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, 2021 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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2021, the last business day of registrant's most recently completed second fiscal quarter, was $4,104,813,741*.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2022 was 23,786,887.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2022 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2021, 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.

Changes from Prior Periodic Reports

In this report we have complied with the disclosures required by the Securities and Exchange Commission ("SEC") release No. 33-10890 "Management's Discussion and Analysis, Selected Financial Data, Supplementary Financial Information."

Management’s Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information

In November 2020, the SEC issued Release No. 33-10890, “Management’s Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information” which became fully effective on August 9, 2021. This release was adopted to modernize, simplify, and enhance certain financial disclosure requirements in Regulation S-K. Specifically, the SEC eliminated the requirement for selected financial data, only requiring quarterly disclosure when there are retrospective changes affecting comprehensive income, and amending the matters required to be presented under Management’s Discussion and Analysis (“MD&A”) to, among other things, eliminate the requirement of the contractual obligations table.

We have eliminated from this document the items discussed above that are no longer required. Information on our contractual obligations is still disclosed in a narrative within the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 of Part II of this report.

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 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. In addition, ICU manufactures automated pharmacy IV compounding systems with workflow technology, closed system transfer devices for preparing and administering hazardous IV drugs and cardiac monitoring systems for critically ill patients.

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 throughout the world.

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.

In September 2021, we entered into a definitive agreement to acquire Smiths Medical 2020 Limited ("Smiths Medical"), the holding company of Smiths Group plc's global medical device business and, on January 6, 2022, the acquisition closed. The Smiths Medical acquisition complements and broadens our existing product portfolio to include syringe and ambulatory infusion devices, vascular access, and vital care products, and significantly strengthens and expands our global market reach. The following business discussion is as of December 31, 2021 and as such does not incorporate the Smiths Medical acquisition.

Products

As of December 31, 2021, 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 Infusion 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* and SwabTip disinfecting caps, used to protect and disinfect any needlefree connector, including competitive brands of connectors, and male luers;

- *ClearGuard HD* antimicrobial barrier caps for hemodialysis catheters; and

- *Tego™* hemodialysis connector used to cap and protect hemodialysis central venous catheter hubs.

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, software and professional services. 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 was the first medical device to be awarded UL Cybersecurity Assurance Program Certification. Also, in 2021 and 2022, the Plum 360 won the award as the top-performing Smart Pump EMR-Integrated; and

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

IV Medication 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 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 and 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 II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K, and is incorporated herein by reference.

Manufacturing

As of December 31, 2021, 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 have four main regional device service centers in 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. In January 2021, we amended our MSA with Pfizer, whereby we manufacture and supply certain agreed upon products to Pfizer. The amendments include a change to the term of the agreement to end on December 31, 2024 with Pfizer's unilateral election to extend through December 31, 2025. Other changes to the terms of the MSA include (i) amendments to our level of supply of products to Pfizer, (ii) certain changes to our manufacturing lines, (iii) updates to our supply price with added volume price tiers for annual periods and (iv) certain minimum purchase requirements for certain products. On February 1, 2022, effective as of January 1, 2022, upon our request, Pfizer executed a Product Addendum (the "Product Addendum") to our MSA agreement, whereby Pfizer manufactures and supplies to us certain agreed upon products. The Product Addendum includes the supply of additional product to us subject to certain time and pricing terms and conditions. The Product Addendum expires on November 30, 2022.

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 United States ("U.S.") dollars, Euro and Canadian dollars. We are not dependent on any single customer.

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 two owned and one leased distribution centers, which include King of Prussia, Pennsylvania; Los Angeles, California; and Dallas, Texas. We also utilize a number of public warehouses as part of our supply chain.

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 drug products, medical devices and combination drug/device products in the U.S. to assure the safety and effectiveness of such medical products for their

intended uses and otherwise meet the applicable requirements of the Federal Food, Drug and Cosmetic Act (“FDC Act”). The Federal Trade Commission ("FTC") 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.

Medical Device Regulation in the U.S.

The majority of our products are regulated by the FDA as medical devices in the U.S. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the U.S. will require either a pre-market notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDC Act, also referred to as a 510(k) clearance, or approval from the FDA of a pre-market approval ("PMA") application. Under the FDC Act, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I devices are those that pose the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of current good manufacturing practices ("cGMPs") for medical devices known as the Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed into Class III.

Manufacturers of most Class II devices are required to obtain from the FDA a 510(k) clearance for permission to commercially distribute the device. Class III devices require approval of a PMA application evidencing safety and effectiveness of the device.

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. A predicate device is a legally marketed device that is not subject to pre-market approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. 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) pre-market notification. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption ("IDE") regulations. If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is "not substantially equivalent," the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* classification request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination not to seek a new 510(k) or other form of marketing authorization for the modification to the 510(k)-cleared product, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) clearance or PMA approval is obtained or a *de novo* classification is granted.

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. Following receipt of a PMA application, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDC Act to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' facilities to ensure compliance with the QSR. The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended

use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement, or in some cases a new PMA.

After a device is cleared or approved or otherwise authorized for marketing, numerous pervasive regulatory requirements continue to apply unless explicitly exempt. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDC Act that may present a risk to health;
- complying with requirements governing Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect public health or to provide additional safety and effectiveness data for the device.

Drug Regulation in the U.S.

Certain of our IV solutions products are regulated by the FDA as drugs. In the U.S., the FDA regulates drugs under the FDC Act, and its implementing regulations, and biologics under the FDC Act and its implementing regulations. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements;
- submission to the FDA of an investigational new drug application ("IND"), which must become effective before clinical trials may begin;
- approval by an institutional review board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended purpose;
- preparation of and submission to the FDA of a New Drug Application ("NDA") or abbreviated new drug application ("ANDA") after completion of all required clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;

- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices ("GCPs"); and

- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the U.S.

Prior to beginning clinical trials of a drug product in the U.S., an IND must be submitted to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. An IND must become effective before human clinical trials may begin. Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. The NDA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product’s chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of an NDA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced and of select clinical trial sites, the FDA may issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will generally describe all of the deficiencies that the FDA has identified in the NDA. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a drug is granted, such approval will be granted for particular indications and may include limitations on the indicated uses for which such drug may be marketed. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more post-market studies and surveillance to further assess and monitor the drug’s safety and effectiveness after commercialization, and may limit further marketing of the drug based on the results of these post-marketing studies.

Any drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Post-Market Enforcement

The FDA may withdraw marketing authorizations for drugs or medical devices if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things: complete withdrawal of the product from the market, product recalls, fines, warning letters, untitled letters, clinical holds on clinical studies, refusal of the FDA to approve pending applications or supplements to approved applications, product seizures or detention, refusal to

permit the import or export of products, consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs, the issuance of corrective information, injunctions, or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of drugs and medical devices. A company can make only those claims relating to safety and efficacy, purity and potency that are cleared or approved by the FDA and in accordance with the provisions of the authorized label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Regulation of Medical Devices in the European Union

The European Union ("EU") has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC (the "EU Medical Devices Directive") which has been repealed and replaced by Regulation (EU) No 2017/745 (the "EU Medical Devices Regulation"). Our current certificates have been granted under the EU Medical Devices Directive whose regime is described below. However, as of May 26, 2021, some of the EU Medical Devices Regulation requirements apply in place of the corresponding requirements of the EU Medical Devices Directive with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of medical devices in the EU will notably require that our devices be certified under the new regime set forth in the EU Medical Devices Regulation when our current certificates expire.

Medical Devices Directive

Under the EU Medical Devices Directive, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I to the EU Medical Devices Directive, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the EU Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the European Conformity ("CE") mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

Medical Devices Regulation

The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the EU Medical Devices Directive, the EU Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims to increase harmonization across the EU.

The EU Medical Devices Regulation became effective on May 26, 2021. The new Regulation among other things:

- strengthens the rules on placing devices on the market (e.g. reclassification of certain devices and wider scope than the EU Medical Devices Directive) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation, in particular the obligations described below.

The EU Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier ("UDI") database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier ("UDI-DI") specific to a device, and a production identifier ("UDI-PI") to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU Medical Devices Regulation. Under this system, serious incidents and Field Safety Corrective Actions ("FSCAs") must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is

fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect, which, directly or indirectly, might have led or might lead to the death of a patient or user or of other persons or to a temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

The advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the U.S., on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA") which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Brexit

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency ("MHRA") has become the sovereign regulatory authority responsible for Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the United Kingdom's ("UK's") withdrawal from the EU ("Brexit") transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA (but manufacturers were given a grace period of four to 12 months, depending on the classification of the device, to comply with the new registration process) before being placed on the Great Britain market. The MHRA only registers devices where the manufacturer or their UK responsible person has a registered place of business in the UK. Manufacturers based outside the UK need to appoint a UK responsible person that has a registered place of business in the UK to register devices with the MHRA in line with the grace periods. By July 1, 2023, in Great Britain, all medical devices will require a UK Conformity Assessed ("UKCA") mark but CE marks issued by EU notified bodies will remain valid until this time. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain.

An MHRA public consultation was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive and the EU In Vitro Diagnostic Medical Devices Directive 98/79/EC), in particular to create a new access pathway to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD regulation and foster sustainability through the reuse and remanufacture of medical devices. The regime is expected to come into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The consultation indicated that the MHRA

will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

In addition, the trade deal between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization-related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

Under the terms of the Northern Ireland Protocol, Northern Ireland follows EU rules on medical devices and devices marketed in Northern Ireland require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark is required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK notified body conducts such assessment, a 'UKNI' mark is applied and the device may only be placed on the market in Northern Ireland and not the EU.

Manufacturing Regulation

We must also comply with FDA and International Organization for Standardization ("ISO") 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 notified bodies and ISO inspections and audits 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, cGMPs and similar foreign requirements. The FDA, other regulatory agencies and notified bodies outside the U.S. monitor compliance with these requirements through inspections and audits 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.

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. 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;

- 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 (physician assistants, nurse practitioners, clinical nurse

specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals and ownership and investment interests held by the physicians described above and their immediate family members; 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.

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 "ACA"), which, 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, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 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 data privacy, security and data breach notification laws governing the collection, use, disclosure and protection of health-related and other personal information. In the U.S., numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the General Data Protection Regulation ("GDPR") imposes strict requirements for processing the personal data of individuals within the EEA. Further, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

In the EU, the GDPR went into effect in May 2018 and imposes stringent data protection requirements for controllers and processors of personal data of persons within the EEA. The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA 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. Data privacy laws in the EU and the EEA are developing rapidly and, in July 2020, the Court of Justice of the European Union ("CJEU") limited how organizations could lawfully transfer personal data from the EEA to the U.S. by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses ("SCCs"). While the CJEU upheld the adequacy of the SCCs, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the SCCs cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. The revised SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021.

Since January 2021, companies have to comply with the GDPR and also the UK GDPR. The relationship between the UK and the EU in relation to certain aspects of data protection law remains uncertain, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and remains under review by the Commission during this period. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reform of UK data protection laws following Brexit. There is a risk that any material changes which are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data.

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 acquired product portfolios have increased our competitiveness as we can now provide a one-stop shop for customers and offer more flexible competitive pricing. We also believe our acquired infusion pump product offering will enable us to pull through a larger volume of higher margin infusion consumables, and we believe we have a wider customer reach through our unified distribution channels.

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"). Our CSTD used for the preparation and safe handling of oncology drugs, compete with similar products from BD, and EquaShield. 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.

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, safety and security 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 and/or pending patent applications relating to the technologies found in the Clave / MicroClave connector, MicroClave Clear connector, Neutron connector, Tego connector, ChemoClave system, ChemoLock connector, SwabCap disinfecting cap, Diana hazardous drug compounding system, ClearGuard antimicrobial barrier cap, Cogent hemodynamic monitoring system, and other products.

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. Since the acquisition, we have filed additional patent applications on technologies relating to infusion pumps, software for operating infusion pumps, and software for communicating information to and from infusion pumps.

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 connector, Neutron connector, Tego connector, Swabcap disinfecting cap, Clearguard antimicrobial barrier cap, ChemoClave system, and ChemoLock connector 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 COVID-19 pandemic surges and its impact on hospital admissions and procedure volumes along with production scheduling and customer 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 $47.5 million in 2021, $42.9 million in 2020 and $48.6 million in 2019.

Human Capital Management

We believe our employees are the foundation of our business and are key to executing our strategy globally. The knowledge, skills and abilities of our diverse workforce is paramount in upholding our mission of connecting patients and caregivers through safe, life-saving, life enhancing IV therapy products, systems, and services.

We believe the health and well-being of our employees are cornerstones for our successful operations. Whether you are a machine operator in one of our four manufacturing locations, a material handler in a distribution center, a service technician supporting our products in the field, or a clinician training the use of our products in a hospital, we strive to prioritize the safety of our team members. This includes designing our work environments with a safety first mindset, providing personal protective equipment and safety training beginning day one.

Our ability to attract and retain talented individuals globally begins with our commitment to offer a career that gives people a unique opportunity to work in an exhilarating, fast-paced, inspiring, and collaborative environment where what they do makes a difference. We offer competitive salaries and participation to all employees in incentive plans based on individual and company performance.

We believe the development of our workforce is critical for personal growth and the success of our company as well. We reinforce this with challenging, yet rewarding assignments, continued learning and training programs through our global iLearning platform, and support continued education globally through tuition reimbursement programs. Our team believes in diversity, collaboration, and removing barriers to communication—all to create an environment where innovation and creativity can flourish. This is principal for us in attracting, developing, retaining and rewarding talent on a global scale.

Finally, our leadership team, with its broad, and deep category knowledge and averaging approximately 17 years of experience in IV therapy has the necessary experience to effectively lead the execution of our strategy.

At December 31, 2021, we had approximately 8,500 employees located in over 20 countries.

Geographic Data

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

COVID-19 Pandemic

In March 2020, the World Health Organization characterized a novel strain of coronavirus ("COVID-19") as a global pandemic. The COVID-19 pandemic continues to have widespread and unpredictable impact on global economies, financial markets, and business practices, and continues to impact our business operations, including our employees, customers and suppliers. See “Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” for discussion regarding the impact of the COVID-19 pandemic on our financial results. Also, see “Part I. Item 1A. Risk Factors” for discussion of the risks and uncertainties associated with the COVID-19 pandemic.

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.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, detail below. These risks include, among others, the following:

- We may not realize the anticipated benefits of the Smiths Medical Transaction, which could adversely impact our business and our operating results.
- The COVID-19 pandemic has had a material impact on the global economy and has disrupted our operations and could continue to have an adverse impact on our employees, suppliers and customers, which could adversely and materially impact our business, financial condition and results of operations.
- We operate in a highly competitive industry, our ability to compete effectively to maintain or gain market share depends upon numerous factors, such as product innovation, the quality, convenience and reliability of our products, access to distribution channels and patent protection and pricing. We can give no assurance that we will be successful in implementing any of our competitive strategies.
- We are dependent on certain key suppliers; any supply interruptions could materially harm our business, financial condition and results of operations.
- Damage to our manufacturing facilities or any other supply chain restrictions could materially impact our business, financial condition and results of operations.
- Changes in or failure to comply with certain federal, state, foreign, legal and health regulations may harm our business and financial condition.
- We depend on the leadership of our executive management team and other key personnel; the loss of one or more of our key employees could disrupt our business.
- Our stock price may be volatile and you may be unable to sell your shares at or above your purchase price.

Risks Related to our Strategic Transactions

We may not realize the anticipated benefits of the Smiths Medical Transaction, which could adversely impact our business and our operating results.

The Smiths Medical acquisition that closed on January 6, 2022 was a significant transaction for us and the Smiths Medical business significantly expands our global presence. The success of our business will depend, in part, on our ability to realize our anticipated benefits, opportunities and synergies from combining the businesses of our company and the Smiths Medical business. We can provide no assurance that the anticipated benefits of the Smiths Medical transaction will be fully realized in the time frame anticipated or at all. Integrating the operations of the Smiths Medical business with that of our own is a complex, costly and time-consuming process and the nature of a carve out acquisition makes it inherently more difficult to assume operations on closing day as well as to integrate activities, as certain systems, processes and people may not all have transferred with the acquired business to support such activities. The integration process may disrupt the businesses and, if implemented ineffectively, would restrict the realization of the full expected benefits. The failure to meet the challenges involved in integrating the two businesses could cause an interruption of, or a loss of momentum in, the activities of the combined businesses and could adversely affect the results of operations of the combined businesses. Potential difficulties that may be encountered in the integration process include the following:

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

Any one or all of these factors may increase operating costs or lower anticipated financial performance. Achieving the anticipated benefits and the potential benefits underlying our reasons for the Smiths Medical business acquisition will depend on successful integration of the businesses. Because of the significance of the Smiths Medical business acquisition to us, our failure to successfully integrate the Smiths Medical business with that of our own could have a material adverse impact on our business, financial condition and results of operations.

The Smiths Medical business acquisition has resulted in organizational change and significant growth to our business. If we fail to effectively manage this growth and change to our business in a manner that preserves our reputation with customers and the key aspects of our corporate culture, our business, financial condition and results of operations could be harmed.

The Smiths Medical business has resulted in significant growth in our personnel and operations. We will continue to incur significant expenditures and the allocation of management time to assimilate the Smiths Medical business employees in a manner that preserves the key aspects of our corporate culture, including a focus on strong customer satisfaction, but there can be no assurance that we will be successful in our efforts. If we do not effectively integrate, train and manage our combined employee base and maintain strong customer relationships, our corporate culture could be undermined, the quality of our products and customer service could suffer, and our reputation could be harmed, each of which could adversely impact our business, financial condition and results of operations.

