

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year ended December 31,		
	2019	**2018**	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 101,035	$ 28,793	$ 68,644
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	76,916	74,735	66,569
Amortization of right-of-use assets	8,294	—	—
Provision for doubtful accounts	14,882	781	2,308
Provision for warranty and returns	(134)	5,353	845
Stock compensation	21,918	24,241	19,352
Loss on disposal or write-off of property, plant and equipment	12,872	8,867	3,778
Contract settlement	—	12,696	—
Write-off of acquired intangibles	—	5,000	—
Bond premium amortization	135	342	103
Debt issuance cost amortization	288	288	48
Impairment of assets held-for-sale	—	269	—
Bargain purchase gain	—	—	(70,890)
Change in fair value of contingent earn-out	(47,400)	20,400	8,000
Usage of spare parts	24,301	7,310	4,820
Other	447	3,856	(220)
Changes in operating assets and liabilities, net of amounts acquired:			
Accounts receivable	(23,684)	(76,742)	(54,533)
Inventories	(24,997)	(21,770)	181,699
Prepaid expenses and other assets	8,588	3,719	(29,652)
Related-party receivables	—	97,443	(95,309)
Other assets	(29,837)	(9,086)	(6,975)
Accounts payable	(2,697)	23,270	46,648
Accrued liabilities	(43,689)	(29,553)	33,813
Income taxes, including excess tax benefits and deferred income taxes	4,680	(19,997)	(24,625)
Net cash provided by operating activities	101,918	160,215	154,423
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(97,312)	(92,720)	(74,479)
Proceeds from sale of assets	33	765	2
Proceeds from the disposal of assets held-for-sale, net	—	13,000	—
Intangible asset additions	(8,728)	(8,059)	(5,203)
Business acquisitions, net of cash acquired	(76,133)	(1,300)	(162,448)
Purchases of investment securities	(26,040)	(30,496)	(24,743)
Proceeds from sale of investment securities	41,292	15,440	—
Net cash used in investing activities	(166,888)	(103,370)	(266,871)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Repayment of long-term obligations	—	—	(75,000)
Proceeds from exercise of stock options	7,732	14,275	32,003
Proceeds from employee stock purchase plan	—	—	2,705
Purchase of treasury stock/tax withholding payments on net share settlement of equity awards	(18,639)	(6,252)	(4,057)
Net cash (used in) provided by financing activities	(10,907)	8,023	(44,349)
Effect of exchange rate changes on cash	(234)	(10,159)	1,787
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(76,111)	54,709	(155,010)
CASH AND CASH EQUIVALENTS, beginning of period	344,781	290,072	445,082
CASH AND CASH EQUIVALENTS, end of period	$ 268,670	$ 344,781	$ 290,072

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

ICU MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS - CONTINUED
(Amounts in thousands)

	Year ended December 31,		
	2019	**2018**	**2017**
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the year for income taxes	$ 9,675	$ 12,598	$ 5,109
Cash paid during the year for interest	$ 549	$ 709	$ 2,047
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Accounts payable for property, plant and equipment	$ 13,912	$ 26,522	$ 5,376
Detail of assets acquired and liabilities assumed in acquisitions:			
Fair value of assets acquired	$ 91,019		$ 886,569
Cash paid for acquisitions, net of cash acquired	(76,133)		(162,448)
Non-cash seller note			(75,000)
Estimated working capital adjustment	—		4,253
Contingent consideration	(17,300)		(19,000)
Issuance of common stock for acquisitions	—		(413,139)
Bargain purchase gain	—		(70,890)
Goodwill, acquired during period	20,026		6,536
Liabilities assumed/Adjustments to liabilities assumed	$ (17,612)		$ (156,881)

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

NOTE 1. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Preparation

ICU Medical, Inc. ("ICU" or "we"), a Delaware corporation, operates in one business segment engaged in the development, manufacturing and sale of innovative medical devices used in vascular therapy, and critical care applications. We are one of the world's leading pure-play infusion therapy companies with a wide-ranging product portfolio that includes IV solutions, IV smart pumps with pain management and safety software technology, dedicated and non-dedicated IV sets and needlefree connectors designed to help meet clinical, safety and workflow goals. We sell the majority of our products through our direct sales force and through independent distributors throughout the U. S. and internationally. Additionally, we sell our products on an original equipment manufacturer basis to other medical device manufacturers. The manufacturing for all product groups occurs in Salt Lake City, Utah, Austin, Texas, Mexico and Costa Rica.

All subsidiaries are wholly owned and are included in the consolidated financial statements. All intercompany accounts and transactions have been eliminated. Results of operations of companies purchased are included from the dates of acquisition.

The consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation. These consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Preparing financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Certain reclassifications have been made to prior year financial statements to conform to classifications used in the current year. These reclassifications had no impact on net income, stockholders' equity or cash flows as previously reported. For the years ended December 31, 2018 and 2017, we reported foreign exchange gains and losses in other income (expense), net, and removed them from selling, general and administrative expenses. We reclassified related-party receivables to prepaid expenses and other current assets for the current year's presentation, as Pfizer, Inc. ("Pfizer") had sold all of its shares of our ICU common stock as of December 31, 2018, thereby ending its related-party relationship with us. For the year ended December 31, 2018, we reclassified operating cash flows due to the purchase and usage of spare parts. The operating cash flows due to the usage of spare parts are included as an adjustment to reconcile net income to net cash provided by operating activities and the purchase of spare parts are presented as cash outflows in operating assets and liabilities-other assets.

Cash, Cash Equivalents

Cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and have original maturities of three months or less from the date of purchase as cash equivalents.

Accounts Receivable

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

Inventories

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

Inventories consist of the following at December 31 (in thousands):

	2019	2018
Raw materials	$ 119,709	$ 104,104
Work in process	39,515	52,909
Finished goods	178,416	154,150
Total	$ 337,640	$ 311,163

Property, Plant and Equipment

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

	2019	2018
Machinery and equipment	$ 219,057	$ 203,431
Land, building and building improvements	230,454	212,283
Molds	60,155	59,700
Computer equipment and software	83,217	80,420
Furniture and fixtures	7,498	7,409
Instruments placed with customers[1]	74,434	60,757
Construction in progress	101,425	70,864
Total property, plant and equipment, cost	776,240	694,864
Accumulated depreciation	(320,155)	(262,223)
Net property, plant and equipment	$ 456,085	$ 432,641

[1]Instruments placed with customers consist of drug-delivery and monitoring systems placed with customer under operating leases.

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

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

We capitalize expenditures that materially increase the life of the related assets; maintenance and repairs are expensed as incurred. The costs and related accumulated depreciation applicable to property, plant and equipment sold or retired are removed from the accounts and any gain or loss is reflected in the statements of operations at the time of disposal. Depreciation expense was $59.3 million, $58.1 million and $51.6 million in the years ended December 31, 2019, 2018 and 2017, respectively.

Goodwill

We test goodwill for impairment on an annual basis in the month of November. If the carrying amount of goodwill exceeds the implied estimated fair value, an impairment charge to current operations is recorded to reduce the carrying value to the implied estimated fair value. There were no accumulated impairment losses as of December 31, 2019, 2018 and 2017.

The following table presents the changes in the carrying amount of our goodwill for 2019, 2018 and 2017 (in thousands):

	Total
Balance as of January 1, 2017	$ 5,577
Goodwill acquired[1]	6,536
Other	244
Balance as of December 31, 2017	12,357
Goodwill acquired[2]	1,300
Other[3]	(2,462)
Balance as of December 31, 2018	11,195
Goodwill acquired[4]	20,026
Other	24
Balance as of December 31, 2019	$ 31,245

[1] In 2017, the goodwill acquired primarily relates to our acquisition of Medical Australia Limited ("MLA").

[2] In 2018, we acquired the consulting arm of a small software company, which resulted in $1.3 million of goodwill.

[3] In 2018, "Other" relates to a $1.9 million measurement period adjustment on our MLA acquisition and foreign currency translation.

[4] In 2019, we acquired Pursuit Vascular, Inc. ("Pursuit"), which resulted in $19.1 million of goodwill. We also acquired a small foreign distributor, which resulted in $0.9 million of goodwill.

Intangible Assets

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

	Weighted Average Amortization Life in Years	December 31, 2019		
		Cost	Accumulated Amortization	Net
Patents	10	$ 22,322	$ 13,519	$ 8,803
Customer contracts	12	10,122	5,506	4,616
Non-contractual customer relationships	9	57,296	19,787	37,509
Trademarks	4	425	425	—
Trade name	15	18,256	2,254	16,002
Developed technology	13	152,354	24,228	128,126
Non-compete	3	2,500	139	2,361
Total amortized intangible assets		$ 263,275	$ 65,858	$ 197,417
Internally developed software*		$ 13,991		$ 13,991
Total intangible assets		$ 277,266	$ 65,858	$ 211,408

* Internally developed software will be amortized when the projects are complete and the assets are ready for their intended use.

	Weighted Average Amortization Life in Years	December 31, 2018		
		Cost	Accumulated Amortization	Net
Patents	10	$ 19,399	$ 12,147	$ 7,252
Customer contracts	9	5,319	5,272	47
Non-contractual customer relationships	9	57,916	13,363	44,553
Trademarks	4	425	425	—
Trade name	15	7,456	1,618	5,838
Developed technology	11	82,857	15,361	67,496
Total		$ 173,372	$ 48,186	$ 125,186
Internally developed software*		$ 8,235		$ 8,235
Total intangible assets		$ 181,607	$ 48,186	$ 133,421

* Internally developed software will be amortized when the projects are complete and the assets are ready for their intended use.

Amortization expense in 2019, 2018 and 2017 was $17.7 million, $16.6 million and $15.0 million, respectively.

As of December 31, 2019 estimated annual amortization for our intangible assets for each of the next five years is approximately (in thousands):

2020	$ 21,692
2021	22,587
2022	22,303
2023	21,461
2024	21,371
Thereafter	88,003
Total	$ 197,417

Our intangible assets that are not subject to amortization are reviewed annually for impairment or more often if there are indications of possible impairment. We perform our annual intangible assets impairment test in November of each year.

Long-Lived Assets

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

Investment Securities

Short-term investments, exclusive of cash equivalents, are marketable securities intended to be sold within one year and may include trading securities, available-for-sale securities, and held-to-maturity securities (if maturing within one year at the time of acquisition). Long-term investments are marketable securities intended to be sold after one year and may include trading securities, available-for-sale securities, and held-to-maturity securities.

Our investment securities are considered available-for-sale and are “investment grade” and carried at fair value. Our investments currently consist of corporate bonds. Available-for-sale securities are recorded at fair value, and unrealized holding gains and losses are recorded, net of tax, as a component of accumulated other comprehensive income (loss). Unrealized losses on available-for-sale securities are charged against net earnings when a decline in fair value is determined to be other than temporary. Our management reviews several factors to determine whether a loss is other than temporary, such as the length and extent of the fair value decline, the financial condition and near term prospects of the issuer, and for equity investments, our intent and ability to hold the security for a period of time sufficient to allow for any anticipated recovery in fair value. For debt securities, management also evaluates whether we have the intent to sell or will likely be required to sell before its anticipated recovery. Realized gains and losses are accounted for on the specific identification method. There have been no realized gains or losses on the disposal of investments. Our investments mature in 2020. All short-term investment securities are all callable within one year.

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

	December 31, 2019		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term corporate bonds	23,967	$ —	$ 23,967
Long-term corporate bonds	—	—	—
Total investment securities	$ 23,967	$ —	$ 23,967

	December 31, 2018		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term corporate bonds	$ 37,329	$ —	$ 37,329
Long-term corporate bonds	2,025	—	2,025
Total investment securities	$ 39,354	$ —	$ 39,354

Income Taxes

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

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

Foreign Currency

Generally, the functional currency of our international subsidiaries is the local currency. Generally, we translate the financial statements of these subsidiaries to U.S. dollars at the exchange rate in effect at the balance sheet date and revenues and expenses are translated at the average monthly exchange rates during the year. Certain of our international subsidiaries consolidate first with another subsidiary that utilizes a functional currency other than U.S. dollars. In those cases, we follow a step by step translation process utilizing the same sequence as the consolidation process. Translation adjustments are recorded as a component of accumulated other comprehensive income (loss), a separate component of stockholders' equity on our consolidated balance sheets and the effect of exchange rate changes on cash and cash equivalents are reflected on our consolidated statements of cash flows. Gains and losses for transactions denominated in a currency other than the functional currency of the entity are included in our statements of operations in other income (expense), net. Foreign currency transaction (gains) losses, net were $(0.7) million in 2019, $7.9 million in 2018 and $1.8 million in 2017.

