2024 Annual Report to Shareholders

and Form 10-K

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human connections

Clinician-founded. Clinically focused.

From our beginnings in 1984 as an innovative clinician-founded company to today—as a global leader in IV therapy—ICU Medical remains committed to bringing our customers clinically-relevant products and technologies that help safely and efficiently meet patient care challenges.

IV Systems

An integrated portfolio of IV pump technologies, informatics, and services

Consumables

A complete line of infusion, vascular access, and specialty consumables

Vital Care

Hemodynamic monitoring, temperature and airway management, and pain kits

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April 3, 2025

Dear ICU Medical Shareholder,

As we move into 2025, ICU Medical is in its strongest operational position since acquiring Smiths Medical, and we continue to build trusted relationships with customers worldwide. In 2024, we grew revenues at an attractive rate and took steps to reduce debt, but we acknowledge that earnings have remained flat over the past three years. Addressing this is a top priority, and we are extremely focused on delivering meaningful earnings improvements in 2025. As noted in our last two letters, the Smiths Medical acquisition and integration has taken time and presented its own challenges, but we are now seeing solid progress and a clear contribution to financial performance and shareholder value.

The significant inflationary effects that impacted us in prior years eased in 2024, and we began to recoup the impact in our renewals of long-term customer contracts and effort around global price increases. At the time of writing, the key macroeconomic factor that could impact our financial results is the potential of US government tariffs and the downstream effects they may have on currency markets and interest rates.

In 2024, we saw solid revenue growth across our core businesses. In Consumables, the legacy ICU product families of IV Therapy and Oncology once again reached record sales, and the Vascular Access lines achieved the best growth in years. In the IV Systems business, the acquired product line of CADD™ ambulatory infusion pumps performed exceptionally well, with strong sales and growing demand. Our Vital Care business overperformed due to the national IV solutions shortage and is expected to return to a more normal level this year.

Looking ahead, we believe we are at the pinnacle of IV Systems device innovation, reflecting years of focused investment and expertise in this critical part of our business. Following approval of the Plum Duo™ infusion pump, we are now in the final stages of the FDA 510(k) review process for our Plum Solo™ single-channel pump and associated LifeShield™ safety software, and we are preparing 510(k) submissions for CADD and next-generation Medfusion™ pumps. These updated devices, combined with our large-volume pump portfolio and connection to LifeShield safety software, will give us the most advanced and integrated fleet of infusion devices in the market.

From an operational perspective, we made progress on a number of key initiatives in 2024 that will help improve mid- and longer-term gross margins. We successfully completed the cutover of our order-to-cash IT systems for North America, enabling us to optimize logistics and customer service infrastructure. We also continued work on multiple factory consolidations to bring additional productivity to a smaller manufacturing network and refined our real estate footprint to support post-pandemic needs. Each of these activities has a clear payback and will contribute to improved gross margins.

Finally, one of the most significant updates of 2024 was the announcement of our joint venture for IV solutions with Otsuka Pharmaceutical Factory—a partnership our teams are working diligently behind the scenes to bring to life. Otsuka's expertise and commitment make them an ideal partner, and we believe this collaboration will strengthen supply chain resiliency and drive much needed innovation in the North American IV solutions market.

In 2025, we remain focused on disciplined execution and driving earnings growth, with the goal of delivering more predictable results and creating long-term value for our shareholders. As we strengthen our financial position and improve leverage, we look forward to returning capital in a thoughtful, balanced way that supports both shareholder returns and continued investment in innovation.

Sincerely,

Vivek Jain
Chairman and CEO

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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, 2024 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

Securities registered pursuant to section 12(g) of the Act: None

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

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

Indicate by check mark whether the 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 the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically 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 ☐

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

Large Accelerated Filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller 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. ☐

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements

of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting stock held by non-affiliates of registrant as of June 30, 2024, the last business day of registrant's most recently completed second fiscal quarter, was $2,671,423,750.

The number of shares outstanding of registrant's common stock, $.10 par value, as of January 31, 2025 was 24,519,000.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for registrant's 2025 Annual Meeting of Stockholders filed or to be filed pursuant to Regulation 14A within 120 days following registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Report.

ICU Medical, Inc.
Form 10-K
For the Year Ended December 31, 2024
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Forward Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of present and historical fact, contained in this Annual Report on Form 10-K, including, without limitation, statements regarding: our future results of operations and financial position, business strategy and approach; the projected timeline as well as the anticipated benefits and costs associated with our purchase agreement with OPF (as defined below); expected capital expenditures; anticipated consumer demand; supply chain constraints; the expected impact of macroeconomic developments, such as foreign exchange, inflation and interest rates, and new accounting and tax regulations; tariffs; as well as plans and objectives of management for future operations, are forward-looking statements. Without limiting the foregoing, in some cases, you can identify forward-looking statements by terms such as "aim," "may," "will," "should," "expect," "exploring," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

The forward looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including without limitation, the following:

- our failure to compete successfully with our competitors and maintain market share;
- significant decline in demand for our products;
- our inability to fund substantial investment in product development and recover such investment through commercial product sales;
- prolonged periods of inflation, rising interest rates and the impact of foreign currency exchange rates as a result of the current global macroeconomic and geopolitical conditions, for example, armed conflicts between Ukraine and Russia and in Israel;
- significant changes in U.S. trade, tax or other policies that restrict imports or increase import tariffs for certain countries, particularly Mexico, will escalate trade wars and will have a material adverse effect on our results of operations.
- continuing pressures to reduce healthcare costs and inadequate coverage and reimbursement;
- disruptions at the FDA, other government agencies or notified bodies caused by funding shortages, global health concerns, or turnover of personnel;
- failure to protect our information technology systems against security breaches, service interruptions, or misappropriation of data;
- our exposure to risks related to foreign currency exchange rates;
- damage to any of our manufacturing facilities or disruption to our supply chain network;
- our dependence 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;
- our failure to achieve expected operating efficiencies or expense reductions associated with cost reduction and restructuring efforts;
- significant sales through our distributors;
- additional risks from international sales, related to competition with larger international companies and established local companies and our possibly higher cost structure;
- actual or perceived failures to comply with foreign, federal, and state data privacy and security laws, regulations and standards, or certain fraud and abuse and transparency laws;
- our failure to defend and enforce our patents or other proprietary rights and the cost of enforcing and of defending patent claims or claims of other proprietary rights; and expiration of our patents;
- our failure to effectively complete the integration of our business resulting from the Smiths Medical acquisition or manage our growth and changes to our business resulting from any other future acquisitions; and
- our use of a significant portion of our cash on hand and incurrence of a substantial amount of debt to finance the Smiths Medical acquisition, which could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness.

The forward looking statements in this report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Annual Report on Form 10-K entitled “Summary Risk Factors,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our securities. Principal risks and uncertainties include:

- 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.

- 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 financial condition and results of operations.

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

- Heightened inflation, higher interest rates and foreign currency rate fluctuations as a result of global macroeconomic and geopolitical conditions have had and could in the future have a material adverse effect on our operations.

- Significant changes in U.S. trade, tax or other policies that restrict imports or increase import tariffs for certain countries, particularly Mexico, can escalate trade wars and could have a meaningful adverse effect on our results of operations.

- Continuing pressures to reduce healthcare costs and inadequate coverage and reimbursement may adversely affect our prices. If we cannot reduce manufacturing costs of existing and new products to counteract such pricing pressures, our sales may not grow and our profitability may decline.

- Our ability to market, distribute and sell our products in the U.S. and other countries may be adversely affected if our products fail to comply with the existing laws and regulations, and applicable requirements of the FDA, governmental agencies in other countries, and notified bodies.

- 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. In particular, if we are unable to resolve or close-out the Warning Letter dated October 1, 2021, received by Smiths Medical ASD, Inc. from the Minneapolis, Minnesota Facility following a February to March 2021 inspection, we could suffer significant sanctions which may impact our ability to sell products globally.

- Disruptions at the FDA, other government agencies or notified bodies caused by funding shortages, global health concerns, or personnel turnover 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.

- Failure to protect our information technology 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.

- Damage to, or interruptions at, any of our manufacturing facilities or our suppliers' facilities could impair our ability to produce our products.

- 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.

- We may not be successful in achieving expected operating efficiencies or expense reductions associated with cost reduction and restructuring efforts and may experience a decline in our profitability, business disruptions or other adverse consequences to our business as a result.

- Significant sales through distributors expose us to risks that could have a material effect on our results of operations.

- Actual or perceived 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 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.

- 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 patents or other proprietary rights becomes excessive or as our patents expire.

- Our operations may be adversely impacted by our exposure to risks related to foreign currency exchange rates.

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

- The Smiths Medical acquisition completed in January 2022 has resulted in organizational changes and an increase in size to our business. If we fail to effectively complete the integration of 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.

- For the Smiths Medical acquisition, we 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 acquisition, which could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness.

See Part I, Item 1A of this Annual Report on Form 10-K for the detailed discussion of the above risk factors.

PART I

ITEM 1. BUSINESS

First person pronouns used in this Annual Report on Form 10-K, such as “we,” “us,” and “our,” refer to ICU Medical, Inc. (“ICU”) and its subsidiaries unless context requires otherwise.

Company Background and Overview of Business

ICU develops, manufactures and sells innovative medical products used in infusion therapy, vascular access, and vital care applications. Our team is focused on providing quality, innovation and value to our clinical customers worldwide. ICU's product portfolio includes ambulatory, syringe, and large volume IV pumps and safety software; dedicated and non-dedicated IV sets, needlefree IV connectors, peripheral IV catheters, sharps safety products, and sterile IV solutions; closed system transfer devices and pharmacy compounding systems; as well as a range of respiratory, anesthesia, patient monitoring, and temperature management products.

Headquartered in San Clemente, California, ICU was founded in 1984. 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 acquisitions.

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 January 2022, we acquired Smiths Medical 2020 Limited (“Smiths Medical”), the holding company of Smiths Group plc’s ("Smiths") global medical device business. The Smiths Medical acquisition complemented and broadened our preexisting product portfolio by adding syringe and ambulatory infusion devices, vascular access, and vital care products, and we believe has significantly strengthened and expanded our global market reach.

In November 2024, we entered into a purchase agreement with Otsuka Pharmaceutical Factory America, Inc. (“Otsuka”), a global IV solutions manufacturing subsidiary of Otsuka Holdings Co., Ltd. Under the agreement, a joint venture will be formed among the Company and ICU Medical Sales, Inc., a wholly owned subsidiary of the Company (collectively, the “ICU Medical Entities”), and Otsuka, to provide additional supply chain resiliency and innovation to our North American IV solutions market under commercial agreements, a services agreement and a license agreement. The transaction is expected to be completed during the second quarter of 2025.

Products

Our primary product offerings are described below.

Consumables

Our Consumables business unit includes Infusion Therapy, Oncology, Vascular Access and Tracheostomy products.

Infusion Therapy

Our Infusion Therapy products include non-dedicated infusion sets, extension sets, needle-free connectors, and disinfection caps. Infusion sets used in hospitals and ambulatory clinics consist of flexible sterile tubing running from an IV bag or bottle containing a drug product or solution to a catheter inserted in a patient’s vein that may or may not be used with an infusion pump. Disinfection caps are used to actively disinfect access points into the infusion sets and catheters. Our primary Infusion Therapy 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;

- Neutron™ catheter patency device, used to help maintain patency of central venous catheters;

- Tego™ needlefree connector utilized to access catheters for hemodialysis and apheresis applications; and

- ClearGuard™, SwabCap™ and SwabTip™ disinfection caps.

Oncology

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 on the healthcare worker and environment. Our primary Oncology products are:

- ChemoLockTM CSTD (“ChemoLock”), 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;

- ChemoClaveTM (“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

- Deltec® GRIPPER® non-coring needles for portal access.

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.

Vascular Access

Our Vascular Access products are used by clinicians to access the patients' bloodstream to deliver fluids and medication or to obtain blood samples. Our primary Vascular Access products are:

- Jelco® safety and conventional peripheral IV catheters and sharps safety devices for hypodermic injection, designed to help prevent accidental needlestick injury;

- Safe-T Wing® venipuncture and blood collection devices;

- Port-A-Cath® implantable ports;

- Portex® arterial blood sampling syringes;

- PowerWand® midline catheters; and

- Cleo® subcutaneous infusion catheters and sets.

Tracheostomy

Our tracheostomy products are used in the placement of a secure airway using both surgical and percutaneous insertion techniques. Our primary Tracheostomy products are:

- Portex BLUselect® PVC tracheostomy tubes, which feature an inner cannula as well as a Suctionaid option for above the cuff suctioning and vocalization capability;

- Portex Bivona® silicone tracheostomy tubes, which offer the added benefits of comfort and mobility and come in a variety of configurations suited to meet the clinical needs of neonatal through adult patients; and

- Portex BLUperc® percutaneous insertion kits, which allow for safe placement of the tracheostomy tube at the bedside.

Infusion Systems

We offer a comprehensive portfolio of infusion pumps, dedicated IV sets, software and professional services to meet the wide range of infusion needs. Our primary Infusion System products are:

Large Volume Pump ("LVP") Hardware:

- Plum 360™ infusion pumps feature a unique delivery system that helps to enhance patient safety and workflow efficiency. The pumps work with PlumSet™ dedicated IV sets that include an air trap to help minimize interruptions and a direct connection to the secondary line that eliminates the risk of setup errors and enables concurrent delivery of two compatible medications through a single line. Plum 360 has been named Best in KLAS for eight years in a row (2018, 2019, 2020, 2023 – Best in KLAS Smart Pump Traditional; 2021, 2022, 2023, 2024, 2025 Best in KLAS Smart Pump EMR Integrated) and was the first medical device to be awarded UL Cybersecurity Assurance Program Certification.

- Plum Duo™ infusion pumps with LifeShield™ safety software are dual channel devices capable of delivering up to four compatible medications at independent rates with a single pump. The Plum Duo combines the award-winning legacy of Plum 360 with modern innovation, including a large touch screen and highly intuitive user interface to help guide users through programming, while streamlining complex tasks.

Ambulatory Infusion Hardware:

- CADD™ ambulatory infusion pumps and disposables, including administration sets and medication cassette reservoirs, serve as a single pain management platform across all types of IV pain management therapies and all clinical care areas from the hospital to outpatient treatment.

Syringe Infusion Hardware:

- Medfusion™ syringe infusion pumps are designed for the administration of fluids and medication to address the needs of the most vulnerable patients requiring precisely controlled infusion rates. Focused on delivery accuracy, the Medfusion 4000 can deliver from a comprehensive portfolio of syringes to meet syringe pump guidance to deliver medication from the smallest syringe size possible.

IV Medication Safety Software:

- ICU Medical MedNet™ software is an enterprise-class medication management platform that can help reduce medication errors, improve quality of care, streamline workflows and maximize revenue capture. ICU Medical MedNet connects our industry-leading Plum 360 smart pumps to a hospital’s electronic health record ("EHR"), asset tracking systems, and alarm notification platforms to further enhance infusion safety and efficiency.

- LifeShield™ infusion safety software for Plum Duo infusion pumps is an enterprise-wide platform designed with the input of pharmacists, nurses and administrators to empower health systems to raise the bar in IV performance. The system’s hybrid architecture provides cloud-based functionality to allowing access anywhere with on-premise management providing security and control.

- PharmGuard™ medication safety software for Medfusion 4000 syringe and CADD-Solis™ pumps allows for customized drug libraries to support the standardization of protocols for medication administration throughout the facility.

Professional Services:

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

Vital Care

Our Vital Care business unit includes IV Solutions, Hemodynamic Monitoring, General Anesthesia and Respiratory, Temperature Management Solutions and Regional Anesthesia/Pain Management products.

IV Solutions

Our IV Solutions products include a broad portfolio of injection, irrigation, nutrition and specialty IV solutions including:

- 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.

Hemodynamic Monitoring

Our Hemodynamic Monitoring products are designed to 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 Hemodynamic Monitoring products include:

- 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;
- SafeSet™ closed blood sampling and conservation system; and
- MEDEX® LogiCal® Pressure Monitoring System and components.

General Anesthesia & Respiratory

We offer a broad range of anesthesia systems and devices and breathing circuits, ventilation, respiratory and specialty airway products that maintain patients' airways before, during and after surgery. Our primary Anesthesia & Respiratory products are:

- Portex® acapella® bronchial hygiene products used to mobilize pulmonary secretions to facilitate the opening of airways in patients with chronic respiratory diseases such as chronic obstructive pulmonary disease, or COPD, asthma and cystic fibrosis.

Temperature Management Solutions

Temperature Management solutions systems are used in perioperative and critical care settings to help monitor and regulate patient temperature. Our primary Temperature Management products include:

- Level 1® rapid infusion, fluid warming, routine blood and fluid warming, irrigation fluid warming, convective patient warming and temperature probes.

Regional Anesthesia/Pain Management Trays

We offer a comprehensive range of Portex® regional anesthesia/pain management trays and components. Our primary products include:

- Epidural Trays;
- Spinal Trays;
- Combined (CSE) Trays;
- Peripheral Nerve Block Trays; and
- Specialty Trays (Lumbar Puncture, Amniocentesis, Myelogram).

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

Facilities

Our manufacturing facilities are concentrated in the United States, Costa Rica, Mexico, and Czech Republic. See Part I, Item 2 of this Annual Report on Form 10-K. Additionally, we have historically relied on certain outside manufacturers for certain product lines in Infusion Systems.

We operate regional device service centers, in a number of locations, including Salt Lake City, Utah, U.S., Grasbrunn, Germany; Sligo, Ireland; San Laurent; Quebec, Canada; Taipei, Taiwan and Rydalmere, Australia. See Part I, Item 2 of this Annual Report on Form 10-K.

Raw Materials

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 single supplier. We currently attempt to manage the risk associated with such suppliers by means of inventory management, relationship management and evaluation of alternative sources when feasible. See Item 1A. Risk Factors - *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.*

Sales, Marketing and Administration

We sell globally through our own direct sales force and through independent distributors. We currently serve customers in over 100 countries throughout the world. The majority of our sales is denominated in U.S. dollars and we have sales denominated in Euros, Canadian dollars, Japanese Yen, British Pound and Australian dollars as well as other currencies. In 2024, 2023, and 2022, we had worldwide net sales to a single distributor of 18%, 16%, and 15% of consolidated net sales, respectively.

Distribution

Our products are marketed and distributed in the U.S. and internationally to medical product manufacturers, independent distributors and directly to end users.

The distribution of our products in the U.S. is supported by a network of owned and leased distribution centers, which include King of Prussia, Pennsylvania; Los Angeles, California; Dallas, Texas and Olive Branch, Mississippi. 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 currently 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, which will be replaced by the QMSR, as defined below, beginning in February of 2026. 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. 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 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 potential inspection of selected clinical investigation sites to assess compliance with Good Clinical Practices; 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. The FDA may also require one or more post-market studies and additional 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 in the U.S.

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. In accordance with the EU Medical Devices Regulation's recently extended transitional provisions, both (i) devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 and (ii) legacy devices lawfully placed on the EU market after May 26, 2021 in accordance with the EU Medical Devices Regulation transitional provisions may generally continue to be made available on the market or put into service, provided that the requirements of the transitional provisions are fulfilled as may be assessed by the notified body. 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 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 and comply with the requirements of notified bodies.

In the EU, there is currently no premarket government review of medical devices. However, the EU requires that all medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. 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 general safety and performance requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that general safety and performance requirements.

Compliance with the general safety and performance requirements of the EU Medical Devices Regulation is a prerequisite for European Conformity marking ("CE mark") without which medical devices cannot be marketed or sold in the EU. To demonstrate compliance with the general safety and performance requirements, 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 general safety and performance 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), where the manufacturer can issue an EC declaration of conformity based on a self-assessment of 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. 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 (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 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.

Throughout the process of the product authorization in accordance with the EU Medical Devices Directive, the manufacturer will be subject to, by the notified body, periodic surveillance audits and other certifications to verify continued compliance with the applicable requirements of the EU Medical Devices Directive. Among other activities, in particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

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. Manufacturers are required to take FSCAs, which are 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. A serious incident is any malfunction or deterioration in the characteristics or performance of a device on the market (e.g., inadequacy in the information supplied by the manufacturer, undesirable side-effect), which, directly or indirectly, might lead to either the death or serious deterioration of the health of a patient, user, or other persons, or to a serious public health threat. 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 are 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.

In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance

and enforcement powers and, if such issues cannot be resolved to their satisfaction, can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

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 and the UK Regulatory Framework

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 all medical devices to be registered with the MHRA 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. Beginning January 1, 2022, 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.

On June 26, 2022, the MHRA published its response to a 10-week consultation 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 in vitro diagnostic regulation and foster sustainability through the reuse and remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the MHRA confirmed that the core elements of the new framework are now expected to be in place in 2025, while draft legislation for priority measures to enhance post-market surveillance were laid before parliament in October 2024. In addition, on November 14, 2024, the MHRA launched a new consultation on proposals to update the regulatory framework for medical devices in Great Britain, covering four topics, namely (1) a new international reliance scheme to enable swifter market access for certain devices that have already been approved in a comparable regulator country; (2) the new UK Conformity Assessed (“UKCA”) mark and, in particular, proposals to remove the requirement to place such UKCA marking on devices; (3) conformity assessment procedures for in vitro diagnostic devices; and (4) maintaining in UK law certain pieces of “assimilated” EU law which are due to sunset in 2025. The MHRA consultation was opened until January 5, 2025 and it is expected that secondary legislation implementing the proposals would be introduced in 2025.