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

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

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 recently acquired the Smiths Medical business, which

includes syringe and ambulatory infusion devices, vascular access, and vital care products, but we have significant integration efforts to achieve the anticipated benefits. See “We may not realize the anticipated benefits of the Smiths Medical Transaction, which could adversely impact our business and our operating results.”

We have additional production facilities outside the U.S. to reduce labor costs. The expansion of our marketing, distribution and product offerings both internally and through acquisitions or by contract may place substantial burdens on our management resources and financial controls. Decentralization of assembly and manufacturing could place further burdens on management to manage those operations and maintain efficiencies and quality control.

The increasing burdens on our management resources and financial controls resulting from internal growth and acquisitions could adversely affect our operating results. In addition, acquisitions may involve a number of special risks in addition to the difficulty of integrating cultures and operations and the diversion of management’s attention, including adverse short-term effects on our reported operating results, dependence on retention, hiring and training of key personnel, risks associated with unanticipated problems or legal liabilities and amortization of acquired intangible assets, some or all of which could materially and adversely affect our operations and financial performance.

As a result of the Smiths Medical acquisition, we have used a significant portion of our cash on hand and incurred a substantial amount of debt to finance the cash consideration portion and certain other amounts paid in connection with the Smiths Medical transaction, which could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness.

Following the financing of the Smiths Medical acquisition transaction, we have significantly less cash, cash equivalents and investment securities on hand than the approximately $571.9 million of cash, cash equivalents and investment securities we had as of December 31, 2021. Although our management believes that we continue to have sufficient access to cash to meet our business objectives and capital needs, we do have a decreased availability of cash, cash equivalents and investment securities and we expect to have such decreased availability of cash for a period of time following the consummation of the Smiths Medical transaction which could constrain our ability to grow our business. In connection with the Smiths Medical transaction and the payment of the cash consideration, we entered into Senior Secured Credit Facilities (the "Senior Secured Credit Facilities") of $2.2 billion consisting of a term loan A facility of $850.0 million, a term loan B facility of $850.0 million and a revolving credit facility of $500.0 million. As a result of the credit facilities, we incurred additional borrowing costs. Our more leveraged financial position following the Smiths Medical transaction could make us vulnerable to general economic downturns and industry conditions, and place us at a competitive disadvantage relative to our competitors. In the event that we do not have adequate capital to maintain or develop our business, additional capital may not be available to us on a timely basis, on favorable terms, or at all. Moreover, our senior secured credit facilities have certain restrictions that may limit how we operate our business, including limiting our ability to engage in certain transactions and to incur additional indebtedness, and our business may be materially and adversely affected if these restrictions prevent us from implementing our business plan.

We have and 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. 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 and we acquired Smiths Medical in January 2022, which includes syringe and ambulatory infusion devices, vascular access, and vital care products. We invested significant time and resources into the HIS integration in order to achieve the anticipated benefits of the transaction and we intend to do the same with the Smiths Medical integration.

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.

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. The price and supply of these materials may be impacted or disrupted for reasons beyond our control including supplier shutdowns, transportation delays, inflationary pricing pressures, work stoppages, labor shortages and governmental regulatory actions. We have experienced, and may continue to experience, significant challenges to our global transportation channels and other aspects of the global supply chain network, including to the cost and availability of raw materials and components due to shortages and resulting cost inflation.

Additionally, the COVID-19 pandemic continues to impact supply channels resulting in raw material shortages and supply chain disruptions generally. 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 and foreign 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 to fully 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 disruption to our 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 COVID-19 pandemic), work stoppages, labor shortages and similar interruptions affecting our manufacturing facilities or our suppliers and logistics partners could materially and adversely impact our business, financial condition and results of operations. The COVID-19 pandemic has caused us to temporarily shut down some of our facilities, to date these shut downs have not had a material impact on our business. Additionally, in 2021, we have experienced supply chain disruptions and general supply constraints as a result of the continued economic uncertainty and in part due to COVID-19 infections and quarantine protocols.

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, work stoppages or labor shortages could render us unable to manufacture our products or require us to reduce the output of products at our facilities. Two of our manufacturing facilities are located near known earthquake fault zones and are vulnerable to damage from earthquakes. 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.

Prolonged periods of inflation could have a material adverse effect on our results of operations.

We have also experienced a significant increase in material component inflation in 2021, as well as inflation in other costs, such as freight and labor prices. Continued supply chain disruptions and delays, as well as continued heightened inflation, could lead to continued inefficiencies and heightened costs that could negatively impact our performance and our results of operations. Additionally the majority of our sales are conducted pursuant to long-term contracts. Although we have attempted to minimize the effect of inflation on our business through contractual protections, the presence of longer pricing periods within our contracts along with sustained or higher than anticipated inflation increases the likelihood that the contract protections do not adequately mitigate the financial impact of inflation. If our contractual protections do not adequately protect us in the context of substantial cost increases and inflationary pressures, it could have a material adverse effect on our results of operations.

The COVID-19 pandemic has disrupted how we, our suppliers and our customers operate and the duration and extent to which this will impact our business, future results of operations, liquidity and overall financial performance remains uncertain.

The COVID-19 pandemic has created significant volatility, uncertainty, and economic disruption. We operate globally and the COVID-19 pandemic and its adverse effects have impacted most of the locations where we, our customers and our suppliers conduct business and, as a result, we have experienced some disruption to our operations, most notably due to reduced demand for our disposable product portfolio.

Many hospitals are limiting access to their facilities to essential personnel and prioritizing their time and attention to COVID patients, which may negatively affect demand for our products by limiting the ability of our sales personnel to negotiate new and maintain existing contracts with customers. We have also experienced significant reductions in demand for certain products as our health care customers re-prioritize the treatment of patients, delay elective procedures and shift resources and operations to fight COVID-19 and the complications it causes. For example, during 2020, we have experienced lower demand from hospital customers for our Infusion Consumables non-dedicated sets and lower demand for our Infusion Systems dedicated sets. Additionally, the COVID-19 pandemic could potentially adversely affect our distributors if they are not able to maintain their historical levels of sales.

Our manufacturing, distribution and pump service facilities are operating under our business continuity plan due to the need for our critical healthcare products; however, we have taken certain precautionary measures including the following to maximize the safety of our employees and to mitigate disruption to our operations:

- implemented physical distancing measures;
- enhanced hygiene protocols and increased frequency of cleaning procedures;
- acquired additional personal protective equipment;
- developed contingency plans and protocols to assess employee illness;
- helped employees with childcare issues due to school and daycare closures;
- initiated a visitor pre-entry questionnaire to limit potential exposure in our facilities.

While we anticipate that the foregoing measures are temporary, we cannot predict the specific duration for which these precautionary measures will stay in effect, and we may elect to take additional measures as the information available to us continues to develop. These actions, and any future actions we may take in response to the COVID-19 pandemic, could negatively impact our business, financial condition and results of operations.

The duration and extent of the impact on our business from the COVID-19 pandemic depends on future developments that cannot be fully predicted at this time, as such, the impact of the COVID-19 pandemic on our future results of operations and overall financial performance remain uncertain and cannot as yet be quantified. Additional factors that have contributed or may contribute to the adverse impact of the COVID-19 pandemic on our business, results of operations, financial condition and liquidity include, without limitation, the following:

- lost revenue or additional costs associated with either disruptions at our production and distribution facilities or interruptions in our supply chain, including shortages of raw materials or components for our product;
- labor shortages as a result of COVID-19 infections and quarantine protocols;

- fluctuations in demand from customers as a result of an increase in COVID-19 patient admissions in hospitals offset by the decline in non-COVID-19 patient admissions;
- healthcare customers that defer the more profitable elective procedures may experience financial difficulties and may be unable to pay within payment terms for the products they purchased;
- potential lower demand in future periods due to over-purchasing of our products due to the COVID-19 pandemic and supply chain disruption;
- reduced revenue due to delays in implementation of our infusion systems and oncology products at hospital locations due to restricted access;
- higher operating costs related to additional compensation paid to our manufacturing and distribution facility workers;
- volatility in cash flow, revenue and income due to foreign currency fluctuations and volatility;
- lower income due to a delay in cost savings projects as a result of the travel and social distancing requirements of COVID-19.

To the extent the COVID-19 pandemic and related containment measures continue to adversely affect regional, national and global economic conditions and financial markets, as well as the business, results of operations, financial conditions and liquidity of us, our suppliers and our customers, it may also have the effect of heightening many of the risks described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2021, including the risks resulting from our dependency on key personnel; impairment of our supply chain or manufacturing facilities; and the impact of negative economic conditions. In addition, in light of the COVID-19 pandemic and the measures taken to limit its spread, our historical information regarding our business, results of operations, financial condition or liquidity may not be representative of the future results of operations, financial condition, liquidity or other financial or operating results of us or our business.

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

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

We are subject to risks associated with debt financing.

The credit agreements governing our Credit Facility and Senior Secured Credit Facilities contain, among other things, certain customary restrictive covenants that limit our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, make certain investments, pay dividends, enter into certain transactions with affiliates, and transfer or dispose of assets as well as financial covenants. While we have not previously breached and are not currently in breach of these or any other covenants contained in our credit agreements, there can be no guarantee that we will not breach these covenants in the future.

Additionally, our ability to comply with these covenants may be affected by events beyond our control, including the COVID-19 pandemic, supply chain interruptions or general economic environment, including increases in inflation and interest rates. These covenants could also limit our ability to seek capital through the incurrence of new indebtedness or, if we are unable to meet our obligations, require us to repay any outstanding amounts with sources of capital we may otherwise use to fund our business. As such, these restrictive covenants contained in our Credit Facility and our Senior Secured Credit Facilities may restrict our ability to pursue our business strategies.

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 organized buying 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 the 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, clearances or certifications, and manufacture quality products in an economic and timely manner. Even if we are able to develop successful 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. 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 notified bodies, 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 2021. We also are adding additional IV Solutions capacity as we transition certain product lines to our Austin manufacturing facility from Rocky Mount.

If we do not achieve significant sales of these new/transitioned 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.

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, GPOs and other payors, 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 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. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory approval or certification may not be available or adequate, 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 our 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.

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.

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.

Changes in and failures to comply with foreign, federal, and state data privacy and security laws, regulations and standards may adversely affect our business, operations and financial performance.

We are subject to various federal, state and foreign laws that govern the collection, use, disclosure, retention and security of personal information, including patient health information. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. In the U.S., numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, federal and state health information privacy laws, and federal and state consumer protection laws and regulations (e.g. Section 5 of the Federal Trade Commission Act (the "FTC Act")). For example, the privacy, security and breach notification rules promulgated under 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, establish a set of national privacy and security standards for the protection of protected health information ("PHI") by health plans, health care clearinghouses and certain health care providers, called covered entities, and the business associates with whom such covered entities contract for services that involve creating, receiving, maintaining or transmitting PHI, as well as their covered subcontractors. HIPAA also requires covered entities to provide individuals with certain rights with respect to their PHI, and requires covered entities to enter into a written business associate contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with the requirements of HIPAA.

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.

Penalties for failure to comply with a requirement of HIPAA vary significantly depending on the nature of violation and could include civil monetary or criminal penalties. 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.

Certain states have also adopted privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, California enacted the California Consumer Privacy Act of 2018 (the "CCPA") went into effect on January 1, 2020. The CCPA applies to certain businesses that collect personal information from California residents. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for health-related information, including PHI maintained by covered entities and business associates, the CCPA may increase our compliance costs and potential liability. Further, the California Privacy Rights Act ("CPRA") recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the U.S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In addition, the CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or applicable state laws.

Furthermore, the FTC and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act. 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.

Foreign data protection laws, including the GDPR, which became effective in May 2018, and EU and EEA member state data protection legislation, may also apply to health-related and other personal data obtained outside of the U.S. The GDPR imposes strict requirements for processing the personal data of individuals within the EEA. The GDPR has and will continue to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process data about them. Fines for non-compliance with the GDPR are significant-the greater of €20 million or 4% of global turnover. The GDPR provides that EU and EEA member states may impose further obligations relating 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. Data privacy laws in the EU and the EEA are developing rapidly and, in July 2020, the Court of Justice of the EU (the "CJEU") limited how organizations could lawfully transfer personal data from the EEA to the U.S. by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses ("SCCs"). While the CJEU upheld the adequacy of the SCCs, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the SCCs cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to

non-EEA entities subject to the GDPR. The revised SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and remains under review by the Commission during this period. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term.

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 2019 through December 2021, our trading price ranged from a high of $282.00 per share to a low of $148.89 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, general economic trends (including the COVID-19 pandemic) and substantial product orders could contribute to the volatility in the price of our common stock.

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 58% of our outstanding shares at the end of 2021. 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.

Disruptions at the FDA, other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved, certified, or commercialized in a timely manner, or at all, 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, foreign regulatory authorities and notified bodies to review and approve or certify new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government's ability to perform routine functions. Average review times at the FDA, other government agencies, foreign regulatory authorities and notified bodies 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. For example, over the last several years, 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020 the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities and notified bodies outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA, other regulatory authorities or notified bodies from conducting their regular inspections, audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. While several notified bodies have been designated the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation as a consequence of which review times have lengthened. This situation could impact our ability to grow our business in the EU and EEA.

Legal, Compliance, and Regulatory Risks

We are subject to certain 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 transparency laws regarding payments and other transfers of value made to physicians and other

licensed healthcare professionals. 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;
- 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. 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. 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;
- 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, 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 U.S. Department of Health and Human Services' CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives, and teaching hospitals), and applicable manufacturers and GPOs, to report annually ownership and investment interests held by physicians and their immediate family members;
- 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 ACA was signed into law introducing comprehensive health insurance and healthcare reforms in the U.S. The ACA, 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. Additionally, the ACA has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payors 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, particularly in light of the new presidential administration. 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 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.

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. Additionally, 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.

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.

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 requirements of the FDA and regulatory agencies in other countries.

We and our products are subject to extensive regulation in the U.S. and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies and notified bodies 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; pre-market clearance, approval and certification; 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 medical device products are subject to clearance or approval by the U.S. FDA under the 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 PMA application from the FDA, unless an exemption applies. Under the 510(k) process, the manufacturer must submit to the FDA a pre-market notification, demonstrating that the device is "substantially equivalent," as defined in the FDC Act, 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.

We currently market certain products that have received 510(k) clearance, and we may pursue 510(k) clearance for future products. 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 be eligible for 510(k) clearance rather than undergoing a more time consuming pre-market approval procedure or that, in any case, they will receive clearance or approval from the FDA. For example, in 2022, we acquired Smiths Medical, which has marketed its PORT-A-CATH implantable access systems pursuant to PMA approval. 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. 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.

We do not know whether we will pass or be found compliant in any future inspections by FDA or other regulatory authorities. 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 or certification 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.

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 steps that the FDA intended to take to modernize the pre-market notification pathway under Section 510(k) of the FDC Act. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included 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. These proposals have not yet been finalized or adopted, and the FDA 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.

More recently, in September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" pre-market review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by demonstrating that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list of device types appropriate for the "safety and performance based pathway" and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA and foreign regulations and guidance are often revised or reinterpreted by the FDA and foreign counterparts in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance, approval, or certification to manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance, approval, or certification; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

For instance, the EU landscape concerning medical devices recently evolved. On May 25, 2017, the EU Medical Devices Regulation entered into force, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation with regard to registration of economic operators and of devices, post-market surveillance, market surveillance and vigilance requirements.

Subject to the transitional provisions and in order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces EU

Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the CE mark to our products, without which they cannot be sold or marketed in the EU. See – Government Regulation. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU.

The aforementioned EU rules are generally applicable in the EEA. Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

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 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. For example, on October 1, 2021, Smiths Medical received a Warning Letter from the FDA following an inspection of Smiths Medical’s Minneapolis, Minnesota Facility on March 30, 2021. The Warning Letter cited, among other things, failures to comply with FDA's medical device reporting requirements and failures to comply with applicable portions of the QSR. Although we believe Smiths Medical will be able to successfully resolve the issues identified in the Warning Letter, there is no guarantee that Smiths Medical will be able to do so in a timely manner or that similar compliance issues will not be identified in a future FDA inspection.

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 or foreign regulatory authorities 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 or certifications of new products or modified products;
- withdrawing clearances, approvals, or certifications 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 EU, we must conform to additional requirements and demonstrate conformance to harmonized quality standards. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). Subject to the transitional provisions, manufacturers of medical devices must also comply with the EU Medical Devices

Regulation. Compliance with these requirements assure that medical devices are both safe and effective and do not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons and meet all applicable established standards prior to being marketed in the EU. There is no assurance that we will continue to meet the requirements for distribution of our products in Europe.

In addition, the EU Medical Devices Regulation, among other things:

- strengthens the rules on placing devices on the market (e.g. reclassification of certain devices and wider scope than the EU Medical Devices Directive) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure 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 certifications, or we may be required to modify products already installed at our customers' facilities to comply with the official interpretations of the EU Medical Devices Regulation.

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 or certifications 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, approved or certified by the FDA, foreign regulatory authorities and notified bodies for specific indications of use. 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 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 authorities determine 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 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.

Litigation, product liability claims or product recalls could be costly and could expose us to loss.

The use of our products exposes us to an inherent risk of product liability. Further, the medical device industry has historically been subject to extensive litigation and we cannot offer any assurance that we will not face product liability or other suits in the future. 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 million per occurrence. However, 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. A successful claim against us in excess of insurance coverage could materially and adversely affect us, and result in substantial liabilities and reputational harm including product recalls or withdrawals from the market, withdrawal of clinical trial participants, the inability to commercialize our existing or new products, distraction of management's attention from our primary business or decreased demand for our products or, if cleared or approved, products in development.

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.

Additionally, 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.