Revenue Recognition

We recognize revenues when we transfer control of promised goods to our customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods. We offer certain volume-based rebates to our distribution customers, which we consider variable consideration when calculating the transaction price. We also provide chargebacks to distributors that sell to end-customers at prices determined under a contract between us and the end-customer.
Chargebacks are the difference between prices we charge our distribution customers and contracted prices we have with the end customer which are processed as credits to our distribution customers. In estimating the most likely rebate and chargeback amounts for use in determining the transaction price, we use information available at the time and our historical experience. We also warrant products against defects and have a policy permitting the return of defective products, for which we accrue and expense at the time of sale using information available and our historical experience. Our revenues are recorded at the net sales price, which includes an estimate for variable consideration related to rebates, chargebacks and product returns.

The vast majority of our sales of Infusion Consumables, Infusion Systems, IV Solutions and Critical Care products are sold on a standalone basis and control of these products transfers to the customer upon shipment.

Our software license renewals are considered to be transferred to a customer at a point in time at the start of each renewal period, therefore revenue is recognized at that time.

Arrangements with Multiple Deliverables

In certain circumstances, we enter into arrangements in which we provide multiple deliverables to our customers. These bundled arrangements typically consist of the sale of infusion systems equipment, along with annual software licenses and related software implementation services, as well as infusion consumables, IV solutions and extended warranties.
Our most significant judgments related to these arrangements are (i) identifying the various performance obligations and (ii) estimating the relative standalone selling price of each performance obligation, typically using a directly observable method or calculated on a cost plus margin basis method. Revenue related to the bundled equipment, software and software implementation services are typically combined into a single performance obligation and recognized upon implementation. As annual software licenses are renewed, we recognize revenue for the license at a point in time, at the start of each annual renewal period. The transaction price allocated to the extended service-type warranty is recognized as revenue over the period the warranty service is provided. Consumables and solutions are separate performance obligations, recognized at a point in time.

Shipping Costs

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

Advertising Expenses

Advertising expenses are expensed as incurred and reflected in selling, general and administrative expenses in our consolidated statements of operations and were $0.1 million in 2019, $0.6 million in 2018 and $0.2 million in 2017.

Post-retirement and Post-employment Benefits

We sponsor a Section 401(k) retirement plan ("plan") for employees. Our contributions to our 401(k) plan were approximately $11.4 million in 2019, $11.4 million in 2018 and $10.3 million in 2017. As a result of the Hospira Infusion Systems ("HIS") acquisition, we assumed certain post-retirement and post-employment obligations related to employees located in certain international countries. These obligations are immaterial to our financial statements taken as a whole.

Research and Development

The majority of our research and development costs are expensed as incurred. In certain circumstances when an asset will have an alternative future use we capitalize the costs related to those assets. Research and development costs include salaries and related benefits, consulting fees, production supplies, samples, travel costs, utilities and other miscellaneous administrative costs.

Net Income Per Share

Net income per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted net income per share is computed by dividing net income by the weighted average number of common shares outstanding plus dilutive securities. Dilutive securities include outstanding common stock options and unvested restricted stock units, less the number of shares that could have been purchased with the proceeds from the exercise of the options, using the treasury stock method. Options that are anti-dilutive, where their exercise price exceeds the average market price of the common stock are not included in the treasury stock method calculation. There were 10,760, 5,300 and 337 anti-dilutive shares in 2019, 2018 and 2017, respectively.

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

	Year ended December 31, (in thousands, except per share data)		
	2019	2018	2017
Net income	$ 101,035	$ 28,793	$ 68,644
Weighted average number of common shares outstanding (basic)	20,629	20,394	19,614
Dilutive securities	916	1,207	1,244
Weighted average common and common equivalent shares outstanding (diluted)	21,545	21,601	20,858
EPS - basic	$ 4.90	$ 1.41	$ 3.50
EPS - diluted	$ 4.69	$ 1.33	$ 3.29

New Accounting Pronouncements

Recently Adopted Accounting Standards

In February 2016, the FASB issued Accounting Standard Update ("ASU") No. 2016-02, Leases (Topic 842). The amendments in this update require an entity to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Recognition, measurement and presentation of expenses will depend on classification as finance or operating lease. The amendments also require certain quantitative and qualitative disclosures about leasing arrangements. The updated guidance required a modified retrospective adoption. In July 2018, the FASB issued ASU No. 2018-11, Targeted Improvements. The amendments in this update provide entities with an additional (and optional) transition method to adopt the new lease requirements by allowing entities to initially apply the requirements by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The amendments in this update also provided lessors with a practical expedient, by class of underlying asset, to not separate nonlease components from the associated lease contract. This expedient is limited to circumstances in which the nonlease components otherwise would be accounted for under the new revenue guidance and both (1) the timing and pattern of transfer are the same for the nonlease components and associated lease component and (2) the lease component, if accounted for separately, would be classified as an operating lease. If the lessor uses this practical expedient they would account for the lease contract in accordance with Topic 606 if the nonlease component is the predominant component otherwise, the lessor should account for the combined component as an operating lease in accordance with Topic 842. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases. This ASU clarifies certain language in ASU 2016-02 and corrects certain references and inconsistencies. We adopted these standards effective January 1, 2019 (see Note 5, Leases for a discussion of the impact and required disclosures).

In January 2017, the FASB issued ASU No. 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The amendments in this update remove the second step of the impairment test. An entity will apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The new guidance does not amend the optional qualitative assessment of goodwill impairment. The amendments in ASU 2017-04 are effective for the annual or interim impairment test in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We early adopted this ASU effective April

1, 2019, which had no impact on our consolidated financial statements or related footnote disclosures. We adopted this ASU early ahead of our annual impairment test to reduce the complexity of the quantitative test if necessary.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal use software license. Costs to develop or obtain internal-use software that cannot be capitalized under subtopic 350-40, such as training costs and certain data conversion costs, also cannot be capitalized for a hosting arrangement that is a service contract. Therefore, an entity in a hosting arrangement that is a service contract determines which project stage (that is, preliminary project stage, application development stage, or post-implementation stage) an implementation activity relates to. Costs for implementation activities in the application development stage are capitalized depending on the nature of the costs, while costs incurred during the preliminary project and post-implementation stages are expensed as the activities are performed. The amendments in this update require the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The amendments in this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. We adopted this ASU effective January 1, 2020. This ASU will not have a material impact on our consolidated financial statements or related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this update modify the disclosure requirements in Topic 820. The amendments remove from disclosure: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels 3; and the valuation processes for Level 3 fair value measurements. The amendments also made the following disclosure modifications: for investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee’s assets and the date when restrictions from redemption might lapse only if the investee has communicated the timing to the entity or announced the timing publicly; and the amendments clarify that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date. The amendments also added the following disclosure requirements: the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period; and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information (such as the median or arithmetic average) in lieu of the weighted average if the entity determines that other quantitative information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements. The amendments in ASU 2018-02 are effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. We adopted this ASU effective January 1, 2020. This ASU will not have a material impact on our consolidated financial statements or related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This update amends the FASB's guidance on the impairment of financial instruments by requiring timelier recording of credit losses on loans and other financial instruments. The ASU adds an impairment model that is based on expected losses rather than incurred losses. The ASU also amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. The amendments in this update will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted as of the fiscal years beginning after December 15, 2018. The updated guidance requires a modified retrospective adoption. In November 2018, the FASB issued ASU No. 2018-19, Codification Improvements to Topic 326, Financial Instruments-Credit Losses. This update clarifies that receivables arising from operating leases are not within the scope of this guidance, instead, impairment of receivables arising from operating leases should be accounted for in accordance with the lease guidance. In November 2019, the FASB issued ASU No. 2019-11, Codification Improvements to Topic 326, Financial Instruments-Credit Losses. We adopted these ASUs effective January 1, 2020. These ASUs will not have a material impact on our consolidated financial statements or related disclosures.

NOTE 2. ACQUISITIONS

2019 Acquisitions

On November 2, 2019, we acquired 100% interest in Pursuit for cash consideration of approximately $75.0 million. Additionally, Pursuit's equity holders are potentially entitled up to $50.0 million in additional cash consideration contingent upon the achievement of certain sales and gross profit targets for specific customers. The earn-out paid will be calculated as a percentage of gross profit achieved during the earn-out period against a pre-determined target gross profit. However, the earn-out is not to exceed $50.0 million. The acquisition of Pursuit and their ClearGuard HD is a natural extension of our needlefree IV connector and other infection control technologies, which together provides us the best of breed solutions.

Preliminary Purchase Price

The following table summarizes the preliminary purchase price and the preliminary allocation of the purchase price related to the assets and liabilities purchased (in thousands):

Cash consideration for acquired assets, net	$	71,533
Fair value of contingent consideration		17,300
Total Estimated Consideration	$	88,833

Preliminary Purchase Price Allocation:		
Trade receivables	$	973
Inventories		2,464
Prepaid expenses and other current assets		74
Property, plant and equipment		609
Intangible assets[(1)]		82,300
Accounts payable		(215)
Accrued liabilities		(2,065)
Total identifiable net assets acquired	$	84,140
Goodwill - not tax deductible		19,116
Deferred tax liability		(14,423)
Estimated Purchase Consideration	$	88,833

[(1)] Identifiable intangible assets includes $69.0 million of developed technology, $10.8 million of trade name and $2.5 million of non-compete agreement. The weighted amortization period for the total identifiable intangible assets is approximately fifteen years for developed technology, and trade name the weighted amortization period is fifteen years, and for the non-compete agreement the weighted amortization period is three years.

The identifiable intangible assets acquired have been valued as Level 3 assets at fair market value. The estimated fair value of identifiable intangible assets were developed using the income approach and are based on critical estimates, judgments and assumptions derived from: analysis of market conditions; discount rate; discounted cash flows; royalty rates; and estimated useful lives. Fixed assets were valued with the consideration of remaining economic lives. The raw materials inventory was valued at historical cost and adjusted for any obsolescence and finished goods inventory was valued at estimated sales proceeds less a nominal profit and costs to sell. The trade receivables, prepaid expenses and other current assets and assumed liabilities were recorded at their carrying values as of the date of the acquisition, as their carrying values approximated their fair values due to their short-term nature.

The above purchase price and purchase price allocation are preliminary and subject to finalization.

During 2019, we also acquired a small foreign distributor for approximately $4.6 million in cash.

Significant 2017 Acquisitions

On February 3, 2017, we acquired 100% interest in Pfizer's HIS business for total cash consideration of approximately $260.0 million (net of estimated working capital adjustments paid at closing), which was financed with existing cash balances and a $75 million three-year interest-only seller note. We also issued 3.2 million shares of our common stock. The fair value of the common shares issued to Pfizer was determined based on the closing price of our common shares on the closing 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 from the closing date. Additionally, Pfizer was 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 ("Earnout Period"). The Earn-out Period ended on December 31, 2019 and we did not meet the required performance targets in order to pay any of the earn-out. The initial fair value of the earn-out was determined by employing a Monte Carlo simulation in a risk neutral framework. The underlying simulated variable was adjusted EBITDA. The adjusted EBITDA volatility estimate was based on a study of historical asset volatility for a set of comparable public companies. The model includes other assumptions including the market price of risk, which was calculated as the weighted average cost of capital ("WACC") less the long term risk free rate. The acquisition of the HIS business, which includes IV pumps, solutions and consumable devices complements our pre-existing business by creating a company that has a complete infusion therapy product portfolio. We believe that the acquisition significantly enhances our global footprint and platform for continued competitiveness and growth.

With the acquisition of HIS, pre-existing long-term supply and distribution contracts between ICU and HIS were effectively terminated.

Deferred Closings

In the Asset Purchase Agreement between us and Pfizer, we agreed to defer the local closing of the HIS business in certain foreign jurisdictions (the “Deferred Closing Businesses”) for periods ranging by jurisdiction from 3 to 12 months after the February 3, 2017 closing date (the "Deferred Closing Period"). The net assets in these jurisdictions represent an immaterial portion of the total HIS business net assets.

At the February 3, 2017 HIS business transaction closing, we entered into a Net Economic Benefit Agreement with Pfizer under which we agreed that (i) during the Deferred Closing Period, the economic benefits and burdens of the Deferred Closing Businesses are for our account, and we are to be treated as the beneficial owner of the Deferred Closing Businesses and (ii) Pfizer would continue to operate the Deferred Closing Businesses under our direction.

All of the deferred closing businesses were effectively closed in 2017.

Purchase Price

The following table summarizes the final purchase price and the final allocation of the purchase price related to the assets and liabilities purchased (in thousands, except per share data):

Cash consideration for acquired assets	$	180,785
Fair value of Seller Note		75,000
Fair value of contingent consideration payable to Pfizer (long-term)		19,000
Issuance of ICU Medical, Inc. common shares:		
Number of shares issued to Pfizer		3,200
Price per share (ICU's trading closing share price on the Closing Date)	$	140.75
Market price of ICU shares issued to Pfizer	$	450,400
Less: Discount due to lack of marketability of 8.3%		(37,261)
Equity portion of purchase price		413,139
Total Consideration	$	687,924
Purchase Price Allocation:		
Cash and cash equivalents	$	31,082
Trade receivables		362
Inventories		417,622
Prepaid expenses and other assets		13,911
Property, plant and equipment		288,134
Intangible assets[(1)]		131,000
Other assets		29,270
Accounts payable		(12,381)
Accrued liabilities		(47,936)
Long-term liabilities[(2)]		(67,170)
Total identifiable net assets acquired	$	783,894
Deferred tax, net		(25,080)
Estimated Gain on Bargain Purchase		(70,890)
Estimated Purchase Consideration	$	687,924

[(1)] Identifiable intangible assets includes $48 million of customer relationships, $44 million of developed technology - pumps and dedicated sets, $34 million of developed technology - consumables, and $5 million of in-process research and development ("IPR&D"). The weighted amortization period for the total identifiable assets is approximately nine years, for customer relationships the weighted amortization period is eight years, for the developed technology - pumps and dedicated sets the weighted amortization period is ten years and for the developed technology - consumables the weighted amortization period is twelve years. The IPR&D is non-amortizing until the associated research and development efforts are complete.