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 UK Northern Ireland (“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 non-physician 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 customers 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.

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.

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, which went into effect on April 1, 2013, and will stay in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 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.

EU Healthcare Reform

Additional healthcare reform measures in the EU may be adopted in the future as well. For instance, in December 2021, Regulation (EU) No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it only began to apply from January 2025 onwards, with preparatory and implementation-related steps that took place in the interim. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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. 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.

Competition

Our industry is highly competitive. We believe our ability to effectively compete in this industry is 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 infusion pump product offering will enable us to achieve sales of a larger volume of higher margin infusion consumables, and we believe we have a wider customer reach through our unified distribution channels.

Consumables

We believe that our ability to effectively compete in the 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 the access to distribution channels. We encounter significant competition in this market both from global, large, established medical device manufacturers and from smaller companies. We compete with products and systems marketed by Becton Dickinson ("BD"), Baxter International ("Baxter"), B. Braun Medical, Inc. ("B. Braun"), Angiodynamics, Teleflex, EquaShield and Medtronic.

Infusion Systems

We face strong global competitors in the Infusion Systems market. In the U.S. our competitors include BD, Baxter, B. Braun, Moog Medical, and Fresenius Kabi, a division of Fresenius Group. Outside of the U.S., our primary competitors are BD, B. Braun, Fresenius, 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 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.

Vital Care

Our IV Solutions products are sold in the U.S. and Canada and compete in the U.S. with Baxter and B. Braun.

Our other Vital Care products compete with numerous competitors due to our broad product portfolio. Our primary competitors include Edwards Lifesciences, Belmont and Intersurgical plc.

Our ability to compete in this market will depend on our ability to continue to make technological advances to our products, thereby increasing customer efficiency, and our ability to provide product support and successful customer training aimed at improving clinical decision-making that ultimately enhances patient safety and focuses on demonstrable patient outcomes.

Patents

Many of our product lines rely on patent protection. We have obtained U.S. and foreign patents relating to certain of the technologies found in our products, and are pursuing additional patent applications. There is however, no single patent or group of patents that we own that we believe is material in relation to our business as a whole.

Our success will depend in part on our ability to obtain, maintain and enforce patent protection for our products and to operate without infringing on 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 the scope of any patent protection will prevent competitors from introducing similar or competing devices or that any of our patents will be held valid if subsequently challenged. We can also lose patent protection through expiration. The inability to obtain effective patent protection or the loss of patent protection on a specific product line could adversely affect our ability to exclude other companies from producing effective competitive products. The loss of a significant portion of our patent portfolio 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 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

Our business is not significantly impacted by seasonal aspects. We can, however, experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which can be driven by global health crisis or pandemics, as well as fluctuations due to supply constraints as a result of other macroeconomic and global geopolitical events. Our expenses do not typically 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

We continue to invest in certain research and development ("R&D") projects to drive future growth and to remain competitive in our product lines. Our main R&D facilities are located in the U.S and India. Our R&D costs primarily relate to headcount and employment expense in support of the ongoing development of new products. Research and development costs were $88.6 million in 2024, $85.3 million in 2023 and $93.0 million in 2022.

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 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 manufacturing locations, a material handler in a distribution center, a service technician supporting our products in the field, or a clinician training customers on the use of our products in a hospital, we strive to prioritize the safety of our team members. This includes designing our work environments intended to prioritize safety first, 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 believe we offer competitive salaries and benefit packages to our employees as well as select participation 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 collaboration and removing barriers to communication—all with the goal of creating 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, we believe that our leadership team, with its broad, and deep category knowledge and averaging approximately 22 years of experience in IV therapy has the necessary experience to effectively lead the execution of our strategy.

At December 31, 2024, we had approximately 15,000 employees located in over 35 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 5 and 6 to the Consolidated Financial Statements, and is incorporated herein by reference.

Available Information

Our website address is http://www.icumed.com. We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and other filings and amendments thereto those reports, free of charge on our website as soon as reasonably practicable after filing or furnishing 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 on Form 10-K. We use our Investor Relations website as a means of disclosing material information. Accordingly, investors should monitor our Investor Relations website, in addition to following our press releases, SEC filings, and public conference calls and webcasts.

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 on Form 10-K and our other reports and registration statements filed with the SEC. Any of the following risks could materially and adversely affect our results of operations or financial condition.

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 continues to experience 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, including demand for more environmentally friendly products and focus on using materials of concern, 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 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 financial condition and 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. The modules are utilized for certain products. If the demand for these products changes significantly, which could happen with the loss of customers 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 certain products in 2025. 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.

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, we may still fail to successfully commercialize such products. The success of new medical 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 in the marketplace quickly or at all because of, among other things, entrenched patterns of clinical practice and uncertainty over third-party reimbursement.

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 we will be able to successfully develop and commercialize enhanced or new products or that they will be accepted in the marketplace. Even if we successfully develop and commercialize enhanced or new products, they may be quickly rendered obsolete by competitors' innovations, changing customer preferences, or changing industry or regulatory standards.

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 and natural gas prices have been volatile in recent years. Crude oil markets have historically been affected by political uncertainty in the Middle East and more recently, by the conflict in Ukraine. As the current conflict in the Middle East and Ukraine continues and geopolitical tensions rise in the region or globally, there is no assurance that crude oil supplies will not be interrupted or crude oil prices will not rise 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. 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 certain cases, we may be unable to pass along increased costs to our customers if they are under long-term fixed price contracts. 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.

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, which would adversely affect our sales.

Heightened inflation, higher interest rates and foreign currency rate fluctuations as a result of global macroeconomic and geopolitical conditions have had and could in the future have a material adverse effect on our operations.

Global macroeconomic conditions and geopolitical tensions and resulting impacts therefrom, for example, heightened inflation, higher interest rates and capital costs, and currency rate fluctuations have resulted in, and may continue to result in, increased raw material costs, higher shipping costs, higher labor costs, and global supply chain disruptions. In 2022, we experienced these supply chain disruptions, increased raw material costs and shipping costs, as prices on several commodities, including oil and gas, increased as a result of the conflict in Ukraine and its impact on the global economy. Although these costs were less volatile in 2023 and 2024, we may continue to experience these inflationary increases in our manufacturing costs and operating expenses, including higher materials and labor costs, as well as negative impacts on our operating results from the strengthening of the U.S. dollar relative to foreign currencies weakening exchange rates. See the risk factor titled "Our operations may be adversely impacted by our exposure to risks related to foreign currency exchange rates" under the "Geographic Risks" subsection for a discussion of risks related to foreign currency exchange rates.

Additionally, the majority of our sales are conducted pursuant to long-term contracts. Our efforts to minimize the impact of inflation on our business through contractual protections may not prove effective, and 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. Heightened inflation may also reduce or delay orders for our products and for certain products we may be unable to satisfy demand, both of which could have a material adverse impact on our sales 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 our suppliers' demand for payment terms.

Disruptions in financial markets worldwide and other worldwide macro-economic challenges have caused and may in the future 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 that are less favorable to us. Any inability of current and/or potential customers to pay us for our products or any demands by suppliers for different payment terms may adversely affect our earnings and cash flow.

Continuing pressures to reduce healthcare costs and inadequate coverage and reimbursement may adversely affect our prices. If we cannot reduce manufacturing costs of existing and new products to counteract such pricing pressures, 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 the kinds of 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 or if the costs to manufacture our products exceeds the price at which we are able to sell 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.

Disruptions at the FDA, other government agencies or notified bodies caused by funding shortages, global health concerns, or personnel turnover 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, 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 leadership and other 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, in recent 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.

One such shut down was as a result of COVID-19, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if a global health concern prevents 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 European Union ("EU"), notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. Their designation process, which is significantly stricter under the new Regulation, has experienced considerable delays. Despite a recent increase in designations, the current number of notified bodies designated under the new Regulation remains significantly lower than the number of notified bodies designated under the previous regime. The current designated notified bodies are therefore facing a backlog of requests as a consequence of which review times have lengthened. This situation may impact the way we are conducting our business in the EU and the European Economic Area ("EEA") and the ability of our notified body to timely review and process our regulatory submissions and perform its audits.

Failure to protect our information technology 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 collect and maintain information in digital form that is necessary to conduct our business, and we depend heavily on information technology infrastructure and systems to achieve our business objectives. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data, and personal information (collectively, "Confidential Information") of customers

and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information. 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 cybersecurity 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 and those of our third-party service providers, strategic partners and other contractors or consultants, which support our operations. Despite the implementation of security measures, our information technology systems, and those of third parties on which we rely, are vulnerable to attack, interruption and damage from, among others, computer viruses, malware (e.g. ransomware), misconfigurations, "bugs" or other vulnerabilities, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyber-attacks or cyber-intrusions over the Internet, phishing and other social engineering schemes, human error, theft or misuse by persons inside our organization, or persons with access to systems inside our organization, fraud, denial or degradation of service attacks and sophisticated nation-state and nation-state-supported actors or similar disruptive problems. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. 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. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our and our third-party service providers', strategic partners', contractors', consultants', CROs' and collaborators' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers have been in the past and may from time to time in the future be subject to cyberattacks and security incidents. Data security breaches and other cybersecurity incidents may result from, for example, non-technical means (e.g., actions by employees or contractors), system failure, accident or unauthorized access. Any such security breach may compromise information stored on our networks or those of third parties on which we rely 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, legal claims and proceedings (such as class actions), regulatory or other governmental investigations, enforcement actions, disruption of our internal operations, and financial exposure, including potential contractual liability, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. 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. Any of these effects could materially and adversely affect our business, financial condition and results of operations. Our cyber liability insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from such an interruption or breach. Furthermore, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

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 public equity market can be highly volatile, and we have experienced significant volatility in the price of our common stock in the past. 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 macroeconomic trends (including as a result of pandemics or other health outbreaks, geopolitical tensions and uncertainties) 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 59% of our outstanding shares at the end of 2024. 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.

Climate-related events and other events could harm our business.

Natural disasters, disease outbreaks and pandemics, power shortages, terrorism, political unrest, telecommunications failure, vandalism, geopolitical instability, war, climate-related events, and other events beyond our control could negatively impact our operations or otherwise harm our business. Such events may result in damage or loss of service to assets that our operations rely on or cause delays in product manufacturing or distribution, any of which may adversely impact our operations.

In addition, the impacts of climate-related events on the global economy and our industry are rapidly evolving. Physical impacts of climate-related events (including but not limited to floods, droughts, more frequent and/or intense storms and wildfires), or chronic changes (such as droughts, heat waves or sea level changes) in climate patterns can adversely impact our operations, as well as the operations of our suppliers and customers.

If a catastrophic event occurs at or near any of our manufacturing facilities or our suppliers' facilities, or utility providers or public health officials take certain actions (e.g., shut off power to our or our suppliers' facilities), our operations may be interrupted, which could adversely impact our business and results of operations. Transition impacts of climate-related events may subject us to increased regulations, reporting requirements, standards or expectations regarding the environmental impacts of our business. Any of such adverse impacts from these or other climate-related events may also adversely affect our reputation, business, or financial performance.

The increasing focus on sustainability and environmental, social and governance ("ESG") initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, patients, the media, governmental and nongovernmental organizations and other stakeholders on a variety of sustainability and ESG matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of risk mitigation strategies related to sustainability. Expectations regarding the management of ESG initiatives also continue to evolve rapidly. While we may from time to time engage in various initiatives (including but not limited to voluntary disclosures, policies or goals) to improve our ESG profile or respond to stakeholder expectations, we cannot guarantee that these initiatives will have the desired effect. If we are not effective in addressing the sustainability and ESG matters affecting our business, or setting and meeting relevant goals, our reputation and financial results may suffer. In addition, even if we are effective at addressing such matters, we may experience increased costs as a result of executing upon our sustainability and ESG goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business, operations and financial condition.

In addition, we operate in various jurisdictions that have adopted or proposed laws and regulations related to sustainability and ESG reporting. For example, we and our subsidiaries may be subject to the European Union's Corporate Sustainability Reporting Directive, which requires in scope entities to provide detailed reporting on various climate change and sustainability topics. California's Climate Corporate Data Accountability Act, Climate-Related Financial Risk Act, both of which are being challenged in federal courts, and Voluntary Carbon Market Disclosures Act would require third-party assurance of greenhouse gas emissions information for certain entities, climate-related financial risk reporting and disclosures regarding carbon reduction claims. The SEC's climate disclosure rule, if it is enforced by the current administration and survives its current federal court challenge, would require new climate-related disclosures in SEC filings and audited financial statements. We may also be subject to the International Sustainability Standards Board's sustainability and climate disclosure standards, to the extent adopted by jurisdictions in which we operate, among other regulations or requirements. Operating in more than one jurisdiction is likely to make our compliance with sustainability and ESG rules more complex and expensive, and potentially expose us to greater levels of legal risks associated with our compliance. Our failure to comply with any

applicable rules or regulations could lead to penalties and adversely impact our reputation, customer attraction and retention, access to capital and employee retention. Such sustainability and ESG matters may also impact our suppliers and customers, which may augment or cause additional impacts on our business, financial condition, or results of operations.

Business and Operating Risks

Damage to, or interruptions at, any of our manufacturing facilities or our suppliers' facilities could impair our ability to produce our products.

A severe weather event, including climate change-related severe weather or disasters, other natural or man-made disasters, or any other significant disruption, such as global epidemics/pandemics, the impact of war or political instability, 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. For example, the impact of COVID-19 caused us to temporarily shut down some of our facilities in 2021.

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 Ensenada, Mexico and Costa Rica rely. Our IV Solutions are manufactured at our manufacturing facility in Austin, Texas or our suppliers' facilities. We also operate various other manufacturing facilities in the U.S., Mexico, Italy and Czech Republic. If our facilities or our suppliers' 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, or interruptions at, any of our facilities or our suppliers' facilities due to work stoppages or labor shortages could render us unable to manufacture our products or require us to reduce the output of products at such facilities. Several 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 be adequate to 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.

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.

We currently rely on a single source supplier for the supply of certain materials (such as resins) that are critical to our ability to manufacture our products. Our risk mitigation plans employed with such key supplier, or that we may use with other key suppliers, may not suffice to ensure that we are able to receive requisite materials as and when needed and in sufficient quantity. 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. Upon identification, the qualification process of new suppliers and component materials can take a considerable amount of time. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Additionally, we are subject to FDA and foreign regulations, which could further delay our ability to obtain a qualified alternative supplier. 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, extreme weather events, geopolitical developments, global economic uncertainty or downturns, sanctions and trade restrictions, and other governmental regulatory actions. Furthermore, our contract manufacturers could require us to move to another one of their production facilities. 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 the cost and availability of raw materials and components due to shortages and resulting cost inflation. If we encounter delays or difficulties in securing these components, materials or services and, if we cannot then obtain an acceptable substitute on a timely basis, our commercial operations could be interrupted, and we could experience an adverse effect on our results of operations and financial condition.

Additionally, 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, as well as entering into long-term fixed price contracts, we may be unable to pass along cost increases for any key components or raw materials 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 results of operations and financial condition.

We may not be successful in achieving expected operating efficiencies or expense reductions associated with cost reduction and restructuring efforts and may experience a decline in our profitability, business disruptions or other adverse consequences to our business as a result.

We have engaged in restructuring activities in the past and may engage in other restructuring activities in the future. For example, since the Smiths Medical acquisition, we have taken realignment and cost reduction initiatives to achieve operating efficiencies for the combined company. 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 fully 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.

The agreements governing our debt contain a number of restrictive covenants which limit our flexibility in operating our business, finance future operations or pursue our business strategies.

The credit agreement governing our Senior Secured Credit Facilities contains, 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 agreement, our ability to comply with these covenants may be affected by events beyond our control, including health crises and global pandemics, other geopolitical events, supply chain interruptions or general economic environment, including high 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 Senior Secured Credit Facility may restrict our ability to pursue our business strategies.

Significant sales through distributors expose us to risks that could have a material effect on our results of operations.

For the years ended December 31, 2024 and 2023, business from a single distributor accounted for approximately 18% and 16% of our consolidated revenues, respectively. We may rely on one or more key distributors for a product, and the loss of these distributors could reduce our revenue. Additionally, distributors may face financial difficulties, including bankruptcy, which could harm our collection of accounts receivable and financial results. Failure to manage risks related to our use of distributors may reduce sales, increase expenses, and weaken our competitive position, any of which could have a material adverse effect on our business and results of operations.

Legal, Compliance, and Regulatory Risks

Our ability to market, distribute and sell our products in the U.S. and other countries may be adversely affected if our products fail to comply with the existing laws and regulations, and applicable requirements of the FDA, governmental agencies in other countries, and notified bodies.

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. For example, in 2022, we acquired Smiths Medical, which has marketed its PORT-A-CATH implantable access systems pursuant to PMA approval, and 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, such as the PMA approval process, or that, in any case, they will receive clearance or approval from the FDA. FDA regulatory processes are time consuming and expensive. Uncertainties as to the time required to obtain FDA clearances or approvals could adversely affect the timing and expense of new product introductions.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. The FDA enforces these regulatory requirements through periodic unannounced inspections. 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.

In addition, new and changing laws, regulations, executive orders and other governmental actions, particularly from the new presidential administration, may also create uncertainty about how laws and regulations will be interpreted and applied. Regulatory changes and other actions that materially affect our business may be announced with little or no advance notice, and we may be unable to effectively mitigate all adverse impacts from such measures. Differing interpretations of such legal obligations can expose us to significant fines, government investigations, litigation and reputational harm. If we are found to have violated laws, regulations, or executive orders, it could materially adversely affect our business, reputation, results of operations and financial condition.

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 or otherwise increase the costs associated with compliance.

For example, 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 example, in February 2024, the FDA issued a final rule to amend and replace the QSR, which sets forth the FDA's current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, establishes the "Quality Management System Regulation," ("QMSR"), which among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, and although our quality system is currently designed to comply with ISO standards in connection with our device certifications outside the United States, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. If we are unable to comply with QMSR, once effective, or with any other changes in the laws or regulations enforced by FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition and results of operations.

In addition, the EU landscape concerning medical devices recently evolved. On May 26, 2021, the EU Medical Devices Regulation became applicable and repealed and replaced 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. In accordance with its recently extended transitional provisions, both (i) devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 and (ii) legacy devices lawfully placed on the EU market after May 26, 2021 in accordance with the EU Medical Devices Regulation transitional provisions may generally continue to be made available on the market or put into service, provided that the requirements of the transitional provisions are fulfilled as may be assessed by the notified body. 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 and comply with the requirements of the notified body.

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 the EU Medical Devices Directive. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. Compliance with these requirements is a prerequisite to be able to affix the European Conformity ("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 including as determined by a notified body would also prevent us from selling our products in these geographies.

The rules applicable in Great Britain differ from the EEA as a result of Brexit. On June 26, 2022, the Medicines and Healthcare Products Regulatory Agency ("MHRA") published its response to a 10-week consultation on the future regulation of medical devices in the United Kingdom ("UK"). The MHRA proposes amendments to the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive), in particular to create new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform in vitro diagnostic regulation, and foster sustainability through the reuse and remanufacture of medical devices. The MHRA has stated that it continues its intention to implement the proposals from such consultation through secondary legislation. In addition, on November 14, 2024, the MHRA launched a new consultation on proposals to update the regulatory framework for medical devices in Great Britain, covering four topics, namely (1) a new international reliance scheme to enable swifter market access for certain devices that have already been approved in a comparable regulator country; (2) the new UK Conformity Assessed ("UKCA") mark and, in particular, proposals to remove the requirement to place such UKCA marking on devices; (3) conformity assessment procedures for in vitro diagnostic devices; and (4) maintaining in UK law certain pieces of "assimilated" EU law which are due to sunset in 2025. The MHRA consultation was opened until January 5, 2025, and it is expected that secondary legislation implementing the proposals would be introduced in 2025. The divergence of the new UK rules from EU law could adversely affect or delay our ability to obtain approval for our products in the UK, which could adversely affect our ability to grow our business. See "Part 1, Item 1. Government Regulation - Regulation of Medical Devices in the European Union – Brexit and the UK Regulatory Framework."

If we or our compo*nent 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. In particular, if we are unable to resolve or close-out the Warning Letter dated October 1, 2021, received by Smiths Medical ASD, Inc. from the Minneapolis, Minnesota Facility following a February to March 2021 inspection, we could suffer significant sanctions which may impact our ability to sell products globally.*

In the United States, we and some of our component manufacturers are required to comply with regulatory requirements known as the FDA's QSR, a complex regulatory scheme which currently 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 QSR applies 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 other 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 during February to 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. There is no guarantee that we will be able to successfully resolve the issues identified in the Warning Letter or do so in a timely manner or that similar compliance issues will not be identified in a future FDA inspection. If we are unable to resolve the Warning Letter, we may be subject to the sanctions listed below.

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 condition 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 the EU and the EEA.

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.

Actual or perceived 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 and information that we may collect in connection with clinical trials. 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively ("HIPAA") 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, which govern the privacy, processing and protection of health-related and other personal information. 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"), as amended by the California Privacy Rights Act (collectively, the CCPA) requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information;, and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states, and are continuing to be proposed at the state and 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. 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. Additionally, federal and state consumer protection laws are increasingly being applied by FTC and states' attorneys general to regulate the collection, use, storage, and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content.

Foreign data protection laws, including the General Data Protection Regulation (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 or in the context of our activities 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. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). 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. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Economic Area, or the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must now be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue 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. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. 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. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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 state and foreign 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.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment (“HTA”) amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it only began to apply from January 2025 onwards, with preparatory and implementation-related steps that took place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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 patents 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.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. We have in the past faced and may in the future face patent infringement claims. 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 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.