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 foreign regulatory authorities, 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 and foreign regulatory authorities 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 or foreign regulatory authorities 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, approval, or certification 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. For example, on June 26, 2020, Smiths Medical ASD initiated Class 1 recalls of a Medfusion Syringe Pump. Although we plan to work with the FDA to complete the Class 1 recall, and ultimately close, this product recall, we can provide no assurance that we will be able to do so

in a timely manner, or at all. In addition, the costs associated with conducting and closing this recall, including any liabilities we may incur, could have a material adverse effect on our business, financial condition and results of operations.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or foreign regulatory agencies may require, or we may decide, that we will need to obtain new clearances, approvals or certifications for the device before we may market or distribute the corrected device. Seeking such clearances, approvals or certifications 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 or foreign regulatory authorities 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 or foreign regulatory authorities. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory authorities. If the FDA or foreign regulatory authorities disagree 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.

Geographic Risks

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 U.S. 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 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 certain exposures related to 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. During 2021, we recorded $1.0 million in foreign exchange losses due to the volatility of foreign exchange rates as a result of continued uncertainty caused by the ongoing COVID-19 pandemic.

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.

General Risk Factors

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 28% of our revenue in 2021 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.

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

- economic and political uncertainty;
- 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;
- 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;
- 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 (including COVID-19); and
- imposition of government controls.

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.

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 forego 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

Our material properties used by us in connection with our corporate administrative operations, manufacturing, distribution, research and development and service centers as of December 31, 2021, 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
Houten, Netherlands	7,341	Corporate Offices	Leased
Montreal, Canada	16,414	Corporate Offices/Device service center	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
Dallas, Texas, U.S.	610,806	Distribution Warehouse	Leased
King of Prussia, Pennsylvania, U.S.	105,571	Distribution Warehouse	Owned
Santa Fe Springs, California, U.S.	76,794	Distribution Warehouse	Owned
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 Annual Report on 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 to pay down our long-term debt 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, 2022, we had 48 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 2021:

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)]
10/01/2021 - 10/31/2021	—	$ —	—	$ 100,000,000
11/01/2021 - 11/30/2021	—	$ —	—	$ 100,000,000
12/01/2021 - 12/31/2021	—	$ —	—	$ 100,000,000
Fourth quarter 2021 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. RESERVED

Not applicable. See "Changes From Prior Periodic Reports" in Part I, Item 1 of this Annual Report on Form 10-K.

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 with pain management and safety software technology, dedicated and nondedicated IV sets and needlefree connectors 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 preparing and administering hazardous IV drugs and cardiac monitoring systems for critically ill patients.

Acquisition of Smiths Medical 2020 Limited

During September 2021, we entered into a definitive agreement to acquire Smiths Medical 2020 Limited ("Smiths Medical"), the holding company of Smiths Group plc's global medical device business and, on January 6, 2022, the acquisition closed for a purchase price of $1.9 billion in cash, 2.5 million of fully paid and non-assessable shares of our common stock, par value $0.10 per share and a potential contingent earn-out payment of $100.0 million in cash, based on our common stock performance and other considerations. Results of operations of acquired companies are included in our consolidated financial results from the date of acquisition; accordingly, Smiths Medical will be consolidated beginning in the first quarter of 2022.

To partially finance the acquisition, on January 6, 2022 we entered into a credit agreement with Wells Fargo Bank, National Association and other lenders. The credit agreement provides for $2.2 billion of Senior Secured Credit Facilities, including a term loan A facility of $850.0 million, a term loan B facility of $850.0 million and a revolving credit facility of $500.0 million. See "Liquidity and Capital Resources" in the remainder of this item and Note 17 in our accompanying consolidated financial statements for additional information.

COVID-19

The novel coronavirus and its variants ("COVID-19") continues to have an impact on our business operations. Our manufacturing, distribution and pump service facilities continue to operate under our business continuity plan and our precautionary safety measures implemented to maximize the safety of our employees and to mitigate disruption to our business remain in effect.

While we continually monitor the ongoing and evolving impact of the effect of the COVID-19 pandemic on our operations the overall impact will not be fully reflected in our results of operations until future periods. The duration and extent of the impact from the COVID-19 pandemic depends on future developments that cannot be fully predicted at this time, as such, the impact of the pandemic on our overall financial performance remains uncertain and cannot as yet be quantified. See “Part I. Item 1A. Risk Factors” for discussion of the risks and uncertainties associated with the COVID-19 pandemic.

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,					
	2021		2020		2019	
	$	% of Revenue	$	% of Revenue	$	% of Revenue
Domestic	$ 941.8	72 %	$ 910.6	72 %	$ 923.3	73 %
International	374.5	28 %	360.4	28 %	342.9	27 %
Total Revenue	$ 1,316.3	100 %	$ 1,271.0	100 %	$ 1,266.2	100 %

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

	Year Ended December 31,		
Product line	2021	2020	2019
Infusion Consumables	42 %	37 %	37 %
Infusion Systems	27 %	28 %	26 %
IV Solutions	27 %	31 %	33 %
Critical Care	4 %	4 %	4 %
	100 %	100 %	100 %

As of December 31, 2021, we manage our product distribution in the U.S. through a network of two owned and one leased distribution facilities in combination with independent distributors and third-party fulfillment and logistics providers. Our end customers, which include healthcare providers and original equipment manufacturer suppliers, may order and receive our products directly from us or through an independent full-line distributor. 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 organizations 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 COVID-19 pandemic surges and its impact on hospital admissions and procedure volumes along with production scheduling and customer 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.

We present income statement data in Item 8. Financial Statements and Supplementary 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		
	2021	2020	2019
Total revenues	100 %	100 %	100 %
Gross profit	37 %	36 %	37 %
Selling, general and administrative expenses	23 %	22 %	22 %
Research and development expenses	4 %	3 %	4 %
Restructuring, strategic transaction and integration expenses	1 %	2 %	6 %
Change in fair value of contingent earn-out	— %	1 %	(4)%
Contract settlement	— %	— %	— %
Total operating expenses	28 %	28 %	28 %
Income from operations	9 %	8 %	9 %
Interest expense	— %	— %	— %
Other income, net	— %	— %	1 %
Income before income taxes	9 %	8 %	10 %
Provision for income taxes	1 %	1 %	1 %
Net income	8 %	7 %	9 %

Total revenues were $1.3 billion, $1.3 billion and $1.3 billion for 2021, 2020 and 2019, respectively.

In addition to comparing changes in revenue on a U.S. GAAP basis, we also compare the changes in revenue from one period to another using constant currency. We provide constant currency information to enhance the visibility of underlying business trends, excluding the effects of changes in foreign currency translation rates. To calculate our constant currency results, we apply the average exchange rate for revenues from the prior year to the current year results. These results should be considered in addition to, not as a substitute for, results reported in accordance with GAAP. Results on a constant currency basis, as we present them, may not be comparable to similarly titled measures used by other companies and are not measures of performance presented in accordance with GAAP.

Infusion Consumables

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2021	2020	2019	2021 over 2020		2020 over 2019	
Infusion Consumables	$ 555.2	$ 473.7	$ 477.6	$ 81.5	17.2 %	$ (3.9)	(0.8)%

Infusion Consumables revenue increased in 2021, as compared to 2020. The increase was due to lower hospital census in 2020 driven by the onset of the COVID-19 pandemic, growth in our global oncology, U.S. core infusion and renal products

and the impact from foreign exchange. On a constant currency basis, Infusion Consumables revenue would have been $546.3 million, an increase of $72.6 million or 15.3%, as compared to 2020.

Infusion Consumables revenue decreased in 2020, as compared to 2019. The decrease was mostly driven by overall lower demand for our products due to the COVID-19 pandemic, partially offset by sales from new customers and sales of our ClearGuard HD product, which we acquired in our fourth quarter 2019 acquisition of Pursuit. On a constant currency basis, Infusion Consumables revenue was comparable at $474.0 million for 2020, as the full year impact of foreign currency was negligible.

Infusion Systems

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2021	2020	2019	2021 over 2020		2020 over 2019	
Infusion Systems	$ 352.3	$ 359.7	$ 328.3	$ (7.4)	(2.1)%	$ 31.4	9.6%

Infusion Systems revenue decreased in 2021, as compared to 2020. The decrease was primarily due to large volume pump sales driven by higher COVID-19-related purchases during the second and third quarters of 2020 and a decline in sales of our non-large volume pump business, which has been partially offset by higher dedicated set sales in 2021 as a result of higher hospital census and larger install base of large volume pump from new customer installations. On a constant currency basis, Infusion Systems revenue in 2021 would have been $351.4 million, a decrease of $8.3 million or 2.3%, as compared to 2020.

Infusion Systems revenue increased in 2020, as compared to 2019. The increase in revenue was primarily due to high demand for our infusion pumps during the COVID-19 pandemic, offset partially by lower demand for our dedicated infusion sets and losses of our non-core ambulatory pump business. On a constant currency basis Infusion Systems revenue in 2020 would have been $364.7 million, an increase of $36.4 million or 11.1%, as compared to 2019.

IV Solutions

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2021	2020	2019	2021 over 2020		2020 over 2019	
IV Solutions	$ 359.5	$ 389.0	$ 415.0	$ (29.5)	(7.6)%	$ (26.0)	(6.3)%

IV Solutions sales decreased in 2021, as compared to 2020, primarily due to lower contract manufacturing sales to Pfizer and lower production volumes due to supply constraints in the market.

IV Solutions sales decreased in 2020, as compared to 2019, due to lower contract manufacturing sales to Pfizer and higher sales in the first quarter of 2019 to non-contracted customers.

Critical Care

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2021	2020	2019	2021 over 2020		2020 over 2019	
Critical Care	$ 49.3	$ 48.6	$ 45.3	$ 0.7	1.4 %	$ 3.3	7.3 %

Critical Care revenue increased for 2021, as compared to 2020 due primarily to higher U.S. hospital census as a result of the COVID-19 pandemic.

Critical Care revenue increased in 2020, as compared to 2019, primarily as a result of growth in the Asia region and improved manufacturing capacity.

Gross Margins

Gross margins were 37.3%, 36.3% and 37.3% for 2021, 2020 and 2019, respectively.

The increase in gross margin in 2021, as compared to 2020 was primarily due to product mix and increased plant volumes, partially offset by increased costs for raw materials, direct labor and freight.

The decrease in gross margin in 2020, as compared to 2019 was primarily due to lower IV Solutions manufacturing volumes and unfavorable product mix as a result of lower demand for our consumables products during the COVID-19 pandemic.

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
	2021	2020	2019	2021 over 2020		2020 over 2019	
SG&A	$ 302.6	$ 284.0	$ 277.0	$ 18.6	6.5 %	$ 7.0	2.5 %

Consolidated SG&A expenses increased in 2021, as compared to 2020. Compensation expense increased $7.9 million, dealer fees increased $5.7 million, stock compensation increased $2.9 million, legal expenses increased $2.3 million and computer expenses increased $1.5 million. Offsetting these increases was a $2.3 million decrease in bad debt expense and $1.6 million decrease in commissions. Compensation expense increased primarily due to increased headcount and annual compensation merit increases. Dealer fees increased due to an increase in revenue from U.S. distributors in the current year. Stock compensation increased due to a change during the current year in the number of performance shares expected to vest. Legal fees increased due to additional services performed in the current year related to various legal matters. Computer expenses increased due to increased maintenance costs as well as increased hardware, software and software subscriptions based on operational needs. Bad debt expense is adjusted quarterly, if deemed necessary, based on an assessment of our accounts receivables and our expectations regarding the collectability of those accounts. Commissions decreased due to the commission plan structure in the prior year, which included certain guaranteed payments.

Consolidated SG&A expenses increased in 2020, as compared to 2019. Dealer fees increased $9.3 million, depreciation and amortization expense increased $7.1 million, compensation expense increased $5.5 million, and stock compensation increased $2.0 million. Offsetting these expense increases was a $6.3 decrease in bad debt expense, a $6.3 million decrease in travel expenses, a $3.7 million decrease in consulting expenses, and a $2.8 million decrease in sales and marketing expenses. Dealer fees increased due to a change to a distribution model from a direct model in Canada and an increase in revenue from distributors. Depreciation and amortization expense increased primarily as a result of the increase in amortization base due to the November 2019 acquisition of Pursuit. Compensation expense increased as a result of lower incentive compensation recognized in the prior year due to results below performance targets. Stock compensation increased in the current year due to a change in the number of performance shares estimated to vest on one of our non-executive performance awards. Bad debt expense is estimated based on an analysis of the expected losses on the accounts receivables at the reporting date, which varies from period-to-period due to the quality of those receivables. Travel expenses decreased in the current year, as compared to prior year, due to travel restrictions in response to COVID-19. Consulting expense was higher in 2019 due to charges incurred related to tax compliance and IT infrastructure expenses. Sales and marketing expenses decreased due to the impact of COVID-19 on trade shows, conferences, and related expenses.

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
	2021	2020	2019	2021 over 2020		2020 over 2019	
R&D	$ 47.5	$ 42.9	$ 48.6	$ 4.6	10.7 %	$ (5.7)	(11.7)%

R&D expenses increased in 2021, as compared to 2020, and decreased in 2020, as compared to 2019. Fluctuations in our R&D expenses are due to the timing and nature of various R&D projects. R&D expenses are primarily related to compensation and benefit expenses, consulting fees, production supplies, samples, travel costs, utilities and other miscellaneous administrative costs incurred on our R&D projects in progress during each year.

Restructuring, Strategic Transaction and Integration Expenses

Restructuring, strategic transaction and integration expenses were $18.0 million, $28.4 million and $80.6 million in 2021, 2020 and 2019, respectively.

Restructuring Charges

In 2021, we adjusted certain facility restructuring liabilities by $2.0 million to reflect actual amounts owed resulting in annual net restructuring credits of $(1.8) million.

In 2020, restructuring charges were $7.9 million. These charges were primarily related to severance and costs related to office and other facility closures.

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.

Strategic Transaction and Integration Expenses

In 2021, we incurred $19.8 million in strategic transaction and integration expenses primarily related to integration costs associated with acquisitions, the Hospira Infusion Systems ("HIS") earn-out dispute with Pfizer, one-time costs incurred to comply with regulatory initiatives and transaction expenses incurred in connection with entering into the definitive agreement to acquire Smiths Medical.

In 2020, we incurred $20.5 million in strategic transaction and integration expenses primarily related to the integration of HIS, which included the migration of IT systems at our Austin facility.

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 reduced 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.

Change in fair value of contingent earn-out

At the end of the second quarter of 2021, the measurement period related to the Pursuit earn-out liability ended and in October 2021 the $26.3 million earn-out was finalized and paid to Pursuit's former shareholders. There were no changes in the fair value of our earn-outs during 2021.

In 2020, the fair value revaluation of our Pursuit contingent earn-out liability resulted in an increase in value of $9.0 million.

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 as of that date we determined we did not meet the necessary performance targets that would require payout of any of the HIS earn-out liability. Pfizer disputed our determination that the performance targets requiring payout of the HIS earn-out liability were not met, and the dispute entered into binding arbitration. In August 2021, the arbitrator concluded that the necessary performance targets that would require payout of the HIS earn-out were not met, and as a result Pfizer is not entitled to any payments in connection with the HIS earn-out liability.

Contract Settlement

In 2021, we recorded $0.1 million in contract settlement expense. In 2020, we recorded $1.0 million in contract settlement income related to the resolution of a dispute with one of our suppliers. In 2019, we incurred a $5.7 million charge related to the resolution of a dispute with a product partner, which resulted in a redefinition of our contractual arrangement and in the rights and remedies determined under such arrangement.

Interest Expense

Interest expense was $0.9 million, $1.8 million and $0.5 million in 2021, 2020 and 2019, respectively.

In 2021 and 2019, interest expense primarily includes the per annum commitment fee charged on the unused portion of the revolver under our five-year Revolving Credit Facility ("Credit Facility") and the amortization of financing costs that were incurred in 2017 in connection with entering into the Credit Facility. The per annum commitment fee was based on the consolidated total leverage ratio in effect and ranged between 0.15% to 0.30% on the unused portion of the Credit Facility (see Note 11: Long-Term Obligations in our accompanying consolidated financial statements for additional information).

In 2020, interest expense was primarily related to borrowings under our Credit Facility and the amortization of financing costs. Borrowing under the Credit Facility bore interest, at our option, based on the Base Rate (as defined in Note 11 in our accompanying consolidated financial statements) plus applicable margin or the London Interbank Offered Rate plus applicable margin (see Note 11: Long-Term Obligations in our accompanying consolidated financial statements for additional information).

In January 2022, we entered into senior secured credit facilities that refinanced our existing Credit Facility in full, see "Liquidity and Capital Resources" in the remainder of this item for additional information and the estimated impact to future interest expense.

Other Income, net

Other income, net was $0.8 million, $1.1 million and $7.9 million in 2021, 2020 and 2019, respectively. In 2021, other income, net was primarily related to $2.8 million of interest income and $0.7 million of miscellaneous income partially offset by $1.7 million of loss from disposed assets and $1.0 million in foreign exchange losses. In 2020, other income, net was primarily related to interest income of $3.7 million, miscellaneous income, net of $2.8 million and gain from the disposal of property, plant and equipment of $1.8 million, which was mostly offset by $7.2 million in foreign exchange losses incurred as a result of the strengthening of the U.S. dollar from the impact of COVID-19 during the first half of the year. In 2019, other income, net was primarily due to interest income of $6.8 million related to our banking and investment accounts.

Income taxes

Income taxes were accrued at an estimated annual effective tax rate of 16%, 11% and 12% in 2021, 2020 and 2019, respectively.

The effective tax rate in 2021 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”), foreign-derived intangible income (“FDII”) and tax credits. The effective tax rate in 2021 included a tax benefit of $4.9 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 2021 also included U.S. federal and state return-to-provision adjustments net of related reserve changes for the year ended December 31, 2020 of $0.9 million tax provision primarily due to changes in estimates for GILTI, FDII, subpart F, and related foreign tax credits along with other prior period adjustments.