[(2)] Long-term liabilities primarily consisted of contract liabilities, product liabilities and long-term employee benefits.

The fair value of the assets acquired and liabilities assumed exceeded the fair value of the consideration to be paid resulting in a bargain purchase gain. Before recognizing a gain on a bargain purchase, we reassessed the methods used in the purchase accounting and verified that we had identified all of the assets acquired and all of the liabilities assumed, and that there were no additional assets or liabilities to be considered. We also reevaluated the fair value of the contingent consideration transferred to determine that it was appropriate. 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. After the continuing review of the product demand and operations of the HIS Business, including the resulting expected restructuring activities, we forecasted our estimated Adjusted EBITDA from the HIS business in 2017 to be $35 million - $40 million, which was considerably lower than the forecast contemplated in initial negotiations with Pfizer, which resulted in an estimated fair value of $19 million related to the $225 million earn out. The bargain purchase gain is separately stated below income from operations in the accompanying consolidated statements of operations for the year ended December 31, 2017.

The identifiable intangible assets and other long-lived assets acquired have been valued as Level 3 assets at fair market value. The estimated fair value of identifiable intangible assets were developed using the income approach and are based on critical estimates, judgments and assumptions derived from: analysis of market conditions; discount rate; discounted cash flows; royalty rates; customer retention rates; and estimated useful lives. Fixed assets were valued with the consideration of remaining economic lives. The raw materials inventory was valued at historical cost and adjusted for any obsolescence, the work in process was valued at estimated sales proceeds less costs to complete and costs to sell, and finished goods inventory was valued at estimated sales proceeds less a nominal profit and costs to sell. The prepaid expenses and other current assets and assumed liabilities were recorded at their carrying values as of the date of the acquisition, as their carrying values approximated their fair values due to their short-term nature.

Unaudited Pro Forma Information

The pro forma financial information in the table below summarizes the combined results of operations for ICU and HIS as though the companies were combined as of the beginning of fiscal 2016. The pro forma financial information includes the business combination accounting effects resulting from this acquisition including our amortization charges from acquired intangible assets, nonrecurring expense related to the fair value adjustment to acquisition-date inventory, acquisition and integration-related costs, interest expense on the Pfizer seller note and the related tax effects.

(In millions)	Revenue	Earnings
Actual from 2/3/2017 - 12/31/2017[3]	$ 1,062	*
2017 supplemental pro forma from 1/1/2017 - 12/31/2017[1][2]	$ 1,373	$ 91

* Impracticable to calculate.
[1] 2017 supplemental pro forma earnings were adjusted to exclude $66.3 million of nonrecurring expense related to the fair value adjustment to acquisition-date inventory, $59.2 million of acquisition and integration-related costs and $70.9 million in bargain purchase gain.
[2] Unaudited.
[3] Amount represents activity of HIS from the date of the acquisition.

NOTE 3. RESTRUCTURING, STRATEGIC TRANSACTION AND INTEGRATION

Restructuring and strategic transaction and integration expenses were $80.6 million, $105.4 million and $78.0 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Restructuring

Restructuring charges were $8.4 million, $4.5 million and $18.8 million for the years ended December 31, 2019, 2018 and 2017, respectively, and are included in the above restructuring, strategic transaction and integration amounts on a separate line item in our consolidated statement of operations.

During the year ended December 31, 2019, restructuring charges were primarily related to severance and facility closure costs. These charges were primarily related to a one-time charge to move our U.S. pump service depot to our existing Salt Lake City facility and other plant restructuring. The cumulative amount incurred to date in connection with the HIS acquisition is $25.1 million.

In 2018 and 2017, we incurred restructuring charges related to the acquisition of the HIS business (see Note 2, Acquisitions). The restructuring charges were incurred as a result of integrating the acquired operations into our business and include severance costs related to involuntary employee terminations and facility exit costs related to the closure of the Dominican Republic manufacturing facilities acquired from Pfizer.

In 2015, we incurred restructuring charges related to an agreement with Dr. Lopez, a member of our Board of Directors and a former employee in our research and development department, pursuant to which we bought out Dr. Lopez's right to employment under his then-existing employment agreement, the buy-out, including payroll taxes, will be paid in equal monthly installments until December 2020. The remaining payments owed are included in accrued liabilities in our consolidated balance sheet.

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

	Accrued Balance January 1, 2018	Charges incurred	Payments	Other Adjustments	Accrued Balance December 31, 2018	Charges incurred	Payments	Other Adjustments	Accrued Balance December 31, 2019
Severance pay and benefits	$ 915	$ 4,311	$ (4,549)	$ —	$ 677	$ 5,634	$ (2,433)	$ —	$ 3,878
Employment agreement buyout	1,114	—	(368)	(7)	739	—	(279)	—	460
Retention and facility closure expenses	—	160	(160)	—	—	2,741	(1,530)	—	1,211
	$ 2,029	$ 4,471	$ (5,077)	$ (7)	$ 1,416	$ 8,375	$ (4,242)	$ —	$ 5,549

Strategic Transaction and Integration Expenses

During the years ended December 31, 2019, 2018 and 2017, we incurred $72.2 million, $100.9 million and $59.2 million, respectively, in transaction and integration costs. These costs were primarily related to the acquisition and integration of HIS business, (see Note 2, Acquisitions). The integration expenses for the year ended December 31, 2019, included a one-time strategic supply chain restructuring charge of $22.1 million, which reduces our contracted commitments to our third party manufacturer and charges related to our Pfizer separation costs, which included a $12.7 million non-cash write-off of related assets.

NOTE 4: REVENUE

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

We adopted ASU No. 2014-09, Revenue from Contracts with Customers (ASC Topic 606), effective January 1, 2018 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for reporting beginning after January 1, 2018 are presented under ASC Topic 606, while prior period amounts are not adjusted and will continue to be reported in accordance with our historic accounting under ASC Topic 605, Revenue Recognition.

Due to the cumulative impact, net of tax, of adopting ASC Topic 606, we recorded a net increase of $6.3 million to opening retained earnings as of January 1, 2018. The impact is primarily related to our bundled arrangements where we sell software licenses and implementation services, in addition to equipment, consumables and solutions. Under ASC Topic 605, revenue for the equipment was recognized upon delivery and software licenses and implementation services were typically recognized over the contract term. Under ASC Topic 606, revenue for the bundled equipment, software and software implementation services are recognized upon implementation. This results in an acceleration of software related revenue, offset by a delay in the recognition of related revenue of the equipment. Under ASC Topic 605, consumables and solutions revenues were typically recognized upon delivery. Under ASC 606, consumables and solutions revenues are recognized as the customer obtains control of the asset, which is at shipping point. This results in an acceleration in the recognition of consumables and solutions revenue.

Additionally, the timing of revenue recognition for software license renewals changed under ASC Topic 606. Under ASC Topic 605, revenue related to software renewals was recognized on a ratable basis over the license period. Under ASC

Topic 606, the license, which is considered functional IP, is considered to be transferred to the customer at a point in time, specifically, at the start of each annual renewal period. As a result, under ASC Topic 606, revenue related to our annual software license renewals is accelerated when compared to ASC Topic 605.

Revenue Recognition

Our primary product lines are Infusion Consumables, Infusion Systems, IV Solutions and Critical Care. The vast majority of our sales of these products are made on a stand-alone basis to hospitals and distributors. Revenue is typically recognized upon transfer of control of the products, which we deem to be at point of shipment.

Payment is typically due in full within 30 days of delivery or the start of the contract term. Revenue is recorded in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We offer certain volume-based rebates to our distribution customers, which we record as variable consideration when calculating the transaction price. Rebates are offered on both a fixed and tiered/variable basis. In both cases, we use information available at the time and our historical experience with each customer to estimate the most likely rebate amount. We also provide chargebacks to distributors that sell to end-customers at prices determined under a contract between us and the end-customer. We use information available at the time and our historical experience to estimate and record provisions for chargebacks.

We also warrant products against defects and have a policy permitting the return of defective products, for which we accrue and expense at the time of sale using information available at that time and our historical experience. We also provide for extended service-type warranties, which we consider to be separate performance obligations. We allocate a portion of the transaction price to the extended service-type warranty based on its estimated relative selling price, and recognize revenue over the period the warranty service is provided. Our revenues are recorded at the net sales price, which includes an estimate for variable consideration related to rebates, chargebacks and product returns.

Arrangements with Multiple Performance Obligations

We also enter into arrangements which include multiple performance obligations, see Note 1, Basis of Presentation and Summary of Significant Accounting Policies.

The most significant judgments related to these arrangements include:

- Identifying the various performance obligations of these arrangements.
- Estimating the relative standalone selling price of each performance obligation, typically using directly observable method or calculated on a cost plus margin basis method.

Revenue disaggregated

The following table represents our revenues disaggregated by product line (in thousands) and our disaggregated product line revenue as a percentage of total revenue:

	For the year ended December 31,					
	2019		2018		2017	
Product line	Revenue	% of Revenue	Revenue	% of Revenue	Revenue	% of Revenue
Infusion Consumables	$ 477,611	37%	$ 483,039	35%	$ 365,665	28%
Infusion Systems	328,282	26%	355,484	25%	290,207	23%
IV Solutions	414,971	33%	507,985	36%	521,963	40%
Critical Care	45,344	4%	53,532	4%	49,961	4%
Other	—	—%	—	—%	64,817	5%
Total Revenues	$ 1,266,208	100%	$ 1,400,040	100%	$ 1,292,613	100%

We report revenue on a "where sold" basis, which reflects the revenue within the country or region in which the ultimate sale is made to our external customer.

The following table represents our revenues disaggregated by geography (in thousands):

	For the year ended December 31,		
Geography	**2019**	**2018**	**2017**
Europe, the Middle East and Africa	$ 130,530	$ 134,363	$ 119,934
Other Foreign	212,336	210,996	192,640
Total Foreign	342,866	345,359	312,574
United States	923,342	1,054,681	980,039
Total Revenues	$ 1,266,208	$ 1,400,040	$ 1,292,613

Domestic sales accounted for 73%, 75% and 76% of total revenue in 2019, 2018 and 2017, respectively. International sales accounted for 27%, 25% and 24% of total revenue in 2019, 2018 and 2017, respectively.

Contract balances

Our contract balances (deferred revenue) are recorded in accrued liabilities and other long-term liabilities in our consolidated balance sheet (see Note 10, Accrued Liabilities and Other Long-term liabilities). The following table presents our changes in the contract balances for the years ended December 31, 2019 and 2018, (in thousands):

	Contract Liabilities
Beginning balance, January 1, 2018	$ (7,066)
Equipment revenue recognized	6,696
Equipment revenue deferred due to implementation	(4,196)
Software revenue recognized	6,553
Software revenue deferred due to implementation	(6,269)
Ending balance, December 31, 2018	$ (4,282)
Equipment revenue recognized	8,807
Equipment revenue deferred due to implementation	(8,794)
Software revenue recognized	3,953
Software revenue deferred due to implementation	(4,539)
Ending balance, December 31, 2019	$ (4,855)

During 2019, we recognized $3.8 million in revenue that was included in the opening contract balances for the year ended December 31, 2018. As of December 31, 2019, revenue from remaining performance obligations related to implementation of software and equipment is $3.3 million. We expect to recognize substantially all of this revenue within the next three months. Revenue from remaining performance obligations related to annual software licenses is $1.6 million. We expect to recognize substantially all of this revenue over the next twelve months.

Costs to Obtain a Contract with a Customer

As part of the cost to obtain a contract, we may pay incremental commissions to sales employees upon entering into a sales contract. Under ASC Topic 606, we have elected to expense these costs as incurred as the period of benefit is less than one year.

Practical expedients and exemptions

In addition to the practical expedient applied to sales commissions, under ASC Topic 606, we elected to apply the practical expedient for shipping and handling costs incurred after the customer has obtained control of a good. We will continue to treat these costs as a fulfillment cost rather than as an additional promised service.