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 lawsuits 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 $50 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 or clinical studies, 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.

Any attempts we take to manage our product liability exposure, for example, by proactively recalling or withdrawing from the market any defective products, and any required 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, approvals or certifications, 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, in June 2024, Smiths Medical ASD initiated Class 1 recalls with respect to certain tracheostomy tube kits, and, in May 2024, Smiths Medical

ASD initiated Class 1 recalls for certain paraPAC plus ventilators. We can provide no assurance that our efforts to work with the FDA to complete, and ultimately close, these product recalls, and any recalls that may occur in the future, will be accomplished in a timely manner, or at all. In addition, the costs associated with conducting and closing these or any other product recalls, 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

Significant changes in U.S. trade, tax or other policies that restrict imports or increase import tariffs for certain countries, particularly Mexico, can escalate trade wars and could have a meaningful adverse effect on our results of operations.

A significant amount of our products are manufactured outside of the U.S. In certain years, the U.S. government has 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 Canada, China and Mexico, have retaliated imposing tariffs on certain U.S. goods. In January 2025, the current administration issued executive orders imposing additional tariffs on imported goods from Canada, Mexico, and China and in response Canada immediately announced similar tariffs on U.S. imports. Imposed tariffs and retaliatory responses to these and further trade measures could prevent or make it difficult and will be more costly for us to import goods. They could also potentially disrupt our existing supply chains and impose additional costs on our business, including, without limitation, costs with respect to raw materials upon which our business depends. The most significant potential impact to us is the additional tariffs on Mexican imports, which could result in a meaningful impact to our results of operations due to our manufacturing facilities in Mexico. Increased tariffs could require us to increase our prices, which likely could decrease demand for our products, and in certain cases we may be unable to pass along increased costs to our customers if they are under long-term fixed price contracts. Additionally, we are subject to income taxes in the U.S. and numerous foreign jurisdictions. Any significant changes in current tax policies could have a material adverse effect on our results of operations.

Our operations may be adversely impacted by our exposure to risks related to foreign currency exchange rates.

We face exposure to adverse movements in foreign currency exchange rates due to our operations in foreign markets through our foreign subsidiaries and other international distributors. Our primary foreign currency exchange rate exposures are currently with the Euro, Mexican Peso, Canadian Dollar, Czech Koruna, Japanese Yen, Chinese Renminbi, and the Australian Dollar against the U.S. dollar. Our income and expenses are based on a mix of currencies, and a decline in one currency relative to the other currencies could adversely affect our operating results. Furthermore, our operating results are reported in U.S. dollars, using the exchange rate in effect at the balance sheet date, or, for revenues and expenses, using the average monthly exchange rates during the year. Accordingly, our operating results have been and continue to be subject to volatility due to fluctuations in foreign currency exchange rates. Generally, when the U.S. dollar weakens against these currencies, the dollar value of foreign-currency denominated revenue and expense increases, and when the U.S. dollar strengthens against these currencies, the dollar value of foreign-currency denominated revenue and expense decreases. We are also exposed to foreign currency risk on outstanding foreign currency denominated receivables and payables. Currency exchange rates have been especially volatile in the recent past. Accordingly, changes in foreign currency exchange rates have adversely affected and may continue to adversely affect our results of operations. During 2024, we recorded $9.8 million in foreign exchange losses due to the volatility of foreign exchange rates later in the year such as the strengthening of the US dollar relative to most of our selling currencies in foreign jurisdictions which impacted margins and the devaluation of the Argentine Peso. See Item 7.

"Management's Discussion and Analysis of Financial Condition and Results of Operations" for a further discussion of the financial impact of exchange rate fluctuations on our results of operations. Fluctuations in currency exchange rates are caused by a number of factors that are beyond our control, including a country's political and economic policies, inflationary conditions, disruptions in the financial markets, and global economic and geopolitical conditions.

We currently only partially hedge against our foreign currency exchange rate risks, related to certain forecasted foreign currency-denominated revenues and expenses. We, therefore, believe our exposure to these risks may be higher than if we entered into hedging transactions, including forward exchange contracts or similar instruments that covered the company on a consolidated basis. If we decide in the future to enter into additional forward foreign exchange contracts to attempt to reduce the risk related to foreign currency exchange rates, these contracts may not mitigate the potential adverse impact on our financial results due to the limitations and difficulty forecasting future activity. In addition, these types of contracts may themselves cause financial harm to us and have inherent levels of counter-party risk over which we would have no control. We attempt to mitigate a portion of foreign currency exchange rate risks through foreign currency hedging. Our hedging activities, however, may not sufficiently offset the adverse financial impact caused by unfavorable movement in foreign currency exchange rates applicable to our business, and such exchange rate impacts could materially adversely affect our financial condition or results of operations. See "Item 7A. Quantitative and Qualitative Disclosures About Market Risk."

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

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 primarily from the U.S. and Mexico and to a lesser extent Costa Rica. 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 products 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 and may continue to result in an increase to our days sales outstanding from previous years. Our prices to our international distributors, outside of Europe, for products 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 has in prior years adversely affected and may in future years adversely affect their ability to profitably sell in their market the products they buy from us, and has in prior years adversely affected and may in future years 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 that region's 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 has had and may continue to have an adverse effect on our ability to hire or retain necessary personnel and has resulted in and may continue to result in higher labor costs. In addition, minimum wages in regions within which we operate have increased labor costs significantly. 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 continue to face increasing labor costs in the future.

Any political or economic disruption in Mexico or a change in its 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.

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.

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. composed approximately 36% of our revenues in 2024 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. include, without limitation:

- 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;
- changing geopolitical conditions arising from political instability and any actual or anticipated military or political conflicts;
- economic instability in other parts of the world and the impact on interest rates, inflation and the credit worthiness of our customers in foreign countries, such as the devaluation of the Argentine Peso;
- tariffs on products imported to the U.S.;
- uncertainties regarding judicial systems and procedures;
- minimal or diminished protection of intellectual property in some countries;
- natural disasters or outbreak of diseases or pandemics;
- fluctuations in foreign currency exchange rates;
- changes to international trade agreements and trade relationships and conflicts between countries; and
- imposition of government controls, such as economic sanctions and export 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.

Risks Related to our Strategic Transactions

The Smiths Medical acquisition completed in January 2022 has resulted in organizational changes and an increase in size to our business. If we fail to effectively complete the integration of 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 acquisition has resulted in significant growth in our personnel and operations, adding approximately 6,700 employees to our headcount at the time of acquisition. Our total headcount as of December 31, 2024 was approximately 15,000 employees. We have incurred and continue to incur significant expenditures and the allocation of management time to assimilate the Smiths Medical 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 Smiths Medical acquisition was a significant acquisition for us and the product offerings within Smiths Medical are not product offerings that we previously offered. The success of our business will depend, in part, on our ability to realize our anticipated benefits, opportunities and synergies from combining our legacy businesses and Smiths Medical. We can provide no assurance that the anticipated benefits of the Smiths Medical acquisition will be fully realized in the time frame anticipated or at all. Integrating the operations of Smiths Medical with that of our legacy business has been and continues to be a complex, costly and time-consuming process. 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 complete the integration of the Smiths Medical business with that of our own could have a material adverse impact on our business, financial condition and results of operations.

If we are unable to effectively manage our internal growth or growth through acquisitions of companies, assets or products, our financial performance may be adversely affected.

We may expand our product offerings through acquisitions of companies or product lines from time to time. 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 challenges. In 2022, we acquired the Smiths Medical business, which includes syringe and ambulatory infusion devices, vascular access, and vital care products, but we have made and continue to make significant integration efforts to achieve the anticipated benefits. See "*The Smiths Medical acquisition completed in January 2022 has resulted in organizational changes 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.*"

We have additional production facilities outside the U.S. to reduce labor costs. 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. 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.

For the Smiths Medical acquisition, we 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

acquisition, which could adversely affect our business, including by restricting our ability to engage in additional transactions or incur additional indebtedness.

At December 31, 2024 and 2023, we had $308.6 million and $254.7 million of cash, cash equivalents and investment securities on hand, respectively, which was significantly less in each case than the balances maintained prior to the Smiths Medical acquisition. Although our management believes that we continue to have sufficient access to cash to meet our business objectives and capital needs, we currently have a decreased availability of cash, cash equivalents and investment securities and expect to continue to have such decreased availability of cash for the foreseeable future which could constrain our ability to grow our business. Furthermore, 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 entering into the Senior Secured Credit Facilities, we incurred additional borrowing costs. At December 31, 2024, our long-term debt outstanding was $1.6 billion. Our more leveraged financial position following the Smiths Medical transaction could make us more 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 and need to seek additional financing, 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 our ability to engage in certain transactions and incur additional indebtedness, and our business may be materially and adversely affected if these restrictions prevent us from implementing our business plan. See "Business and Operating Risks - The agreements governing our debt contain a number of restrictive covenants which limit our flexibility in operating our business, finance future operations or pursue our business strategies."

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

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, joint ventures 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, joint venture 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 have been and continue to do the same with the Smiths Medical integration.

More recently, in November 2024, we entered into a purchase agreement (the "Agreement") with Otsuka to form a joint venture (the "Joint Venture") for our IV Solutions product line. With Otsuka expected to have a 60% equity interest, we will be a minority holder with a 40% equity interest. The failure to complete this transaction or, if completed, for the Joint Venture to meet our performance and financial expectations could adversely impact our ability to meet internal forecasts and expectations. Additionally, pursuant to the terms of the Agreement, we will not have sole decision-making authority with matters related to the Joint Venture, or have the ability exert control over the actions of Otsuka, which could result in impasses on decisions or decisions made by our partners, which we may be unable to resolve in a manner that will be favorable to us. Further, Otsuka may have economic or business interests that are, or may become, inconsistent with our interests.

Acquisitions, investments, joint ventures and alliances involve numerous risks and uncertainties, including, without limitation, the failure to identify suitable acquisition candidates and partners, the ability to complete the transaction on acceptable terms and conditions, the incurrence of liabilities greater than anticipated or operating results that are less than anticipated, the inability to realize the projected value, and the inability to realize projected synergies, 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 or investments will be successful.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We leverage guidance from the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF"), which provides an outline of enterprise security processes and controls, to inform the design and assessment of our cybersecurity risk management program. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is overseen by a cross-functional team comprised of our business-functional and IT employees. Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- evaluations of our readiness to assess, respond and, as applicable, recover from potential cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity training to educate our employees (including senior management and incident response personnel), consultants, and other users about their individual responsibilities regarding protecting our IT systems and data;
- a third-party risk management process for service providers, suppliers and vendors who have access to our critical systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled "Risk Factor—Market and Other External Risks—*Failure to protect our information technology 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."*

Cybersecurity Governance

Our cybersecurity risk management program is led by our Chief Information Officer ("CIO") through our Information Security Committee ("ISC"), which includes a cross-functional group of senior leaders who are responsible for the dissemination and promotion of our cybersecurity strategy, implementation of cybersecurity objectives and top-down communication and monitoring of the risk management program as described above. Our ISC is responsible for the regular oversight of cybersecurity risk, information security and technology risk and assessing and managing our material risks from cybersecurity threats and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants.

Our ISC facilitates communications between executive, business/process level and the implementation/operations level to coordinate the implementation of our cybersecurity risk program. The ISC team meets on a regular basis, at least quarterly and more frequently as needed, to discuss significant initiatives, critical metrics and address certain risk responses.

Our ISC members includes our Chief Information Security Officer ("CISO") and our Director of IT Security, Risk and Compliance who have a combined 20 years of risk management experience encompassing cybersecurity and technology security, such as threat assessments, risk management, cybersecurity insurance, incident response, end user awareness and vulnerability management.

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of cybersecurity and other information technology risks. Our Audit Committee oversees management's implementation of our cybersecurity risk management program. On a quarterly basis, our Audit Committee receives updates from our CISO with respect to the status of our cybersecurity initiatives to strengthen our cybersecurity risk management. In addition, our CISO updates the Audit Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential. Our Audit Committee discusses the potential impact of cybersecurity risks on our financial condition, results of operations or our reputation. Our Audit Committee periodically reports to the Board regarding its activities, including those related to cybersecurity. The Board also periodically receives briefings from management on our cyber risk management program. Board members receive periodic presentations on cybersecurity topics from our CISO, internal security staff or external experts as part of the Board's continuing education on topics that impact public companies.

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, 2024, 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.	9,779	Corporate Headquarters	Leased
San Diego, California, U.S.	13,237	Corporate Offices and R&D	Leased
Lake Forest, Illinois, U.S.	54,298	Corporate Offices	Leased
Dublin, Ohio, U.S.	13,021	Corporate Offices	Leased
Houten, Netherlands	7,341	Corporate Offices	Leased
Montreal, Canada	31,890	Corporate Offices/Device Service Center	Leased
Rydalmere, NSW Australia	14,735	Corporate Offices/Device Service Center	Leased
Chennai, India	36,879	R&D	Leased
Plymouth, Minnesota, U.S.	182,250	Corporate Offices	Leased
Kent, United Kingdom	24,172	Corporate Offices	Leased
Ontario, Canada	25,020	Corporate Offices	Leased
Grasbrunn, Germany	38,155	Corporate Offices/Device Service Center	Leased
Austin, Texas, U.S.	594,602	Manufacturing	Owned
Ensenada, Baja California, Mexico	265,021	Manufacturing	Owned
Monterrey, Mexico	100,000	Manufacturing	Owned
La Aurora, Costa Rica	626,869	Manufacturing	Owned
Salt Lake City, Utah, U.S.	440,104	Manufacturing/Device Service Center	Owned
Dublin, Ohio, U.S.	153,121	Manufacturing	Owned
Gary, Indiana, U.S.	45,416	Manufacturing	Owned
Gary, Indiana, U.S.	14,040	Manufacturing/Corporate Offices	Leased
Southington, Connecticut, U.S.	132,000	Manufacturing	Owned
Tijuana, Mexico (multiple locations)	243,935	Manufacturing	Leased
Hranice, Czech Republic	129,953	Manufacturing	Leased
Latina, Italy	62,441	Manufacturing	Owned
Keene, New Hampshire, U.S.	153,427	Warehouse/Manufacturing	Owned
Oakdale, Minnesota, U.S.	93,648	Warehouse/Device Service Center	Leased
Round Rock, Texas, U.S.	80,929	Warehouse/Manufacturing	Owned
Dallas, Texas, U.S.	610,806	Distribution Warehouse	Leased
King of Prussia, Pennsylvania, U.S.	105,611	Distribution Warehouse	Owned
Santa Fe Springs, California, U.S.	76,794	Distribution Warehouse	Owned
Wijchen, Netherlands	149,565	Distribution Warehouse	Leased
Olive Branch, Mississippi, U.S.	239,863	Distribution Warehouse	Leased
Sligo, Ireland	26,000	Device service center	Leased

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

ITEM 3. LEGAL PROCEEDINGS

The information required with respect to this Item 3. is discussed in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K in Note 16. 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 trades on the Nasdaq Global Select Market under the symbol “ICUI.”

Stockholders

As of January 31, 2025, we had 40 stockholders of record. This does not include persons whose shares are held 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.

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.

Issuer Purchases of Equity Securities

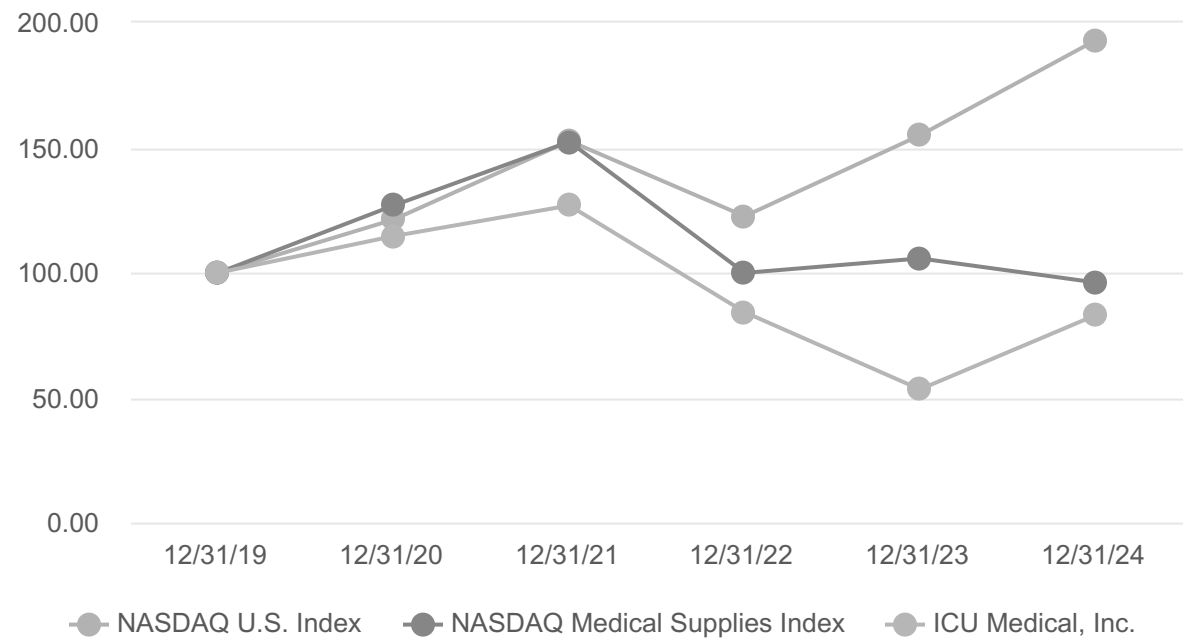
The following is a summary of our stock repurchasing activity during the fourth quarter of 2024:

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)]
10/01/2024 - 10/31/2024	—	$ —	—	$ 100,000,000
11/01/2024 - 11/30/2024	—	$ —	—	$ 100,000,000
12/01/2024 - 12/31/2024	—	$ —	—	$ 100,000,000
Fourth quarter 2024 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, depending on a variety of factors, including our financial position, earnings, share price, capital requirements, other investment opportunities (including mergers and acquisitions and related financings), market conditions and other factors. Purchases made under our stock purchase program can be discontinued at any time we determine additional purchases are not warranted.

COMPARISON OF CUMULATIVE TOTAL RETURN FROM DECEMBER 31, 2019 TO DECEMBER 31, 2024 OF ICU MEDICAL, INC., NASDAQ AND NASDAQ MEDICAL SUPPLIES INDEX

The following graph shows the total stockholder return on our common stock based on the market price of the common stock from December 31, 2019 to December 31, 2024 and the total returns of the NASDAQ U.S. Index and NASDAQ Medical Supplies Index for the same period.



	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
ICU Medical, Inc.	100.00	114.63	126.84	84.16	53.30	82.93
Nasdaq U.S. Index	100.00	121.27	152.67	122.55	154.93	192.86
Nasdaq Medical Supplies Index	100.00	126.91	152.33	99.88	105.67	96.08

Assumes $100 invested on December 31, 2019 in ICU Medical Inc.'s common stock, the NASDAQ U.S. Index and the NASDAQ Medical Supplies Index and that all dividends, if any, were reinvested.

ITEM 6. RESERVED

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current plans, expectations and beliefs involving risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Part I, Item 1A. "Risk Factors" or in other sections of this Annual Report on Form 10-K as may be further updated from time to time in our other filings with the SEC.

Business Overview and Highlights

We develop, manufacture, and sell innovative medical products used in infusion systems, infusion consumables and high-value critical care products used in hospital, alternate site and home care settings. Our team is focused on providing quality, innovation and value to our clinical customers worldwide. Our product portfolio includes ambulatory, syringe, and large volume IV pumps and safety software; dedicated and non-dedicated IV sets, needlefree IV connectors, peripheral IV

catheters, and sterile IV solutions; closed system transfer devices and pharmacy compounding systems; as well as a range of respiratory, anesthesia, patient monitoring, and temperature management products.

Global Economic Challenges

We have experienced and may continue to experience significant impacts to our business as a result of global economic challenges, resulting from, among other events, health pandemics and geopolitical conflicts. These impacts, which negatively impacted our gross profit margin during 2023 and 2022, include the impact of rising inflation, especially with respect to freight costs driven by higher fuel prices, increased cost and shortages of raw materials, and supply chain disruptions. While we expect the pressure on the supply chain to lessen and inflation to continue to subside, freight costs are expected to remain subject to volatility in the market.

We also continue to expect higher interest rates and volatility in foreign currency rates due to the strengthening of the U.S. dollar against most global currencies. Our 2024, 2023 and 2022 financial results were negatively impacted by foreign exchange losses and our results of operations may continue to be impacted in the future.

More recently, in January 2025, the current administration issued executive orders imposing tariffs on imported goods from Canada, Mexico, and China. In response, Canada announced similar tariffs on U.S. imports. A meaningful portion of our global revenues are from products manufactured in our Mexico manufacturing facilities and imported into the U.S. In addition, Canada is our second largest country in terms of revenue and the vast majority of products sold in Canada are imported from the U.S. The 25% tariff levied on all goods shipped from Mexico to the U.S., combined with the 25% tariff on products shipped from the U.S. to Canada could potentially have a meaningful impact to our costs and any further trade war escalation could increase that impact.

While we continually monitor the ongoing and evolving impact of the above events on our operations the overall impact remains uncertain and may not be fully reflected in our results of operations until future periods. The overall impact to our results of operations will depend on a number of factors, many of which are out of our control, none of which can be fully predicted at this time. See "Part I. Item 1A. Risk Factors" for a discussion of risks and uncertainties.