The effective tax rate in 2020 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"), foreign-derived intangible income ("FDII") and tax credits. The effective tax rate in 2020 included a tax benefit of $5.3 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 2020 also included U.S. federal and state return-to-provision adjustments net of related reserve changes for the year ended December 31, 2019 of $3.8 million tax benefit primarily due to changes in estimates for GILTI, FDII, and related foreign tax credits.

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, 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.

Liquidity and Capital Resources

We regularly evaluate our liquidity and capital resources, including our access to external capital, to ensure we can adequately meet our principal cash requirements, which include working capital requirements, planned capital investments in our business, commitments, acquisition restructuring and integration expenses, investments in quality systems and quality compliance objectives, repayment of outstanding borrowings, income tax obligations and acquisition opportunities in accordance with our growth strategy.

Sources of Liquidity

Our primary sources of liquidity are cash and cash equivalents, our short-term investment portfolio, cash flows from our operations and access to borrowing arrangements.

Funds generated from operations are held in cash and cash equivalents and investment securities. During 2021, our cash and cash equivalents and short-term investment securities increased by $156.5 million from $410.8 million at December 31, 2020 to $567.2 million at December 31, 2021. Our short-term investment portfolio consists of investment-grade corporate bonds and is primarily intended to facilitate capital preservation.

Credit Facilities and Access to Capital

On November 8, 2017, we entered into a five year revolving Credit Facility with various lenders which includes $150.0 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 $10.0 million and the aggregate unused amount of the revolving credit available. Our five-year $150.0 million Credit Facility provides us with fast, flexible funding for operational needs. There were no outstanding borrowings under the Credit Facility at December 31, 2021.

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 entered into Senior Secured Credit Facilities in January 2022 which terminated our existing Credit Facility, see below.

2022 Senior Secured Credit Facilities

We entered into a credit agreement with various lenders dated January 6, 2022 in connection with the closing of the Smiths Medical acquisition. The credit agreement provides for senior secured credit facilities, which include a five-year term loan A facility of $850.0 million, a seven-year term loan B facility of $850.0 million and a five-year revolving credit facility of $500.0 million. The proceeds from the term loans were used to finance a portion of the cash consideration for the Smiths Medical acquisition (see Note 17: Subsequent Events in our accompanying consolidated financial statements for additional information). The outstanding aggregate principal amount of the term loans is $1.7 billion as of the issuance of this report, which includes the term loan A that will mature in January 2027 and the term loan B that will mature in January 2029. The proceeds of future borrowings under the $500.0 million revolving credit facility, which expires in January 2027, may be used as a source of liquidity to support our ongoing working capital requirements and other general corporate purposes. There are no outstanding borrowings under the $500.0 million revolving credit facility as of the issuance of this report. Our existing $150.0 million Credit Facility, described above which was set to expire in November 2022, was terminated upon entering into the new Senior Secured Credit Facilities. As part of entering into the Senior Secured Credit Facilities we were assigned issuer and term loan B facility credit ratings. At the time of this report, our issuer and term loan B credit ratings assigned and outlook were as follows:

	Issuer/Term Loan B Credit Ratings	Outlook
Moody's	Ba3	Stable
Fitch	BB/BBB-	Stable
Standard & Poor's	BB/BB	Stable

We believe that our existing cash and cash equivalents along with cash flows expected to be generated from future operations and the funds received under the Senior Secured Credit Facilities will provide us with sufficient liquidity to finance our cash requirements for the next twelve months. In the event that we experience downturns, cyclical fluctuations in our business that are more severe or longer than anticipated, fail to achieve anticipated revenue and expense levels, or have significant unplanned cash expenditures, 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. Our ability to generate cash flows from operations, issue debt or enter into other financing arrangements on acceptable terms could be adversely affected if there is a material decline in the demand for our products or in the solvency of our customers or suppliers, deterioration in our key financial ratios or credit ratings or other significantly unfavorable changes in conditions. See Part I. Item 1A. Risk Factors” for discussion of the risks and uncertainties associated with our debt financing.

Uses of Liquidity

Capital Expenditures

Our capital expenditures relate to the expansion and maintenance of our business. While we can provide no assurances, we estimate that our capital expenditures in 2022 will be in the range of $100 million to $120.0 million. We anticipate making additional investments in machinery and equipment in our manufacturing operations in Costa Rica, Europe, Mexico and the U.S. to support new and existing products and in infusion pumps that get placed with customers outside the U.S. 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.

2022 Acquisitions

In September 2021, we entered into a definitive agreement to acquire Smiths Medical and on January 6, 2022 the acquisition was completed. We financed the $1.9 billion cash portion of the purchase price at closing with a combination of proceeds from the Senior Secured Credit Facilities and our cash and cash equivalents. See above and Note 17: Subsequent Events in our accompanying consolidated financial statements for additional information.

Contractual Obligations

Our principal commitments at December 31, 2021 include both short and long-term future obligations.

Operating Leases

We have non-cancelable operating lease agreements where we are contractually obligated for certain lease payment amounts. For more information regarding our operating lease obligations, (see Note 5: Leases in our accompanying consolidated financial statements).

Long-term Debt Obligations

As discussed above, in January 2022, we incurred borrowings under Senior Secured Credit Facilities. The principal repayment obligations and estimated interest payments on the term loans and estimated commitment fee payments on the revolver are estimated in the below table. Interest payments on the term loans were estimated using an Adjusted Term SOFR rate and a starting applicable margin on of 1.75% for term loan A and 2.50% for term loan B and the revolver commitment fees were estimated using the initial rate of 0.25%. The applicable margin rate and commitment fee rate will change from time to time in accordance with a preset pricing grid based on the leverage ratio (see Note 17: Subsequent Events in our accompanying consolidated financial statements for pricing grids related to the Senior Secured Credit Facilities). We expect to fund these obligations with our existing cash and cash equivalents and cash generated from our future operations.

	(in millions)					
	2022	**2023**	**2024**	**2025**	**2026**	**Thereafter**
Term Loan A Principal Payments	$ 15.9	$ 21.3	$ 42.5	$ 42.5	$ 63.8	$ 664.1
Term Loan A Interest Payments	20.2	26.0	27.8	28.6	27.8	0.4
Term Loan B Principal Payments	6.4	8.5	8.5	8.5	8.5	809.6
Term Loan B Interest Payments	26.6	31.8	36.4	39.6	40.4	80.3
Revolver Commitment Fee	1.2	1.1	0.9	0.8	0.8	—
	$ 70.3	$ 88.7	$ 116.1	$ 120.0	$ 141.3	$ 1,554.4

Minimum Purchase Obligations

On February 1, 2022, effective as of January 1, 2022, upon our request, Pfizer executed a Product Addendum to our MSA agreement, see under Part I Item 1 Business Section above for further detail. The Product Addendum includes a minimum purchase obligation of $29.6 million. The Product Addendum expires on November 30, 2022.

Other Future Capital Investments

In connection with the January 2022 acquisition of Smiths Medical we estimate the investment needed over the next three years for restructuring and integration expenses along with spending to support quality systems and quality compliance objectives to be in the range of $200.0 million to $300.0 million. We expect to fund these obligations with our cash and cash equivalents and cash generated from our operations.

Indemnifications

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.

Historical Cash Flows

Cash Flows from Operating Activities

Our cash provided by operations was $267.5 million in 2021. Net income plus adjustments for non-cash net expenses contributed $252.5 million to cash provided by operations. Net cash provided by operations as a result of changes in operating assets and liabilities was $15.0 million. The changes in operating assets and liabilities included a $20.8 million decrease in inventories, a $13.8 million decrease in accounts receivable, a $6.3 million increase in accrued liabilities, a $2.3 million increase in accounts payable, and $0.9 million in net changes in income taxes, including excess tax benefits and deferred income taxes. Offsetting these amounts was a $21.0 million increase in other assets and a $8.0 million increase in prepaid expenses and other current assets. The decrease in inventory was primarily due to the timing of production and customer purchases. The decrease in accounts receivable is primarily due to collection efforts. The increase in accrued liabilities was primarily due to the accrual of incentive bonuses, deferred revenue collected on certain arrangements and accruals related to the Smiths Medical transaction. The increase in accounts payable was primarily due to the timing of payments. 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 net increase in prepaid expenses and other current assets was primarily due to an increase in deferred costs.

Our cash provided by operations was $222.8 million in 2020. Net income plus adjustments for non-cash net expenses contributed $239.7 million to cash provided by operations. Net cash used in operations as a result of changes in operating assets and liabilities was $17.0 million. The changes in operating assets and liabilities included a $46.4 million decrease in accounts payable, a $29.4 million decrease in accrued liabilities, $18.0 million in net changes in income taxes, including excess tax benefits and deferred income taxes, a $16.1 million increase in other assets, and a $4.3 million increase in prepaid expenses and other current assets. Offsetting these amounts was a $78.0 million decrease in accounts receivable and a $19.2 million decrease in inventories. The decrease in accounts payable was due to the payment of integration-related expenses with extended payment terms and the timing of other payments. The decrease in accrued liabilities was due to the payment of one-time accrued supply chain reorganization costs. The increase in other assets was due to the purchase of spare parts. The net changes in income taxes was a result of the timing of payments. The increase in prepaid expenses and other current assets was primarily due to an increase in deferred costs. The decrease in accounts receivable is primarily due to collection efforts. The decrease in inventory was primarily due to improved inventory management and increased demand for certain products driven by the COVID-19 pandemic at the end of the year.

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 was mainly due to the reclassification of receivables from Pfizer and the timing of revenue and collections. Beginning in 2019, receivables from Pfizer were 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.

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		
	2021	2020	2019	2021	2020	
Investing Cash Flows:						
Purchases of property, plant and equipment	$ (68,542)	$ (92,005)	$ (97,312)	$ 23,463	$ 5,307	(1)
Proceeds from sale of assets	218	6,176	33	(5,958)	6,143	(2)
Intangible asset additions	(12,627)	(8,385)	(8,728)	(4,242)	343	(3)
Business acquisitions, net of cash acquired	(14,452)	—	(76,133)	(14,452)	76,133	(4)
Investments in non-marketable equity securities	(3,250)	—	—	(3,250)	—	(5)
Purchases of investment securities	(10,034)	(32,825)	(26,040)	22,791	(6,785)	(6)
Proceeds from sale of investment securities	18,000	28,900	41,292	(10,900)	(12,392)	(7)
Net cash used in investing activities	$ (90,687)	$ (98,139)	$ (166,888)	$ 7,452	$ 68,749	

(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 2020, we sold our Farmers Branch, Texas, U.S. distribution facility for $6.0 million.

(3) In 2021, we recorded a $6.6 million intangible asset related to a three-year non-compete agreement with one of our international distributors, of which $2.6 million was non-cash offset with a contingent earn-out.

(4) Our business acquisitions will vary from period to period based upon our current growth strategy and our ability to execute on desirable target companies. In 2021, we acquired a small foreign infusion systems supplier for approximately $15.4 million. 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.

(5) In 2021, we paid $3.3 million to acquire approximately a 20% non-marketable equity interest in a non public company.

(6) Our purchases of investment securities will vary from period to period based on current cash needs, planning for known future transactions and changes in our investment strategy. Our investment policy allows 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.

(7) Proceeds from the sale of our investment securities will vary based on the maturity dates of the investments.

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		
	2021	2020	2019	2021	2020	
Financing Cash Flows:						
Proceeds from short-term debt	$ —	$ 150,000	$ —	$ (150,000)	$ 150,000	(1)
Repayment of short-term debt	—	(150,000)	—	150,000	(150,000)	(1)
Proceeds from exercise of stock options	9,372	13,193	7,732	(3,821)	5,461	(2)
Payments on finance leases	(607)	(357)	—	(250)	(357)	
Payment of contingent earn-out	(17,300)	—	—	(17,300)	—	(3)
Tax withholding payments related to net share settlement of equity awards	(8,335)	(12,876)	(18,639)	4,541	5,763	(4)
Net cash used in financing activities	$ (16,870)	$ (40)	$ (10,907)	$ (16,830)	$ 10,867	

(1) During 2020, as a result of market uncertainty caused by COVID-19, we borrowed $150.0 million under our revolving Credit Facility as a precautionary measure to increase liquidity. We had fully repaid all amounts borrowed as of December 31, 2020.

(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) During 2021, we paid $26.3 million in cash related to the settlement of the Pursuit contingent earn-out. Of the $26.3 million, the amount recorded as the acquisition date fair value, which is considered financing cash flows, was $17.3 million (see Note 8: Fair Value Measurements).

(4) In 2021, our employees surrendered 40,350 shares of our common stock from vested restricted stock awards as consideration for approximately $8.3 million in minimum statutory withholding obligations paid on their behalf. In 2020, our employees surrendered 67,041 shares of our common stock from vested restricted stock awards as consideration for approximately $12.9 million in minimum statutory withholding obligations paid on their behalf. 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.

Our common stock purchase plan, which authorized the repurchase of up to $100.0 million of our common stock, was approved by our Board of Directors in August 2019. This plan has no expiration date. As of December 31, 2021, all of the $100.0 million available for purchase was remaining under the plan. We are limited on share purchases in accordance with the terms and conditions of our Credit Facility (see Note 11: Long-Term Obligations in our accompanying consolidated financial statements).

New Accounting Pronouncements

See Note 1: Basis of Presentation and Summary of Significant Accounting Policies to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

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 revenue recognition, accounts receivable 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. 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. 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 expected value of chargeback amounts for use in determining the transaction price, we use information available at the time, including 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 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 an analysis of the age of the receivable, on specific past due accounts for which we consider collection to be doubtful and based on current receivables where known economic conditions specific to individual significant customers may indicate collection is 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.

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 and a probability-weighted cash flow model, as appropriate (see Note 8: Fair Value Measurements to the consolidated financial statements in Part II, Item 8 of this Annual Report on 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 the Smiths Medical business); 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 Smiths Medical 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:

- the impacts of the COVID-19 pandemic on us, our business and on domestic and global economies generally;
- the integration of Smiths Medical by the Company being more difficult, time-consuming or costly than expected;
- general economic and business conditions, both in the U.S. and internationally;
- unexpected changes in our arrangements with Pfizer or our other large customers;
- outcome of litigation;
- fluctuations in foreign exchange rates and other risks of doing business internationally;
- increased competition for skilled workers;
- decreases in 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;
- acquisition and integration expenses (including as it relates to the Smiths Medical acquisition);
- the availability of patent protection and the cost of enforcing and of defending patent claims;
- natural disasters and outbreak of disease or illness;
- labor shortages;
- supply chain constraints or disruptions;
- impact of inflation on raw materials, freight charges and labor, especially in the U.S.; and
- interest rate increases.

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

Interest Rate Risk

If we were to incur borrowings under our Credit Facility, we would face market risk stemming from changes in interest rates.

In connection with the Smiths Medical acquisition on January 6, 2022 we entered into Senior Secured Credit Facilities totaling approximately $2.2 billion consisting of a variable-rate term loan A facility of $850.0 million, a variable-rate term loan B facility of $850.0 million and a revolving credit facility of $500.0 million. We will be exposed to changes in interest rates on all of these variable-rate debt instruments. In order to mitigate a portion of the interest rate risk exposure associated with these debt instruments in November 2021 we entered into forward-starting interest rate swaps to achieve a targeted mix of fixed and variable-rate debt (see Note 7: Derivatives and Hedging Activities to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K).

Foreign Exchange Risk

We transact business globally in multiple currencies, some of which are considered volatile. Our international revenues and expenses and working capital positions denominated in these foreign currencies expose us to the risk of fluctuations in foreign currency exchange rates against the U.S. dollar. As the receiver of foreign currencies we are adversely affected by the strengthening of the U.S. dollar relative to the foreign currency.

In our European operations, our net Euro asset position at December 31, 2021 was approximately €35.9 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, 2021 spot rate would impact our consolidated amounts on these balance sheet items by approximately $4.1 million, or 0.9% of these net assets. We expect that in the future, with the growth of our European distribution operations, net Euro denominated instruments will continue to increase. We currently do not hedge our Euro foreign currency exposures.

We have manufacturing facilities and conduct business transactions denominated in the Mexican Peso. We hedge a portion of our manufacturing spend, which reduces our exposure to the foreign currency exchange risk related to the Mexican Peso (see Note 7: Derivatives and Hedging Activities to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on 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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ICU Medical, Inc. and subsidiaries (the "Company") as of December 31, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 February 25, 2022, 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 Notes 1 and 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 historical experience. Accounts receivable as of December 31, 2021 of $106 million and total revenues for the year ended December 31, 2021 of $1,316 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 chargeback amount related to 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 reserve included the following, among others:

- We tested the effectiveness of controls related to management’s assessment of assumptions related to estimating the provision for chargeback reserves, the provisioning, processing, and monitoring of chargeback transactions, and the reconciliation of chargeback reserves.
- We tested chargeback estimates for purposes of determining whether revenues recognized at the time of sale were recorded in the proper period.
- We evaluated the methods and assumptions used by management to estimate the chargeback reserve by:

- Analyzing trends in the chargeback provision as a percent of revenues and the chargeback reserve as a percent of revenues.

- Testing the underlying data, including historical sales to distribution customers and chargeback settlements with distribution 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 monthly sales to distribution customers, historical experience, and the time to settle chargeback obligations, and comparing our expectation to the amount recorded by management.