NOTE 5. LEASES

Adoption of ASC Topic 842, "Lease Accounting"

We adopted ASU No. 2016-02, Leases (ASC Topic 842), effective January 1, 2019 on a modified retrospective transition method through a cumulative-effect adjustment at the beginning of the first quarter of 2019. We elected the 'package of practical expedients', which permitted us not to reassess our prior conclusions about lease identification, lease classification and initial direct costs. We did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to us. We elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we did not recognize right-of-use ("ROU") assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Furthermore, we elected the practical expedient to not separate lease and non-lease components for all of our leases, non-lease components are primarily common area maintenance charges that we combine with the lease component when applying this ASU.

The impact of adopting this standard was the recognition of ROU assets and lease liabilities for our operating leases of $40.4 million as of January 1, 2019. The adoption of ASC 842 did not have a material impact on our consolidated earnings or on our cash flows.

Leases

We determine if an arrangement is a lease at inception. Our operating leases with a term greater than one year are included in operating lease ROU assets, accrued liabilities, and other long-term liabilities on our consolidated balance sheets.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Most of our leases do not provide an implicit rate, therefore we use our incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term based on the information available at commencement date. The operating lease ROU asset excludes initial direct costs incurred. Our lease terms include options to extend when it is reasonably certain that we will exercise that option. All of our operating leases have stated lease payments, which may include fixed rental increases. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We have operating leases for corporate, R&D and sales and support offices, device service centers, distribution warehouses and certain equipment. Our leases have original lease terms of one year to fifteen years, some of which include options to extend the leases for up to an additional five years. For all of our leases, we do not include optional periods of extension in our current lease terms for the exercise of options to extend is not reasonably certain.

The following table presents the components of our lease cost (in thousands):

	For the year ended December 31, 2019
Operating lease cost	$ 10,011
Short-term lease cost	322
Total lease cost	$ 10,333

The following table presents the supplemental cash flow information related to our leases (in thousands):

	For the year ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 10,344
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	$ 3,230

The following table presents the supplemental balance sheet information related to our leases (in thousands, except lease term and discount rate):

	As of December 31, 2019
Operating leases	
Operating lease right-of-use assets	$ 34,465
Accrued liabilities	$ 7,362
Other long-term liabilities	28,896
Total operating lease liabilities	$ 36,258
Weighted Average Remaining Lease Term	
Operating leases	6 years
Weighted Average Discount Rate	
Operating leases	5.57%

As of December 31, 2019, the maturities of our lease liabilities for each of the next five years are approximately (in thousands):

	Operating Leases
2020	$ 8,850
2021	7,412
2022	6,621
2023	6,204
2024	5,896
Thereafter	7,765
Total Lease Payments	42,748
Less imputed interest	(6,490)
Total	$ 36,258

As of December 31, 2018, the maturities of our operating lease liabilities for each of the next five years were approximately (in thousands):

	Operating Leases
2019	$ 8,326
2020	8,572
2021	6,489
2022	5,914
2023	5,615
Thereafter	13,235
Total Lease Payments[1]	$ 48,151

[1]The lease payment maturities as of December 31, 2018 are not calculated at present value.

During the third quarter 2019, we signed a ten-year lease for a 610,806 square foot warehouse. The commencement of the lease is not expected until the first quarter of 2020 subject to the completion of landlord build-outs which will make the space available for use. Over the ten-year lease term, we expect the lease payments to total at least $21.8 million.

NOTE 6. SHARE BASED AWARDS

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

We incur stock compensation expense for stock options, restricted stock units ("RSU"), performance restricted stock units ("PRSU") and in years prior to 2018 stock purchased under our employee stock purchase plan ("ESPP"), which was suspended in 2017. We receive a tax benefit on stock compensation expense and direct tax benefits from the exercise of stock options. We also have indirect tax benefits upon exercise of stock options related to research and development tax credits which are recorded as a reduction of income tax expense.

The table below summarizes compensation costs and related tax benefits (in thousands):

	Year ended December 31,		
(In thousands)	2019	2018	2017
Stock compensation expense	$ 21,918	$ 24,241	$ 19,352
Tax benefit from stock-based compensation cost	$ 4,840	$ 5,706	$ 7,247
Indirect tax benefit	$ 680	$ 2,199	$ 1,374

As of December 31, 2019, we had $23.6 million of unamortized stock compensation cost which we will recognize as an expense over approximately 0.8 years.

Stock Incentive and Stock Option Plans

Our 2011 Stock Incentive Plan ("2011 Plan") replaced our 2003 Stock Option Plan (“2003 Plan”). Our 2011 Plan initially had 650,000 shares available for issuance, plus the remaining available shares for grant from the 2003 Plan and any shares that were forfeited, terminated or expired that would have otherwise returned to the 2003 Plan. In 2012, 2014 and 2017, our stockholders approved amendments to the 2011 plan that increased the shares available for issuance by 3,275,000, bringing the initial shares available for issuance to 3,925,000, plus the remaining 248,700 shares that remained available for grant from the 2003 Plan. As of December 31, 2019, the 2011 Plan has 4,188,300 shares of common stock reserved for issuance to employees, which includes 263,300 shares that transferred from the 2003 Plan. Shares issued as options or stock appreciation rights ("SARs") are charged against the 2011 Plan's share reserve as one share for one share issued. Shares subject to awards other than options and SARs are charged against the 2011 Plan's share reserve as 2.09 shares for 1 share issued. Options may be granted with exercise prices at no less than fair market value at date of grant. Options granted under the 2011 Plan may be

"non-statutory stock options" which expire no more than ten years from date of grant or "incentive stock options" as defined in Section 422 of the Internal Revenue Code of 1986, as amended.

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

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

Time-based Stock Options

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

The fair value of time-based option grants is calculated using the Black-Scholes option valuation model. The expected term for the option grants was based on historical experience and expected future employee behavior. We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock, based on the average expected exercise term. The table below summarizes the total time-based stock options granted, total valuation and the weighted average assumptions (dollars in thousands, except per option amounts):

	Year ended December 31,		
	2019	2018	2017
Number of time-based options granted	6,265	5,815	8,825
Grant date fair value of options granted (in thousands)	$ 424	$ 425	$ 375
Weighted average assumptions for stock option valuation:			
Expected term (years)	5.5	5.5	5.5
Expected stock price volatility	28.0%	24.0%	27.0%
Risk-free interest rate	2.2%	2.3%	1.1%
Expected dividend yield	—%	—%	—%
Weighted average grant price per option	$ 225.27	$ 269.80	$ 158.20
Weighted average grant date fair value per option	$ 67.73	$ 73.14	$ 42.51

A summary of our stock option activity as of and for the year ended December 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	1,186,928	$ 63.66		
Granted	6,265	$ 225.27		
Exercised	(145,339)	$ 53.18		
Forfeited or expired	—	$ —		
Outstanding at December 31, 2019	1,047,854	$ 66.08	4.1	$ 127,556
Exercisable at December 31, 2019	1,041,589	$ 65.12	4.0	$ 127,556
Vested and expected to vest, December 31, 2019	1,047,854	$ 66.08	4.1	$ 127,556

The intrinsic values for options exercisable, outstanding and vested or expected to vest at December 31, 2019 is based on our closing stock price of $187.12 at December 31, 2019 and are before applicable taxes.

The following table presents information regarding stock option activity:

	Year ended December 31,		
(In thousands)	**2019**	**2018**	**2017**
Intrinsic value of options exercised	$ 22,976	$ 51,105	$ 71,283
Cash received from exercise of stock options	$ 7,732	$ 14,275	$ 32,003
Tax benefit from stock option exercises	$ 9,653	$ 12,617	$ 20,004

Stock Awards

In 2019, we granted performance restricted stock units ("PRSU") to our executive officers. For the executive officers other than the Chief Executive Officer ("CEO") and the Chief Operations Officer ("COO"), the PRSUs will vest subject to a three-year time vesting and further subject to a determination by the Compensation Committee that the officers have met their individual performance goals for the applicable years. For the CEO and the COO, the performance shares will cliff-vest ending on March 6, 2022 and further subject to the achievement of a minimum Cumulative Adjusted EBITDA. If for the three year period ending on December 31, 2021 the Cumulative Adjusted EBITDA has a growth of at least 6% to 8%, 50% of the awarded units will vest. If on the vesting date the Cumulative Adjusted EBITDA has a growth of between 8% to 10%, 100% of the awarded units will vest. If on the vesting date the Cumulative Adjusted EBITDA has a growth of over 10%, 200% of the awarded units will vest. In 2019, we also granted PRSUs to one of our non-executive employees. These PRSUs will vest at the end of a three-year period ending on March 31, 2022, if certain minimum performance goals are met.

In 2018, we granted PRSUs to our executive officers. For the executive officers other than the CEO and the COO, the PRSUs will vest subject to a three-year time vesting and further subject to a determination by the Compensation Committee that the officers have met their individual performance goals for the applicable year. For the CEO and the COO, the performance shares will cliff-vest ending on February 15, 2021 and further subject to the achievement of a minimum Cumulative Adjusted EBITDA. If for the three year period ending on December 31, 2020 the Cumulative Adjusted EBITDA has a growth of at least 6% to 8%, 50% of the awarded units will vest. If on the vesting date the Cumulative Adjusted EBITDA has a growth of between 8% to 10%, 100% of the awarded units will vest. If on the vesting date the Cumulative Adjusted EBITDA has a growth of over 10%, 200% of the awarded units will vest.

In 2017, we granted PRSUs to our executive officers. The PRSUs were scheduled to vest, if at all, upon the achievement of a minimum Cumulative Adjusted EBITDA, subject to a three-year cliff vesting ending on December 31, 2019. If at that date, our Cumulative Adjusted EBITDA is at least $600 million but less than $650 million, 100% of the awarded units will vest. If our Cumulative Adjusted EBITDA is at least $650 million but less than $700 million, 200% of the awarded units will vest. If our Cumulative Adjusted EBITDA is at least $700 million, 300% of the awarded units will vest. On January 17, 2020, the Compensation Committee made the determination that the 2017 PRSU shares were earned by our executive officers at the 300% achievement level.

In 2016, we granted PRSUs to our executive officers, which vested on December 31, 2018. During the first quarter of 2019, the Compensation Committee determined the award granted vested at 300%, as a minimum specified compound annual growth rate ("CAGR") in adjusted EBITDA per share of greater than 12% was reached for the 3-year performance period January 1, 2016 through December 31, 2018. The total number of shares of 2016 PRSUs that were earned by our executive officers was 109,110 shares.

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

In 2019, 2018 and 2017, we granted RSUs to certain employees that vest ratably on the anniversary of the grant over three years. We recognize forfeitures as they occur.

The grant date fair market value of our PRSUs and RSUs is determined by our stock price on the grant date.

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

	Year ended December 31,		
(In thousands except shares and per share amounts)	2019	2018	2017
PRSU			
Shares granted	37,657	30,348	20,686
Shares earned	114,032	—	—
Grant date fair value per share	$ 231.63	$ 248.65	$ 154.75
Grant date fair value	$ 8,723	$ 7,546	$ 3,201
Intrinsic value vested	$ 26,445	$ —	$ —
RSU			
Shares granted	61,856	63,094	107,678
Grant date fair value per share	$ 227.42	$ 252.42	$ 156.49
Grant date fair value	$ 14,067	$ 15,926	$ 16,851
Intrinsic value vested	$ 16,753	$ 17,086	$ 9,813

The table below provides a summary of our PRSU and RSU activity as of and for the year ended December 31, 2019:

	Number of Units	Grant Date Fair Value Per Share	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Non-vested at December 31, 2018	340,704	$ 155.27		
Change in units due to performance expectations [(a)]	(14,444)	$ 238.03		
Granted	99,513	$ 229.01		
Vested	(185,662)	$ 122.55		
Forfeited	(7,584)	$ 216.29		
Non-vested and expected to vest at December 31, 2019	232,527	$ 205.82	0.7	$ 43,510

[(a)] Relates to 2018 and 2019 CEO and COO PRSUs, assumes attainment of a reduced payout rate based on performance expectations.

ESPP

We have an ESPP under which U.S. employees may purchase up to $25,000 annually of common stock at 85% of its fair market value at the beginning or the end of a six-month offering period, whichever is lower. There are 750,000 shares of common stock reserved for issuance under the ESPP, which is subject to an annual increase of the least of 300,000 shares, two percent of the shares outstanding or such a number as determined by the Board. To date, there have been no increases. As of December 31, 2019, there were 133,487 shares available for future issuance. The ESPP is intended to constitute an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. We suspended our ESPP in 2017.

The fair value of rights to purchase shares under the ESPP is calculated using the Black-Scholes option valuation model. The table below summarizes the number and intrinsic value of ESPP share purchases and the weighted average valuation assumptions for the 2017 purchase period.

	2017
ESPP shares purchased by employees	23,426
Intrinsic value of ESPP purchases (in thousands)	$ 986
Weighted average assumptions for ESPP valuation:	
Expected term (in years)	0.5
Expected stock price volatility	28.1%
Risk-free interest rate	0.6%
Expected dividend yield	—%

NOTE 7. DERIVATIVES AND HEDGING ACTIVITIES

Hedge Accounting and Hedging Program

The purpose of our cash flow hedging program is to manage the foreign currency exchange rate risk on forecasted expenses denominated in currencies other than the functional currency of the operating unit. We do not issue derivatives for trading or speculative purposes.