Consolidated Results of Operations

We present our consolidated statements of operations for each of the three years ended December 31, 2024, 2023 and 2022 in Item 8. Financial Statements and Supplementary Data. The following table shows, for each of the three most recent years, the respective percentages of items in our statements of operations in relation to total revenues:

	Percentage of Revenues		
	2024	2023	2022
Total revenues	100 %	100 %	100 %
Gross profit	35 %	33 %	31 %
Selling, general and administrative expenses	27 %	27 %	27 %
Research and development expenses	4 %	4 %	4 %
Restructuring, strategic transaction and integration expenses	3 %	2 %	3 %
Change in fair value of contingent earn-out	— %	(1)%	(1)%
Total operating expenses	34 %	32 %	33 %
Income from operations	1 %	1 %	(2)%
Interest expense, net	(4)%	(4)%	(3)%
Other expense, net	(1)%	— %	— %
Loss before income taxes	(4)%	(3)%	(5)%
Provision (benefit) for income taxes	2 %	(2)%	(2)%
Net loss	(6)%	(1)%	(3)%

Total revenues were $2.4 billion, $2.3 billion and $2.3 billion for 2024, 2023 and 2022, respectively.

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

Product line	Year Ended December 31, 2024	2023	2022
Consumables	44 %	43 %	43 %
Infusion Systems	27 %	28 %	27 %
Vital Care	29 %	29 %	30 %
	100 %	100 %	100 %

We manage our product distribution through a network of owned and 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.

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.

Seasonality/Quarterly Results

There are no significant seasonal aspects to our business. We can experience fluctuations in net sales as a result of variations in the ordering patterns of our largest customers, which may be driven more by production scheduling and 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.

Non-GAAP Financial Measures

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. The presentation of revenues on a constant currency basis is a non-GAAP financial measure that excludes the impact of fluctuations in foreign currency exchange rates that occurred between the comparative periods. We provide constant currency information to enhance the visibility of underlying business trends, excluding the effects of changes in foreign currency translation rates. We believe this information is useful to investors to facilitate comparisons and better identify trends in our business. Our constant currency revenues reflect current year local currency revenues at prior year's average exchange rates. We consistently apply this approach to revenues for all currencies where the functional currency is not the U.S. dollar. These results should be considered in addition to, not as a substitute for, results reported in accordance with GAAP. Revenues 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.

Consumables

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

	Year Ended December 31, 2024	2023	2022	$ change 2024 over 2023	% change 2024 over 2023	$ change 2023 over 2022	% change 2023 over 2022
Consumables revenue (GAAP)	$1,038.9	$ 969.1	$ 975.0	$ 69.8	7.2 %	$ (5.9)	(0.6)%
Impact of foreign exchange rate changes	2.8	$ 4.0					
Consumables revenue on a constant currency basis (non-GAAP)	$1,041.7	$ 973.1					
$ Change in constant currency	$ 72.6	$ (1.9)					
% Change in constant currency	7.5 %	(0.2)%					

Consumables revenue increased in 2024, as compared to 2023, primarily due to new customer installations and increased demand for our Infusion Consumables, Vascular Access and Oncology product lines.

Consumables revenue decreased in 2023, as compared to 2022, primarily due to a decrease in our vascular access revenues as a result of lost customers and backorder recovery in 2022. The revenue decrease was partially offset by an increase in Infusion Therapy and Oncology revenues.

Infusion Systems

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2024	2023	2022	2024 over 2023		2023 over 2022	
Infusion Systems (GAAP)	$ 652.4	$ 629.0	$ 617.4	$ 23.4	3.7 %	$ 11.6	1.9 %
Impact of foreign exchange rate changes	20.3	$ 10.5					
Infusion Systems on a constant currency basis (non-GAAP)	$ 672.7	$ 639.5					
$ Change in constant currency	$ 43.7	$ 22.1					
% Change in constant currency	6.9 %	3.6 %					

Infusion Systems revenue increased in 2024, as compared to 2023, primarily due to higher sales of our large volume pump ("LVP") dedicated sets on a larger installed base, as well as growth in our ambulatory hardware and dedicated sets.

Infusion Systems revenue increased in 2023, as compared to 2022, primarily due to higher sales of our syringe pumps and LVP dedicated sets.

Vital Care

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

	Year Ended December 31,			$ change	% change	$ change	% change
	2024	2023	2022	2024 over 2023		2023 over 2022	
Vital Care (GAAP)	$ 690.7	$ 661.0	$ 687.6	$ 29.7	4.5 %	$ (26.6)	(3.9)%
Impact of foreign exchange rate changes	2.9	$ 4.5					
Vital Care on a constant currency basis (non-GAAP)	$ 693.6	$ 665.5					
$ Change in constant currency	$ 32.6	$ (22.1)					
% Change in constant currency	4.9 %	(3.2)%					

Vital Care revenue increased in 2024, as compared to 2023, due to higher sales volume of IV Solutions primarily driven by a market shortage of these products in the U.S. during the fourth quarter of 2024, as explained below.

During the third quarter of 2024, a competitor's U.S. IV solutions manufacturing facility was damaged as a result of Hurricane Helene causing a national shortage of IV solutions. In response, we actively increased production of our IV Solutions product lines in anticipation of increased demand due to the temporary market shortage. We experienced increased demand for our IV Solutions product lines in the fourth quarter of 2024 and may continue to see elevated demand in the near term given the sustained market shortage until conditions normalize.

Vital Care revenue decreased in 2023, as compared to 2022, primarily due to lower sales volume of IV Solutions which was impacted by supply disruptions related to finished good products purchased from third-party manufacturers and lower sales volume for products acquired from Smiths Group plc ("Smiths") due to backorder recovery in 2022.

Gross Margins

Gross margins were 34.6%, 32.8% and 30.6% for 2024, 2023 and 2022, respectively.

The increase in gross margin in 2024, as compared to 2023, was primarily driven by lower supply chain costs due to synergies and freight rates, price increases, reduced spend on quality remediation activities and the impact of foreign exchange rate changes which was partially offset by lower manufacturing absorption and higher inventory write-offs.

The increase in gross margin in 2023, as compared to 2022, was primarily driven by lower freight costs, lower spend on quality remediation and the cost recognition of a purchase accounting write-up of inventory in 2022, offset by continued inflationary impacts on costs and stronger Mexican peso.

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
	2024	2023	2022	2024 over 2023		2023 over 2022	
SG&A	$ 638.8	$ 606.7	$ 608.3	$ 32.1	5.3 %	$ (1.6)	(0.3)%

Consolidated SG&A expenses increased in 2024, as compared to 2023, primarily due to increases of $11.3 million in compensation costs, $9.4 million in commissions, $5.6 million in stock based compensation and $5.2 million in dealer fees. The increases were partially offset by decreases of $8.8 million in depreciation and amortization. Compensation costs increased primarily due to an increase in cash incentive compensation and employee benefits. Commissions increased primarily due to increased sales performance in the current period measured against preset sales targets as compared to sales performance achieved against targets in the comparable prior year period. Stock based compensation primarily increased due to a change in the probability of meeting a certain earning potential related to a performance based equity award. Dealer fees increased due to an increase in revenues to distributors. Depreciation and amortization decreased in 2024 due to certain assets reaching the end of their useful lives and certain assets classified as held for sale during the fourth quarter.

Consolidated SG&A expenses decreased slightly in 2023, as compared to 2022, primarily due to decreases of $7.5 million in depreciation and amortization, $4.8 million in dealer fees, $3.9 million of office expenses, and $2.6 million of IT expenses. The overall decreases were mostly offset by increases of $7.8 million in compensation costs, $5.2 million in commissions, $3.5 million in stock based compensation, and $1.3 million in sales and marketing expenses. Depreciation and amortization decreased in 2023 as the trademark intangible recognized as part of the January 2022 Smiths Medical acquisition had a useful life of six months and was fully amortized in 2022. Dealer fees decreased due to a decrease in revenues to distributors. Office and IT expenses decreased based on current operating needs. Compensation costs increased primarily due to an increase in cash incentive compensation and employee benefits. Commissions increased primarily due to sales performance in 2023 measured against preset sales targets as compared to sales performance achieved against targets in the comparable 2022 period. Stock based compensation increased due to an increase in the fair value of amounts awarded in 2023 over the fair value of the awards in 2022. Sales and marketing expenses increased due to an increase in trade show, conference, 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
	2024	2023	2022	2024 over 2023		2023 over 2022	
R&D	$ 88.6	$ 85.3	$ 93.0	$ 3.3	3.9 %	$ (7.7)	(8.3)%

R&D expenses increased in 2024, as compared to 2023, primarily due to higher headcount and employment expense in support of ongoing R&D projects. R&D expenses generally include compensation and benefit expenses, consulting fees, production supplies, samples, travel costs, utilities and other miscellaneous administrative costs incurred in our ongoing R&D projects.

R&D expenses decreased in 2023, as compared to 2022, due to organizational synergies and project reprioritization as a result as a result of the Smiths Medical acquisition. R&D expenses are primarily related to headcount and employment expenses in support of ongoing R&D projects. R&D expenses generally include compensation and benefit expenses, consulting

fees, production supplies, samples, travel costs, utilities and other miscellaneous administrative costs incurred in our ongoing R&D projects.

Restructuring, Strategic Transaction and Integration Expenses

Restructuring, strategic transaction and integration expenses were $59.8 million, $41.3 million and $71.4 million in 2024, 2023 and 2022, respectively.

Restructuring Charges

In 2024, we incurred restructuring charges of $19.6 million primarily related to severance costs.

In 2023, we incurred restructuring charges net of reversed accruals of $5.7 million primarily related to severance costs. We reversed approximately $1.0 million in accrued restructuring balances related to severance and facility closure costs that will not be utilized.

In 2022, we incurred restructuring charges of $9.7 million primarily related to severance costs.

Strategic Transaction and Integration Expenses

In 2024, we incurred $40.2 million in strategic transaction and integration expenses primarily related to consulting expenses and employee costs incurred to integrate our Smiths Medical business acquired in 2022.

In 2023, we incurred $35.6 million in strategic transaction and integration expenses primarily related to consulting expenses and employee costs incurred to integrate our Smiths Medical business acquired in 2022.

In 2022, we incurred $61.7 million in strategic transaction and integration expenses primarily related to our acquisition of Smiths Medical, which included legal expenses, bank fees and employee costs, and a United Kingdom stamp tax.

Change in fair value of contingent earn-out

In 2024, the fair value revaluation of our contingent earn-outs resulted in a decrease in value of $5.4 million. This decrease was related to the fair value revaluation of our Smiths Medical contingent earn-out liability and the fair value revaluation of a contingent earn-out recognized in 2021 upon the acquisition of a small foreign infusion systems supplier. The Smiths Medical contingent earn-out was adjusted to zero during 2024. As of December 31, 2024, Smiths had sold all of its ownership interest in ICU Medical shares. Smiths no longer holds the shares necessary to meet the minimum beneficial ownership percentage required to earn the contingent earn-out.

In 2023, the fair value revaluation of our contingent earn-outs resulted in a decrease in value of $16.2 million. This decrease was primarily related to the fair value revaluation of our Smiths Medical contingent earn-out liability. The change in fair value of the Smiths Medical contingent earn-out was driven by a decrease in our stock price.

Interest expense, net

The following table presents interest expense, net (in thousands):

	Year ended December 31,		
	2024	2023	2022
Interest expense	$ (106,541)	$ (102,727)	$ (70,805)
Interest income	$ 10,788	$ 7,508	$ 4,430
Interest expense, net	$ (95,753)	$ (95,219)	$ (66,375)

In 2024, 2023 and 2022, interest expense primarily includes the contractual interest incurred on borrowings under the Credit Agreement, the per annum commitment fee charged on the available amount of the revolving credit facility contained in the Credit Agreement, the amortization of debt issuance costs incurred in connection with entering into the Credit Agreement (see Note 13: Long-Term Obligations in our accompanying consolidated financial statements) offset by the impact of the interest rate swaps (see Note 9: Derivatives and Hedging in our accompanying consolidated financial statements). The interest

expense increased in 2024, as compared to 2023, primarily due to amortization of certain swaps. The interest expense increased in 2023, as compared to 2022, primarily due to increases in the applicable SOFR reference rate.

Interest income in all years was related to interest earned on interest-bearing securities and cash holdings.

Other expense, net

The following table presents other expense, net (in thousands):

	Year ended December 31,		
	2024	2023	2022
Foreign exchange losses, net	$ (9,792)	$ (5,918)	$ (5,780)
Loss on disposition of assets	(1,608)	(153)	(2,554)
Other miscellaneous (expense) income, net	(1,823)	166	3,198
Other expense, net	$ (13,223)	$ (5,905)	$ (5,136)

The foreign exchange losses in 2024 were primarily related to the strengthening of the U.S. dollar relative to certain foreign currencies, including the Mexican peso and Argentine peso. The foreign exchange losses in 2023 were primarily related to the devaluation of the Argentine peso during the fourth quarter of 2023.

In 2024, other miscellaneous (expense) income, net primarily includes $2.6 million in fees associated with our accounts receivable purchase program with BMO Bank N.A. ("BMO") (see Note: 18 Accounts Receivable Purchase Program). In 2023, other miscellaneous (expense) income, net primarily includes $3.7 million in fees related to our accounts receivable purchase program (see Note 18: Accounts Receivable Purchase Program) mostly offset by a business interruption gain recognized upon receipt of insurance proceeds. We received total insurance recoveries for property damage and business interruption of $3.1 million, $2.6 million of which was related to insurance proceeds for business interruption included within other miscellaneous (expense) income, net.

Income taxes

Income taxes were accrued at an estimated annual effective tax rate of (78)%, 62% and 35% in 2024, 2023 and 2022, respectively.

The effective tax rate in 2024 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign income, foreign-derived intangible income (“FDII”), federal and state valuation allowance, tax reserve releases, and tax credits. The effective tax rate in 2024 included a tax benefit of $10.1 million primarily related to unrecognized tax benefits released as a result of the expiration of the statute of limitations offset by a tax expense of $81.7 million related to a valuation allowance against certain U.S. federal and state deferred tax assets.

The Company regularly assesses the realizability of deferred tax assets and records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. In assessing the realizability of our deferred tax assets, we weigh all available positive and negative evidence. This evidence includes, but is not limited to, historical earnings, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. Due to the weight of objectively verifiable negative evidence, the Company recorded a valuation allowance of $81.7 million tax expense and $3.9 million foreign currency translation and derivative instrument adjustments against certain U.S. federal and state deferred tax assets for the tax years ending December 31, 2024. The significant piece of objectively verifiable negative evidence evaluated was the recent U.S. cumulative losses. Our ability to use our deferred tax assets depends on the amount of taxable income in future periods.

In December 2022, the European Union (EU) agreed to implement Pillar Two, the OECD’s global minimum tax rate of 15% for multinationals that meet a global revenue threshold. All of the EU countries and some of the non-EU countries in which we operate have enacted or have announced plans to enact legislation to adopt Pillar Two. The Pillar Two legislation is effective for our fiscal year beginning January 1, 2024 and for fiscal year 2024, Pillar 2 did not have a material impact to our tax provision or effective tax rate. However, the Pillar Two rules continue to evolve and their application may alter our tax obligations in certain countries in which we operate for fiscal periods beyond 2024 as we continue to assess the impact of tax legislation in these jurisdictions.

The effective tax rate in 2023 differs from the federal statutory rate of 21% principally because of the effect of the mix of U.S. and foreign income, state income taxes, section 162(m) excess compensation, foreign-derived intangible income ("FDII"), and tax credits. The effective tax rate in 2023 included a tax benefit of $9.6 million primarily related to unrecognized tax benefits released as a result of the expiration of the statute of limitations. The effective tax rate for 2023 also included a tax benefit of $0.8 million related to the excess tax benefits recognized on stock option exercises and the vesting of restricted stock units during the period. Additionally, the effective tax rate for 2023 included a tax benefit of $6.5 million related to U.S. federal and state return-to-provision adjustments net of related tax reserves. The adjustments related to primarily to changes in estimates for the research and development credit and foreign tax credits. Additionally, the effective tax rate 2023 included the tax impact of the revaluation of contingent consideration of $16.2 million.

The effective tax rate in 2022 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, section 162(m) excess compensation, FDII, global intangible low-taxed income ("GILTI") and tax credits. The effective tax rate during 2022 included a tax benefit of $4.2 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 during 2022 also included a $0.0 million tax impact of the revaluation of contingent consideration of $6.8 million.

Liquidity and Capital Resources

We regularly evaluate our liquidity and capital resources, including our access to external capital, to assess our ability to 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, payment of interest expense, repayment of outstanding borrowings, income tax obligations and acquisition opportunities in accordance with our growth strategy.

Sources of Liquidity

Our current primary sources of liquidity are cash and cash equivalents and cash flows from our operations including access to borrowing arrangements.

Funds generated from operations are held in cash and cash equivalents and investment securities. During 2024, our cash and cash equivalents and short-term investment securities increased by $53.8 million from $254.7 million at December 31, 2023 to $308.6 million at December 31, 2024. This increase was primarily due to cash generated from operations.

2022 Credit Facilities and Access to Capital

As discussed in Note 13: Long-Term Obligations to our accompanying consolidated financial statements, we entered into the Credit Agreement with various lenders on January 6, 2022 in connection with the closing of the Smiths Medical acquisition. The Credit Agreement provides for a five-year term loan A facility of $850.0 million (the "Term Loan A"), a seven-year term loan B facility of $850.0 million (the "Term Loan B") and a five-year revolving credit facility of $500.0 million (the "Revolving Credit Facility") (collectively, the "Senior Secured Credit Facilities"). The proceeds from the term loans were used to finance a portion of the cash consideration for the Smiths Medical acquisition. The outstanding aggregate principal amount of the term loans is $1.6 billion as of December 31, 2024, 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 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 Revolving Credit Facility as of December 31, 2024. As part of entering into the Senior Secured Credit Facilities, we were assigned issuer and Term Loan B credit ratings. At the date of issuance 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	B1/B1	Stable
Fitch	BB/BB+	Negative
Standard & Poor's	BB-/BB-	Negative

The Credit Agreement contains financial covenants that pertain to the Term Loan A and the Revolving Credit Facility. Specifically, we were required to maintain a Senior Secured Leverage Ratio of no more than 4.50 to 1.00 until June 30, 2024, with a stepdown to 4.00 to 1.00 thereafter, and an Interest Coverage Ratio of no less than 3.00 to 1.00 (defined and discussed in

greater detail in Note 13: Long-Term Obligations to our accompanying consolidated financial statements). We were in compliance with these financial covenants as of December 31, 2024.

In January 2023, we entered into a receivables purchase agreement with Bank of the West, which was subsequently acquired by BMO in February 2023. This agreement provides for an additional source of capital; however as of December 31, 2024, we are not currently utilizing this program (see Note 18: Accounts Receivable Purchase Program).

We believe that our existing cash and cash equivalents along with cash flows expected to be generated from future operations and the funds received and accessible under the Senior Secured Credit Facilities will provide us with sufficient liquidity to finance our cash requirements for the next twelve months and the foreseeable future. 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 economic 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 2025 will be in the range of $90 million to $110 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 expenditures. Amounts of spending are estimates and actual spending may substantially differ from those amounts.

2022 Acquisitions

On January 6, 2022, we acquired Smiths Medical. 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 Note 2: Acquisitions and Note 13: Long-Term Obligations in our accompanying consolidated financial statements for additional information.

Contractual Obligations

Our principal commitments at December 31, 2024 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 7: 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 table below. Interest payments on the term loans were estimated using an Adjusted Term SOFR rate and an applicable margin on of 2.00% for term loan A and 2.50% for term loan B and the revolver commitment fees were estimated using a rate of 0.30%. 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 13: Long-Term Obligations 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)					
	2025	2026	2027	2028	2029	Thereafter
Term Loan A Principal Payments	$ 42.5	$ 63.8	$ 664.1	$ —	$ —	$ —
Term Loan A Interest Payments	47.9	41.9	0.6	—	—	—
Term Loan B Principal Payments	8.5	8.5	8.5	8.5	792.6	—
Term Loan B Interest Payments	56.4	54.2	52.4	51.5	0.8	—
Revolver Commitment Fee	1.5	1.3	—	—	—	—
	$ 156.8	$ 169.7	$ 725.6	$ 60.0	$ 793.4	$ —

Other Future Capital Investments

In connection with the January 2022 acquisition of Smiths Medical, we estimate the investment needed in 2025 for restructuring and integration expenses along with spending to support quality systems and quality compliance objectives to be in the range of $90 million to $110 million, which includes acquired accrued field action liabilities. We expect to fund these obligations with our cash and cash equivalents and cash generated from our operations.

Contingent Payments

In 2015, the Italy Medical Device Payback ("IMDP") was enacted in Italy,which requires medical device companies to make payments to the Italian government if Italy's medical device expenditures for certain years exceeded annual regional expenditure ceilings. Since its enactment, the legislation has been subject to appeals in the Italian court system. In the third quarter of 2024, Italy's Constitutional Court issued two judgments, one of which confirmed the legitimacy of the IMDP. However, litigation proceedings are still pending and the ultimate resolution remains unknown. As of December 31, 2024, we have accrued $23.9 million for potential payments related to the IMDP, which is classified within our accrued liabilities. Given the uncertainty regarding this legislation and its enforcement, the timing and amount of payments could ultimately differ from our current expectations.