- Performing retrospective reviews comparing management's estimates of expected chargeback reserves to actual amounts incurred subsequent to the dates of estimation, 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
February 25, 2022

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,	
	2021	2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 552,827	$ 396,097
Short-term investment securities	14,420	14,687
TOTAL CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENT SECURITIES	567,247	410,784
Accounts receivable, net of allowance for doubtful accounts of $7,038 and $21,490 at December 31, 2021 and 2020, respectively	105,894	124,093
Inventories	290,235	314,928
Prepaid income taxes	19,586	29,480
Prepaid expenses and other current assets	46,847	41,492
TOTAL CURRENT ASSETS	1,029,809	920,777
PROPERTY, PLANT AND EQUIPMENT, net	468,365	466,628
OPERATING LEASE RIGHT-OF-USE ASSETS	39,847	46,571
LONG-TERM INVESTMENT SECURITIES	4,620	12,974
GOODWILL	43,439	33,001
INTANGIBLE ASSETS, net	188,311	197,231
DEFERRED INCOME TAXES	42,604	31,034
OTHER ASSETS	63,743	55,475
TOTAL ASSETS	$ 1,880,738	$ 1,763,691
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 81,128	$ 71,864
Accrued liabilities	118,195	97,021
Income tax payable	1,454	303
Contingent earn-out liability	—	26,300
TOTAL CURRENT LIABILITIES	200,777	195,488
CONTINGENT EARN-OUT LIABILITY	2,589	—
OTHER LONG-TERM LIABILITIES	41,830	47,835
DEFERRED INCOME TAXES	1,490	1,663
INCOME TAX LIABILITY	18,021	16,440
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—21,280 and 21,058 shares at December 31, 2021 and 2020, respectively, and outstanding—21,280 and 21,058 shares at December 31, 2021 and 2020, respectively	2,128	2,106
Additional paid-in capital	721,412	693,068
Treasury stock, at cost (119 and 209 shares, respectively)	(27)	(39)
Retained earnings	911,787	808,652
Accumulated other comprehensive loss	(19,269)	(1,522)
TOTAL STOCKHOLDERS' EQUITY	1,616,031	1,502,265
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,880,738	$ 1,763,691

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,		
	2021	2020	2019
TOTAL REVENUES	$ 1,316,308	$ 1,271,004	$ 1,266,208
COST OF GOODS SOLD	824,818	809,507	794,344
GROSS PROFIT	491,490	461,497	471,864
OPERATING EXPENSES:			
Selling, general and administrative	302,583	283,953	276,982
Research and development	47,498	42,948	48,611
Restructuring, strategic transaction and integration	18,037	28,409	80,574
Change in fair value of contingent earn-out	—	9,000	(47,400)
Contract settlement	127	(975)	5,737
TOTAL OPERATING EXPENSES	368,245	363,335	364,504
INCOME FROM OPERATIONS	123,245	98,162	107,360
INTEREST EXPENSE	(858)	(1,753)	(549)
OTHER INCOME, NET	799	1,085	7,896
INCOME BEFORE INCOME TAXES	123,186	97,494	114,707
PROVISION FOR INCOME TAXES	(20,051)	(10,624)	(13,672)
NET INCOME	$ 103,135	$ 86,870	$ 101,035
NET INCOME PER SHARE			
Basic	$ 4.86	$ 4.16	$ 4.90
Diluted	$ 4.74	$ 4.02	$ 4.69
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	21,206	20,907	20,629
Diluted	21,781	21,591	21,545

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,		
	2021	**2020**	**2019**
NET INCOME	$ 103,135	$ 86,870	$ 101,035
Other comprehensive (loss) income, net of tax:			
Cash flow hedge adjustments, net of tax of $(954), $285 and $392 for the years ended December 31, 2021, 2020 and 2019, respectively	(3,021)	904	1,242
Foreign currency translation adjustment, net of tax of $0 for all periods	(14,664)	12,929	372
Other adjustments, net of tax of $0 for all periods	(62)	47	(71)
Other comprehensive (loss) income, net of tax	(17,747)	13,880	1,543
COMPREHENSIVE INCOME	$ 85,388	$ 100,750	$ 102,578

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, 2019	**20,491**	**$ 2,049**	**$ 657,899**	**$ (95)**	**$ 620,747**	**$ (16,945)**	**$1,263,655**
Issuance of restricted stock and exercise of stock options	331	25	(10,870)	18,577	—	—	7,732
Tax withholding payments related to net share settlement of equity awards	(80)	—	—	(18,639)	—	—	(18,639)
Stock compensation	—	—	21,918	—	—	—	21,918
Other comprehensive income, net of tax	—	—	—	—	—	1,543	1,543
Net income	—	—	—	—	101,035	—	101,035
Balance, December 31, 2019	**20,742**	**2,074**	**668,947**	**(157)**	**721,782**	**(15,402)**	**1,377,244**
Issuance of restricted stock and exercise of stock options	383	32	167	12,994	—	—	13,193
Tax withholding payments related to net share settlement of equity awards	(67)	—	—	(12,876)	—	—	(12,876)
Stock compensation	—	—	23,954	—	—	—	23,954
Other comprehensive income, net of tax	—	—	—	—	—	13,880	13,880
Net income	—	—	—	—	86,870	—	86,870
Balance, December 31, 2020	**21,058**	**2,106**	**693,068**	**(39)**	**808,652**	**(1,522)**	**1,502,265**
Issuance of restricted stock and exercise of stock options	262	22	1,003	8,347	—	—	9,372
Tax withholding payments related to net share settlement of equity awards	(40)	—	—	(8,335)	—	—	(8,335)
Stock compensation	—	—	27,341	—	—	—	27,341
Other comprehensive loss, net of tax	—	—	—	—	—	(17,747)	(17,747)
Net income	—	—	—	—	103,135	—	103,135
Balance, December 31, 2021	**21,280**	**$ 2,128**	**$ 721,412**	**$ (27)**	**$ 911,787**	**$ (19,269)**	**$1,616,031**

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,		
	2021	**2020**	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 103,135	$ 86,870	$ 101,035
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	89,698	85,631	76,916
Noncash lease expense	9,594	9,216	8,294
Provision for doubtful accounts	345	7,137	14,882
Provision for warranty and returns	831	(1,576)	(134)
Stock compensation	27,341	23,954	21,918
Loss (gain) on disposal or write-off of property, plant and equipment	1,652	(1,789)	12,872
Bond premium amortization	655	231	135
Debt issuance cost amortization	240	288	288
Change in fair value of contingent earn-out	—	9,000	(47,400)
Product-related charges	3,380	2,626	—
Usage of spare parts	13,046	11,191	24,301
Other	2,582	6,939	447
Changes in operating assets and liabilities, net of amounts acquired:			
Accounts receivable	13,755	78,049	(23,684)
Inventories	20,815	19,196	(24,997)
Prepaid expenses and other current assets	(7,973)	(4,311)	8,588
Other assets	(21,038)	(16,069)	(29,837)
Accounts payable	2,347	(46,415)	(2,697)
Accrued liabilities	6,259	(29,379)	(43,689)
Income taxes, including excess tax benefits and deferred income taxes	874	(18,037)	4,680
Net cash provided by operating activities	267,538	222,752	101,918
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(68,542)	(92,005)	(97,312)
Proceeds from sale of assets	218	6,176	33
Intangible asset additions	(12,627)	(8,385)	(8,728)
Business acquisitions, net of cash acquired	(14,452)	—	(76,133)
Investments in non-marketable equity securities	(3,250)	—	—
Purchases of investment securities	(10,034)	(32,825)	(26,040)
Proceeds from sale of investment securities	18,000	28,900	41,292
Net cash used in investing activities	(90,687)	(98,139)	(166,888)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from short-term debt	—	150,000	—
Repayment of short-term debt	—	(150,000)	—
Proceeds from exercise of stock options	9,372	13,193	7,732
Payments on finance leases	(607)	(357)	—
Payment of contingent earn-out	(17,300)	—	—
Tax withholding payments related to net share settlement of equity awards	(8,335)	(12,876)	(18,639)
Net cash used in financing activities	(16,870)	(40)	(10,907)
Effect of exchange rate changes on cash	(3,251)	2,854	(234)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	156,730	127,427	(76,111)
CASH AND CASH EQUIVALENTS, beginning of period	396,097	268,670	344,781
CASH AND CASH EQUIVALENTS, end of period	$ 552,827	$ 396,097	$ 268,670

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,		
	2021	2020	2019
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the year for income taxes	$ 19,562	$ 31,628	$ 9,675
Cash paid during the year for interest	$ 858	$ 1,753	$ 549
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:			
Accounts payable for property, plant and equipment	$ 9,338	$ 2,211	$ 13,912
Non-compete agreement with associated contingent earn-out liability	$ 2,589	$ —	$ —
Detail of assets acquired and liabilities assumed in acquisitions:			
Fair value of assets acquired	$ 4,592		$ 91,019
Cash paid for acquisitions, net of cash acquired	(14,452)		(76,133)
Contingent consideration	—		(17,300)
Goodwill, acquired during period	10,626		20,026
Liabilities assumed/Adjustments to liabilities assumed	$ 766		$ (17,612)

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 infusion 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 U.S. ("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.

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.

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 our products.

Inventories consist of the following (in thousands):

	As of December 31,	
	2021	2020
Raw materials	$ 135,528	$ 126,499
Work in process	36,490	33,053
Finished goods	118,217	155,376
Total	$ 290,235	$ 314,928

Property, Plant and Equipment

Property, plant and equipment consists of the following (in thousands):

	As of December 31,	
	2021	2020
Machinery and equipment	$ 321,078	$ 291,331
Land, building and building improvements	243,377	241,199
Molds	60,463	60,381
Computer equipment and software	102,979	98,311
Furniture and fixtures	7,670	7,767
Instruments placed with customers[(1)]	97,384	90,383
Construction in progress	72,153	53,724
Total property, plant and equipment, cost	905,104	843,096
Accumulated depreciation	(436,739)	(376,468)
Property, plant and equipment, net	$ 468,365	$ 466,628

(1) Instruments placed with customers consist of drug-delivery and monitoring systems placed with customers 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 $65.9 million, $62.4 million and $59.3 million in 2021, 2020 and 2019, respectively.

Goodwill

We test goodwill for impairment on an annual basis in the month of November, or more frequently if an event occurs or circumstances change that would indicate that impairment may exist. Generally, we first perform a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If, based on an assessment of relevant qualitative factors, we determine that this is not the case, then the quantitative impairment test is not required to be performed. Conversely, if we determine based on the qualitative assessment that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, we will perform the quantitative impairment test. For the quantitative impairment test, we calculate the estimated fair value of the reporting unit. If the estimated fair value of the reporting unit is less than its carrying amount, the goodwill of the reporting unit is determined to be impaired. An impairment charge is recorded in an amount equal to the excess of the carrying amount over its estimated fair value, limited to the total amount of goodwill allocated to the reporting unit. For our annual impairment test for the year ended December 31, 2021, we performed a qualitative assessment and concluded that it was more likely than not that the fair value of our reporting unit exceeded its carrying amount, and therefore, no further impairment testing was required. There were no accumulated impairment losses as of December 31, 2021, 2020 and 2019.

The following table presents the changes in the carrying amount of our goodwill for 2021, 2020 and 2019 (in thousands):

	Total
Balance as of January 1, 2019	$ 11,195
Goodwill acquired[1]	20,026
Other	24
Balance as of December 31, 2019	$ 31,245
Other[2]	1,756
Balance as of December 31, 2020	33,001
Goodwill[3]	10,626
Currency translation	(188)
Balance as of December 31, 2021	$ 43,439

(1) 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.

(2) In 2020, "Other" relates to a $1.3 million measurement period adjustment to deferred taxes related to the Pursuit acquisition and foreign currency translation.

(3) In 2021, we acquired a small foreign infusion systems supplier, which resulted in $10.6 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, 2021		
		Cost	Accumulated Amortization	Net
Patents	10	$ 27,429	$ 16,764	$ 10,665
Customer contracts	12	10,412	6,196	4,216
Non-contractual customer relationships	9	57,316	33,004	24,312
Trademarks	4	425	425	—
Trade name	15	18,260	4,731	13,529
Developed technology	13	152,893	49,406	103,487
Non-compete	3	9,100	2,356	6,744
Total amortized intangible assets		$ 275,835	$ 112,882	$ 162,953
Internally developed software*		$ 25,358		$ 25,358
Total intangible assets		$ 301,193	$ 112,882	$ 188,311

* 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, 2020		
		Cost	Accumulated Amortization	Net
Patents	10	$ 24,797	$ 15,056	$ 9,741
Customer contracts	12	10,365	5,852	4,513
Non-contractual customer relationships	9	58,061	26,711	31,350
Trademarks	4	425	425	—
Trade name	15	18,270	3,500	14,770
Developed technology	13	152,893	36,927	115,966
Non-compete	3	2,500	972	1,528
Total amortized intangible assets		$ 267,311	$ 89,443	$ 177,868
Internally developed software*		$ 19,363		$ 19,363
Total intangible assets		$ 286,674	$ 89,443	$ 197,231

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

Amortization expense was $23.8 million, $23.2 million and $17.7 million in 2021, 2020 and 2019, respectively.

As of December 31, 2021, estimated annual amortization for our intangible assets for each of the next five years is approximately (in thousands):

2022	$ 25,668
2023	24,191
2024	23,551
2025	16,057
2026	15,324
Thereafter	58,162
Total	$ 162,953

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. We did not have any intangible asset impairments in 2021, 2020 or 2019.

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. We did not have any long-lived asset impairments in 2021, 2020 or 2019.

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.

Investments in Available-for-sale Securities

Our investment securities are considered available-for-sale and currently consist of short-term and long-term corporate bonds. These securities are considered “investment grade” and are carried at fair value. We assess our investment in available-for-sale debt securities for impairment each reporting period. If an unrealized loss exists, we determine whether any portion of the decline in fair value below the carrying value is credit-related by reviewing several factors, including, but not limited to, the extent of the fair value decline and changes in the financial condition of the issuer. We record an impairment for credit-related losses through an allowance, limited to the amount of the unrealized loss. If we either intend to sell or it is more likely than not we will be required to sell the debt security before its anticipated recovery, any allowance is written off and the amortized cost basis is written down to fair value through a charge against net earnings. Unrealized gains and non-credit-related unrealized losses are recorded, net of tax, in other comprehensive income (loss). We did not have any investments in available-for-sale debt securities in unrealized loss positions as of December 31, 2021 or 2020.

The amortized cost of the debt securities is adjusted for the amortization of premiums computed under the effective interest method. Such amortization is included in other income, net in the consolidated statements of operations. Realized gains and losses are accounted for on the specific identification method. There have been no realized gains or losses on the disposal of these investments. The scheduled maturities of the debt securities are between 2022 and 2024. All short-term investment securities are callable within one year.

Our short-term and long-term investments in available-for-sale securities consist of the following (in thousands):

	As of December 31, 2021		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term corporate bonds	$ 14,420	$ —	$ 14,420
Long-term corporate bonds	4,620	—	4,620
Total investment securities	$ 19,040	$ —	$ 19,040

	As of December 31, 2020		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term corporate bonds	$ 14,687	$ —	$ 14,687
Long-term corporate bonds	12,974	—	12,974
Total investment securities	$ 27,661	$ —	$ 27,661

Investments in Non-Marketable Equity Securities

In the third quarter of 2021, we acquired approximately a 20.0% non-marketable equity interest in a nonpublic company and entered into a three-year distribution agreement where we have the exclusive rights to market, sell and distribute the company's products in exchange for a cash payment of $3.3 million. In addition, we were granted an exclusive license for all of the seller's intellectual property. At the expiration of the distribution agreement we have the right but not the obligation to acquire the remaining interest in the business.

We apply the equity method of accounting for investments when we determine we have a significant influence, but not a controlling interest in the investee. We determine whether we have significant influence by considering key factors such as ownership interest, representation on the board of directors, participation in policy making decisions, business relationship and material intra-entity transactions, among other factors. Our equity method investment is reported at cost and adjusted each period for our share of the investee's income or (loss) and dividend paid, if any. We eliminate any intra-entity profits to the extent of our beneficial interest. We record our share of the investee's income or (loss) on a one quarter lag. We report our

proportionate share of the investee's income or (loss) resulting from this investment in other income, net in our consolidated statements of operations. The carrying value of our equity method investment is reported in other assets on the consolidated balance sheets. We assess our equity method investments for impairment on an annual basis or whenever events or circumstances indicate that the carrying value of the investment may not be recoverable. During 2021, there were no indications that our non-marketable equity method investment was impaired. Our recorded share of the investee's loss was not material for the year ended December 31, 2021. We did not receive any dividend distributions from this investment during 2021.

Our non-marketable equity method investment consists of the following (in thousands):

	As of December 31,	
	2021	2020
Equity method investment	$ 3,238	$ —

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 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 consolidated statements of operations in other income, net. Foreign currency transaction losses (gains), net were $1.0 million, $7.2 million and $(0.7) million in 2021, 2020 and 2019, respectively.

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. 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. 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 expected value of chargeback amounts for use in determining the transaction price, we use information available at the time, including 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 $0.2 million, $0.2 million and $0.1 million in 2021, 2020 and 2019, respectively.