In May 2017, we entered into a two-year cross-currency par forward contract to hedge a portion of our Mexico forecasted expenses denominated in Pesos ("MXN"). To receive hedge accounting treatment, all hedging relationships are formally documented at the inception of the hedge, and the hedges must be highly effective in offsetting changes to future cash flows on hedged transactions. The par forward contract is designated and qualifies as a cash flow hedge. Our derivative instrument is recorded at fair value on the Consolidated Balance Sheets and is classified based on the instrument's maturity date. We record changes in the fair value of the effective portion of the derivative instrument as a component of Other Comprehensive Income (Loss) and we reclassify that gain or loss into earnings in the same line item associated with the forecasted transaction and in the same period during which the hedged transaction affects earnings. The term of this currency forward contract was May 1, 2017 to May 1, 2019. The derivative instrument had a fixed forward rate of 20.01MXN/USD over the term of the two-year contract.

In January 2018, we entered into an additional six-month cross-currency par forward contract that extended our previous hedge of a portion of our Mexico forecasted expenses denominated in MXN. The term of this six-month contract was May 1, 2019 to November 1, 2019. The derivative instrument had a fixed forward rate of 20.43 MXN/USD over the term of the six-month contract.

In November 2018, we entered into a one-year cross-currency par forward contract again extending the hedge of a portion of our Mexico forecasted expenses denominated in MXN. The total notional amount of this outstanding derivative as of December 31, 2019 was approximately 364.8 million MXN. The term of the one-year hedge is November 1, 2019 to November 3, 2020. The derivative instrument matures in equal monthly amounts at a fixed forward rate of 22.109 MXN/USD.

The following table presents the fair values of our derivative instruments included within the Consolidated Balance Sheets (in thousands):

	Derivatives		
		December 31,	
	Consolidated Balance Sheet Location	2019	2018
Derivatives designated as cash flow hedging instruments			
Foreign exchange forward contract:	Prepaid expenses and other current assets	$ 2,366	$ 187
	Other assets	—	545
Total derivatives designated as cash flow hedging instruments		$ 2,366	$ 732

The following table presents the amounts affecting the Consolidated Statements of Operations (in thousands):

		Year Ended December 31,		
	Line Item in the Consolidated Statements of Operations	2019	2018	2017
Derivatives designated as cash flow hedging instruments				
Foreign exchange forward contracts	Cost of goods sold	$ 916	$ 743	$ 885

We recognized the following gains on our foreign exchange contract designated as a cash flow hedge (in thousands):

	Amount of Gain Recognized in Other Comprehensive Income on Derivatives			Amount of Gain Reclassified From Accumulated Other Comprehensive Income into Income			
	Year Ended December 31,				Year Ended December 31,		
	2019	2018	2017	Location of Gain Reclassified From Accumulated Other Comprehensive Income into Income	2019	2018	2017
Derivatives designated as cash flow hedges:							
Foreign exchange forward contract	$ 2,550	$ 2,063	$ 296	Cost of goods sold	$ 916	$ 743	$ 885
Total derivatives designated as cash flow hedging instruments	$ 2,550	$ 2,063	$ 296		$ 916	$ 743	$ 885

As of December 31, 2019, we expect approximately $2.4 million of the deferred gain on the outstanding derivatives in accumulated other comprehensive income to be reclassified to net income during the next 12 months concurrent with the underlying hedged transactions also being reported in net income.

NOTE 8. FAIR VALUE MEASUREMENTS

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

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

In 2017, we recognized an earn-out liability upon the acquisition of HIS from Pfizer. Pfizer was entitled up to $225 million in cash if certain performance targets for the combined company for the three years ending December 31, 2019 were achieved. The initial fair value of the earn-out was determined by employing a Monte Carlo simulation in a risk neutral framework. The underlying simulated variable was adjusted EBITDA. The adjusted EBITDA volatility estimate was based on a study of historical asset volatility for a set of comparable public companies. The model included other assumptions including the market price of risk, which was calculated as the weighted average cost of capital ("WACC") less the long term risk free rate. The initial value assigned to the contingent consideration was a result of forecasted product demand of our HIS business, as discussed further in Note 2: Acquisitions. At each reporting date subsequent to the acquisition we remeasured the earn-out using the same methodology above and recognize any changes in value. As of December 31, 2019, it was determined that we did not meet the necessary performance targets that would require payout of any of the HIS earn-out liability.

In the fourth quarter of 2019, we recognized an earn-out liability related to the acquisition of Pursuit (see Note 2, Acquisitions). Pursuit's equity holders are potentially entitled up to $50.0 million in additional cash consideration contingent upon the achievement of certain sales and gross profit targets for specific customers.The earn-out paid will be calculated as a percentage of gross profit achieved during the earn-out period against a pre-determined target gross profit, not to exceed $50.0 million. We used a Monte Carlo simulation model to determine the fair value of the earn-out. The Monte Carlo simulation model utilizes multiple input variables to determine the value of the earn-out including historical volatility, a risk free interest rate, counter party credit risk and projected future gross profit, see below simulation input table related to Pursuit. The historical volatility was based on the median of ICU and a certain peer group. The risk-free interest rate is equal to the yield, as of the valuation date, of the zero-coupon U.S. Treasury bill that is commensurate with the term of the earn-out. The counter party credit risk is based on a synthetic credit rating of B1. If the probabilities in the model significantly change from what we initially and subsequently anticipate, the change could have a significant impact on our financial statements in the period recognized. Our contingent earn-out liability is separately stated in our consolidated balance sheets.

The following table provides a reconciliation of our Level 3 earn-out liabilities measured at estimated fair value based on an initial valuation and updated quarterly for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Earn-out Liability
Contingent earn-out liability, January 1, 2017	$ —
Acquisition date fair value estimate of earn-out	19,000
Change in fair value of contingent earn-out (included in income from operations as a separate line item)	8,000
Contingent earn-out liability, December 31, 2017	$ 27,000
Acquisition date fair value estimate of earn-out	—
Change in fair value of contingent earn-out (included in income from operations as a separate line item)	20,400
Contingent earn-out liability, December 31, 2018	47,400
Acquisition date fair value estimate of earn-out[(1)]	17,300
Change in fair value of contingent earn-out (included in income from operations as a separate line item)	(47,400)
Contingent earn-out liability, December 31, 2019	$ 17,300

(1) Relates to our acquisition of Pursuit, (see Note 2, Acquisitions).

Changes in the fair value of the HIS earn-out subsequent to the fair value calculated at acquisition are due to a change in the forecast of the underlying target, adjusted EBITDA, and due to changes in other assumptions used in the Monte Carlo simulation, as detailed in the below table.

The following tables provide quantitative information about Level 3 inputs for fair value measurement of our earn-out liabilities as of the acquisition date to December 31, 2019. Significant increases or decreases in these inputs in isolation could result in a significant impact on our fair value measurement.

HIS Earn-out

Simulation Input	As of December 31, 2018	As of December 31, 2017	At Acquisition February 3, 2017
Adjusted EBITDA Volatility	30.00%	26.00%	29.00%
WACC	8.25%	8.75%	10.00%
20-year risk free rate	2.87%	2.58%	2.82%
Market price of risk	5.24%	5.99%	6.93%
Cost of debt	5.25%	4.08%	4.16%

Pursuit Earn-out

Simulation Input	As of December 31, 2019	At Acquisition November 2, 2019
Revenue/Gross Profit Volatility	20.00%	20.00%
Discount Rate	15.00%	15.00%
Risk free rate	1.55%	1.55%
Counter Party Risk	6.00%	6.00%

The fair value of our investments, which consists of corporate bonds, is estimated using observable market based inputs such as quoted prices, interest rates and yield curves or Level 2 inputs.

The fair value of our Level 2 forward currency contract is estimated using observable market inputs such as known notional value amounts, spot and forward exchange rates. These inputs relate to liquid, heavily traded currencies with active markets which are available for the full term of the derivative.

There were no transfers between levels in 2019 or 2018.

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

	Fair value measurements at December 31, 2019			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets:				
Available for sale debt securities:				
Short-term	$ 23,967	$ —	$ 23,967	$ —
Foreign exchange forwards:				
Prepaid expenses and other current assets	2,366	—	2,366	—
Total Assets	$ 26,333	$ —	$ 26,333	$ —
Liabilities:				
Earn-out liability	$ 17,300	$ —	$ —	$ 17,300
Total Liabilities	$ 17,300	$ —	$ —	$ 17,300

	Fair value measurements at December 31, 2018			
	Total carrying value	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Assets:				
Available for sale debt securities:				
Short-term	$ 37,329	$ —	$ 37,329	$ —
Long-term	2,025	—	2,025	—
Foreign exchange forwards:				
Prepaid expenses and other current assets	187	$ —	$ 187	$ —
Other assets	545	$ —	$ 545	$ —
Total Assets	$ 39,354	$ —	$ 39,354	$ —
Liabilities:				
Earn-out liability	$ 47,400	$ —	$ —	$ 47,400
Total Liabilities	$ 47,400	$ —	$ —	$ 47,400

NOTE 9. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2019	2018
Deposits	$ 1,375	$ 1,087
Other prepaid expenses and receivables	13,778	12,476
Receivables from Pfizer related to HIS business acquisition[(1)]	—	20,137
Deferred costs	3,332	1,951
Prepaid insurance and property taxes	5,450	2,666
VAT/GST receivable	4,422	5,072
Deferred tax charge	1,266	1,180
Other	4,358	1,548
	$ 33,981	$ 46,117

[(1)] We reclassified the December 31, 2018 related-party receivable due from Pfizer to prepaid expenses and other current assets for current year presentation purposes. During the years 2018 and 2017, Pfizer was a related party to us as we issued 3.2 million shares of our common stock as partial consideration for the 2017 acquisition of HIS. As of December 31, 2018, Pfizer had sold all of its shares of our common stock. During 2018, in connection with the sale of the 2.5 million of the shares Pfizer held, we incurred a one-time fee payable to Pfizer in the amount of $8.0 million included in restructuring, strategic transaction and integration expense in our consolidated statement of operations.

Related-party revenue for goods manufactured for Pfizer under our Manufacturing and Supply Agreements with Pfizer (see Note 16, Collaborative and Other Arrangements) was $78.2 million and $72.4 million during the years 2018 and 2017, respectively, and the cost of product manufactured by Pfizer for us under those agreements was $81.0 million and $70.2 million during the years 2018 and 2017, respectively.

NOTE 10. ACCRUED LIABILITIES AND OTHER LONG-TERM LIABILITIES

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2019	2018
Salaries and benefits	$ 21,116	$ 20,538
Incentive compensation	15,221	42,913
Accrued supply chain restructuring costs	23,119	—
Operating lease liability-ST	7,362	—
Accrued professional fees	4,782	15,996
Accrued product field action	2,096	5,316
Consigned inventory	—	1,118
Third-party inventory	—	1,089
Legal accrual	826	1,400
Accrued sales taxes	2,615	2,941
Warranties and returns	782	1,124
Deferred revenue	4,761	3,814
Accrued other taxes	4,054	3,213
Distribution fees	3,942	3,977
Accrued freight	11,238	10,953
Restructuring accrual	5,459	1,046
Contract liabilities-ST	1,935	—
Contract settlement	1,667	2,083
Accrued research and development	—	1,451
Other	6,801	9,848
	$ 117,776	$ 128,820

Other long-term liabilities consist of the following (in thousands):

	December 31,	
	2019	2018
Operating lease liabilities-LT	$ 28,896	$ —
Contract liabilities[(1)]	472	14,020
Deferred revenue	94	468
Benefits	1,131	962
Accrued rent	1,642	1,779
Contract settlement	—	1,667
Other	585	1,696
	$ 32,820	$ 20,592

[(1)] Consists of contracts with customers and suppliers that were valued at below market at the time of the HIS acquisition.

NOTE 11. LONG-TERM OBLIGATIONS

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, swingline lender and issuing lender. As of December 31, 2019 and 2018, we had no borrowings and $150 million of availability under the Credit Facility. The Credit Facility matures on November 8, 2022.

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.

In connection with the Credit Facility, for the year ended December 31, 2017, we incurred $1.4 million in financing costs, which were capitalized and are included in prepaid expenses and other current assets and other assets in our consolidated balance sheets, in accordance with the appropriate short-term or long-term classification. These fees are being amortized to interest expense over the remaining term of the Credit Facility.

Principal payments

Principal payments, when drawn on the Credit Facility, are made at our discretion with the entire unpaid amount due at maturity.

Interest rate

In general, borrowing under the Credit Facility (other than Swingline loans) bears interest, at our option, based on the Base Rate plus applicable margin or the London Interbank Offered Rate ("LIBOR") rate plus applicable margin, as defined below:

(A) Base Rate is defined as the highest of: (a) the Prime Rate; (b) the Federal Funds Rate plus 0.50%; and (c) the daily LIBOR (as defined below) for a one month Interest Period plus 1%.