Historical Cash Flows

Cash Flows from Operating Activities

Our cash provided by operations was $204.0 million in 2024. The changes in operating assets and liabilities included a $46.8 million increase in accounts receivable, a $23.2 million increase in other assets, and $8.8 million increase in prepaid expenses and other current assets. Offsetting these amounts was a $20.7 million increase in accrued liabilities, a $16.8 million decrease in inventories, a $12.5 million increase in accounts payable and $26.2 million in net changes in income taxes, including excess tax benefits and deferred income taxes. The increase in accounts receivable was primarily due to the amount and timing of revenues and we sold less receivables under our accounts receivable purchase program with BMO as we did not utilize the program during the fourth quarter of 2024 (see Note 18: Accounts Receivable Purchase Program). The increase in other assets was due to the purchase of spare parts. The increase in prepaid expenses and other current assets was primarily attributable to deferred costs related to infusion pumps sold and insurance and property taxes. The net change in income taxes was a result of recording the current deferred provision and the timing of payments. The primary drivers for the net increase in accrued liabilities was primarily due to accrued employee costs, accrued restructuring costs and distributor rebates partially offset by operating lease payments. The decrease in inventory was primarily due to our focus on reducing inventory levels.

Our cash provided by operations was $166.2 million in 2023. The changes in operating assets and liabilities included a $48.6 million decrease in accounts receivable and a $11.7 million decrease in prepaid expenses and other current assets. Offsetting these amounts was a $6.1 million increase in inventories, a $68.3 million decrease in accounts payable, a $24.7 million increase in other assets, a $14.5 million decrease in accrued liabilities, and $82.4 million in net changes in income taxes, including excess tax benefits and deferred income taxes. The decrease in accounts receivable was primarily due to the sale of accounts receivable as part of our accounts receivable purchase program with BMO (see Note 18: Accounts Receivable Purchase Program). The decrease in prepaid expenses and other current assets was primarily attributable to insurance, property taxes, and prepaid vendor expenses. The increase in inventory was primarily to build inventory safety stock levels. The decrease in accounts payable was due to the timing of payments. The increase in other assets was due to the purchase of spare parts. The primary drivers for the net decrease in accrued liabilities was primarily due to payments for field corrective actions,

operating lease liabilities and distributor rebates as well as a decrease in deferred revenue offset partially by increases in accrued employee costs. The net changes in income taxes was a result of recording the current deferred provision and the timing of payments.

Our cash used by operations was $(62.1) million in 2022. The changes in operating assets and liabilities included a $201.1 million increase in inventories, a $21.3 million increase in other assets, a $55.8 million decrease in accrued liabilities, $66.7 million in net changes in income taxes, including excess tax benefits and deferred income taxes, and a $19.2 million increase in accounts receivable. Offsetting these amounts was a $22.9 million decrease in prepaid expenses and other current assets and a $37.5 million increase in accounts payable. The increase in inventory was primarily to build inventory safety stock levels. The increase in other assets was due to the purchase of spare parts. The primary drivers for the net decrease in accrued liabilities was primarily due to the payout of annual bonuses and decrease in deferred revenue. The net changes in income taxes was a result of recording the current deferred provision and the timing of payments. The increase in accounts receivable was primarily due to the net impact of collection efforts and the timing of revenue. The net decrease in prepaid expenses and other current assets was primarily due to a decrease in deferred costs mostly offset by capitalized debt issuance costs allocated to the revolving credit facility. The increase in accounts payable was due to the timing of payments.

Cash Flows from Investing Activities

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

	For the Years Ended December 31,			Variance		
	2024	2023	2022	2024	2023	
Investing Cash Flows:						
Purchases of property, plant and equipment	$ (79,373)	$ (83,893)	$ (90,311)	$ 4,520	$ 6,418	(1)
Proceeds from sale of assets	746	1,501	989	(755)	512	
Intangible asset additions	(10,833)	(9,777)	(9,018)	(1,056)	(759)	
Business acquisitions, net of cash acquired	—	—	(1,844,164)	—	1,844,164	(2)
Purchases of investment securities	—	—	(3,397)	—	3,397	(3)
Proceeds from sale of investment securities	500	4,222	36,433	(3,722)	(32,211)	(4)
Net cash used in investing activities	$ (88,960)	$ (87,947)	$ (1,909,468)	$ (1,013)	$ 1,821,521	

(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) 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 2022, we acquired Smiths Medical. The cash consideration for the transaction was $1.9 billion, which was financed with existing cash balances and borrowings under the Credit Agreement. Acquired cash was $78.8 million.

(3) 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.

(4) Proceeds from the sale of our investment securities will vary based on the maturity dates of the investments. In 2022, proceeds from sale of investment securities includes $19.0 million received from a promissory note related to an acquired investment as part of the Smiths Medical acquisition.

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		
	2024	2023	2022	2024	2023	
Financing Cash Flows:						
Proceeds from issuance of long-term debt, net of lender debt issuance costs	$ —	$ —	$1,664,362	$ —	$(1,664,362)	(1)
Principal payments on long-term debt	(51,000)	(29,688)	(22,375)	(21,312)	(7,313)	(2)
Payment of third-party debt issuance costs	—	—	(2,177)	—	2,177	(3)
Proceeds from exercise of stock options	10,939	4,022	8,785	6,917	(4,763)	(4)
Payments on finance leases	(1,147)	(963)	(680)	(184)	(283)	
Payment of contingent earn-out	(2,600)	—	—	(2,600)	—	(5)
Tax withholding payments related to net share settlement of equity awards	(11,992)	(9,350)	(10,883)	(2,642)	1,533	(6)
Net cash (used in) provided by financing activities	$ (55,800)	$ (35,979)	$1,637,032	$ (19,821)	$(1,673,011)	

(1) During 2022, we borrowed an aggregate of $1.7 billion under the Senior Secured Credit Facilities contained in the Credit Agreement to partially finance our acquisition of Smiths Medical (see Note 13: Long-Term Obligations to our accompanying consolidated financial statements for additional information). The proceeds are net of $37.8 million in payments of lender debt issuance costs.

(2) Relates to scheduled principal payments on the Senior Secured Credit Facilities.

(3) Relates to third-party debt issuance costs in connection with entering into the Senior Secured Credit Facilities.

(4) 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.

(5) During the first quarter of 2024, we paid $3.4 million in cash related to the settlement of the Mediverse contingent earn-out. Of the $3.4 million, the amount recorded as the acquisition date fair value, which is considered financing cash flows, was $2.6 million (see Note 10: Fair Value Measurements).

(6) In 2024, our employees surrendered 114,787 shares of our common stock from vested restricted stock awards as consideration for approximately $12.0 million in minimum statutory withholding obligations paid on their behalf. In 2023, our employees surrendered 59,377 shares of our common stock from vested restricted stock awards as consideration for approximately $9.4 million in minimum statutory withholding obligations paid on their behalf. In 2022, our employees surrendered 47,664 shares of our common stock from vested restricted stock awards as consideration for approximately $10.9 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, 2024, 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 Agreement (see Note 13: Long-Term Obligations in our accompanying consolidated financial statements).

New Accounting Pronouncements

See Note 1: Basis of Presentation and 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, which for the majority of our sales of products sold on a standalone basis to our distributors and end customers for direct sales, is deemed to be at point of 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.

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 include variable consideration in net sales only to the extent that a significant reversal in revenue is not probable when the uncertainty is resolved.

Our variable consideration includes distributor chargebacks, product returns and end customer rebates, with distributor chargebacks representing the majority and subject to the greatest judgment.

Chargebacks are the difference between the prices we charge our distribution customers at the time they purchase our products and the contracted prices we have with the end customer, most often in the U.S. and Canada. When a distributor sells our products to one of our contracted end customers, the distributor typically will claim a refund from us for the chargeback amount which we process as a credit to the distributor.

In estimating the transaction price to present as net revenue for sales to distributors, we must estimate the expected chargeback amount that we will refund to the distributor after they sell our product to a contracted end customer. Determining the appropriate chargeback reserve requires judgment around the following assumptions:

(i) The estimated chargeback amount (the difference between the price we invoice the distributor and the contractually agreed price with specified end customers); and

(ii) The estimated period of time between the sale to the distributor and the receipt of a chargeback claim.

For purposes of estimating the expected chargeback amount, we utilize actual recent historical chargebacks paid to the specific distributor for similar products as determined at either a product or product-family level. While individual chargeback rates can vary significantly depending on the product and contracted prices with distributors and end customers, our chargeback reserve estimate is not overly sensitive to those individual price changes due to the long-term nature of our distributor and end customer contracts as well as consistency in purchasing patterns. Additionally, the use of the actual chargeback history to calculate an average chargeback rate has historically resulted in a reasonable estimation of overall current contract rates.

For purposes of estimating the period of time between the sale to the distributor and the receipt of a chargeback claim, we utilize several sources of information including actual inventory quantities of our products on hand at distributors. This inventory on hand information is received from the distributors or, when specific quantities are not provided, estimated by using the targeted days of inventory on hand for distributors. Historical experience of actual chargebacks paid has indicated that use of this information has reasonable predictive value of outstanding chargebacks and accounts for the variability of purchasing patterns and expected timing and volume of sales to end customers. The value of the chargeback reserve generally represents approximately two months of obligation due to the timing difference between the initial sale to a distributor and the processing of a chargeback claim after the product is sold to the end customer.

The chargeback reserve estimates change from period-to-period primarily based on changes in revenue from/and the inventory levels of distributors. Our judgments regarding the information used to calculate the chargeback reserve are consistent from period to period; however, on a regular basis, we evaluate the adequacy of the chargeback reserve to reassess and ensure that the variable consideration is appropriately constrained, and the likelihood of future revenue reversal is not probable. We use metrics including chargeback provision as a percentage of gross revenue, movements in inventory on hand at distributors, trends in accrued versus paid chargebacks and impacts from price changes and similar metrics.

The chargeback reserve reflects a reasonable estimate of the amount of consideration using the expected value method and is recorded as a reduction of accounts receivable, net on the consolidated balance sheets.

We also offer certain volume-based rebates to both our distribution and end-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, including current contractual requirements, our historical experience with each customer and forecasted customer purchasing patterns, to estimate the most likely rebate amount.

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.

Accounts receivable

Accounts receivable are stated at net realizable value. Our accounts receivable are recorded net of reserves including distributor chargebacks, estimated rebates and allowance for doubtful accounts. See above for significant judgments related to distributor chargebacks and rebates. 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. We also have credit exposure 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/valuation 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. Other critical estimates used to estimate the fair value are derived from royalty rates, customer retention rates and/or estimated useful lives.

- *Contingent 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 10: 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

In connection with the Smiths Medical acquisition on January 6, 2022 we entered into the 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 are exposed to changes in interest rates on all of these variable-rate debt instruments.

The term loan A facility currently bears interest based on Adjusted Term SOFR plus an applicable margin of 2.00% per year. The term loan B facility currently bears interest based on Adjusted Term SOFR subject to a 0.50% floor plus an applicable margin of 2.50%. We used a sensitivity analysis to measure our interest rate risk exposure. If the SOFR rate increases or decreases 1% from December 31, 2024, the additional annual interest expense or savings related to the term loans would be approximately $16.0 million.

In order to mitigate and offset a portion of this interest rate risk exposure associated with these debt instruments we entered into interest rate swaps to achieve a targeted mix of fixed and variable-rate debt. 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 on March 30, 2027 and we pay a fixed rate of 1.32% and receive the greater of 3-month USD SOFR or (0.15)%. 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 on March 30, 2026 and we pay a fixed rate of 1.17% and receive the greater of 3-month USD SOFR or 0.35%. In June 2023, we entered into an additional swap with a notional amount of $300.0 million with a maturity date of June 30, 2028 and we pay a fixed rate of 3.8765% starting on June 30, 2023 and receive 3-month USD SOFR. (see Note 9: Derivatives and Hedging Activities to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K).

Accounts Receivable Purchase Program

Additionally, our accounts receivable purchase program with BMO bears discount rates tied to SOFR. These variable discount rates would affect the amount of factoring costs we incur, and the amount of cash we receive upon the sales of accounts receivable under this program. A 1% change in SOFR rates on the accounts receivable sales would not have a material impact on our results of operations, (see Note 18: Accounts Receivable Purchase Program 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 and other currencies relative to the operating unit functional currency. Our hedging policy attempts to manage these risks to an acceptable level. We manage our foreign currency exposures on a consolidated basis to take advantage of net exposures and natural offsets, which are then further reduced by the gains and losses of our hedging instruments. Gains and losses on the hedging instruments offset gains and losses on the hedged forecasted transactions and reduce the earnings volatility related to foreign exchange, however we do not hedge our entire foreign exchange exposure and are still subject to potentially significant earnings volatility due to foreign exchange risk.

We use foreign exchange forward contracts to hedge a portion of our forecasted foreign currency-denominated revenues and expenses (principally Mexican Pesos, Euros, Czech Koruna, Japanese Yen, Swedish Krona, Danish Krone, Chinese Renminbi, Canadian Dollar, U.S. Dollar, and Australian Dollar) that differ from the functional currency of the operating unit. These derivative contracts are designated and qualify as cash flow hedges (see Note 9: Derivatives and Hedging Activities to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K). We performed a sensitivity analysis to estimate changes in the fair value of our foreign exchange derivatives due to potential changes in near-term foreign exchange rates. At December 31, 2024, the effect of a hypothetical 10% weakening in the actual foreign exchange rates used for the applicable currencies would result in an estimated decrease in the fair value of these outstanding derivatives contracts by approximately $5.4 million. The sensitivity analysis recalculates the fair value of the exchange contracts outstanding at December 31, 2024 using the actual forward rates at December 31, 2024, which are then adjusted to be 10% weaker for each respective currency.

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, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 27, 2025, 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 5 to the financial statements

Critical Audit Matter Description

The Company recognizes revenue and the related accounts receivable 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. Variable consideration is included in net sales only to the extent that a significant reversal in revenue is not probable when the uncertainty is resolved. The Company estimates and reserves for chargebacks as a reduction of revenue and the related accounts receivable at the time of sale to its distribution customers using information available at that time, including historical experience.

Given the subjectivity and complexity of evaluating management's assumptions used in the determination of the chargeback reserve, including the estimated chargeback amount for 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 certain 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, chargeback settlements with distribution customers, and inventory days on hand reported from distributors, 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 27, 2025

We have served as the Company's auditor since 2008

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, 2024, 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, 2024, 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, 2024, of the Company and our report dated February 27, 2025, 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 27, 2025

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

	December 31,	
	2024	2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 308,566	$ 254,222
Short-term investment securities	—	501
TOTAL CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENT SECURITIES	308,566	254,723
Accounts receivable, net of allowance of $12,977 and $11,064 at December 31, 2024 and 2023, respectively	182,828	161,566
Inventories	584,676	709,360
Prepaid income taxes	11,244	21,983
Prepaid expenses and other current assets	70,287	73,640
Assets held for sale	284,382	—
TOTAL CURRENT ASSETS	1,441,983	1,221,272
PROPERTY, PLANT AND EQUIPMENT, net	442,746	612,909
OPERATING LEASE RIGHT-OF-USE ASSETS	53,295	69,909
GOODWILL	1,432,772	1,472,446
INTANGIBLE ASSETS, net	740,789	870,588
DEFERRED INCOME TAXES	24,211	37,295
OTHER ASSETS	68,135	94,020
TOTAL ASSETS	$ 4,203,931	$ 4,378,439
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 148,020	$ 150,030
Accrued liabilities	306,923	268,215
Current portion of long-term debt	51,000	51,000
Income tax payable	17,328	7,714
Contingent earn-out liability	—	4,879
Liabilities held for sale	32,911	—
TOTAL CURRENT LIABILITIES	556,182	481,838
CONTINGENT EARN-OUT LIABILITY	—	3,991
LONG-TERM DEBT	1,531,858	1,577,770
OTHER LONG-TERM LIABILITIES	66,745	100,497
DEFERRED INCOME TAXES	48,814	55,873
INCOME TAX LIABILITY	35,097	35,060
COMMITMENTS AND CONTINGENCIES (Note 16)	—	—
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—24,518 and 24,144 shares at December 31, 2024 and 2023, respectively, and outstanding—24,517 and 24,141 shares at December 31, 2024 and 2023, respectively	2,452	2,414
Additional paid-in capital	1,412,118	1,366,493
Treasury stock, at cost (571 and 2,428 shares, respectively)	(92)	(262)
Retained earnings	690,158	807,846
Accumulated other comprehensive loss	(139,401)	(53,081)
TOTAL STOCKHOLDERS' EQUITY	1,965,235	2,123,410
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 4,203,931	$ 4,378,439

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,		
	2024	2023	2022
TOTAL REVENUES	$ 2,382,046	$ 2,259,126	$ 2,279,997
COST OF GOODS SOLD	1,557,264	1,519,253	1,582,236
GROSS PROFIT	824,782	739,873	697,761
OPERATING EXPENSES:			
Selling, general and administrative	638,762	606,693	608,345
Research and development	88,615	85,344	92,984
Restructuring, strategic transaction and integration	59,840	41,258	71,421
Change in fair value of contingent earn-out	(5,399)	(16,247)	(32,091)
TOTAL OPERATING EXPENSES	781,818	717,048	740,659
INCOME (LOSS) FROM OPERATIONS	42,964	22,825	(42,898)
INTEREST EXPENSE, NET	(95,753)	(95,219)	(66,375)
OTHER EXPENSE, NET	(13,223)	(5,905)	(5,136)
LOSS BEFORE INCOME TAXES	(66,012)	(78,299)	(114,409)
(PROVISION) BENEFIT FOR INCOME TAXES	(51,676)	48,644	40,123
NET LOSS	$ (117,688)	$ (29,655)	$ (74,286)
NET LOSS PER SHARE			
Basic	$ (4.83)	$ (1.23)	$ (3.11)
Diluted	$ (4.83)	$ (1.23)	$ (3.11)
WEIGHTED AVERAGE NUMBER OF SHARES			
Basic	24,388	24,091	23,868
Diluted	24,388	24,091	23,868

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

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

	Year ended December 31,		
	2024	2023	2022
NET LOSS	$ (117,688)	$ (29,655)	$ (74,286)
Other comprehensive loss, net of tax:			
Cash flow hedge adjustments, net of tax of $0, $(5,951) and $12,941 for the years ended December 31, 2024, 2023 and 2022, respectively	(16,162)	(18,895)	41,016
Foreign currency translation adjustment, net of tax of $0 for all periods	(70,158)	46,189	(103,928)
Other adjustments, net of tax of $0 for all periods	—	603	1,203
Other comprehensive (loss) income, net of tax	(86,320)	27,897	(61,709)
COMPREHENSIVE LOSS	$ (204,008)	$ (1,758)	$ (135,995)

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, 2022	**21,280**	**$ 2,128**	**$ 721,412**	**$ (27)**	**$ 911,787**	**$ (19,269)**	**$ 1,616,031**
Issuance of restricted stock and exercise of stock options	263	21	(1,903)	10,667	—	—	8,785
Tax withholding payments related to net share settlement of equity awards	(48)	—	—	(10,883)	—	—	(10,883)
Issuance of common stock for acquisitions	2,500	250	575,725	—	—	—	575,975
Stock compensation	—	—	36,025	—	—	—	36,025
Other comprehensive loss, net of tax	—	—	(10)	—	—	(61,709)	(61,719)
Net loss	—	—	—	—	(74,286)	—	(74,286)
Balance, December 31, 2022	**23,995**	**2,399**	**1,331,249**	**(243)**	**837,501**	**(80,978)**	**2,089,928**
Issuance of restricted stock and exercise of stock options	208	15	(5,324)	9,331	—	—	4,022
Tax withholding payments related to net share settlement of equity awards	(59)	—	—	(9,350)	—	—	(9,350)
Stock compensation	—	—	40,563	—	—	—	40,563
Other comprehensive income, net of tax	—	—	5	—	—	27,897	27,902
Net loss	—	—	—	—	(29,655)	—	(29,655)
Balance, December 31, 2023	**24,144**	**2,414**	**1,366,493**	**(262)**	**807,846**	**(53,081)**	**2,123,410**
Issuance of restricted stock and exercise of stock options	489	38	(1,261)	12,162	—	—	10,939
Tax withholding payments related to net share settlement of equity awards	(115)	—	—	(11,992)	—	—	(11,992)
Stock compensation	—	—	46,883	—	—	—	46,883
Other comprehensive loss, net of tax	—	—	3	—	—	(86,320)	(86,317)
Net loss	—	—	—	—	(117,688)	—	(117,688)
Balance, December 31, 2024	**24,518**	**$ 2,452**	**$ 1,412,118**	**$ (92)**	**$ 690,158**	**$ (139,401)**	**$ 1,965,235**

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,		
	2024	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net Loss	$ (117,688)	$ (29,655)	$ (74,286)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	219,512	228,774	235,151
Noncash expense for inventory step-up	—	—	26,519
Noncash lease expense	21,344	21,910	23,651
Provision for doubtful accounts	5,800	838	1,036
Provision for warranty and returns	1,130	21,582	4,902
Stock compensation	46,883	40,563	36,025
Loss on disposal or write-off of property, plant and equipment	2,522	2,109	2,010
Debt issuance cost amortization	6,807	6,814	6,972
Change in fair value of contingent earn-out	(5,399)	(16,247)	(32,091)
Usage of spare parts	18,298	17,050	11,924
Other	7,393	8,066	(213)
Changes in operating assets and liabilities, net of amounts acquired:			
Accounts receivable	(46,844)	48,635	(19,151)
Inventories	16,829	(6,079)	(201,095)
Prepaid expenses and other current assets	(8,829)	11,672	22,903
Other assets	(23,154)	(24,695)	(21,290)
Accounts payable	12,531	(68,301)	37,472
Accrued liabilities	20,668	(14,479)	(55,834)
Income taxes, including excess tax benefits and deferred income taxes	26,230	(82,356)	(66,734)
Net cash provided by (used in) operating activities	204,033	166,201	(62,129)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(79,373)	(83,893)	(90,311)
Proceeds from sale of assets	746	1,501	989
Intangible asset additions	(10,833)	(9,777)	(9,018)
Business acquisitions, net of cash acquired	—	—	(1,844,164)
Purchases of investment securities	—	—	(3,397)
Proceeds from sale of investment securities	500	4,222	36,433
Net cash used in investing activities	(88,960)	(87,947)	(1,909,468)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of long-term debt, net of lender debt issuance costs	—	—	1,664,362
Principal repayments of long-term debt	(51,000)	(29,688)	(22,375)
Payment of third-party debt issuance costs	—	—	(2,177)
Proceeds from exercise of stock options	10,939	4,022	8,785
Payments on finance leases	(1,147)	(963)	(680)
Payment of contingent earn-out	(2,600)	—	—
Tax withholding payments related to net share settlement of equity awards	(11,992)	(9,350)	(10,883)
Net cash (used in) provided by financing activities	(55,800)	(35,979)	1,637,032
Effect of exchange rate changes on cash	(4,929)	3,163	(9,478)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	54,344	45,438	(344,043)
CASH AND CASH EQUIVALENTS, beginning of period	254,222	208,784	552,827
CASH AND CASH EQUIVALENTS, end of period	$ 308,566	$ 254,222	$ 208,784

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,		
	2024	2023	2022
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the year for income taxes	$ 25,253	$ 35,809	$ 27,504
Cash paid during the year for interest	$ 99,717	$ 95,913	$ 63,713
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING ACTIVITIES:			
Accounts payable for property, plant and equipment	$ 7,443	$ 6,570	$ 4,854
Detail of assets acquired and liabilities assumed in acquisitions:			
Fair value of assets acquired			$ 1,606,300
Cash paid for acquisitions, net of cash acquired			(1,844,164)
Issuance of common stock for acquisitions			(575,975)
Contingent consideration			(55,158)
Goodwill, acquired/adjusted during period			1,462,752
Liabilities assumed/Adjustments to liabilities assumed			$ 593,755

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

NOTE 1. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

ICU Medical, Inc. ("ICU" or "we"), a Delaware corporation, develops, manufactures and sells innovative medical products used in infusion therapy, vascular access, and vital care applications. ICU's product portfolio includes ambulatory, syringe, and large volume IV pumps and safety software; dedicated and non-dedicated IV sets, needlefree IV connectors, peripheral IV catheters, and sterile IV solutions; closed system transfer devices and pharmacy compounding systems; as well as a range of respiratory, anesthesia, patient monitoring, and temperature management products.