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 $11.0 million, $10.7 million and $11.4 million in 2021, 2020 and 2019, respectively. We also have 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. Restricted stock units that are anti-dilutive are not included in the treasury stock method. There were 12,354, 12,083 and 10,760 anti-dilutive shares in 2021, 2020 and 2019, 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,		
	2021	2020	2019
Net income	$ 103,135	$ 86,870	$ 101,035
Weighted-average number of common shares outstanding (basic)	21,206	20,907	20,629
Dilutive securities	575	684	916
Weighted-average common and common equivalent shares outstanding (diluted)	21,781	21,591	21,545
EPS — basic	$ 4.86	$ 4.16	$ 4.90
EPS — diluted	$ 4.74	$ 4.02	$ 4.69

New Accounting Pronouncements

Recently Issued Accounting Standards

In March 2020, the Financial Accounting Standards Board ("FASB") issued ASU No. 2020-04, Reference Rate Reform (Topic 848) - Facilitation of the Effects of Reference Rate Reform on Financial Reporting. The amendments in this update provide optional guidance for a limited period of time to ease the potential burden for reference rate reform on financial reporting. Due to concerns about structural risks of interbank offered rates and, particularly, the risk of cessation of the London Interbank Offered Rate ("LIBOR"), regulators around the world have undertaken reference rate reform initiatives to identify alternative reference rates that are more observable or transaction based and less susceptible to manipulation. The amendments in this update apply only to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued as a result of reference rate reform. Optional expedients may be applied to contracts that are modified as a result of the reference rate reform. Modifications of contracts within the scope of Topic 470, Debt, should be accounted for by prospectively adjusting the effective interest rate. Modifications of contracts within the scope of ASC 842, Leases, should be accounted for as a continuation of the existing contracts with no reassessments of the lease classification and the discount rate (incremental borrowing rate). Exceptions to Topic 815, Derivatives and Hedging, results in not having a dedesignation of a hedging relationship if certain criteria are met. The amendments in this ASU are effective for all entities as of March 12, 2020 through December 31, 2022. In November 2021, we entered into two forward-starting swaps whereby the variable leg of the swap references LIBOR, these swaps will be amended in early 2022 to transition to an alternative reference rate (see Note 7: Derivatives and Hedging Activities). The amendments in this ASU allow for certain expedients that will allow us to assume that our hedged interest payments are probable of occurring regardless of any expected modification in their terms related to reference rate reform and will allow us to continue hedge accounting for a cash flow hedge for which the hedged interest rate risk changes if the hedge is highly effective under ASC 815, Derivatives and Hedging or the optional expedient under this ASU is elected. The impact of this ASU on our contracts has not been and is not expected to be material.

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 were 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 was 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. As of June 30, 2021, the earn-out measurement period ended and based on the actual sales and gross profit achieved during the measurement period, we calculated the actual earn-out amount to be $26.3 million. The $26.3 million earn-out calculation was finalized and accepted by Pursuit's former equity holders and was paid out in during the fourth quarter of 2021. 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.

Final 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):

Cash consideration for acquired assets, net	$	71,533
Fair value of contingent consideration		17,300
Total Consideration	$	88,833
Final 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		20,462
Deferred tax liability		(15,769)
Purchase Consideration	$	88,833

(1) Identifiable intangible assets included $69.0 million of developed technology, $10.8 million of trade name and $2.5 million of non-compete agreement. The weighted-average amortization periods for the identifiable intangible assets are as follows: approximately fifteen years for developed technology, fifteen years for trade name and three years for the non-compete agreement.

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.

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

2021 Acquisitions

During November 2021, we acquired a small foreign infusion systems supplier and paid an initial gross cash payment of approximately $15.4 million. The total consideration and purchase price allocation is preliminary pending the finalization of the valuation. In addition to the initial cash consideration, total consideration for the acquisition includes an additional holdback of $0.5 million, to be paid two years from the completion date of the acquisition, and also a potential earn-out payment of up to $2.5 million, consisting of (i) a cash payment of $1.0 million contingent on the achievement of certain revenue targets for the annual period ending December 31, 2022 and, separately, (ii) a cash payment of $1.5 million contingent on certain product-related regulatory certifications obtained by May 26, 2024.

NOTE 3. RESTRUCTURING, STRATEGIC TRANSACTION AND INTEGRATION

Restructuring, strategic transaction and integration expenses were $18.0 million, $28.4 million and $80.6 million in 2021, 2020 and 2019, respectively.

Restructuring

Restructuring charges were $(1.8) million, $7.9 million and $8.4 million in 2021, 2020 and 2019, respectively, and are included in the above restructuring, strategic transaction and integration expenses in our consolidated statement of operations.

In 2021, we adjusted certain facility restructuring liabilities by $2.0 million, shown in the table below under "Other adjustments," to reflect actual amounts owed which resulted in net restructuring credits of $(1.8) million.

In 2020, restructuring charges were primarily related to severance and costs related to office and other facility closures.

In 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.

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, was paid in equal monthly installments until December 2020. This has been fully paid as of December 31, 2020.

The following table summarizes the activity in our restructuring-related accrual by major type of cost (in thousands):

	Severance Pay and Benefits	Employment Agreement Buyout	Retention and Facility Closure Costs	Total
Accrued balance, January 1, 2020	$ 3,878	$ 460	$ 1,211	$ 5,549
Charges incurred	4,288	—	3,641	7,929
Payments	(6,331)	(460)	(3,570)	(10,361)
Currency translation	23	—	281	304
Accrued balance, December 31, 2020	$ 1,858	$ —	$ 1,563	$ 3,421
Charges incurred	140	—	—	140
Payments	(969)	—	—	(969)
Currency translation	(2)	—	31	29
Other adjustments[(1)]	(528)	—	(1,429)	(1,957)
Accrued balance, December 31, 2021	$ 499	$ —	$ 165	$ 664

(1) The estimated liabilities related to a prior year's facility closure restructuring were adjusted to actual amounts owed.

Strategic Transaction and Integration Expenses

We incurred $19.8 million, $20.5 million and $72.2 million in strategic transaction and integration expenses in 2021, 2020 and 2019, respectively, which are included in restructuring, strategic transaction and integration expenses in our consolidated statement of operations. The strategic transaction and integration expenses during 2021 were related to integration costs associated with acquisitions, the Hospira Infusion Systems ("HIS") earn-out dispute with Pfizer, one-time costs incurred to comply with regulatory initiatives and transaction expenses incurred in connection with entering into a definitive agreement to acquire Smiths Medical 2020 Limited ("Smiths Medical") (see Note 17: Subsequent Events). The integration expenses during 2020 were related to the integration of HIS and included expenses for the migration of IT systems at our Austin facility. The strategic transaction and integration expenses during 2019 were primarily related to HIS, including a one-time strategic supply chain restructuring charge of $22.1 million, which reduced 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

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. However, for purposes of revenue recognition for our software licenses and renewals, we consider the control of these products to be transferred to a customer at a certain point in time; therefore, we recognize revenue at the start of the applicable license term.

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. Chargebacks are the difference between the prices we charge our distribution customers and the contracted prices we have with the end customer which are processed as credits to our distribution customers. In estimating the expected value of chargeback amounts in order to determine the transaction price, we use information available at the time, including 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 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 a 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:

	Year ended December 31,					
	2021		2020		2019	
Product line	**Revenue**	**% of Revenue**	**Revenue**	**% of Revenue**	**Revenue**	**% of Revenue**
Infusion Consumables	$ 555,189	42 %	$ 473,740	37 %	$ 477,611	37 %
Infusion Systems	352,321	27 %	359,691	28 %	328,282	26 %
IV Solutions	359,477	27 %	388,971	31 %	414,971	33 %
Critical Care	49,321	4 %	48,602	4 %	45,344	4 %
Total Revenues	$ 1,316,308	100 %	$ 1,271,004	100 %	$ 1,266,208	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):

	Year ended December 31,		
Geography	**2021**	**2020**	**2019**
Europe, the Middle East and Africa	$ 147,488	$ 132,763	$ 130,530
Other Foreign	227,011	227,614	212,336
Total Foreign	374,499	360,377	342,866
United States	941,809	910,627	923,342
Total Revenues	$ 1,316,308	$ 1,271,004	$ 1,266,208

Domestic sales accounted for 72%, 72% and 73% of total revenue in 2021, 2020 and 2019, respectively. International sales accounted for 28%, 28% and 27% of total revenue in 2021, 2020 and 2019, 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 the changes in our contract balances for the years ended December 31, 2021 and 2020, (in thousands):

	Contract Liabilities
Beginning balance, January 1, 2020	$ (4,855)
Equipment revenue recognized	14,408
Equipment revenue deferred due to implementation	(14,341)
Software revenue recognized	5,721
Software revenue deferred due to implementation	(7,363)
Ending balance, December 31, 2020	$ (6,430)
Equipment revenue recognized	10,048
Equipment revenue deferred due to implementation	(13,725)
Software revenue recognized	7,261
Software revenue deferred due to implementation	(4,615)
Ending balance, December 31, 2021	$ (7,461)

During 2021, we recognized $5.1 million in revenue that was included in the opening contract balances as of December 31, 2020. As of December 31, 2021, revenue from remaining performance obligations related to implementation of software and equipment is $5.6 million. We expect to recognize substantially all of this revenue within the next three to six months dependent on implementation restrictions due to the novel coronavirus and its variants ("COVID-19"). Revenue from remaining performance obligations related to annual software licenses is $1.9 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

We determine if an arrangement is a lease at inception. Our operating lease assets are separately stated in operating lease right-of-use ("ROU") assets and our financing lease assets are included in other assets on our consolidated balance sheets. Our lease liabilities are included in accrued liabilities, and other long-term liabilities on our consolidated balance sheets. We have elected not to recognize an ROU asset and lease liability for leases with terms of twelve months or less.

Lease ROU assets and 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. Our lease ROU assets exclude lease incentives and 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 leases have stated lease payments, which may include fixed rental increases.

Our leases are for corporate, research and development and sales and support offices, a distribution facility, device service centers 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):

	Year ended December 31,	
	2021	2020
Operating lease cost	$ 11,251	$ 11,284
Finance lease cost — interest	122	91
Finance lease cost — reduction of ROU asset	648	383
Short-term lease cost	14	263
Total lease cost	$ 12,035	$ 12,021

Interest expense on our finance leases is included in other income (expense), net in our consolidated statements of operations. The reduction of the operating and finance ROU assets is included as noncash lease expense in selling, general and administrative expenses in our consolidated statements of operations.

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

	Year ended December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 11,256	$ 10,185
Operating cash flows from finance leases	$ 122	$ 91
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 2,589	$ 20,847
Finance leases	$ 558	$ 3,062

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

	As of December 31,	
	2021	2020
Operating leases		
Operating lease right-of-use assets	$ 39,847	$ 46,571
Accrued liabilities	$ 9,009	$ 8,740
Other long-term liabilities	33,971	41,019
Total operating lease liabilities	$ 42,980	$ 49,759
Weighted-Average Remaining Lease Term		
Operating leases	5.9 years	6.7 years
Weighted-Average Discount Rate		
Operating leases	4.98 %	5.02 %

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

	As of December 31,	
	2021	2020
Finance leases		
Finance lease right-of-use assets	$ 2,673	$ 2,915
Accrued liabilities	$ 643	$ 554
Other long-term liabilities	2,067	2,388
Total finance lease liabilities	$ 2,710	$ 2,942
Weighted-Average Remaining Lease Term		
Finance leases	5.6 years	6.4 years
Weighted-Average Discount Rate		
Finance leases	4.28 %	4.27 %

As of December 31, 2021, the maturities of our operating and finance lease liabilities for each of the next five years are approximately (in thousands):

	Operating Leases	Finance Leases
2022	$ 10,887	$ 749
2023	9,453	749
2024	8,488	458
2025	5,129	267
2026	4,842	214
Thereafter	10,577	615
Total Lease Payments	49,376	3,052
Less imputed interest	(6,396)	(342)
Total	$ 42,980	$ 2,710

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 and vesting of restricted stock units. We also have indirect tax benefits upon exercise of stock options and vesting of restricted stock units 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):

(In thousands)	Year ended December 31, 2021	2020	2019
Stock compensation expense	$ 27,341	$ 23,954	$ 21,918
Tax benefit from stock-based compensation cost	$ 6,391	$ 5,564	$ 4,840
Indirect tax benefit	$ 285	$ 1,203	$ 680

As of December 31, 2021, we had $31.2 million of unamortized stock compensation cost which we will recognize as an expense over a weighted-average period of approximately 0.9 years.

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, 2021, 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.

Time-based Stock Options

To date, all options granted under 2011 Plan and 2003 Plan have been non-statutory stock options. The majority of the time-based outstanding employee option grants vested 25% after one year from the grant date and the balance vested ratably on a monthly basis over 36 months. The outstanding employee option grants are all fully vested. 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, 2021	2020	2019
Number of time-based options granted	7,910	7,190	6,265
Grant-date fair value of options granted (in thousands)	$ 528	$ 425	$ 424
Weighted-average assumptions for stock option valuation:			
Expected term (years)	5.5	5.5	5.5
Expected stock price volatility	35.0 %	35.0 %	28.0 %
Risk-free interest rate	0.9 %	0.4 %	2.2 %
Expected dividend yield	— %	— %	— %
Weighted-average grant-price per option	$ 200.07	$ 181.99	$ 225.27
Weighted-average grant-date fair value per option	$ 66.78	$ 59.09	$ 67.73

A summary of our stock option activity as of and for the year ended December 31, 2021 is as follows:

	Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	817,800	$ 70.13		
Granted	7,910	$ 200.07		
Exercised	(162,612)	$ 57.64		
Forfeited or expired	—	$ —		
Outstanding at December 31, 2021	663,098	$ 74.75	2.6	$ 108,003
Exercisable at December 31, 2021	656,483	$ 73.48	2.5	$ 107,761
Vested and expected to vest, December 31, 2021	663,098	$ 74.75	2.6	$ 108,003

The intrinsic values for options exercisable, outstanding and vested or expected to vest at December 31, 2021 are based on our closing stock price of $237.34 at December 31, 2021 and are before applicable taxes.

The following table presents information regarding stock option activity:

	Year ended December 31,		
(In thousands)	2021	2020	2019
Intrinsic value of options exercised	$ 27,534	$ 32,915	$ 22,976
Cash received from exercise of stock options	$ 9,372	$ 13,193	$ 7,732
Tax benefit from stock option exercises	$ 5,092	$ 5,179	$ 9,653

Stock Awards

In 2021, we granted PRSUs to our executive officers. For the executive officers other than the Chief Executive Officer ("CEO"), Chief Operations Officer ("COO") and the Chief Financial Officer ("CFO"), 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, COO and the CFO, the performance shares will cliff-vest ending on March 6, 2024 and further be subject to the achievement of minimum three-year cumulative revenue and EPS targets, commencing on January 1, 2021 and ending on December 31, 2023, which when reviewed against a predetermined vesting matrix could result in 0% to 250% of the awarded units that could vest.

In 2020, we granted PRSUs to our executive officers. For the executive officers other than the CEO, COO and the CFO, 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, COO and the CFO, the performance shares will cliff-vest ending on March 6, 2023 and further be subject to the achievement of minimum three-year cumulative revenue and EPS targets, which when reviewed against a predetermined vesting matrix could result in 0% to 250% of the awarded units that could vest. On February 15, 2021, the Compensation Committee made the determination that the executive officers other than the CEO, COO and CFO met their individual performance goals for 2021, therefore one-third of their 2020 PRSU shares awarded vested during 2021. Additionally, during February 2021, the Compensation Committee, modified the potential vesting percentages related to the 2020 PRSU awards for the CEO, COO and CFO, as the original potential percentages were established immediately before the onset of the COVID-19 pandemic. The Compensation Committee determined to adjust the CEO, COO and CFO's potential to earn from between 0% and 250% of the award granted, to an increased potential to earn between 50% and 300% of the award granted, subject to the same minimum threshold revenue and EPS targets to be achieved by the Company. The additional compensation expense as a result of modifying the 2020 PRSUs granted to our CEO, COO and CFO totaled $2.1 million recognized over the remaining amortization period from the date of modification.

In 2019, 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 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. On February 15, 2021, the Compensation Committee made the determination that the executive officers other than the CEO and COO met their individual performance goals for 2021, therefore one-third of their 2019 PRSU shares awarded vested during 2021. The performance period related to the 2019 CEO and COO PRSUs ended on December 31, 2021 and based on the Cumulative Adjusted EBITDA achieved during the performance period zero payout is expected, subject to Compensation Committee review and determination.

In 2018, we granted PRSUs to our executive officers. For the executive officers other than the CEO and the COO, the PRSUs were to 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 were to 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. On February 15, 2021, the Compensation Committee made the determination that the executive officers other than the CEO and COO met their individual performance goals for 2021, therefore one-third of their 2018 PRSU shares awarded vested during 2021. Also on February 15, 2021, the Compensation Committee determined that the CEO and COO's 2018 PRSUs were earned at 100% of the awards granted.

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.

Restricted stock units are granted annually to our Board of Directors and vest on the first anniversary of the grant date, or the date of our annual meeting, whichever occurs first.

In 2021, 2020 and 2019, 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):

(In thousands, except shares and per share amounts)	Year ended December 31, 2021	2020	2019
PRSU			
Shares granted	53,246	38,633	37,657
Shares earned [(a)]	32,013	80,654	114,032
Grant-date fair value per share	$ 198.16	$ 188.34	$ 231.63
Grant-date fair value	$ 10,551	$ 7,276	$ 8,723
Intrinsic value vested	$ 6,777	$ 15,627	$ 26,445
RSU			
Shares granted	84,388	87,830	61,856
Grant-date fair value per share	$ 199.13	$ 188.13	$ 227.42
Grant-date fair value	$ 16,804	$ 16,523	$ 14,067
Intrinsic value vested	$ 13,681	$ 12,314	$ 16,753

[(a)] PRSU shares earned in 2019 were related to performance awards granted to executives in 2016 and 2018, PRSU shares earned in 2020 were related to performance awards granted to executives in 2017, 2018 and 2019. PRSU shares earned in 2021 were related to performance awards granted to executives in 2018, 2019 and 2020.