(B) LIBOR Rate, as determined by the Administrative Agent, is defined as the rate per annum obtained by dividing (1) LIBOR by (2) 1.00 - Eurodollar Reserve Percentage.

Swingline loans will bear interest at the Base Rate plus the applicable Interest Margin. The Credit Facility has a per annum commitment fee (see table below) that will accrue on the unused amounts of the commitments under the Credit Facility.

The applicable interest margins and the commitment fee with respect to the Credit Facility shall be based on the Total Leverage Ratio pursuant to the following pricing grid:

Level	Consolidated Total Leverage Ratio	Commitment Fee	LIBOR +	Base Rate +
I	Less than 1.00 to 1.00	0.15%	1.25%	0.25%
II	Greater than or equal to 1.00 to 1.00 but less than 2.00 to 1.00	0.20%	1.50%	0.50%
III	Greater than or equal to 2.00 to 1.00 but less than 2.50 to 1.00	0.25%	1.75%	0.75%
IV	Greater than or equal to 2.50 to 1.00	0.30%	2.00%	1.00%

Guarantors and Collateral

Our obligations under the Credit Facility are unconditionally guaranteed, on a joint and several basis, by ICU Medical, Inc. and certain of our existing subsidiaries. Our obligations are secured by: (i) 100% of the equity interests of our guarantor subsidiaries; and (ii) all of the tangible and intangible personal property and assets related to us and our guarantor subsidiaries

(including, without limitation, all accounts, equipment, inventory and other goods, all instruments, intellectual property and other general intangibles, deposit accounts, securities accounts and other investment property and cash), and (iii) all products, profits and proceeds of the foregoing. Notwithstanding the foregoing, the collateral shall not include certain excluded property.

Debt Covenants

The Credit Facility contains certain financial covenants pertaining to Consolidated Fixed Charge Coverage and Consolidated Total Leverage Ratios. In addition, the Credit Facility has restrictions pertaining to limitations on debt, liens, negative pledges, loans, advances, acquisitions, other investments, dividends, distributions, redemptions, repurchases of equity interests, fundamental changes and asset sales and other dispositions, prepayments, redemptions and purchases of subordinated debt and other junior debt, transactions with affiliates, dividend and payment restrictions affecting subsidiaries, changes in line of business, fiscal year and accounting practices and amendment of organizational documents and junior debt documents.

The Consolidated Leverage Ratio is defined as the ratio of Consolidated Total Funded Indebtedness on such date, to Consolidated Adjusted EBITDA, as defined under the Credit Facility Agreement, for the most recently completed four fiscal quarters. The maximum Consolidated Leverage Ratio is not more than 3.00 to 1.00.

The Consolidated Fixed Charge Coverage Ratio is defined as the ratio of: (a) Consolidated Adjusted EBITDA less the sum of (i) capital expenditures, (ii) federal, state, local and foreign income taxes paid in cash and (iii) cash restricted payments made after the closing date, to (b) Consolidated Fixed Charges for the most recently completed four fiscal quarters, calculated on a pro forma basis. The minimum Consolidated Fixed Charge Coverage Ratio is 2.00 to 1.00.

We were in compliance with all financial covenants as of December 31, 2019.

Three-Year Interest-Only Senior Note

On February 3, 2017, we partially funded the acquisition of the HIS business from Pfizer with a $75 million Seller Note issued by Pfizer contemporaneous with the acquisition. We had fully repaid the seller note as of December 31, 2017.

NOTE 12. INCOME TAXES

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

	Year Ended December 31,		
	2019	2018	2017
United States	$ 32,849	$ (8,600)	$ 59,872
Foreign	81,858	30,974	(8,589)
	$ 114,707	$ 22,374	$ 51,283

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

	Year Ended December 31,		
	2019	2018	2017
Current:			
Federal	$ 6,851	$ 492	$ 2,774
State	2,532	1,865	2,263
Foreign	7,994	9,136	3,170
	17,377	11,493	8,207
Deferred:			
Federal	$ (6,720)	$ (9,118)	$ (20,878)
State	(325)	(3,072)	(4,619)
Foreign	3,340	(5,722)	(71)
	(3,705)	(17,912)	(25,568)
	$ 13,672	$ (6,419)	$ (17,361)

We have accrued for tax contingencies for potential tax assessments, and in 2019 we recognized a $4.2 million net increase, most of which related to various federal, state and foreign tax reserves.

On December 22, 2017, the Tax Act was enacted into legislation, 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, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S. owned undistributed foreign earnings and profits known as the toll charge or transition tax.

Pursuant to the SEC Staff Accounting Bulletin ("SAB") No. 118, "Income Tax Accounting Implications of the Tax Cuts and Jobs Act" ("SAB 118"), a company selects between one of three scenarios to reflect the impact of the Tax Act in its financial statements within a measurement period. Those scenarios are (i) a final estimate which effectively closes the measurement period; (ii) a reasonable estimate leaving the measurement period open for future revisions; and (iii) no estimate as the law is still being analyzed in which case a company continues to apply its accounting on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Act. SAB 118 allows for the reporting provisional amounts for certain income tax effects in scenario (ii) and (iii). The measurement period begins in the reporting period that includes the Act’s enactment date and ends when an entity has obtained, prepared, and analyzed the information that was needed in order to complete the accounting requirements under ASC Topic 740. As of December 31, 2018, our accounting for the Tax Act was complete.

The toll charge on undistributed foreign earnings and profits (the “Transition Tax”) is a tax on certain untaxed accumulated and current earnings and profits ("E&P") of our foreign subsidiaries. We were able to reasonably estimate the Transition Tax and recorded a provisional Transition Tax expense of $2.0 million for the year ended December 31, 2017. On the basis of revised E&P computations that were completed during the reporting period, we recognized an additional measurement-period adjustment of $0.6 million to the Transition Tax obligation, with a corresponding adjustment of $0.6 million to income tax expense.

The revaluation of deferred taxes is an adjustment to future tax obligations as a result of the reduction of the corporate tax rate from 35% to 21%. We were able to reasonably estimate the effect of the revaluation of deferred taxes and recorded a provisional tax expense of $1.1 million for the year ended December 31, 2017. The computation of timing differences was completed during the reporting period. We recognized an additional measurement-period adjustment of $0.2 million, with a corresponding adjustment of $0.2 million to income tax expense.

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

	Year Ended December 31,					
	2019		2018		2017	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ 24,088	21.0 %	$ 4,699	21.0 %	$ 17,950	35.0 %
State income tax, net of federal effect	1,269	1.1 %	927	4.1 %	(403)	(0.8)%
Tax credits	(2,896)	(2.5)%	(4,961)	(22.2)%	(2,783)	(5.4)%
Global intangible low-taxed income	6,118	5.3 %	2,363	10.6 %	—	— %
Foreign income tax differential	(5,939)	(5.2)%	(2,944)	(13.2)%	3,481	6.8 %
Stock based compensation	(8,446)	(7.4)%	(11,040)	(49.3)%	(18,958)	(37.0)%
Impact of the Tax Act	—	— %	826	3.7 %	3,076	6.0 %
IP installment sale and repatriation	(2,118)	(1.8)%	3,252	14.5 %	3,367	6.6 %
Bargain purchase gain	—	— %	—	— %	(24,811)	(48.4)%
Section 162(m)	203	0.2 %	456	2.0 %	595	1.2 %
Other	1,393	1.2 %	3	0.1 %	1,125	2.2 %
	$ 13,672	11.9 %	$ (6,419)	(28.7)%	$ (17,361)	(33.8)%

Tax credits in 2019, 2018 and 2017 consist principally of research and developmental tax credits.

The tax effect of the gain on bargain purchase is treated as a part of purchase accounting and is not a component of the income tax provision.

Certain intellectual property and assets were repatriated in 2019 from a liquidation of foreign subsidiaries to the U.S. parent. The tax effect of the repatriation is included as IP repatriation.

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

	December 31,	
	2019	2018
Deferred tax asset:		
Accruals/other	2,632	11,109
Contingent consideration	—	12,451
Net operating loss carryforwards	—	12,686
Acquired future tax deductions	8,711	10,722
Stock-based compensation	9,654	10,775
Foreign currency translation adjustments	2,716	3,108
Tax credits	11,331	14,470
Inventory reserves	4,305	5,674
Allowance for doubtful accounts	4,242	830
Accrued restructuring	7,072	182
Chargebacks, discounts, customer concessions	20,975	—
Valuation allowance	(3,677)	(5,436)
	$ 67,961	$ 76,571
Deferred tax liability:		
State income taxes	$ 2,600	$ 2,639
Foreign	997	612
Depreciation and amortization	23,839	35,387
Section 481(a) adjustment - change in accounting method	14,618	—
	$ 42,054	$ 38,638
Deferred tax asset, net	$ 25,907	$ 37,933

Tax Holidays and Carryforwards

Net operating loss ("NOL") carryforwards consist of: (a) federal NOL carryforwards of $14.8 million which will expire at various dates from 2020 to indefinite carryforward periods, (b) state NOL carryforwards of $1.4 million which will expire at various dates from 2029 to indefinite carryforward periods and (c) foreign NOL carryforwards of $18.4 million which will expire at various dates from 2020 to indefinite carryforward periods. Under Section 382 of the Internal Revenue Code, certain ownership changes limit the utilization of the NOL carryforwards, and the amount of federal NOL carryforwards recorded is the net federal benefit available.

Other carryforwards include state research and development (“R&D”) tax credit carryforwards of $14.7 million, which have an indefinite carryforward period.

A substantial portion of our manufacturing operations in Costa Rica operate under various tax holiday and tax incentive programs due to expire in whole or in part in 2027. Certain of the holidays may be extended if specific conditions are met. The net impact of these tax holiday and tax incentives was an increase to our net earnings by $7.8 million or $0.36 per diluted share in 2019 and by $8.8 million or $0.41 per diluted share in 2018.

Foreign currency translation adjustments, and related tax effects, are an element of “other comprehensive income” and are not included in net income other than the revaluation of the associated deferred tax asset due to the Tax Act.

As of December 31, 2019, we have estimated $78.5 million of undistributed foreign earnings and profits. Such earnings were previously subject to U.S. tax as a result of the Tax Act and much of any future remittances would generally be subject to no U.S. tax as a result of dividends received deductions and/or foreign tax credit relief. We intend to invest

substantially all of our foreign subsidiary earnings, as well as our capital in our foreign subsidiaries, indefinitely outside of the U.S. in those jurisdictions in which we incur significant additional costs upon repatriation of such amounts.

We are subject to taxation in the United States and various states and foreign jurisdictions. Our United States federal income tax returns for tax years 2016 and forward are subject to examination by the Internal Revenue Service. Our principal state income tax returns for tax years 2012 and forward are subject to examination by the state tax authorities. The total gross amount of unrecognized tax benefits as of December 31, 2019 was $15.0 million which, if recognized, would impact the effective tax rate. We believe that adequate provision has been made for any adjustments that may result from tax examinations. However, the outcome of tax examinations cannot be predicted with certainty. As of December 31, 2019, it is not possible to estimate the amount of change, if any, in the unrecognized tax benefits that is reasonably possible within the next twelve months. We recognize accrued interest and penalties related to unrecognized tax benefits as a component of income tax expense. We have not accrued any penalties or interest as of December 31, 2019 or December 31, 2018.

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

	Year Ended December 31,		
	2019	2018	2017
Beginning balance	$ 10,824	$ 6,527	$ 2,000
Increases to prior year tax positions	138	—	77
Increases due to acquisitions	—	—	640
Increases to current year tax positions	4,231	4,536	3,992
Decreases to prior year tax positions	(3)	(146)	(12)
Decrease related to lapse of statute of limitations	(163)	(93)	(170)
Ending balance	$ 15,027	$ 10,824	$ 6,527

NOTE 13. GEOGRAPHIC INFORMATION AND SIGNIFICANT CUSTOMERS

Significant Customers

We sell products worldwide, on credit terms on an unsecured basis, as an OEM supplier, to independent medical supply distributors and directly to the end customer. The manufacturers and distributors, in turn, sell our products to healthcare providers. We do not currently derive a significant portion of our revenues from any one customer.

Geographic Information

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

	As of December 31,	
	2019	2018
Costa Rica	$ 96,442	$ 81,920
Mexico	69,141	64,242
Other LATAM	31,905	22,828
Canada	4,769	4,545
Italy	7,921	7,819
Spain	6,411	6,516
Other Europe	3,135	2,427
APAC	17,200	15,152
Total Foreign	$ 236,924	$ 205,449
United States	539,316	489,415
Worldwide Total	$ 776,240	$ 694,864

NOTE 14. STOCKHOLDERS' EQUITY

Treasury Stock

In August 2019, our Board of Directors approved a common stock purchase plan to purchase up to $100.0 million of our common stock. This plan replaced our prior plan and has no expiration date. We have $100.0 million remaining on this purchase plan. We did not purchase any of our common stock under our common stock purchase plan in 2019, 2018 or 2017. We are currently limited on share purchases in accordance with the terms and conditions of our Credit Facility, (see Note 11, Long-Term Obligations).