We sell the majority of our products globally through our direct sales force and through independent distributors throughout the U.S. and internationally. We also sell certain products on an original equipment manufacturer basis to other medical device manufacturers.

Basis of Presentation

All subsidiaries are wholly owned and are included in the consolidated financial statements. All intercompany balances 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").

Certain reclassifications have been made to the prior year financial statements and footnotes to conform to the presentation used in the current year. In the consolidated statements of cash flows, we reclassified bond premium amortization to other. The reclassification had no impact on cash flows from operating activities as previously reported. In Note 14: Income Taxes, we reclassified certain provision (benefit) for income taxes and tax asset categories. These reclassifications had no impact on the consolidated statement of operations and consolidated balance sheets.

Segment Reporting

We operate as a single operating and reportable segment. Our Chief Operating Decision Maker ("CODM"), the Chief Executive Officer, reviews financial information presented on a consolidated basis for purposes of allocating resources and assessing performance. See Note 6: Segment Data.

Use of Estimates

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 and 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, the financial status of our customers 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,	
	2024	2023
Raw materials	$ 265,275	$ 296,037
Work in process	37,528	58,906
Finished goods	281,873	354,417
Total	$ 584,676	$ 709,360

As of December 31, 2024, inventory account balances that are part of a disposal group that met the criteria for assets held for sale during the fourth quarter of 2024 were combined with other disposal group assets and presented as a separate line item "Assets Held For Sale" in our consolidated balance sheet (See Note 4:Assets Held For Sale).

Property, Plant and Equipment

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

	As of December 31,	
	2024	2023
Machinery and equipment[1]	$ 400,861	$ 483,382
Land, building and building improvements[1]	177,089	278,251
Molds	96,318	89,573
Computer equipment and software[1]	122,208	122,038
Furniture and fixtures[1]	27,871	30,662
Instruments placed with customers[2]	124,290	115,672
Construction in progress[1]	87,006	117,219
Total property, plant and equipment, cost	1,035,643	1,236,797
Accumulated depreciation[1]	(592,897)	(623,888)
Property, plant and equipment, net [1]	$ 442,746	$ 612,909

(1) As of December 31, 2024, certain property, plant and equipment category account balances that are part of a disposal group that met the criteria for assets held for sale during the fourth quarter of 2024 were combined with other disposal group assets and presented as a separate line item "Assets held For Sale" in our consolidated balance sheet, $99.4 million of accumulated depreciation was included in the disposal group and reclassified to assets held for sale. See Note 4: Assets Held For Sale.

(2) 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 and 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 $85.2 million, $96.7 million and $95.8 million in 2024, 2023 and 2022, respectively, of which $73.7 million, $75.4 million, and $74.1 million, respectively, are included in cost of goods sold.

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. In 2024, 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. We concluded that there was no impairment of goodwill during fiscal 2024, 2023, or 2022.

The following table presents the changes in the carrying amount of our goodwill for 2024, 2023 and 2022 (in thousands):

	Total
Balance as of January 1, 2022	$ 43,439
Goodwill[1]	1,469,880
Other[2]	(7,128)
Disposition[3]	(650)
Currency translation	(56,283)
Balance as of December 31, 2022	1,449,258
Currency translation	23,188
Balance as of December 31, 2023	1,472,446
Currency translation	(39,674)
Balance as of December 31, 2024	$ 1,432,772

(1) Relates to Smiths Medical acquired on January 6, 2022 (see Note 2: Acquisitions).
(2) Reflects a measurement period adjustment related to the 2021 acquisition of a small foreign infusion systems supplier.
(3) Relates to the sale of a certain line of infusion products in China.

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, 2024		
		Cost	Accumulated Amortization	Net
Patents	10	$ 36,811	$ 22,913	$ 13,898
Customer contracts	12	9,818	6,994	2,824
Non-contractual customer relationships	8	546,404	236,267	310,137
Trademarks	1	5,425	5,425	—
Trade name	15	18,239	8,357	9,882
Developed technology[(1)]	10	619,540	227,869	391,671
Non-compete	3	9,100	9,100	—
Total amortized intangible assets		$ 1,245,337	$ 516,925	$ 728,412
Internally developed software[(2)]		$ 12,377		$ 12,377
Total intangible assets		$ 1,257,714	$ 516,925	$ 740,789

(1) Developed technology primarily consists acquired patented technologies and internally developed software. Upon completion of development, the assets will be amortized over their estimated useful lives.

(2) Internally developed software will be reclassified to developed technology and amortized when the projects are complete and the assets are ready for their intended use. During 2024, we reclassified $33.2 million to developed technology.

	Weighted-Average Amortization Life in Years	December 31, 2023		
		Cost	Accumulated Amortization	Net
Patents	10	$ 33,261	$ 20,637	$ 12,624
Customer contracts	12	10,018	6,755	3,263
Non-contractual customer relationships	8	554,982	171,279	383,703
Trademarks	1	5,425	5,425	—
Trade name	15	18,251	7,162	11,089
Developed technology	10	587,852	167,913	419,939
Non-compete	3	9,100	7,450	1,650
Total amortized intangible assets		$ 1,218,889	$ 386,621	$ 832,268
Internally developed software*		$ 38,320		$ 38,320
Total intangible assets		$ 1,257,209	$ 386,621	$ 870,588

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

Amortization expense was $134.3 million, $132.1 million and $139.4 million in 2024, 2023 and 2022, respectively, of which $1.7 million, $— million, and $0.3 million, respectively, are included in cost of goods sold.

As of December 31, 2024, estimated annual amortization for our intangible assets for each of the next five years and thereafter is approximately (in thousands):

2025	$	129,604
2026		127,612
2027		117,450
2028		116,852
2029		113,775
Thereafter		123,119
Total	$	728,412

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 2024, 2023 or 2022.

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 2024, 2023 or 2022.

Assets Held for Sale

We classify a long-lived asset or disposal groups as held for sale in the period in which all of the following criteria are met: (1) management, having the authority to approve the action, commits to a plan to sell the asset or disposal group; (2) the asset or disposal group is available for immediate sale in its present condition subject only to terms that are usual and customary for sales of such assets or disposal groups; (3) an active program to locate a buyer and other actions required to complete the plan to sell the asset or disposal group have been initiated; (4) the sale of the asset or disposal group is probable, and transfer of the asset or disposal group is expected to qualify for recognition as a completed sale within one year, except if events or circumstances beyond our control extend the period of time required to sell the asset or disposal group beyond one year; (5) the asset or disposal group is being actively marketed for sale at a price that is reasonable in relation to its current fair value; and (6) actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn. We initially measure a long-lived asset or disposal group that is classified as held for sale at the lower of its carrying value or fair value less any costs to sell and immediately recognize any estimated losses. Conversely, gains are not recognized on the sale of a long-lived asset or disposal group until the date of sale. Each reporting period that a long-lived asset or disposal group remains as held for sale, the carrying value of the long-lived asset or disposal group is adjusted for subsequent changes in fair value less cost to sell, losses are recognized for a subsequent write-down to fair value less cost to sell and gains are recognized for an increase in fair value less cost to sell although limited to the amount of any previous cumulative losses recognized. We cease depreciation and amortization of a long-lived asset, or assets within a disposal group, upon their designation as held for sale. See Note 4: Assets Held For Sale.

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).

Investments in Available-for-sale Securities

Our investment securities were historically considered available-for-sale and consisted of corporate bonds, U.S. treasury securities, and government bonds. These securities were considered “investment grade” and were 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 (loss) income. We did not have any investments in available-for-sale debt securities in unrealized loss positions as of December 31, 2024 or 2023.

The amortized cost of the debt securities and U.S treasury securities is adjusted for the amortization of premiums computed under the effective interest method. Such amortization is included in interest expense, 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. All short-term investment securities are callable within one year.

As of December 31, 2024, we did not have any investment securities. As of December 31, 2023, the amortized cost, unrealized holding gains (losses) and fair value of our available-for-sale investment securities were as follows (in thousands):

	As of December 31, 2023		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term corporate bonds	$ 501	$ —	$ 501

Investments in Non-Marketable Equity Securities

We own 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 report our proportionate share of the investee's income or (loss) resulting from this investment in other expense, 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. Our recorded share of the investee's loss was not material for the years ended December 31, 2024, 2023 or 2022. We did not receive any dividend distributions from this investment during 2024, 2023 or 2022.

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

	As of December 31,	
	2024	2023
Equity method investment	$ 3,038	$ 3,120

Investments in non-marketable debt securities

In 2022, we received $19.0 million in proceeds from a promissory note related to an acquired investment as part of the Smiths Medical acquisition.

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 accrued for interest and penalties of $2.6 million and $1.6 million, respectively, as of December 31, 2024 and $2.9 million and $2.0 million, respectively, as of December 31, 2023.

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 expense, net (see Other expense, net table below). Foreign currency transaction losses, net were $9.8 million, $5.9 million and $5.8 million in 2024, 2023 and 2022, respectively.

Revenue Recognition

We recognize revenues when we transfer control of promised goods to our customers, which for the majority of our sales of products sold on a standalone basis to our distributors and end customers for direct sales, is deemed to be at point of 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.

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 include variable consideration in net sales only to the extent that a significant reversal in revenue is not probable when the uncertainty is resolved.

Our variable consideration includes distributor chargebacks, product returns and end customer rebates, with distributor chargebacks representing the majority and subject to the greatest judgment.

Chargebacks are the difference between the prices we charge our distribution customers at the time they purchase our products and the contracted prices we have with the end customer, most often in the U.S. and Canada. When a distributor sells our products to one of our contracted end customers, the distributor typically will claim a refund from us for the chargeback amount which we process as a credit to the distributor.

In estimating the transaction price to present as net revenue for sales to distributors, we must estimate the expected chargeback amount that we will refund to the distributor after they sell our product to a contracted end customer. Determining the appropriate chargeback reserve requires judgment around the following assumptions:

(i) The estimated chargeback amount (the difference between the price we invoice the distributor and the contractually agreed price with specified end customers); and

(ii) The estimated period of time between the sale to the distributor and the receipt of a chargeback claim.

For purposes of estimating the expected chargeback amount, we utilize actual recent historical chargebacks paid to the specific distributor for similar products as determined at either a product or product-family level. While individual chargeback

rates can vary significantly depending on the product and contracted prices with distributors and end customers, our chargeback reserve estimate is not overly sensitive to those individual price changes due to the long-term nature of our distributor and end customer contracts as well as consistency in purchasing patterns. Additionally, the use of the actual chargeback history to calculate an average chargeback rate has historically resulted in a reasonable estimation of overall current contract rates.

For purposes of estimating the period of time between the sale to the distributor and the receipt of a chargeback claim, we utilize several sources of information including actual inventory quantities of our products on hand at distributors. This inventory on hand information is received from the distributors or, when specific quantities are not provided, estimated by using the targeted days of inventory on hand for distributors. Historical experience of actual chargebacks paid has indicated that use of this information has reasonable predictive value of outstanding chargebacks and accounts for the variability of purchasing patterns and expected timing and volume of sales to end customers. The value of the chargeback reserve generally represents approximately two months of obligation due to the timing difference between the initial sale to a distributor and the processing of a chargeback claim after the product is sold to the end customer.

The chargeback reserve estimates change from period-to-period primarily based on changes in revenue from/and the inventory levels of distributors. Our judgments regarding the information used to calculate the chargeback reserve are consistent from period to period; however, on a regular basis, we evaluate the adequacy of the chargeback reserve to reassess and ensure that the variable consideration is appropriately constrained, and the likelihood of future revenue reversal is not probable. We use metrics including chargeback provision as a percentage of gross revenue, movements in inventory on hand at distributors, trends in accrued versus paid chargebacks and impacts from price changes and similar metrics.

The chargeback reserve reflects a reasonable estimate of the amount of consideration using the expected value method and is recorded as a reduction of accounts receivable, net on the consolidated balance sheets.

We also offer certain volume-based rebates to both our distribution and end 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, including current contractual requirements, our historical experience with each customer and forecasted customer purchasing patterns, to estimate the most likely rebate amount.

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.

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, software maintenance services 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.

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 $19.1 million, $19.2 million and $14.6 million in 2024, 2023 and 2022, 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.

Interest expense, net

The following table presents interest (expense) income, net (in thousands):

	As of December 31,		
	2024	2023	2022
Interest expense	$ (106,541)	$ (102,727)	$ (70,805)
Interest income	10,788	7,508	4,430
Interest expense, net	$ (95,753)	$ (95,219)	$ (66,375)

Other expense, net

The following table presents other expense, net (in thousands):

	As of December 31,		
	2024	2023	2022
Foreign exchange losses, net	$ (9,792)	$ (5,918)	$ (5,780)
Loss on disposition of assets	(1,608)	(153)	(2,554)
Other miscellaneous (expense) income, net	(1,823)	166	3,198
Other expense, net	$ (13,223)	$ (5,905)	$ (5,136)

The foreign exchange losses in 2024 were primarily related to the strengthening of the U.S. dollar relative to certain foreign currencies, including the Mexican peso and Argentine peso.

In 2024, other miscellaneous (expense) income, net primarily includes $2.6 million in fees related to our accounts receivable purchase program. In 2023, other miscellaneous (expense) income, net primarily includes $3.7 million in fees related to our accounts receivable purchase program (see Note 18: Accounts Receivable Purchase Program) mostly offset by a business interruption gain. We received total insurance recoveries for property damage and business interruption of $3.1 million, $2.6 million of which was related to insurance proceeds for business interruption included within other miscellaneous (expense) income, net.

Net Loss Per Share

Due to the net loss for the years ended December 31, 2024, 2023 and 2022, both basic and diluted net loss per share are computed by dividing net loss by the weighted-average number of common shares outstanding for the period. With net losses the inclusion of any potential securities is antidilutive, accordingly, basic and diluted net loss per share are the same in periods with losses.

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,		
	2024	2023	2022
Net loss	$ (117,688)	$ (29,655)	$ (74,286)
Weighted-average number of common shares outstanding (basic)	24,388	24,091	23,868
Dilutive securities	—	—	—
Weighted-average common and common equivalent shares outstanding (diluted)	24,388	24,091	23,868
EPS — basic	$ (4.83)	$ (1.23)	$ (3.11)
EPS — diluted	$ (4.83)	$ (1.23)	$ (3.11)
Total anti-dilutive stock options and restricted stock awards (*shares in thousands)*	42	129	141

New Accounting Pronouncements

Recently Issued Accounting Standards Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06, Disclosure Improvements - Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. The amendments in this update modify the disclosure or presentation requirements of a variety of Topics in the Accounting Standards Codification ("ASC") in response to the SEC's Release No. 33-10532, Disclosure Update and Simplification Initiative, and align the ASC's requirements with the SEC's regulations. For entities within the scope, the guidance will be applied prospectively with the effective date for each amendment to be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. If the SEC has not removed the related disclosure from its regulations by June 30, 2027, the amendments will be removed from the Codification and will not become effective. We are currently assessing what impact this guidance will have on the Company's consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The amendments in this update expand disclosures in an entity's income tax rate reconciliation table and regarding cash taxes paid information. The update will be effective for annual periods beginning after December 15, 2024 and is applicable to our Annual Report on Form 10-K for the fiscal year December 31, 2025, with early application permitted. We are currently assessing the effect of this update on our consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses. The guidance requires disclosure of disaggregated income statement expense information about specific categories (including purchases of inventory, employee compensation, depreciation, and intangible asset amortization) in the notes to financial statements. In January 2025, FASB released ASU 2025-01 to clarify the guidance will be effective for annual periods beginning after December 15, 2026. This update will be applicable to our Annual Report on Form 10-K for the fiscal year December 31, 2027, with early application permitted. We are currently assessing the effect of this update on our consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update (ASU) 2023-07 "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," which requires the Company to expand the breadth and frequency of segment disclosures to include additional information about significant segment expenses, the chief operating decision maker (CODM) and other items, and also require the annual disclosures on an interim basis. This guidance was effective for annual periods beginning with the Company's fiscal year 2024, and in interim periods within the Company's fiscal year 2025. The Company adopted the requirements of this ASU in Note 6, Segment Data of this Annual Report.

NOTE 2. ACQUISITIONS

2022 Acquisitions

On January 6, 2022, we acquired 100% of the equity interests in Smiths Medical, the holding company of Smiths Group plc's global medical device business, from Smiths Group International Holdings Limited (“Smiths”). The acquisition of Smiths Medical aligns with our strategic growth plans, enabling us to broaden our product offerings to include syringe and ambulatory infusion devices, vascular access, and vital care products and to strengthen and expand our global market reach.

Total cash consideration for the acquisition was $1.9 billion, which was financed with existing cash balances and proceeds from the credit agreement entered into on January 6, 2022 (see Note 13: Long-Term Obligations). We also issued share consideration to Smiths of 2.5 million shares of our common stock. The fair value of the shares of common stock issued to Smiths was determined based on the opening market price of our common stock on the acquisition date. Smiths may be entitled to an additional $100.0 million in cash consideration contingent on our common stock achieving certain price targets for certain periods after closing in accordance with the terms of the Share Sale and Purchase Agreement (the "Purchase Agreement"). In the event that (a) on or prior to the third anniversary of closing the 30-day volume-weighted average price for our common stock, as defined in the Purchase Agreement, equals or exceeds $300.00 per share or (b) on or prior to the fourth anniversary of closing the 45-day volume-weighted average price for our common stock, as defined in the Purchase Agreement, equals or exceeds $300.00 per share (each a "Price Target"), and provided Smiths beneficially owns at least 50.0% of the shares of common stock issued at closing at the time the Price Target is achieved, then Smiths will be entitled to receive the additional $100.0 million in cash consideration. The fair value of the contingent consideration was determined using an option pricing model, specifically the Monte Carlo Simulation. In the analysis, the determinants of payout are simulated in a risk neutral framework over a large number of simulation paths. The fair value of the contingent consideration is then calculated as the average present value across all simulated paths. During July 2024, Smiths sold 1.2 million shares of common stock of ICU Medical, Inc. which were issued as partial consideration for the 2022 acquisition of Smiths Medical. The sale of shares when combined with other sales in prior periods rendered Smiths unable to achieve the contingent consideration based on certain price targets during the third and fourth anniversary of closing as Smiths no longer meets the required minimum beneficial ownership percentage. Accordingly, the valuation of the contingent earn-out liability as of December 31, 2024 has been reduced to zero.

Smiths became a related party to us when we issued 2.5 million shares of our common stock as partial consideration for the acquisition of Smiths Medical. Additionally, we entered in to a transition services agreement ("TSA") with certain members of Smiths Group, plc. The TSA includes certain information technology, human resource and tax support services for an initial term of twelve months with the option to extend up to 24 months. In 2023, we expensed $8.3 million for services provided by Smiths under the TSA. Since December 31, 2023, there were no services being provided under the TSA and we had no remaining related-party open payables as of December 31, 2023.