The table below provides a summary of our PRSU and RSU activity as of and for the year ended December 31, 2021:

	Number of Units	Grant-Date Fair Value Per Share	Weighted-Average Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Non-vested at December 31, 2020	220,760	$ 209.77		
Change in units due to performance expectations [(a)]	24,601	$ 209.64		
Granted	137,634	$ 198.75		
Vested	(99,363)	$ 219.77		
Forfeited	(7,871)	$ 196.01		
Non-vested and expected to vest at December 31, 2021	275,761	$ 201.05	1.0	$ 65,449

[(a)] Relates to 2019-2021 PRSUs granted to a non-executive employee and 2021 and 2020 CEO, COO and CFO PRSUs granted, assumes attainment of an increased 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, 2021, 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.

NOTE 7. DERIVATIVES AND HEDGING ACTIVITIES

Hedge Accounting and Hedging Program

The purposes of our cash flow hedging programs are to manage the foreign currency exchange rate risk on forecasted expenses denominated in currencies other than the functional currency of the operating unit, and to manage floating interest rate risk associated with future interest payments on variable-rate term loans issued in January 2022 subsequent to our fiscal year end. We do not issue derivatives for trading or speculative purposes.

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 and forward-starting interest rate swaps are designated and qualify as cash flow hedges. Our derivative instruments are recorded at fair value on the consolidated balance sheets and are classified based on the instrument's maturity date. We record changes in the fair value of the effective portion of the gain or loss on 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.

Foreign Currency Exchange Rate Risk

We began hedging a portion of our Mexico forecasted expenses denominated in Pesos ("MXN") in May 2017 by entering into a two-year cross-currency par forward contract. The term of this currency forward contract was May 1, 2017 to May 1, 2019. The derivative instrument had a fixed forward rate of 20.01 MXN/USD over the term of the two-year contract.

In January 2018, we entered into a six-month cross-currency par forward contract. 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. The term of the one-year hedge was November 1, 2019 to November 3, 2020. The derivative instrument matured in equal monthly amounts at a fixed forward rate of 22.11 MXN/USD.

In March 2020, we entered into a one-year cross-currency par forward contract. The total notional amount of this outstanding derivative as of December 31, 2020 was approximately 436.8 million MXN. The term of this one-year contract was November 3, 2020 to December 1, 2021. The derivative instrument matured in equal monthly amounts at a fixed forward rate of 24.26 MXN/USD.

In November 2021, we entered into a one-year cross-currency par forward contract. The total notional amount of this outstanding derivative as of December 31, 2021 was approximately 413.1 million MXN. The term of this one-year contract is December 1, 2021 to December 1, 2022. The derivative instrument matures in equal monthly amounts at a fixed forward rate of 21.60 MXN/USD.

Floating Interest Rate Risk

In November 2021, in anticipation of entering into new senior secured credit facilities in January 2022, which includes a variable-rate term loan A and a variable-rate term loan B (see Note 17: Subsequent Events for additional information), we entered into two forward-starting interest rate swaps. Under the interest rate swap agreements we exchange, at specified intervals, the difference between fixed and floating interest amounts calculated by reference to an agreed-upon notional amount. The term loan A swap has an initial notional amount of $300.0 million, reducing to $150.0 million evenly on a quarterly basis through its final maturity in April 2027. We will pay a fixed rate of 1.49% and will receive the greater of 3-month USD LIBOR or 0%. The term loan B swap has an initial notional amount of $750.0 million, reducing to $46.9 million evenly on a quarterly basis through its final maturity in April 2026. We will pay a fixed rate of 1.31% and will receive the greater of 3-month USD LIBOR or 0.50%. These forward-starting swaps will effectively convert the relevant portion of the floating-rate term loans to fixed rates.

The following table presents the fair values of our derivative instruments included within the consolidated balance sheets (in thousands):

Consolidated Balance Sheet Location	Derivatives Designated as Cash Flow Hedging Instruments		
	Foreign Exchange Forward Contracts	Forward-Starting Interest Rate Swaps	Gross Derivatives
(In thousands)			
As of December 31, 2021			
Prepaid expenses and other current assets	$ 1,061	$ —	$ 1,061
Other assets	—	—	—
Total assets	$ 1,061	$ —	$ 1,061
Accrued liabilities	$ —	$ —	$ —
Other long-term liabilities	—	1,480	1,480
Total liabilities	$ —	$ 1,480	$ 1,480
As of December 31, 2020			
Prepaid expenses and other current assets	$ 3,555	$ —	$ 3,555
Other assets	—	—	—
Total assets	$ 3,555	$ —	$ 3,555
Accrued liabilities	$ —	$ —	$ —
Other long-term liabilities	—	—	—
Total liabilities	$ —	$ —	$ —

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

	Location of Gain in the Consolidated Statements of Operations	Year Ended December 31,		
		2021	2020	2019
Derivatives designated as cash flow hedging instruments:				
Foreign exchange forward contracts	Cost of goods sold	$ 3,444	$ 790	$ 916
Forward-starting interest rate swaps	Interest expense	$ —	$ —	$ —

We recognized the following gains (losses) on our derivative instruments designated as cash flow hedges (in thousands):

	Amount of Gain (Loss) Recognized in Other Comprehensive Income			Amount of Gain Reclassified From Accumulated Other Comprehensive Income into Income			
	Year Ended December 31,				Year Ended December 31,		
	2021	2020	2019	Location of Gain Reclassified From Accumulated Other Comprehensive Income into Income	2021	2020	2019
Derivatives designated as cash flow hedging instruments:							
Foreign exchange forward contracts	$ 950	$ 1,980	$ 2,550	Cost of goods sold	$ 3,444	$ 790	$ 916
Forward-starting interest rate swaps	(1,480)	—	—	Interest expense	—	—	—
Total derivatives designated as cash flow hedging instruments	$ (530)	$ 1,980	$ 2,550		$ 3,444	$ 790	$ 916

As of December 31, 2021, we expect an estimated $1.1 million in deferred gains on the outstanding foreign exchange forward contract and an estimated $5.6 million in deferred losses on the forward-starting interest rate swaps will be reclassified from accumulated other comprehensive loss 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.

Contingent earn-out liabilities

In the fourth quarter of 2019, we recognized an earn-out liability related to the acquisition of Pursuit (see Note 2: Acquisitions). Pursuit's former equity holders were 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 was 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. During the earn-out period, we used a Monte Carlo simulation model to determine the fair value of the earn-out liability. The Monte Carlo simulation model utilized multiple input variables to determine the value of the earn-out liability including historical volatility, a risk-free interest rate, counter party credit risk and projected future gross profit (see the simulation input table below related to Pursuit). The historical volatility was based on the median of ICU and a certain peer group. The risk-free interest rate was equal to the yield, as of the valuation date, of the zero-coupon U.S. Treasury bill that was commensurate with the term of the earn-out. The counter party credit risk was based on a synthetic credit rating of B1. As of June 30, 2021, the

earn-out measurement period ended. Based on the actual sales and gross profit achieved during the measurement period, we calculated the actual earn-out amount to be $26.3 million. The $26.3 million earn-out calculation was finalized and accepted by Pursuit's former equity holders and was paid out in the fourth quarter of 2021.

In August 2021, we entered into an agreement with one of our international distributors whereby that distributor would not compete with us in a specific territory for a three-year period that will end in September 2024. The terms of the agreement include a contingent earn-out payment. The contingent earn-out payment shall not exceed $6.0 million, which will be earned based on certain revenue targets over a twelve-month measurement period determined by the highest four consecutive quarters commencing over a two-year period starting on the closing date of the agreement and provided that the distributor is in compliance with its obligations under the agreement. As of December 31, 2021, the fair value of the contingent earn-out was estimated at $2.6 million. The estimated fair value of the contingent earn-out is calculated using a probability-weighted cash flow model based on historical revenue streams and the likelihood that the revenue targets will be met.

During November 2021, we acquired a small foreign infusion systems supplier. Total consideration for the acquisition includes a potential earn-out payment of up to $2.5 million, consisting of (i) a cash payment of $1.0 million contingent on the achievement of certain revenue targets for the annual period ending December 31, 2022 and, separately, (ii) a cash payment of $1.5 million contingent on certain product-related regulatory certifications obtained by May 26, 2024. The initial estimated fair value of the contingent consideration related to this acquisition is immaterial.

Our contingent earn-out liabilities are separately stated on 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, 2021, 2020 and 2019 (in thousands):

		Earn-out Liability
Contingent earn-out liability, January 1, 2019	$	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)[(2)]		(47,400)
Contingent earn-out liability, December 31, 2019	$	17,300
Change in fair value of contingent earn-out (included in income from operations as a separate line item)[(3)]		9,000
Contingent earn-out liability, December 31, 2020	$	26,300
Contingent earn-out — non-compete arrangement		2,589
Transfer of Pursuit earn-out liability into Level 2[(4)]		(26,300)
Contingent earn-out liability, December 31, 2021	$	2,589

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

(2) The change in the fair value of the HIS earn-out related to our 2017 acquisition of HIS from Pfizer which was based on actual results as compared to the earn-out performance targets. This adjustment reduced the HIS earn-out to zero.

(3) The fair value of the Pursuit earn-out increased during 2020 primarily due to changes in the probabilities within the valuation model.

(4) The Pursuit earn-out was transferred out of Level 3 and into Level 2 in the third quarter of 2021 when the amount of the actual payment was known, and subsequently settled during the fourth quarter of 2021.

The following table provides quantitative information about Level 3 inputs for fair value measurement of the Pursuit earn-out liability as of the acquisition date to December 31, 2020:

Pursuit Earn-out

Simulation Input	As of December 31, 2020	At Acquisition November 2, 2019
Revenue/Gross Profit Volatility	25.00 %	20.00 %
Discount Rate	12.50 %	15.00 %
Risk-free rate	0.09 %	1.55 %
Counter Party Risk	3.10 %	6.00 %

Investments, Foreign Currency Contracts and Interest Rate Contracts

The fair value of our investments, which consist 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 contracts 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.

The fair value of our Level 2 forward-starting interest rate swaps is estimated using a pricing model that reflects the terms of the contracts, including the period to maturity, and relies on observable market inputs such as known notional value amounts and USD interest rate curves.

Other than the Pursuit earn-out liability described above, there were no transfers between levels in 2021 or 2020.

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 as of December 31, 2021			
	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	$ 14,420	$ —	$ 14,420	$ —
Long-term	4,620	—	4,620	—
Foreign exchange forwards:				
Prepaid expenses and other current assets	1,061	—	1,061	—
Total Assets	$ 20,101	$ —	$ 20,101	$ —
Liabilities:				
Contingent earn-out liability - LT	$ 2,589	$ —	$ —	$ 2,589
Forward-starting interest rate swaps:				
Other long-term liabilities	1,480	—	1,480	—
Total Liabilities	$ 4,069	$ —	$ 1,480	$ 2,589

	Fair value measurements as of December 31, 2020			
	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	$ 14,687	$ —	$ 14,687	$ —
Long-term	12,974	—	12,974	—
Foreign exchange forwards:				
Prepaid expenses and other current assets	3,555	—	3,555	—
Total Assets	$ 31,216	$ —	$ 31,216	$ —
Liabilities:				
Earn-out liability	$ 26,300	$ —	$ —	$ 26,300
Total Liabilities	$ 26,300	$ —	$ —	$ 26,300

NOTE 9. PREPAID EXPENSES AND OTHER CURRENT ASSETS AND OTHER ASSETS

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

	As of December 31,	
	2021	2020
Other prepaid expenses and receivables	$ 14,763	$ 14,964
Deferred costs	12,746	6,402
Prepaid insurance and property taxes	6,310	6,178
VAT/GST receivable	4,156	3,676
Deferred tax charge	4,241	3,542
Foreign exchange forward contract	1,061	3,555
Deposits	1,343	1,353
Other	2,227	1,822
	$ 46,847	$ 41,492

Other assets consist of the following (in thousands):

	As of December 31,	
	2021	2020
Pump lease receivables	$ 25,941	$ 28,948
Spare parts	28,538	22,725
Equity method investments	3,238	—
Deferred debt issuance costs	2,827	—
Finance lease right-of-use assets	2,673	2,915
Other	526	887
	$ 63,743	$ 55,475

NOTE 10. ACCRUED LIABILITIES AND OTHER LONG-TERM LIABILITIES

Accrued liabilities consist of the following (in thousands):

	As of December 31,	
	2021	2020
Salaries and benefits	$ 27,304	$ 25,786
Incentive compensation	33,107	27,023
Operating lease liability-ST	9,009	8,740
Accrued professional fees	773	1,273
Legal accrual	3,897	900
Accrued sales taxes	1,980	2,146
Warranties and returns	532	1,027
Deferred revenue	12,646	5,566
Accrued other taxes	4,337	3,540
Distribution fees	5,645	5,300
Accrued freight	9,194	6,784
Restructuring accrual	664	3,421
Other	9,107	5,515
	$ 118,195	$ 97,021

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

	As of December 31,	
	2021	2020
Operating lease liability-LT	$ 33,971	$ 41,019
Finance lease liability-LT	2,067	2,388
Contract liabilities[(1)]	202	337
Forward-starting interest rate swaps	1,480	—
Benefits	1,369	1,183
Accrued rent	1,262	1,462
Other	1,479	1,446
	$ 41,830	$ 47,835

(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 Senior Secured Revolving Credit Facility ("Credit Facility")

On November 8, 2017, we entered into a five-year Revolving Credit Facility ("Credit Facility") with various lenders for $150.0 million, with Wells Fargo Bank, N.A. as the administrative agent, swingline lender and issuing lender. During March 2020, as a result of market uncertainty caused by the COVID-19 pandemic, we preemptively borrowed $150.0 million on our Credit Facility as a conservative measure to manage any potential short-term liquidity risk. As of December 31, 2020, we had fully repaid all amounts borrowed. As of December 31, 2021 and 2020, we had no borrowings and $150.0 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) $100.0 million and (ii) 2.00x Total Leverage.

In connection with the Credit Facility, during 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 on 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.

On January 6, 2022, we completed the acquisition of Smiths Medical which was partially financed by entering into Senior Secured Credit Facilities consisting of a term loan A facility of $850.0 million, a term loan B facility of $850.0 million and a revolving credit facility of $500.0 million.

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 entered into Senior Secured Credit Facilities in January 2022, which terminated our existing Credit Facility (see Note 17: Subsequent Events).

NOTE 12. INCOME TAXES

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

	Year Ended December 31,		
	2021	2020	2019
United States	$ 81,484	$ 41,194	$ 32,849
Foreign	41,702	56,300	81,858
	$ 123,186	$ 97,494	$ 114,707

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

	Year Ended December 31,		
	2021	2020	2019
Current:			
Federal	$ 20,646	$ 6,032	$ 6,851
State	3,444	2,422	2,532
Foreign	7,236	7,290	7,994
	$ 31,326	$ 15,744	$ 17,377
Deferred:			
Federal	$ (8,154)	$ (5,319)	$ (6,720)
State	(1,815)	(1,850)	(325)
Foreign	(1,306)	2,049	3,340
	(11,275)	(5,120)	(3,705)
	$ 20,051	$ 10,624	$ 13,672

We have accrued for tax contingencies for potential tax assessments, and in 2021 we recognized a $3.0 million net increase, most of which related to various federal, state and foreign tax reserves.

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

	Year Ended December 31,					
	2021		2020		2019	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ 25,869	21.0 %	$ 20,474	21.0 %	$ 24,088	21.0 %
State income tax, net of federal effect	2,907	2.4 %	2,099	2.2 %	1,269	1.1 %
Tax credits	(2,443)	(2.0)%	(3,269)	(3.4)%	(2,896)	(2.5)%
Global intangible low-taxed income	711	0.6 %	163	0.2 %	6,634	5.8 %
Foreign income tax differential	(2,983)	(2.4)%	(3,888)	(4.0)%	(5,939)	(5.2)%
Stock-based compensation	(4,263)	(3.5)%	(4,686)	(4.8)%	(8,446)	(7.4)%
Foreign-derived intangible income	(3,775)	(3.1)%	(2,718)	(2.8)%	(516)	(0.5)%
IP installment sale and repatriation	—	— %	—	— %	(2,118)	(1.8)%
Contingent consideration	(29)	— %	1,566	1.6 %	—	— %
Section 162(m)	1,812	1.5 %	1,079	1.1 %	203	0.2 %
Other	2,245	1.8 %	(196)	(0.2)%	1,393	1.2 %
	$ 20,051	16.3 %	$ 10,624	10.9 %	$ 13,672	11.9 %

Tax credits in 2021, 2020 and 2019 consist principally of research and developmental tax credits.

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 installment sale and repatriation.

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

	As of December 31,	
	2021	2020
Deferred tax asset:		
Accruals/other	$ 6,866	$ 4,406
Acquired future tax deductions	5,440	7,781
Stock-based compensation	7,283	7,138
Foreign currency translation adjustments	3,360	2,406
Tax credits	11,953	12,444
Inventory reserves	8,199	8,493
Allowance for doubtful accounts	926	4,460
Accrued restructuring	131	1,293
Chargebacks, discounts, customer concessions	27,970	22,874
Valuation allowance	(2,934)	(3,891)
	$ 69,194	$ 67,404
Deferred tax liability:		
State income taxes	$ 2,724	$ 2,398
Foreign	—	776
Depreciation and amortization	20,483	25,113
Section 481(a) adjustment - change in accounting method	4,873	9,746
	$ 28,080	$ 38,033
Deferred tax asset, net	$ 41,114	$ 29,371

Tax Holidays and Carryforwards

Net operating loss ("NOL") carryforwards consist of: (a) federal NOL carryforwards of $2.5 million which will expire at various dates from 2023 to indefinite carryforward periods, (b) state NOL carryforwards of $8.2 million which will expire at various dates from 2022 to indefinite carryforward periods and (c) foreign NOL carryforwards of $15.0 million which will expire at various dates from 2022 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 $16.9 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 $9.8 million or $0.45 per diluted share in 2021 and by $8.0 million or $0.37 per diluted share in 2020.