In 2019, we withheld 80,186 shares of our common stock from employee vested restricted stock units in consideration for $18.6 million in payments for the employee's share award income tax withholding obligations. We had 850 shares remaining in treasury at December 31, 2019.

In 2018, we withheld 26,307 shares of our common stock from employee vested restricted stock units in consideration for $6.3 million in payments for the employee's share award income tax withholding obligations. We have 408 shares remaining in treasury at December 31, 2018.

In 2017, we withheld 27,636 shares of our common stock from employee vested restricted stock units in consideration for $4.1 million in payments for the employee's share award income tax withholding obligations. We had no shares remaining in treasury at December 31, 2017.

We use treasury stock to issue shares for stock option exercises, restricted stock grants.

Accumulated Other Comprehensive (Loss) Income ("AOCI")

The components of AOCI, net of tax, were as follows (in thousands):

	Foreign Currency Translation Adjustments	Unrealized Gains on Cash Flow Hedges	Other Adjustments	Total
Balance as of January 1, 2017	$ (21,272)	$ —	$ —	$ (21,272)
Other comprehensive income (loss) before reclassifications	6,694	184	(16)	6,862
Amounts reclassified from AOCI	—	(549)	—	(549)
Other comprehensive income (loss)	6,694	(365)	(16)	6,313
Balance as of December 31, 2017	(14,578)	(365)	(16)	(14,959)
Other comprehensive (loss) income before reclassifications	(3,104)	1,568	115	(1,421)
Amounts reclassified from AOCI	—	(565)	—	(565)
Other comprehensive (loss) income	(3,104)	1,003	115	(1,986)
Balance as of December 31, 2018	$ (17,682)	$ 638	$ 99	$ (16,945)
Other comprehensive income (loss) before reclassifications	372	1,938	(71)	2,239
Amounts reclassified from AOCI	—	(696)	—	(696)
Other comprehensive income (loss)	372	1,242	(71)	1,543
Balance as of December 31, 2019	$ (17,310)	$ 1,880	$ 28	$ (15,402)

NOTE 15. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

Beginning in November 2016, purported class actions were filed in the U.S. District Court for the Northern District of Illinois against Pfizer, Inc. subsidiaries, Hospira, Inc., Hospira Worldwide, Inc. and certain other defendants relating to the intravenous saline solutions part of the HIS business. Plaintiffs seek to represent classes consisting of all persons and entities in the U.S. who directly purchased intravenous saline solution sold by any of the defendants from January 1, 2013 until the time the defendants' allegedly unlawful conduct ceases. Plaintiffs allege that U.S. manufacturer defendants conspired together to restrict output and artificially fix, raise, maintain and/or stabilize the prices of intravenous saline solution sold throughout the U.S. in violation of federal antitrust laws. Plaintiffs seek treble damages (for themselves and on behalf of the putative classes) and an injunction against defendants for alleged price overcharges for intravenous saline solution in the U.S. since January 1, 2013. On July 5, 2018, the District Court granted defendants' motion to dismiss the operative complaint for failing to state a valid antitrust claim, but allowed the plaintiffs to file a second amended complaint. On September 6, 2018, plaintiffs filed a second amended complaint adding new allegations in support of their conspiracy claims and adding ICU as a defendant. All defendants have filed a motion to dismiss this second amended complaint. Briefing is complete and we are awaiting the Court's ruling. On February 3, 2017, we completed the acquisition of the HIS business from Pfizer. This litigation is the subject of a claim for indemnification against us by Pfizer and a cross-claim for indemnification against Pfizer by us under the HIS stock and asset purchase agreement.

In addition, in August 2015, the New York Attorney General issued a subpoena to Hospira, Inc. requesting that the company provide information regarding certain business practices in the intravenous solutions part of the HIS business. Separately, in April 2017, we received a grand jury subpoena issued by the United States District Court for the Eastern District of Pennsylvania, in connection with an investigation by the U.S. Department of Justice, Antitrust Division. The subpoenas call for production of documents related to the manufacturing, selling, pricing and shortages of intravenous solutions, including saline, as well as communications among market participants regarding these issues. On December 10, 2018, we were informed by the U.S. Department of Justice, Antitrust Division, that their investigation has been closed.

In April 2018, the U.S. Department of Justice issued a HIPAA subpoena to Hospira, Inc., requesting production of documents and records regarding the manufacturing, production, testing, quality and validation of the Sapphire™ infusion pumps, sets and related accessories distributed by the company. We have coordinated with Pfizer to produce the requested records to the Department of Justice.

In March 2018, a dispute with a product partner resulted in a redefinition of our contractual arrangement and in the rights and remedies determined under such arrangement. In March 2018, the resolution of the dispute resulted in a $28.9 million net charge to the consolidated statement of operations. In addition, during the fourth quarter of 2018, we incurred $12.7 million in additional contract settlement charges related to this arrangement as a result of the write-off of assets and additional expenses associated with the restructuring of products.

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

Off Balance Sheet Arrangements

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

Contingencies

We had a contractual earn-out arrangement in connection with our acquisition of the HIS business that ended on December 31, 2019, whereby Pfizer was entitled up to an additional $225 million in cash upon achievement of performance

targets for the company for the three years ending December 31, 2019. We did not meet the performance targets required for payout of this earn-out.

During November 2019, we acquired Pursuit (see Note 2, Acquisitions). Total consideration for the acquisition includes a potential contractual earn-out of up to $50.0 million calculated based upon the achievement of certain performance targets during the earn-out period.

NOTE 16. COLLABORATIVE AND OTHER ARRANGEMENTS

On February 3, 2017, we entered into two MSA's, (i) whereby Pfizer will manufacture and supply us with certain agreed upon products for an initial five-year term with a one-time two-year option to extend and (ii) whereby we will manufacture and supply Pfizer certain agreed upon products for a term of five or ten years depending on the product, also with a one-time two-year option to extend. The MSA's provide each party with mutually beneficial interests and both of the MSA's are to be jointly managed by both Pfizer and ICU. The initial supply price, which will be annually updated, is in full consideration for all costs associated with the manufacture, documentation, packaging and certification of the products.

On February 3, 2017, as part of the HIS business acquisition, we had entered into an agreement with Pfizer, whereby Pfizer were to provide certain transitional services to us for finance, business technology, regulatory, human resources, global operations, procurement, quality and global commercial operation services ("Enabling Function Services"). We paid a monthly service fee for each service provided, and shared equally with Pfizer in certain set-up costs and, as applicable, service exit costs. Our share of the set-up costs and service exit costs, in the aggregate, were not to exceed $22.0 million. The service fees were subject to a fee cap of (i) $62.5 million during the initial twelve month period and (ii) $31.3 million during the subsequent six month period. Only the Enabling Function Services were subject to the fee cap, any services provided after expiration of the agreement or services that were not Enabling Function Services were to result in service fees outside the fee cap. The service fees were intended to reasonably approximate Pfizer’s cost of providing the Enabling Function Services. We had also entered into a reverse transitional services agreement, where we provided to Pfizer certain transitional services ranging in term from three to eighteen months. Services included support for real estate, research and development, infrastructure, logistics, quality, site operations, safety, commercial and finance, and regulatory support services. This transitional service agreement with Pfizer ended in 2018.

NOTE 17. SELECTED QUARTERLY FINANCIAL DATA - UNAUDITED

	Quarter Ended			
	Mar. 31	Jun. 30	Sept. 30	Dec. 31
	(in thousands except per share data)			
2019				
Total revenue	$ 330,932	$ 312,282	$ 307,471	$ 315,523
Gross profit	$ 135,303	$ 103,869	$ 118,552	$ 114,140
Net income	$ 30,998	$ 22,833	$ 26,563	$ 20,641
Net income per share:				
Basic	$ 1.51	$ 1.11	$ 1.29	$ 1.00
Diluted	$ 1.44	$ 1.06	$ 1.24	$ 0.96
2018				
Total revenue	$ 372,033	$ 360,460	$ 327,169	$ 340,378
Gross profit	$ 149,001	$ 151,800	$ 134,587	$ 134,640
Net income (loss)	$ 4,875	$ 31,054	$ 219	$ (7,355)
Net income (loss) per share:				
Basic	$ 0.24	$ 1.53	$ 0.01	$ (0.36)
Diluted	$ 0.23	$ 1.44	$ 0.01	$ (0.36)

Net loss for the quarter ended December 31, 2018 included the impact of $41.1 million in restructuring, strategic transaction and integration expenses. We also incurred an $8.6 million non-cash charge in the quarter ended December 31, 2018 associated

with a contract settlement that took place in the quarter ended March 31, 2018, which is included in contract settlement. Management of the Company concluded the contract settlement charge is not material to the three months ended December 31, 2018, or to any previously issued interim financial statements.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

Changes in Internal Control Over Financial Reporting

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

Management’s Annual Report on Internal Control over Financial Reporting

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

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

Based on this criteria, management of the Company has concluded that the Company has maintained effective internal control over its financial reporting as of December 31, 2019.

Our independent registered public accounting firm that audited the December 31, 2019 financial statements included in this Annual Report on Form 10-K has independently assessed the effectiveness of our internal control over financial reporting and its report is below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of ICU Medical, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of ICU Medical, Inc and subsidiaries (the "Company") as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated March 2, 2020, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Definition and Limitations of Internal Control over Financial Reporting

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ DELOITTE & TOUCHE LLP

Costa Mesa, California
March 2, 2020

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 of Form 10-K is set forth under the captions *Executive Officers*, *Election of Directors*, *Audit Committee* and *Compliance with Section 16(a) Beneficial Ownership Reporting Compliance* in our definitive Proxy Statement to be filed in connection with our 2020 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 of Form 10-K is set forth under the caption *Executive Officer and Director Compensation*, *Compensation Committee* and *Compensation Committee Interlocks and Insider Participation* in our definitive Proxy Statement to be filed in connection with our 2020 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 of Form 10-K is set forth under the caption *Security Ownership of Certain Beneficial Owners and Management* and *Equity Compensation Plan Information* in our definitive Proxy Statement to be filed in connection with our 2020 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 of Form 10-K is set forth under the caption *Transactions with Related Persons*, *Policies and Procedures Regarding Transactions with Related Persons* and *Director Independence* in our definitive Proxy Statement to be filed in connection with our 2020 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 of Form 10-K is set forth under the caption *Ratification of Auditors* in our definitive Proxy Statement to be filed in connection with our 2020 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

EXHIBIT INDEX

Exhibit Number	Exhibit Description
2.1	Amended and Restated Stock and Asset Purchase Agreement, dated as of January 5, 2017, by and between Pfizer Inc., a Delaware corporation, and ICU Medical, Inc., a Delaware corporation. Filed as Exhibit 2.1 to Registrant’s Current Report on Form 8-K filed January 5, 2017, and incorporated herein by reference.
3.1	Registrant's Certificate of Incorporation, as amended and restated. Filed as an exhibit to Registrant's Current Report on Form 8-K filed on June 10, 2014, and incorporated herein by reference.
3.2	Registrant's Bylaws, as amended and restated. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed August 3, 2016, and incorporated herein by reference.
4.1	Description of Securities Registered Under Section 12 of the Exchange Act.
10.1	Form of Indemnification Agreement with Directors and Executive Officers. Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2010, filed October 22, 2010 (File No. 001-34634), and incorporated herein by reference.
10.2	Registrant's 2001 Directors' Stock Option Plan.* Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 3, 2002 (File No. 000-19974), and incorporated herein by reference.
10.3	Registrant's 2002 Employee Stock Purchase Plan.* Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 3, 2002 (File No. 000-19974), and incorporated herein by reference.
10.4	Registrant's 2003 Stock Option Plan.* Filed as an Exhibit to Registrant's definitive Proxy Statement filed pursuant to Regulation 14A on April 25, 2003 (File No. 000-19974), and incorporated herein by reference.
10.5	Executive officer compensation*
10.6	Non-employee director compensation*
10.7	2008 Performance-Based Incentive Plan, as amended.* Filed as Annex A to Registrant's proxy statement filed April 3, 2013 (File No. 001-34634), and incorporated herein by reference.
10.8	Amendment No. 1 to 2001 Directors' Stock Option Plan.* Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2009, filed October 22, 2009 (File No. 000-19974), and incorporated herein by reference.