Final Price Allocation

The following table summarizes the final purchase price and the final allocation of the purchase price related to the assets acquired and liabilities assumed (in thousands):

Cash consideration for acquired assets	$	1,922,955
Fair value of contingent consideration payable to Smiths		53,520
Issuance of ICU Medical, Inc. common shares:		
Number of shares issued to Smiths		2,500
Price per share (ICU's opening market price on the acquisition date)	$	230.39
Fair value of ICU shares issued to Smiths	$	575,975
Total Consideration	$	2,552,450
Purchase Price Allocation		
Cash and cash equivalents	$	78,791
Accounts receivables		106,132
Inventories		228,919
Prepaid expenses and other current assets		53,554
Property, plant and equipment		206,333
Operating lease right-of-use assets		55,161
Intangible assets[(1)]		945,000
Other assets		379
Accounts payable		(105,291)
Accrued liabilities[(2)]		(173,151)
Income tax payable		(40,312)
Other long-term liabilities		(85,490)
Deferred income taxes		(187,455)
Total identifiable net assets acquired	$	1,082,570
Goodwill - not tax deductible		1,469,880
Purchase Consideration	$	2,552,450

(1) Identifiable intangible assets included $510.0 million of customer relationships, $400.0 million of developed technology, $30.0 million of internally developed software, and $5.0 million of trade mark. The estimated weighted-average amortization period for the total identifiable intangible assets is approximately nine years, and, for each identifiable intangible asset is estimated as follows: eight years for customer relationships, ten years for developed technology, five years for internally developed software, and six months for the trademark.

(2) Accrued liabilities includes, among other things, accrued warranty reserves, accrued restructuring initiatives, accrued salaries and related benefits, deferred revenue and accrued sales and use taxes.

The identifiable intangible assets and other long-lived assets acquired have been valued utilizing Level 3 inputs as defined in Note 10: Fair Value Measurements. The fair value of identifiable intangible assets were generally developed using the income approach and are based on critical estimates, judgments and assumptions derived from: analysis of market conditions; discount rate; discounted cash flows; royalty rates; customer retention rates; and/or estimated useful lives. Certain other intangible assets were valued using a cost to replace method, estimating the labor and non-labor costs required to replace the asset under the premise that it was not part of the transaction. Property, plant and equipment was valued with the consideration of remaining economic lives. The raw materials inventory was valued at historical cost and adjusted for any obsolescence which we estimate to approximate replacement cost, the work in process inventory was valued at estimated sales proceeds less costs to complete and costs to sell, and finished goods inventory was valued at estimated sales proceeds less costs to sell. The prepaid expenses and other current assets and assumed liabilities were recorded at their carrying values as of the date of the acquisition, as their carrying values approximated their fair values due to their short-term nature.

Unaudited Pro Forma Information

Smiths Medical is included in our consolidated results beginning on January 7, 2022. Total revenues and net loss attributable to Smiths Medical for the period from January 7, 2022 to December 31, 2022 were $950.7 million and $(74.3) million, respectively. The net loss figure is an estimate as the results by company are less identifiable due to integration. The following unaudited pro forma financial information presents the combined results of operations of ICU and Smiths Medical as if the acquisition had occurred on January 1, 2021. The pro forma financial information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place on the date indicated or of results that may occur in the future.

(In thousands)	Twelve months ended December 31, 2022
Revenues	$ 2,300,371
Net (Loss) Income	$ (70,286)

The unaudited pro forma results presented above include the impact of the following adjustments: incremental amortization expense on intangible assets acquired of $1.9 million for the twelve months ended December 31, 2022, and incremental interest expense, including amortization of debt discount and debt issuance costs, on the Credit Facilities of $1.2 million for the twelve months ended December 31, 2022. The unaudited pro forma results include IFRS to U.S. GAAP adjustments for Smiths Medical historical results and adjustments for accounting policy alignment, which were materially similar to the Company. Any differences in accounting policies were adjusted to reflect the accounting policies of the Company in the unaudited pro forma results presented.

NOTE 3. RESTRUCTURING, STRATEGIC TRANSACTION AND INTEGRATION

Restructuring, strategic transaction and integration expenses were $59.8 million, $41.3 million and $71.4 million in 2024, 2023 and 2022, respectively.

Restructuring

Restructuring charges net of any reversed accruals were $19.6 million, $5.7 million and $9.7 million in 2024, 2023 and 2022, respectively, and are included in the above restructuring, strategic transaction and integration expenses in our consolidated statement of operations.

In 2024, we incurred restructuring charges primarily related to severance expenses. We adjusted certain severance restructuring accrued balances, shown in the table below under "Other adjustments", as a result of merging Smiths Medical entities during 2024.

In 2023, we incurred restructuring charges primarily related to severance expenses. We adjusted certain facility and severance restructuring accrued balances, shown in the table below under "Other adjustments", to reverse certain accrued balances that will not be utilized.

In 2022, we incurred restructuring charges primarily related to severance in connection with the January 6, 2022 acquisition of Smiths Medical, see Note 2: Acquisitions.

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

	Severance Pay and Benefits	Retention and Facility Closure Costs	Total
Accrued balance, January 1, 2023	$ 4,416	$ 1,507	$ 5,923
Charges incurred	5,521	1,189	6,710
Payments	(6,694)	(1,192)	(7,886)
Other adjustments[(1)]	(234)	(785)	(1,019)
Currency translation	(198)	38	(160)
Accrued balance, December 31, 2023	$ 2,811	$ 757	$ 3,568
Charges incurred	18,299	1,272	19,571
Payments	(11,687)	(1,632)	(13,319)
Other adjustments[(2)]	327	—	327
Currency translation	(212)	10	(202)
Accrued balance, December 31, 2024	$ 9,538	$ 407	$ 9,945

(1) Relates to accrued restructuring charges for estimated facility closure costs and severance costs that will not be utilized and were reversed during the year.

(2) Relates to adjustments to accrued restructuring charges as a result of merging Smiths Medical entities during 2024.

Strategic Transaction and Integration Expenses

We incurred $40.2 million, $35.6 million and $61.7 million in strategic transaction and integration expenses in 2024, 2023 and 2022, respectively, which are included in restructuring, strategic transaction and integration expenses in our consolidated statement of operations. The strategic transaction and integration expenses during 2024 and 2023 were primarily related to consulting expenses and employee costs incurred to integrate our Smiths Medical business acquired in 2022. The strategic transaction and integration expenses during 2022 were primarily related to transaction and integration expenses associated with our acquisition of Smiths Medical on January 6, 2022 (see Note 2: Acquisitions) which primarily included legal expenses, bank fees, employee costs and a United Kingdom stamp tax.

NOTE 4: ASSETS HELD FOR SALE

On November 12, 2024, the Company and ICU Medical Sales, Inc., a Delaware corporation (collectively, the "ICU Medical Entities") entered into a purchase agreement (the "Agreement") with Otsuka Pharmaceutical Factory America, Inc., a Delaware corporation ("OPF"). Pursuant to the Agreement, prior to the closing, the ICU Medical Entities will form a Delaware limited liability company (the "LLC") and the ICU Medical Entities, and the LLC shall enter into a contribution agreement under which the ICU Medical Entities shall transfer the assets, liabilities and operations that comprise the IV Solutions product line to the LLC. At the closing, OPF will acquire a 60% equity interest in the LLC from the ICU Medical Entities. Pursuant to the Agreement, the consideration receivable by the ICU Medical Entities is comprised of (a) estimated cash consideration of approximately $200 million at closing and (b) a milestone payment paid by OPF to the Company for any incremental revenue and incremental gross profit recognized by the LLC, as calculated under the terms of the Agreement upon the final determination of the LLC's audited financial statements for the year-ending and as of December 31, 2026. Additionally, at closing, the LLC, ICU Medical Entities and OPF shall enter into an operating agreement, and the LLC and the Company shall enter into one or more commercial agreements, a services agreement and a license agreement, which will provide for, among other things, certain administrative, marketing, distribution, sales support and logistic services to the LLC for a specified period of time. The transaction is expected to be completed during the second quarter of 2025. Based upon initial estimates, no impairment in the assets held for sale was identified and the expected gain from the sale will be recognized upon close of the transaction.

As of December 31, 2024, certain presentation criteria were met (see Note:1 Basis of Presentation and Significant Accounting Policies-*Assets Held For Sale),* accordingly we presented certain IV Solutions assets and liabilities as held for sale.

The following table summarizes the carrying values of the assets and liabilities presented as held for sale in our consolidated balances sheet as of December 31, 2024 (in thousands):

Assets:	**2024**
Accounts receivable, net of allowance of $465 at December 31, 2024	$ 13,331
Inventories	88,656
Prepaid expenses and other current assets	4,140
Property, plant and equipment, net	155,426
Other assets	22,829
Total assets held for sale	$ 284,382
Liabilities:	
Accounts payable	$ 13,533
Accrued liabilities	19,378
Total liabilities held for sale	$ 32,911
Net assets held for sale	$ 251,471

NOTE 5: REVENUE

Revenue Recognition

Our business units are Consumables, Infusion Systems and Vital Care. The vast majority of our sales of these products within these business units 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. 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 include variable consideration in net sales only to the extent that a significant reversal in revenue is not probable when the uncertainty is resolved. Our variable consideration includes distributor chargebacks, product returns and end customer rebates with distributor chargebacks representing the majority and subject to the greatest judgment, (see Note 1: Basis of Presentation and Significant Accounting Policies).

We also offer certain volume-based rebates to both our distribution and end customers, which is recorded 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, including current contractual requirements, our historical experience with each customer and forecasted customer purchasing patterns, to estimate the most likely rebate amount. We also warrant products against defects and have a policy permitting the return of defective products. 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. See Note 1. Basis of Presentation and Significant Accounting Policies for further discussion.

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,					
	2024		2023		2022	
Product line	**Revenue**	**% of Revenue**	**Revenue**	**% of Revenue**	**Revenue**	**% of Revenue**
Consumables	$ 1,038,869	44 %	$ 969,129	43 %	$ 974,993	43 %
Infusion Systems	652,410	27 %	629,043	28 %	617,435	27 %
Vital Care	690,767	29 %	660,954	29 %	687,569	30 %
Total Revenues	$ 2,382,046	100 %	$ 2,259,126	100 %	$ 2,279,997	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	**2024**	**2023**	**2022**
United States	$ 1,532,104	$ 1,440,017	$ 1,460,069
Europe, the Middle East and Africa	393,530	373,571	367,411
Asia-Pacific	232,820	241,699	257,208
Other Foreign	223,592	203,839	195,309
Total Revenues	$ 2,382,046	$ 2,259,126	$ 2,279,997

Domestic sales accounted for 64%, 64% and 64% of total revenue in 2024, 2023 and 2022, respectively. International sales accounted for 36%, 36% and 36% of total revenue in 2024, 2023 and 2022, 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 12: Accrued Liabilities and Other Long-term Liabilities). The following table presents the changes in our contract balances for the years ended December 31, 2024 and 2023, (in thousands):

	Contract Liabilities
Beginning balance, January 1, 2023	$ 45,866
Equipment revenue recognized	(34,121)
Equipment revenue deferred due to implementation	35,868
Software revenue recognized	(18,526)
Software revenue deferred due to implementation	19,947
Government grant income recognized[(1)]	(3,684)
Government grant income deferred	944
Other deferred revenue recognized	(6,041)
Other deferred revenue	1,924
Ending balance, December 31, 2023	42,177
Equipment revenue recognized	(56,182)
Equipment revenue deferred due to implementation	55,932
Software revenue recognized	(28,292)
Software revenue deferred due to implementation	29,913
Government grant income recognized[(1)]	(2,072)
Government grant income deferred	—
Other deferred revenue recognized	(2,576)
Other deferred revenue	503
Ending balance, December 31, 2024	$ 39,403

[(1)] The government grant income deferred is amortized over the life of the related depreciable asset as a reduction to depreciation expense.

During 2024, we recognized $26.0 million in revenue that was included in the opening contract balances as of December 31, 2023.

As of December 31, 2024, revenue from remaining performance obligations is as follows (in thousands):

	Recognition Timing	
	<12 Months	> 12 Months
Equipment revenue	$ 17,050	$ 1,231
Software revenue	11,214	471
Government grant deferred income[1]	2,064	7,343
Other deferred revenue[2]	30	—
Total	$ 30,358	$ 9,045

(1) The government grant deferred income is amortized over the life of the related depreciable asset as a reduction to depreciation expense.

(2) Other deferred revenue includes pump development programs, purchased training and extended warranty.

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 6. SEGMENT DATA

The Company has a single operating and reportable segment. The segment is organized by and derives revenues from the manufacture and sale of our medical products which are used in infusion therapy, vascular access, and vital care applications. Our product portfolio includes ambulatory, syringe, and large volume IV pumps and safety software; dedicated and non-dedicated IV sets, needlefree IV connectors, IV catheters, sharps safety products, and sterile IV solutions; closed system transfer devices and pharmacy compounding systems; as well as a range of respiratory, anesthesia, patient monitoring, and temperature management products. Our product lines, as disclosed in Note 5: Revenue, were determined to be a single operating segment as discrete financial information by product-line is limited to revenue and standard cost. Other cost of sale expenses, which include above-site manufacturing costs, manufacturing variances and supply chain costs including freight and warehousing are not allocated to individual product lines. Similarly, quality, regulatory and other operating expenses are only provided to our chief operating decision maker ("CODM") at the consolidated level.

The accounting policies of our single reportable segment are the same as those described in Note 1: Basis of Presentation and Significant Accounting Policies.

For information on disaggregation of revenues by product-line and geography, see Note 5: Revenue.

Our chief executive officer is our CODM. Our CODM uses net profit (loss) to manage our business activities on a consolidated basis and to evaluate and assess the performance of the Company when determining how to allocate capital resources. Our segment performance is monitored and resource allocation is determined during the annual budget/forecast processes. The measure of segment assets is reported on the consolidated balance sheets as total assets. In 2024, 2023 and 2022, expenditures for additions to long-lived assets were $90.2 million, $93.7 million, and $99.3 million, respectively.

The following table presents information about our segment revenue, segment profit or loss, and significant segment expenses (in thousands):

	Year ended December 31,		
	2024	2023	2022
REVENUES	$ 2,382,046	$ 2,259,126	$ 2,279,997
Less:			
Standard COGS[1]	1,193,994	1,114,294	1,052,455
Quality remediation/recall[2]	19,126	58,243	70,036
Other COGS[3]	344,144	346,716	459,745
Selling, general and administrative	638,762	606,693	608,345
Research and development	88,615	85,344	92,984
Restructuring and integration	59,840	41,258	71,421
Other segment items[4]	(2,964)	(17,850)	(31,385)
Interest expense	106,541	102,727	70,805
Income tax provision (benefit)	51,676	(48,644)	(40,123)
Consolidated net loss	$ (117,688)	$ (29,655)	$ (74,286)

[1] Represents the average annual budgeted cost of producing each good sold in the period.
[2] Represents significant labor and material costs to replace or repair a product outside the scope of standard warranty and compliance costs related to quality systems and manufacturing operations.
[3] Includes costs related to capitalized manufacturing variances to standard COGS, supply chain and logistics costs including freight, inventory management and reserves, hardware service, quality and regulatory, and operations and supply chain management costs.
[4] Includes changes in fair value of contingent earn-out, interest income, gain/loss on disposition of assets, gain/loss on foreign exchange, other miscellaneous income/expense and equity in the income of equity method investees.

For information on depreciation and amortization expense, see Note 1: Basis of Presentation and Significant Accounting Policies.

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 end customers. The manufacturers and distributors, in turn, sell our products to healthcare providers. In 2024, 2023 and 2022, we had net sales to a single distributor of 18%, 16% and 15%, respectively of consolidated worldwide net sales.

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,	
	2024	2023
Costa Rica	$ 156,149	$ 143,380
Mexico	111,043	110,124
Other LATAM	55,451	47,564
Canada	5,284	5,694
Italy	29,124	28,201
Spain	17,141	21,921
Czech Republic	11,909	12,256
Other Europe	11,445	11,440
APAC	27,550	22,966
Total Foreign	$ 425,096	$ 403,546
United States*	610,547	833,251
Worldwide Total	$ 1,035,643	$ 1,236,797

*During the fourth quarter of 2024, we presented within the assets held for sale line item in our consolidated balance sheet, the gross long-lived assets that were part of a disposal group that met the criteria as held for sale during the fourth quarter (See Note 4: Assets Held For Sale).

NOTE 7. 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, manufacturing and distribution facilities, 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 because we determined 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,		
	2024	2023	2022
Operating lease cost	$ 22,037	$ 24,024	$ 22,038
Finance lease cost — interest	182	125	112
Finance lease cost — reduction of ROU asset	1,158	1,035	712
Short-term lease cost	9	29	7
Total lease cost	$ 23,386	$ 25,213	$ 22,869

Interest expense on our finance leases is included in interest expense, net in our consolidated statements of operations. The reduction of the operating and finance ROU assets is included as noncash lease expense in costs of goods sold and 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,		
	2024	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 24,251	$ 24,604	$ 25,225
Operating cash flows from finance leases	$ 182	$ 125	$ 112
Right-of-use assets obtained in exchange for lease obligations:			
Operating leases	$ 12,580	$ 15,873	$ 5,994
Finance leases	$ 1,809	$ 1,028	$ 715

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,	
	2024	2023
Operating leases		
Operating lease right-of-use assets	$ 53,295	$ 69,909
Accrued liabilities	$ 15,695	$ 20,161
Other long-term liabilities	40,777	52,972
Total operating lease liabilities	$ 56,472	$ 73,133
Weighted-Average Remaining Lease Term		
Operating leases	5.8 years	5.6 years
Weighted-Average Discount Rate		
Operating leases	4.90 %	4.31 %

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,	
	2024	2023
Finance leases		
Other assets	$ 3,259	$ 2,707
Accrued liabilities	$ 1,066	$ 860
Other long-term liabilities	2,332	1,954
Total finance lease liabilities	$ 3,398	$ 2,814
Weighted-Average Remaining Lease Term		
Finance leases	3.5 years	4.1 years
Weighted-Average Discount Rate		
Finance leases	5.63 %	4.93 %

As of December 31, 2024, the maturities of our operating and finance lease liabilities for each of the next five years are approximately (in thousands):

	Operating Leases	Finance Leases
2025	$ 17,996	$ 1,215
2026	13,506	1,104
2027	9,093	759
2028	6,612	420
2029	5,280	197
Thereafter	11,620	47
Total Lease Payments	64,107	3,742
Less imputed interest	(7,635)	(344)
Total	$ 56,472	$ 3,398

NOTE 8. SHARE-BASED AWARDS

We have a stock incentive plan for employees and directors and an employee stock purchase plan; however, the employee stock purchase plan was suspended in 2017. 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") and performance restricted stock units ("PRSU"). 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 had 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):

	Year ended December 31,		
	2024	2023	2022
Stock compensation expense	$ 46,883	$ 40,563	$ 36,025
Tax benefit from stock-based compensation cost	$ 5,524	$ 5,379	$ 4,636
Indirect tax benefit	$ —	$ —	$ 749

As of December 31, 2024, we had $55.3 million of unamortized stock compensation cost which we will recognize as an expense over a weighted-average period of approximately 0.7 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 years 2012, 2014, 2017 and 2023, our stockholders approved amendments to the 2011 plan that increased the shares available for issuance by a total of 5,461,000, bringing the initial shares available for issuance to 6,111,000, plus the remaining 248,700 shares that remained available for grant from the 2003 Plan. As of December 31, 2024, the 2011 Plan has 6,374,300 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 and shares in thousands, except per option amounts):

	Year ended December 31, 2022
Number of time-based options granted	7,620
Grant-date fair value of options granted	$ 540
Weighted-average assumptions for stock option valuation:	
Expected term (years)	5.5
Expected stock price volatility	36.0 %
Risk-free interest rate	3.0 %
Expected dividend yield	— %
Weighted-average grant-price per option	$ 185.79
Weighted-average grant-date fair value per option	$ 70.86

There were no stock options granted during the years ended December 31, 2024 and 2023.

A summary of our stock option activity as of and for the year ended December 31, 2024 is as follows:

	Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	459,828	$ 82.95		
Granted	—	$ —		
Exercised	(351,688)	$ 66.61		
Forfeited or expired	—	$ —		
Outstanding at December 31, 2024	108,140	$ 136.12	2.21	$ 3,963
Exercisable at December 31, 2024	108,140	$ 136.12	2.21	$ 3,963
Vested and expected to vest, December 31, 2024	108,140	$ 136.12	2.21	$ 3,963

The intrinsic values for options exercisable, outstanding and vested or expected to vest at December 31, 2024 are based on our closing stock price of $155.17 at December 31, 2024 and are before applicable taxes.

The following table presents information regarding stock option activity (in thousands):

	Year ended December 31,		
	2024	2023	2022
Intrinsic value of options exercised	$ 18,651	$ 8,441	$ 17,340
Cash received from exercise of stock options	$ 10,939	$ 4,022	$ 8,785
Tax benefit from stock option exercises	$ 1,034	$ 1,733	$ 3,637

Stock Awards

In 2024, we granted PRSUs to our executive officers and certain other non-executive employees. The PRSUs will cliff-vest on March 8, 2026, subject to continued service through such vesting date and the achievement of minimum two-year cumulative adjusted EBITDA, commencing on January 1, 2024 and ending on December 31, 2025, which when reviewed against a predetermined vesting matrix could result in the vesting of 0% to 250% of the awarded PRSUs. We also granted certain other one-off PRSU awards to non-executive employees with various performance requirements, whereby the PRSUs will be earned if the minimum requirements are met.