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, 2021, we have estimated $98.6 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 U.S. and various states and foreign jurisdictions. Our U.S. federal income tax returns for tax years 2018 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, 2021 was $21.5 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, 2021, 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, 2021 or 2020.

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

	Year Ended December 31,		
	2021	2020	2019
Beginning balance	$ 18,443	$ 15,027	$ 10,824
Increases to prior year tax positions	231	502	138
Increases to current year tax positions	3,242	2,987	4,231
Decreases to prior year tax positions	—	(15)	(3)
Decrease related to lapse of statute of limitations	(31)	(58)	(163)
Decrease related to settlements with tax authorities	(348)	—	—
Ending balance	$ 21,537	$ 18,443	$ 15,027

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,	
	2021	2020
Costa Rica	$ 115,187	$ 104,015
Mexico	79,567	76,004
Other LATAM	36,907	37,485
Canada	4,716	4,672
Italy	12,435	11,098
Spain	13,295	8,701
Other Europe	4,171	3,795
APAC	20,452	19,836
Total Foreign	$ 286,730	$ 265,606
United States	618,374	577,490
Worldwide Total	$ 905,104	$ 843,096

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 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 2021, 2020 or 2019. We are limited on share purchases in accordance with the terms and conditions of our Credit Facility (see Note 11: Long-Term Obligations).

In 2021, we withheld 40,350 shares of our common stock from employee vested restricted stock units in consideration for $8.3 million in payments for the employees' share award income tax withholding obligations. We had 119 shares remaining in treasury at December 31, 2021.

In 2020, we withheld 67,041 shares of our common stock from employee vested restricted stock units in consideration for $12.9 million in payments for the employees' share award income tax withholding obligations. We had 209 shares remaining in treasury at December 31, 2020.

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 employees' share award income tax withholding obligations. We had 850 shares remaining in treasury at December 31, 2019.

We use treasury stock to issue shares for stock option exercises and 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 (Losses) on Cash Flow Hedges	Other Adjustments	Total
Balance as of January 1, 2019	$ (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)
Other comprehensive income before reclassifications	12,929	1,505	47	14,481
Amounts reclassified from AOCI	—	(601)	—	(601)
Other comprehensive income	12,929	904	47	13,880
Balance as of December 31, 2020	$ (4,381)	$ 2,784	$ 75	$ (1,522)
Other comprehensive loss before reclassifications	(14,664)	(403)	(62)	(15,129)
Amounts reclassified from AOCI	—	(2,618)	—	(2,618)
Other comprehensive loss	(14,664)	(3,021)	(62)	(17,747)
Balance as of December 31, 2021	$ (19,045)	$ (237)	$ 13	$ (19,269)

NOTE 15. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

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

In 2017, we recognized an earn-out liability in connection with our acquisition of HIS from Pfizer. Pfizer was entitled to receive between $191.3 million and $225.0 million in additional cash consideration based on the achievement of certain performance targets for the combined company for the three years ending December 31, 2019. As of December 31, 2019, we determined we did not meet the necessary performance targets that would require payout of any of the HIS earn-out liability. Pfizer disputed our determination that the performance targets requiring payout of the HIS earn-out liability were not met, therefore the dispute entered into binding arbitration. In August 2021, the arbitrator concluded that the necessary performance targets that would require payout of the HIS earn-out were not met, and as a result Pfizer is not entitled to any payments in connection with the HIS earn-out liability.

During November 2019, we acquired Pursuit (see Note 2: Acquisitions). Total consideration for the acquisition included a potential contractual earn-out of up to $50.0 million to be paid to former Pursuit equity holders, calculated based upon the achievement of certain performance targets during the earn-out period. As of June 30, 2021, the earn-out measurement period had ended and based on the actual sales and gross profit achieved during the measurement period we calculated the actual earn-out to be $26.3 million. In October 2021, the $26.3 million earn-out was finalized and paid to the former Pursuit equity holders (see Note 8: Fair Value Measurements).

In August 2021, we entered into an agreement with one of our international distributors whereby that distributor would not compete with us in a specific territory for a three-year period that will end in September 2024. The terms of the agreement include a contingent earn-out payment. The contingent earn-out shall not exceed $6.0 million, which will be earned based on certain revenue targets over a twelve-month measurement period determined by the highest four consecutive quarters commencing over a two-year period starting on the closing date of the agreement and provided that the distributor is in compliance with its obligations under the agreement. As of December 31, 2021, the fair value of the contingent earn-out was estimated at $2.6 million (see Note 8: Fair Value Measurements).

During November 2021, we acquired a small foreign infusion systems supplier. Total consideration for the acquisition includes a potential earn-out payment of up to $2.5 million, consisting of (i) a cash payment of $1.0 million contingent on the achievement of certain revenue targets for the annual period ending December 31, 2022 and, separately, (ii) a cash payment of $1.5 million contingent on certain product-related regulatory certifications obtained by May 26, 2024. The initial estimated fair value of the contingent consideration related to this acquisition is immaterial.

Commitments

We have non-cancelable operating lease agreements where we are contractually obligated to pay certain lease payment amounts (see Note 5: Leases).

NOTE 16. COLLABORATIVE AND OTHER ARRANGEMENTS

On February 3, 2017, we entered into two Manufacturing and Supply Agreements ("MSAs") whereby (i) 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) 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 MSAs provide each party with mutually beneficial interests and both of the MSAs 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 January 1, 2021, we amended our MSA with Pfizer, whereby we manufacture and supply certain agreed upon products to Pfizer. The amendments included a change to the term of the agreement to end on December 31, 2024 with Pfizer's unilateral election to extend through December 31, 2025. Other changes to the terms of the MSA included (i) amendments to our level of supply of products to Pfizer, (ii) certain changes to our manufacturing lines, (iii) updates to our supply price with added volume price tiers for annual periods and (iv) certain minimum purchase requirements for certain products. On February 1, 2022, effective as of January 1, 2022, upon our request, Pfizer executed a Product Addendum (the "Product Addendum") to our MSA agreement, whereby Pfizer manufactures and supplies to us certain agreed upon products. The Product Addendum includes the supply of additional product to us subject to certain time and pricing terms and conditions. The Product Addendum includes a minimum purchase obligation of $29.6 million. The Product Addendum expires on November 30, 2022.

NOTE 17. SUBSEQUENT EVENTS

Acquisition of Smiths Medical 2020 Limited

On January 6, 2022, we completed the acquisition of Smiths Medical, the holding company of Smiths Group plc's global medical device business, from Smiths Group International Holdings Limited (the “Seller”). In accordance with the Share Sale and Purchase Agreement (the "Purchase Agreement"), we purchased 100% of the equity interests of Smiths Medical for approximately $1.9 billion in cash and issued of 2.5 million of fully paid and non-assessable shares of our common stock, par value $0.10 per share. The Purchase Agreement also includes a potential contingent earn-out payment of $100.0 million in cash, which is to be based upon our common stock achieving a certain volume-weighted average price for certain periods from closing to the third or fourth anniversary of closing. The acquisition of Smiths Medical adds to and complements our current product portfolio and the combining of both businesses allows us to be a scaled U.S.-based global competitor that increases the stability of the medical supply chain and allows for future growth.

At closing, in connection with the issuance of the stock consideration to the Seller, we entered into a Shareholders Agreement (the “Shareholders Agreement”). The Shareholders Agreement imposes certain restrictions on the Seller including prohibiting certain transfers of the shares of our common stock issued (i) for 6 months following the closing of the acquisition transaction and (ii) to certain of our competitors and certain other parties, as well as customary standstill limitations. Under the Shareholders Agreement, the Seller has the right to designate one individual for election to our board of directors so long as the Seller beneficially owns at least 5.0% of the total outstanding shares of our common stock.

We expect to account for the Smiths acquisition as a business combination, however the initial accounting for the business combination is incomplete. We are unable to provide preliminary estimates of asset and liability fair market values as the external valuation of the assets acquired and liabilities assumed is incomplete. We plan to file the required historical financial statements and the required pro forma financial statements of the combined results of ICU and Smiths Medical in a Form 8-K/A to amend the Current Report on Form 8-K filed on January 7, 2022 by March 22, 2022.

Issuance of Senior Secured Credit Facilities

On January 6, 2022, to partially finance the acquisition of Smiths Medical, we entered into a credit agreement (the "Credit Agreement") with Wells Fargo Bank, National Association, Wells Fargo Securities, LLC, Barclays Bank PLC and certain other financial institutions (the “Lenders”), pursuant to which, among other things, the Lenders provided us with credit facilities in the aggregate amount of $2.2 billion consisting of (i) a five-year term loan A of $850.0 million, (ii) a seven-year Term Loan B of $850.0 million and (iii) a five-year Revolving Credit Facility of $500.0 million.

Principal Payments

Principal payments on the term loan A and term loan B Facilities are due on the last day of each calendar quarter commencing on June 30, 2022. The term loan A Facility will amortize in an amount equal to 2.50% of the original principal amount in the first two years, 5.00% in the third and fourth years and 7.50% in the fifth year, with a final payment of the outstanding principal balance due on the respective maturity date. The term loan B Facility will mature in twenty-seven consecutive quarterly installments in an amount equal to 0.25% of the aggregate principal amount of the term loan B outstanding on the Closing Date, with a final payment of the outstanding principal balance due on the respective maturity date. All outstanding revolving loans over the term of the revolver are to be paid by the applicable maturity date.

Interest Rate Terms

In general, U.S. dollar revolving and term loans under the credit facilities may bear interest, at our option, on either (1) the Base Rate, as defined in the Credit Agreement, plus the applicable margin, as indicated below or (2) Adjusted Term secured overnight financing rate, as defined in the Credit Agreement, plus applicable margin as indicated below.

Revolving Credit Facility Commitment Fee

The revolving credit facility has a per annum commitment fee at an initial rate of 0.25% which is applied to the available amount of the revolving credit facility. The commitment fee after the quarter ending June 30, 2022 is calculated based on the leverage ratio as indicated below.

Applicable Interest Margins

The applicable interest margins with respect to revolving loans and the term loan A Facility shall initially be 1.75% for RFR Loans, as defined in the Credit Agreement. The following pricing grid for the revolving credit facility and the term loan A Facility will become effective after the quarter ending June 30, 2022 and will be based on changes in the Leverage Ratio as follows:

Leverage Ratio	Applicable Margin for RFR Loans	Applicable Margin for Base Rate Loans	Commitment Fee Rate
>4.00 to 1.0	2.25%	1.25%	0.35%
≤4.00 to 1.0 but >3.00 to 1.0	2.00%	1.00%	0.30%
≤3.00 to 1.0 but >2.50 to 1.0	1.75%	0.75%	0.25%
≤2.50 to 1.0 but >2.00 to 1.0	1.50%	0.50%	0.20%
≤2.00 to 1.0	1.25%	0.25%	0.15%

The applicable interest margins for the term loan B Facility shall initially be set at 2.50% for Eurocurrency Rate Loans. The following pricing grid will become effective on the Adjustment Date and will be based on changes in the Leverage Ratio as follows:

Leverage Ratio	Applicable Margin for Eurocurrency Rate Loans	Applicable Margin for Base Rate Loans
>2.75 to 1.0	2.50%	1.50%
≤2.75 to 1.0	2.25%	1.25%

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to the Loan Parties and the restricted subsidiaries of the Company, including, without limitation, restrictions on liens, indebtedness, investments, fundamental changes, dispositions, restricted payments and prepayment of junior indebtedness. The Credit Agreement contains financial covenants on the revolving credit facility and term loan A Facility that require the Loan Parties and the restricted subsidiaries of the Company to (i) not exceed a maximum secured net leverage ratio initially set at 4.50 to 1.00, with stepdowns to 4.00 to 1.00 on June 30, 2024 and (ii) a minimum interest coverage ratio of 3.00 to 1.00.

The Credit Agreement contains customary events of default, including, without limitation, payment defaults, covenant defaults, breaches of certain representations and warranties, cross defaults and cross-acceleration to certain material indebtedness, certain events of bankruptcy and insolvency, impairment of security, certain events under ERISA, material judgments and a change of control. If an event of default occurs and is not cured within any applicable grace period or is not waived, the administrative agent and the lenders are entitled to take various actions, including, without limitation, the acceleration of amounts due thereunder and termination of commitments under the Facilities.

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, 2021.

Our independent registered public accounting firm that audited the December 31, 2021 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, 2021, 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, 2021, 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, 2021, of the Company and our report dated February 25, 2022, 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
February 25, 2022

ITEM 9B. OTHER INFORMATION

None

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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 2022 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 2022 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 2022 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 2022 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information about aggregate fees billed to us by our principal accountant, Deloitte & Touche LLP (PCAOB No. 34) as 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 2022 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

EXHIBIT INDEX

Exhibit Number	Exhibit Description
2.1	Share Sale and Purchase Agreement, dated September 8, 2021, by and between Smiths Group International Holdings Limited, a private limited company incorporated in England and Wales, and ICU Medical, Inc., a Delaware corporation. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed September 8, 2021, and incorporated herein by reference.
2.2	Put Option Deed from ICU Medical, Inc., a Delaware corporation to Smiths Group International Holdings Limited, a private limited company incorporated in England and Wales. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed September 8, 2021, 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. Filed as an Exhibit to Registrant's Annual Report of Form 10-K for the year ended December 31, 2019, filed March 2, 3020, and incorporated herein by reference.
10.1	Form of Indemnification Agreement with Directors and Executive Officers. Filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q for the Quarter ended September 30, 2010, filed October 22, 2010 (File No. 001-34634), and incorporated herein by reference.
10.2	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.
10.3	Executive officer compensation*
10.4	Non-employee director compensation*
10.5	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.
10.6	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.

10.7	First Amendment to ICU Medical, Inc. Amended and Restated 2011 Stock Incentive Plan. Filed as an exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 2019, filed March 2, 2020 (File No.001-34634) and incorporated herein by reference.
10.8	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.
10.9	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.
10.10	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.
10.11	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.
10.13	Credit Agreement, dated as of January 6, 2022, by and among ICU Medical, Inc. as Borrower, certain subsidiaries as guarantors, Wells Fargo Bank, National Association, as Administrative Agent, Wells Fargo Securities, LLC and Barclays Bank PLC as joint bookrunners and joint lead arrangers and the other joint bookrunners and joint lead arrangers listed therein. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed January 7, 2022.
10.14	Shareholders Agreement, dated as of January 6, 2022, by and between ICU Medical, Inc. and Smiths Group International Holdings Limited. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed January 7, 2022.
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, 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
For the year ended December 31, 2020:					
Allowance for doubtful accounts	$ 20,219	$ 7,137	$ (5,866)	$ —	$ 21,490
Warranty and return reserve - accounts receivable	$ 6,377	$ (3,609)	$ (61)	$ —	$ 2,707
Warranty and return reserve - inventory	$ (3,477)	$ 2,033	$ (169)	$ —	$ (1,613)
Deferred tax asset valuation allowance	$ 3,677	$ —	$ 214	$ —	$ 3,891
For the year ended December 31, 2021:					
Allowance for doubtful accounts	$ 21,490	$ 345	$ (14,797)	$ —	$ 7,038
Warranty and return reserve - accounts receivable	$ 2,707	$ 568	$ (790)	$ —	$ 2,485
Warranty and return reserve - inventory	$ (1,613)	$ 263	$ (533)	$ —	$ (1,883)
Deferred tax asset valuation allowance	$ 3,891	$ —	$ (957)	$ —	$ 2,934

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: February 25, 2022

SIGNATURES

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

Signature	Title	Date
/s/ Vivek Jain Vivek Jain	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 25, 2022
/s/ Brian M. Bonnell Brian M. Bonnell	Chief Financial Officer (Principal Financial Officer)	February 25, 2022
/s/ Kevin J. McGrody Kevin J. McGrody	Chief Accounting Officer (Principal Accounting Officer)	February 25, 2022
/s/ George A. Lopez, M.D. George A. Lopez, M.D.	Director	February 25, 2022
/s/ David C. Greenberg David C. Greenberg	Director	February 25, 2022
/s/ Elisha W. Finney Elisha W. Finney	Director	February 25, 2022
/s/ David F. Hoffmeister David F. Hoffmeister	Director	February 25, 2022
/s/ Donald M. Abbey Donald M. Abbey	Director	February 25, 2022
/s/ Laurie Hernandez Laurie Hernandez	Director	February 25, 2022
/s/ Kolleen T. Kennedy Kolleen T. Kennedy	Director	February 25, 2022
/s/ William Seeger William Seeger	Director	February 25, 2022

Exhibit 10.3

Executive Officer Compensation

The annual base salaries for our executive officers as of January 1, 2021 are as follows:

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

Exhibit 10.4

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 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 Bidco Ltd	United Kingdom
ICU Medical Germany GmbH	Germany
ICU Medical B.V.	Netherlands
ICU Medical Australia Holdings Pty Limited	Australia
Medima s.p. z.o.o.	Poland
ICU Medical SA Pty Ltd	South Africa
EXC Holding Corp.	Delaware
Tangent Medical Technologies, Inc.	Delaware
Excelsior Medical Corporation	Delaware
ICU Medical France S.A.S.	France
ICU Medical Canada Inc.	Canada
ICU Medical 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
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. 333-90464, 333-175239, 333-198256, and 333-219106 on Form S-8 and 333-228390 on Form S- 3 of our reports dated February 25, 2022, relating to the financial statements of ICU Medical, Inc. and the effectiveness of ICU Medical Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ DELOITTE & TOUCHE LLP

Costa Mesa, California
February 25, 2022

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: February 25, 2022

/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, Brian M. Bonnell, 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: February 25, 2022

/s/ Brian M. Bonnell
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, 2021 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.

February 25, 2022

/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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian M. Bonnell, 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.

February 25, 2022

/s/ Brian M. Bonnell
Brian M. Bonnell