10.9	Amendment No. 2 to 2001 Directors' Stock Option Plan.* Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2009, filed October 22, 2009 (File No. 000-19974), and incorporated herein by reference.
10.10	Amendment No. 3 to 2001 Directors' Stock Option Plan.* Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2009, filed October 22, 2009 (File No. 000-19974), and incorporated herein by reference.
10.11	Amended and Restated ICU Medical, Inc. 2011 Stock Incentive Plan.* Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2018, and incorporated herein by reference.
10.12	First Amendment to ICU Medical, Inc. Amended and Restated 2011 Stock Incentive Plan.
10.13	2014 Inducement Stock Incentive Plan.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed February 26, 2014 (File No. 001-34634) and incorporated herein by reference.
10.14	Amended and Restated Executive Employment Agreement, dated as of May 8, 2017, by and between ICU Medical, Inc. and Vivek Jain.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed May 8, 2017, and incorporated herein by reference.
10.15	Buy-Out Agreement between Registrant and George A. Lopez, M.D. effective September 30, 2015.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed October 1, 2015, and incorporated herein by reference.
10.16	Letter agreement between the Registrant and Alison Burcar, effective April 1, 2019. Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2019, and incorporated herein by reference.
10.17	ICU Medical, Inc. Executive Severance Plan.* Filed as an Exhibit to Registrant’s Current Report on Form 8-K filed January 6, 2017, and incorporated herein by reference.
10.18	First Amendment to the ICU Medical, Inc. Executive Severance Plan. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed January 6, 2020, and incorporated herein by reference.
10.19	Revolving Credit Agreement, dated as of November 8, 2017, among ICU Medical, Inc., as borrower, certain lenders party thereto and Wells Fargo Bank, N.A., as administrative agent and swingline lender. Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2017, and incorporated herein by reference.
10.20	Transitional Services Agreement, between ICU Medical, Inc. and Pfizer Inc., dated as of February 3, 2017. Filed as an Exhibit to Registrant’s Current Report on Form 8-K filed February 9, 2017, and incorporated herein by reference.
21	Subsidiaries of Registrant.
23.1	Consent of Deloitte & Touche LLP
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Exhibit 101.INS	The instance document does not appear in the interactive data file because its XBRL (Extensible Business Reporting Language) tags are embedded within the Inline XBRL document.
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

*Executive compensation plan or other arrangement

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands) Description	Balance at Beginning of Period	Additions		Write-off/ Disposals	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
For the year ended December 31, 2017:					
Allowance for doubtful accounts	$ 1,073	$ 2,308	$ 90	$ (160)	$ 3,311
Warranty and return reserve - accounts receivable	$ 1,122	$ 604	$ —	$ —	$ 1,726
Deferred tax asset valuation allowance	$ —	$ 7,385	$ —	$ —	$ 7,385
For the year ended December 31, 2018:					
Allowance for doubtful accounts	$ 3,311	$ 781	$ 1,676	$ —	$ 5,768
Warranty and return reserve - accounts receivable	$ 1,726	$ 2,445	$ 2,581	$ —	$ 6,752
Warranty and return reserve - inventory	$ (503)	$ 2,908	$ 133	$ —	$ 2,538
Deferred tax asset valuation allowance	$ 7,385	$ —	$ —	$ (1,949)	$ 5,436
For the year ended December 31, 2019:					
Allowance for doubtful accounts	$ 5,768	$ 14,882	$ (431)	$ —	$ 20,219
Warranty and return reserve - accounts receivable	$ 6,752	$ 83	$ (458)	$ —	$ 6,377
Warranty and return reserve - inventory	$ 2,538	$ 217	$ 722		$ 3,477
Deferred tax asset valuation allowance	$ 5,436	$ —	$ (1,584)	$ (175)	$ 3,677

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURE

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

ICU MEDICAL, INC.

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

Dated: March 2, 2020

SIGNATURES

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

Signature	Title	Date
/s/ Vivek Jain Vivek Jain	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 2, 2020
/s/ Scott E. Lamb Scott E. Lamb	Chief Financial Officer (Principal Financial Officer)	March 2, 2020
/s/ Kevin J. McGrody Kevin J. McGrody	Chief Accounting Officer (Principal Accounting Officer)	March 2, 2020
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Director	March 2, 2020
/s/ Robert S. Swinney, M.D. Robert S. Swinney, M.D.	Director	March 2, 2020
/s/ David C. Greenberg David C. Greenberg	Director	March 2, 2020
/s/ Elisha W. Finney Elisha W. Finney	Director	March 2, 2020
/s/ David F. Hoffmeister David F. Hoffmeister	Director	March 2, 2020
/s/ Donald M. Abbey Donald M. Abbey	Director	March 2, 2020

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURUSANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

AS of March 2, 2020, ICU Medical, Inc. ("we," "our," "us," or the "Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock. The following summary of the terms of our common stock is based upon our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws. This summary does not purport to be complete and is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, which are filed or incorporated by reference as exhibits to our Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and the applicable provisions of the Delaware General Corporation Law for more information.

DESCRIPTION OF STOCK

Our authorized capital stock consists of 80,500,000 shares consisting of 80,000,000 shares of common stock with a par value of $0.10 per share, and 500,000 shares of preferred stock with a par value of $1.00 per share.

Common Stock

Holders of common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. There is no cumulative voting in the election of directors. Holders of common stock have no rights to convert their shares into other securities or have their shares redeemed and no preemptive rights or other rights to subscribe for additional securities. Subject to preferences that may be applicable to any shares of preferred stock then outstanding, the holders of common stock are entitled to receive such dividends, if any, as may be declared by our board of directors out of legally available funds and to share ratably in any distribution to the stockholders, including any distribution upon liquidation of the Company.

Issuance of Preferred Stock

Our amended and restated certificate of incorporation provides that our board of directors is authorized to direct us to divide the preferred stock into one or more series and to increase or decrease the number of shares of any such series, but not below the number of shares of any such series then outstanding, without stockholder approval. Our board of directors has the discretion to determine the designation, powers, voting powers, preferences and the relative, participating, optional, conversion or other rights of the shares of each such series of preferred stock, and the qualifications, limitations or restrictions thereof. The authority of our board of directors with respect to each series shall include, but not be limited to, determination of any dividend rights, dividend rates, conversion rights, voting rights, rights and terms of redemption, rights upon dissolution or liquidation, sinking funds, and any other rights, preferences and limitations of any series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Listed Exchange and Transfer Agent

Our common stock is listed on The NASDAQ Global Select Market under the symbol "ICUI". The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Authorized but Unissued Shares

The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of The NASDAQ Global Select Market. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Anti-Takeover Effects of Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law ("Section 203"). Under Section 203, we would generally be prohibited from engaging in any “business combination” with any “interested stockholder” for a period of three years following the time that this stockholder became an interested stockholder unless the business combination is approved in a prescribed manner. Under Section 203, a “business combination” includes any merger or consolidation involving the corporation and the interested stockholder, any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder or the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Certain Other Provisions of Our Certificate of Incorporation or Bylaws

The Certificate of Incorporation and/or the Company’s Bylaws, include the following provisions, not previously discussed above, that may have an effect of delaying, deferring or preventing a change in control of the Company:

- our Bylaws establish an advance notice procedure for stockholders to submit proposed nominations of persons for election to our Board of Directors and other proposals for business to be brought before an annual meeting of our stockholders;
- our stockholders may not act by written consent and special meetings of our stockholders may only be called by our Board of Directors, the Chairman of the Board of Directors, or the President of the Company; and
- amendments to our Bylaws may be made by a majority of our Board of Directors and also by the affirmative vote of two-thirds of our shares outstanding and entitled to vote thereon.

Exhibit 10.5

Executive Officer Compensation

The annual base salaries for our executive officers as of January 1, 2019 are as follows:

Name	Title		
Vivek Jain	Chairman of the Board and Chief Executive Officer	$	650,000
Christian Voigtlander	Chief Operating Officer	$	420,000
Scott E. Lamb	Chief Financial Officer	$	395,150
Daniel Woolson	Corporate Vice President, General Manager - Infusion Systems	$	300,000
Virginia Sanzone	Corporate Vice President, General Counsel	$	300,000

Exhibit 10.6

Non-Employee Director Compensation

We currently pay our non-employee directors the following:

- annual retainer of $93,500 for the Lead Director
- annual retainer of $97,000 for the Chairperson of the Audit Committee
- annual retainer of $87,500 for the Chairperson of the Compensation Committee
- annual retainer of $85,000 for the Chairperson of the Nominating and Governance Committee

The equity component of the director's compensation is valued at $170,000. The annual equity package consists of 50% in stock options and 50% in restricted stock units. The options become exercisable one year after the grant date and expire ten years after the grant date. The restricted stock units vest one year from the grant date.

Exhibit 10.12

FIRST AMENDMENT TO
ICU MEDICAL, INC. AMENDED AND RESTATED
2011 STOCK INCENTIVE PLAN

THIS FIRST AMENDMENT TO THE ICU MEDICAL, INC. AMENDED AND RESTATED 2011 STOCK INCENTIVE PLAN (this "First Amendment"), dated as of December 31, 2019, is made and adopted by the Board of Directors (the "Board") of ICU Medical, Inc., a Delaware corporation (the "Corporation"). Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to them in the Plan (as defined below).

RECITALS

WHEREAS, the Corporation maintains the ICU Medical, Inc. Amended and Restated 2011 Stock Incentive Plan (the "Plan");

WHEREAS, pursuant to Section 13(a) of the Plan, the Board may at any time amend the Plan; and

WHEREAS, the Corporation desires to amend the Plan as set forth herein.

NOW, THEREFORE, BE IT RESOLVED, that the Plan is hereby amended as set forth herein.

AMENDMENT

1. The last sentence of Section 7(c) of the Plan is hereby amended and restated in its entirety as follows:

> "Upon exercise or vesting of an Award, the Company shall withhold or collect from the Grantee an amount sufficient to satisfy such tax obligations, including, but not limited to, by surrender of the whole number of Shares which have a Fair Market Value on the date of repurchase no greater than the aggregate amount of such liabilities based on the maximum applicable statutory tax withholding rates incident to the exercise or vesting of an Award (reduced to the lowest whole number of Shares if such number of Shares withheld would result in withholding a fractional Share with any remaining tax withholding settled in cash)."

2. This First Amendment shall be and is hereby incorporated in and forms a part of the Plan.
3. Except as expressly provided herein, all terms and provisions of the Plan shall remain in full force and effect.

[*Signature Page Follows*]

I hereby certify that the foregoing First Amendment was duly adopted by the Board of Directors of ICU Medical, Inc. on December 31, 2019.

Executed on this 31st day of December, 2019.

/s/ Scott Lamb
Scott Lamb
CFO & Treasurer

Exhibit 21

Subsidiaries of Registrant

Name	State or Country of Incorporation
ICU Medical Sales, Inc.	Delaware
ICU Medical de Mexico, S. de R. L. de C.V.	Mexico
ICU Medical Europe S.r.l.	Italy
ICU World, Inc.	Delaware
ICU Medical Germany GmbH	Germany
ICU Medical Slovakia S.r.o.	Slovak Republic
ICU Medical B.V.	Netherlands
ICU Medical Australia Holdings Pty Limited	Australia
ICU Medical SA Pty Ltd	South Africa
EXC Holding Corp.	Delaware
Pursuit Vascular, Inc.	Minnesota
Tangent Medical Technologies, Inc.	Delaware
Excelsior Medical Corporation	Delaware
ICU Medical France S.A.S.	France
ICU Medical Canada Inc.	Canada
ICU Medical Latam LLC	Delaware
ICU UK Medical Limited	United Kingdom
ICU Medical Ireland Limited	Ireland
ICU Medical Argentina S.R.L.	Argentina
ICU Medical Costa Rica, Ltd	Bahamas
ICU Medical Bahamas, Ltd	Bahamas
ICU Medical Chile Limitada	Chile
Hospira Chile Limitada	Chile
ICU Medical Colombia Limitada	Colombia
ICU Medical HIS Mexico S. de R.L. de C.V.	Mexico
ICU Medical Peru S.R.L.	Peru
ICU Medical Australia Pty Limited	Australia
Medical Australia Pty Limited	Australia
Medivet Pty Ltd	Australia
ICU Medical Hong Kong Limited	Hong Kong
ICU Medical India LLP	India
ICU Medical Philippines, Inc.	Philippines
ICU Medical Unlimited Company	Ireland
ICU Medical Italia S.r.l.	Italy
ICU Medical Productos Farmacéuticos y Hospitalarios, S.L.	Spain
BMDI Tuta Healthcare UK Ltd	United Kingdom
ICU Medical Aust MLA Pty Limited	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-90462, 333-90464, 333-04167, 333-175239, 333-198256, and 333-219106 on Form S-8 and 333-228390 on Form S- 3 of our reports dated March 2, 2020, relating to the financial statements of ICU Medical, Inc. and subsidiaries and the effectiveness of ICU Medical Inc. and subsidiaries' internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Costa Mesa, California
March 2, 2020

Exhibit 31.1

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

I, Vivek Jain, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 2, 2020

/s/ Vivek Jain

Chief Executive Officer

Exhibit 31.2

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

I, Scott E. Lamb, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 2, 2020

/s/ Scott E. Lamb

Chief Financial Officer

Exhibit 32

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

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Vivek Jain, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

March 2, 2020

/s/ Vivek Jain

Vivek Jain

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

In connection with the Annual Report of ICU Medical, Inc. (the "Company") on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott E. Lamb, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

March 2, 2020

/s/ Scott E. Lamb

Scott E. Lamb