In 2023, we granted PRSUs to our executive officers. For the executive officers other than the CEO, COO, CFO and the CVP, GC, the PRSUs will vest as to one-third of the total number of PRSUs underlying the award on the first, second and third anniversaries of the applicable grant date, subject to a determination by the CEO and Compensation Committee that the officers have met their individual performance goals for the applicable year and continued service through such vesting date. For the CEO, COO, the CFO, and the CVP, GC, the PRSUs will cliff-vest on March 15, 2026, subject to continued service through such vesting date and the achievement of minimum three-year adjusted revenue and adjusted EBITDA compound annual growth rates, commencing on January 1, 2023 and ending on December 31, 2025, which when reviewed against a predetermined vesting matrix could result in the vesting of 0% to 250% of the awarded PRSUs. In February 2024, the Compensation Committee made the determination that the executive officers other than the CEO, CFO, COO and CVP, GC met their individual performance goals for 2023 with respect to the PRSUs subject to annual vesting, as outlined above, and therefore one-third of their 2023 PRSUs vested during 2024.

In 2022, we granted our annual PRSUs to our executive officers and certain other non-executive employees. These PRSUs cliff-vested on March 7, 2024, subject to continued service through such vesting date and the achievement of net synergy savings targets related to the Smiths Medical acquisition achieved during the performance period commencing on January 1, 2022 and ending on December 31, 2023, which when reviewed against predetermined targets could have resulted in the vesting of 0% to 200% of the awarded PRSUs. We also granted certain other one-off PRSU awards to non-executive employees with various performance requirements, whereby the PRSUs will be earned if the minimum requirements are met within a specified time period. The performance period related to the annual 2022 PRSUs ended on December 31, 2023 and in

February 2024 the Compensation Committee determined that 200% of the PRSUs awarded were earned based on the actual net synergy savings related to the Smiths Medical acquisition achieved during the performance period.

In 2021, we granted PRSUs to our executive officers. For the executive officers other than the CEO, COO and the CFO, the PRSUs vested as to one-third of the total number of PRSUs underlying the award on the first, second and third anniversaries of the applicable grant date, subject to a determination by the CEO and Compensation Committee that the officers had met their individual performance goals for the applicable years and continued service through such vesting date. In February 2022, 2023 and 2024, the Compensation Committee made the determination that the executive officers other than the CEO, CFO and COO met their individual performance goals for 2021, 2022 and 2023, respectively, and therefore one-third of their 2021 PRSUs vested during each of 2022, 2023 and 2024. For the CEO, COO and the CFO, the PRSUs cliff-vested on March 8, 2024, subject to continued service through such vesting date and the achievement of minimum three-year cumulative adjusted revenue dollar target growth rate and adjusted EPS dollar target growth rate targets, commencing on January 1, 2021 and ending on December 31, 2023, which when reviewed against a predetermined vesting matrix could have resulted in the vesting of 0% to 250% of the awarded PRSUs. The performance period related to the 2021 CEO, COO and CFO PRSUs ended on December 31, 2023 and in February 2024 the Compensation Committee determined that 110% of the awarded PRSUs were earned based on the actual cumulative adjusted revenue dollar target growth rate and adjusted EPS dollar target growth rate achieved during the performance period.

In 2020, we granted PRSUs to our executive officers. For the executive officers other than the CEO, COO and the CFO, the PRSUs vested as to one-third of the total number of PRSUs underlying the award on the first, second and third anniversaries of the applicable grant date, subject to a determination by the CEO and Compensation Committee that the officers had met their individual performance goals for the applicable years and continued service through such vesting date. In February 2021, 2022, and 2023, the Compensation Committee made the determination that the executive officers other than the CEO, CFO and COO met their individual performance goals for 2021, 2022 and 2023, respectively, and therefore one-third of their 2020 PRSUs awarded vested during 2021, 2022 and 2023. For the CEO, COO and the CFO, the PRSUs cliff-vested on March 6, 2023, subject to continued service through such vesting date and the achievement of minimum three-year cumulative adjusted revenue dollar target growth rate and adjusted EPS dollar target growth rate targets, which when reviewed against a predetermined vesting matrix such PRSUs originally had the potential to vest from 0% to 250% of the awarded PRSUs. 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 awarded PRSUs, to an increased potential to earn between 50% and 300% of the award granted, subject to the same minimum threshold revenue and EPS targets set forth above 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. The performance period related to the 2020 CEO, COO and CFO PRSUs ended on December 31, 2022 and in February 2023 the Compensation Committee determined that 188% of the awarded PRSUs were earned based on the actual cumulative adjusted revenue dollar growth rate and adjusted EPS dollar target growth rate achieved during the performance period.

In 2019, we granted PRSUs to our executive officers. For the executive officers other than the CEO and the COO, the PRSUs vested as to one-third of the total number of PRSUs underlying the award on the first, second and third anniversaries of the applicable grant date, subject to a determination by the CEO and Compensation Committee that the officers had met their individual performance goals for the applicable years and continued service through such vesting date. In February 2020, 2021 and 2022, the Compensation Committee made the determination that the executive officers other than the CEO and COO met their individual performance goals for 2019, 2020 and 2021, respectively, and therefore one-third of their 2019 PRSUs awarded vested during 2020, 2021 and 2022. For the CEO and the COO, the PRSUs were to cliff-vest on March 6, 2022, subject to continued service through such vesting date and the achievement of a minimum Cumulative Adjusted EBITDA growth target over the performance period. If, for the three-year period ending on December 31, 2021, the Cumulative Adjusted EBITDA had a growth of at least 6% to 8%, 50% of the awarded PRSUs would have vested. If, on the vesting date, the Cumulative Adjusted EBITDA had a growth of between 8% to 10%, 100% of the awarded PRSUs would have vested. If, on the vesting date, the Cumulative Adjusted EBITDA had a growth of over 10%, 200% of the awarded PRSUs would have vested. The performance period related to the 2019 CEO and COO PRSUs ended on December 31, 2021 and in February 2022 the Compensation Committee determined that zero PRSUs were earned based on the actual Cumulative Adjusted EBITDA growth achieved during the performance period. In 2019, we also granted PRSUs to one of our non-executive employees. These PRSUs vested at the end of a three-year period ending on March 31, 2022, based on meeting certain minimum performance goals.

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

In 2024, 2023 and 2022, we granted RSUs to certain employees that typically vest ratably on the anniversary of the grant over three years. We recognize forfeitures as they occur.

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

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

	Year ended December 31,		
	2024	2023	2022
PRSU			
Shares granted	150,218	78,213	60,383
Shares earned [1]	142,735	49,314	46,317
Grant-date fair value per share	$ 104.52	$ 190.02	$ 230.31
Grant-date fair value	$ 15,701	$ 14,862	$ 13,907
Intrinsic value vested	$ 15,145	$ 8,024	$ 10,487
RSU			
Shares granted	223,899	156,111	116,870
Grant-date fair value per share	$ 105.94	$ 173.10	$ 221.65
Grant-date fair value	$ 23,721	$ 27,024	$ 25,905
Intrinsic value vested	$ 11,963	$ 14,179	$ 16,438

(1) PRSU shares earned in 2024 were related to performance awards granted to executives and certain other employees in 2021, 2022 and 2023. PRSU shares earned in 2023 were related to performance awards granted to executives in 2020 and 2021 and performance awards granted to a non-executive employees in 2022. PRSU shares earned in 2022 were related to performance awards granted to executives in 2019, 2020 and 2021 and performance award granted to a non-executive employee in 2019, 2020, and 2021.

The table below provides a summary of our PRSU and RSU activity as of and for the year ended December 31, 2024:

	Number of Units	Grant-Date Fair Value Per Share	Weighted-Average Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Non-vested at December 31, 2023	448,601	$ 199.68		
Change in units due to performance expectations [1]	2,081	$ 198.05		
Granted	374,117	$ 105.37		
Vested	(258,756)	$ 207.72		
Forfeited	(15,032)	$ 140.87		
Non-vested and expected to vest at December 31, 2024	551,011	$ 133.47	1.0	$ 85,500

(1) Relates to adjustments to 2021 PRSUs granted to executives that vested during 2024.

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 were 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. 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. All shares unissued under the plan expired during 2022.

NOTE 9. 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 revenues and 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 2022. 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 derivative instruments we utilize, including various foreign exchange contracts and 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 (loss) income 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

Foreign Exchange Forward Contracts

We enter into foreign exchange forward contracts to hedge a portion of our forecasted foreign currency-denominated revenues and expenses to minimize the effect of foreign exchange rate movements on the related cash flows. These contracts are agreements to buy or sell a quantity of a currency at a predetermined future date and at a predetermined exchange rate. Our current foreign exchange forward contracts hedge exposures principally denominated in Mexican Pesos ("MXN"), Euros, Japanese Yen ("JPY"), Chinese Renminbi ("CNH"), Canadian Dollar ("CAD"), U.S. Dollar ("USD") and Australian Dollar ("AUD") and have varying maturities with an average term of approximately eleven months. The total notional amount of these outstanding derivative contracts as of December 31, 2024 was $112.5 million, which included the notional equivalent of $53.4 million in MXN, $6.9 million in Euros, $6.5 million in CAD, $6.4 million in AUD, $30.6 million in USD and $8.7 million in other foreign currencies, with terms currently through December 2025.

Cross-currency Par Forward Contracts

We entered into cross-currency par forward contracts to hedge a portion of our Mexico forecasted expenses denominated in MXN. These contracts are agreements to exchange cash flows from one currency to another at specified intervals over the contract term with all exchanges occurring at the same predetermined rate.

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 was December 1, 2021 to December 1, 2022. The derivative instrument matured in equal monthly amounts at a fixed forward rate of 21.60 MXN/USD.

Floating Interest Rate Risk

In 2022, we entered into interest rate swaps to reduce the interest rate volatility on our variable-rate term loan A and variable-rate term loan B (see Note 13: Long-Term Obligations). We exchange, at specified intervals, the difference between

fixed and floating interest amounts calculated by reference to an agreed-upon notional amount. Effective March 30, 2022, the term loan A swap, as amended, has an initial notional amount of $300.0 million, reducing to $150.0 million evenly on a quarterly basis through its final maturity on March 30, 2027. We pay a fixed rate of 1.32% and will receive the greater of 3-month USD SOFR or (0.15)%. The total notional amount of this outstanding derivative as of December 31, 2024 was approximately $213.2 million. Effective March 30, 2022, the term loan B swap, as amended, has an initial notional amount of $750.0 million, reducing to $46.9 million evenly on a quarterly basis through its final maturity on March 30, 2026. We pay a fixed rate of 1.17% and receive the greater of 3-month USD SOFR or 0.35%. The total notional amount of this outstanding derivative as of December 31, 2024 was approximately $234.4 million. In June 2023, we entered into an additional interest rate swap that hedges both term loan A and term loan B interest payments. The total notional amount of the swap is $300.0 million. The hedge matures on June 30, 2028. We pay a fixed rate of 3.88% and receive 3-months USD SOFR. These forward-starting swaps 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):

	Derivatives Designated as Cash Flow Hedging Instruments		
Consolidated Balance Sheet Location	**Foreign Exchange Forward Contracts**	**Interest Rate Swaps**	**Gross Derivatives**
As of December 31, 2024			
Prepaid expenses and other current assets	$ 6,716	$ 11,038	$ 17,754
Other assets	—	5,724	5,724
Total assets	$ 6,716	$ 16,762	$ 23,478
Accrued liabilities	$ 7,391	$ —	$ 7,391
Total liabilities	$ 7,391	$ —	$ 7,391

	Derivatives Designated as Cash Flow Hedging Instruments		
As of December 31, 2023	**Foreign Exchange Forward Contracts**	**Forward-Starting Interest Rate Swaps**	**Gross Derivatives**
Prepaid expenses and other current assets	$ 6,785	$ 23,065	$ 29,850
Other assets	673	4,876	5,549
Total assets	$ 7,458	$ 27,941	$ 35,399
Accrued liabilities	$ 2,590	$ —	$ 2,590
Other long-term liabilities	240	—	240
Total liabilities	$ 2,830	$ —	$ 2,830

The following table presents the effects of our derivative instruments designated as cash flow hedges on the Consolidated Statements of Operations (in thousands):

	Gain Reclassified From Accumulated Other Comprehensive (Loss) Income into Income			
	Location of Gain in the Consolidated Statements of Operations	Year Ended December 31,		
		2024	2023	2022
Derivatives designated as cash flow hedging instruments:				
Foreign exchange forward contracts	Total revenues	$ 2,981	$ 296	$ 3,829
Foreign exchange forward contracts	Cost of goods sold	91	7,852	7,751
Foreign exchange forward contracts	Other expense, net[(1)]	—	229	—
Foreign exchange forward contracts	Interest expense[(2)]	—	13	717
Interest rate swaps	Interest expense	27,132	32,444	6,122
Total derivatives designated as cash flow hedging instruments		$ 30,204	$ 40,834	$ 18,419

(1) Represents location of gain reclassified from accumulated other comprehensive (loss) income into other expense, net as a result of ineffectiveness.
(2) Represents location of gain reclassified from accumulated other comprehensive (loss) income into interest expense as a result of a forecasted transaction being no longer probable of occurring.

We recognized the following (losses) gains on our derivative instruments designated as cash flow hedges in other comprehensive loss before reclassifications to income (in thousands):

	Amount of Gain Recognized in Other Comprehensive Loss		
	Year Ended December 31,		
	2024	2023	2022
Derivatives designated as cash flow hedging instruments:			
Foreign exchange forward contracts	$ (1,912)	$ 10,788	$ 9,588
Interest rate swaps	15,954	5,200	62,786
Total derivatives designated as cash flow hedging instruments	$ 14,042	$ 15,988	$ 72,374

As of December 31, 2024, we expect an estimated $0.7 million in deferred losses on the outstanding foreign exchange forward contract and an estimated $11.4 million in deferred gains 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 (loss) income.

NOTE 10. 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 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 ended September 2024. The terms of the agreement included a contingent earn-out payment. The contingent earn-out payment could not exceed $6.0 million and was to 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. The estimated fair value of the contingent earn-out was calculated using a probability-weighted cash flow model based on historical revenue streams and the likelihood that the revenue targets will be met. As of December 31, 2023, the earn-out measurement period ended. The fair value of the contingent earn-out was determined to be $3.4 million and was paid out in the first quarter of 2024.

In 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 obtaining certain product-related regulatory certifications by May 26, 2024. As of December 31, 2022, the measurement period related to the contingent earn-out based on certain revenue targets ended and based on the actual revenue achieved during the measurement period, the fair value of the contingent earn-out was determined to be zero as the minimum threshold for earning the earn-out was not met. As of December 31, 2024, the earn-out measurement period related to certain product-related regulatory certifications had ended and the product-related regulatory certification had not been achieved, accordingly, the estimated fair value for the contingent consideration was reduced to zero.

In 2022, we acquired Smiths Medical with a combination of cash consideration and share consideration issued at closing. Total consideration for the acquisition included a potential earn-out payment of $100.0 million in cash contingent on our common stock achieving a certain volume-weighted average price (the "Price Targets") from the closing date to either the third or fourth anniversary of closing and provided Smiths beneficially owns at least 50.0% of the shares of common stock issued at closing at the time the Price Target is achieved. The initial estimated fair value of the earn-out was determined to be $53.5 million using a Monte Carlo simulation model. The model utilized several assumptions including volatility and the risk-free interest rate. The assumed volatility is based on the average of the historical volatility of our common stock price and the implied volatility of certain at-the-money traded options. The risk-free interest rate is equal to the yield on U.S. Treasury securities at constant maturity for the period commensurate with the term of the earn-out. At each reporting date subsequent to the acquisition, we remeasured the earn-out liability and recognized any changes in its fair value in our consolidated statements of operations. If the probability of achieving the Price Targets during their respective measurement periods was significantly greater than initially anticipated, the realization of an additional liability and related expense would have had a significant impact on our consolidated financial statements in the period recognized. As of December 31, 2023, the estimated fair value of the contingent earn-out was $4.0 million. During 2024, Smiths sold all of their remaining shares of common stock of ICU Medical, Inc. The sale of these shares rendered Smiths unable to achieve the contingent consideration based on certain price targets during the third and fourth anniversary of closing as Smiths no longer met the required minimum beneficial ownership percentage. Accordingly, the valuation of the contingent earn-out liability as of December 31, 2024 was zero.

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, 2024, 2023 and 2022 (in thousands):

	Earn-out Liability
Contingent earn-out liability, January 1, 2022	$ 2,589
Acquisition date fair value estimate of earn-out[(1)]	55,158
Change in fair value of contingent earn-out (included in income from operations as a separate line item)[(2)]	(32,091)
Currency translation	(84)
Contingent earn-out liability, December 31, 2022	25,572
Change in fair value of contingent earn-out (included in income from operations as a separate line item)[(3]	(16,247)
Other[(4)]	(496)
Transfer of Mediverse earn-out liability into Level 2[(5)]	(3,379)
Currency translation	41
Contingent earn-out liability, December 31, 2023	5,491
Change in fair value of contingent earn-out (included in income from operations as a separate line item)[(6)]	(5,399)
Currency translation	(92)
Contingent earn-out liability, December 31, 2024	$ —

(1) $53.5 million relates to our acquisition of Smiths Medical and $1.6 million relates to our acquisition of a small foreign infusions systems supplier in the fourth quarter of 2021 (see Note 2: Acquisitions).

(2) Primarily relates to the change in fair value of our Smiths Medical earn-out and an adjustment to reduce to zero a contingent earn-out issued as part of the 2021 acquisition of a small foreign infusion systems supplier. The contingent earn-out was not earned based on our determination that the threshold target was not met.

(3) Primarily relates to the change in fair value of our Smiths Medical earn-out.

(4) Primarily relates to the reclassification to accrued liabilities of a holdback liability not subject to unobservable inputs when determining the fair market value.

(5) The Mediverse earn-out was transferred out of Level 3 and into Level 2 in the fourth quarter of 2023 when the amount of the actual payment was known, and subsequently settled during first quarter of 2024.

(6) Relates to the change in fair value of our Smiths Medical earn-out and the earn-out with one of our small foreign infusion systems suppliers, both of which were written down to zero as of December 31, 2024.

The following table provides quantitative information about Level 3 inputs for fair value measurement of our earn-out liabilities related to Smiths Medical:

Smiths Medical Earn-out

Simulation Input	As of December 31, 2023
Volatility	47.00 %
Risk-Free Rate	4.18 %

Investments, Foreign Currency Contracts and Interest Rate Contracts

Our investments historically consist of corporate, government bonds and U.S. treasury securities. The fair value of our corporate and government bonds are estimated using observable market-based inputs such as quoted prices, interest rates and yield curves or Level 2 inputs. The fair value of our U.S. treasury securities are based on quoted market prices in active markets and are included in the Level 1 fair value hierarchy.

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 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 Mediverse earn-out liability described above, there were no transfers between levels in 2024 or 2023.

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, 2024			
	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:				
Foreign exchange forwards:				
Prepaid expenses and other current assets	$ 6,716	$ —	$ 6,716	$ —
Interest rate contracts:				
Prepaid expenses and other current assets	11,038	—	11,038	—
Other assets	5,724	—	5,724	—
Total Assets	$ 23,478	$ —	$ 23,478	$ —
Liabilities:				
Foreign exchange contracts:				
Accrued liabilities	$ 7,391	$ —	$ 7,391	$ —
Total Liabilities	$ 7,391	$ —	$ 7,391	$ —

	Fair value measurements as of December 31, 2023			
	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 corporate bonds	$ 501	$ —	$ 501	$ —
Foreign exchange forwards:				
Prepaid expenses and other current assets	6,785	—	6,785	—
Other assets	673	—	673	—
Interest rate contracts:				
Prepaid expenses and other current assets	23,065	—	23,065	—
Other assets	4,876	—	4,876	—
Total Assets	$ 35,900	$ —	$ 35,900	$ —
Liabilities:				
Contingent earn-out liability-ST	$ 4,879		$ 3,379	$ 1,500
Contingent earn-out liability - LT	3,991	$ —	—	$ 3,991
Foreign exchange contracts:				
Accrued liabilities	2,590	—	2,590	—
Other long-term liabilities	240	—	240	—
Total Liabilities	$ 11,700	$ —	$ 6,209	$ 5,491

NOTE 11. 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,	
	2024	2023
Other prepaid expenses and receivables*	$ 15,423	$ 17,833
Prepaid vendor expenses	1,889	1,309
Deferred costs	9,060	1,668
Prepaid insurance and property taxes*	10,284	9,547
VAT/GST receivable	4,445	2,748
Deferred tax charge	5,511	5,822
Foreign exchange forward contract	6,716	6,785
Interest rate contracts	11,038	23,065
Deposits*	1,207	1,196
Other	4,714	3,667
	$ 70,287	$ 73,640

*As of December 31, 2024, certain prepaid expense account balances that are part of a disposal group that met the criteria for assets held for sale during the fourth quarter of 2024 were combined with other disposal group assets and presented as a separate line item "Assets Held For Sale" in our consolidated balance sheet (See Note 4:Assets Held For Sale).

Other assets consist of the following (in thousands):

	As of December 31,	
	2024	2023
Pump lease receivables	$ 23,631	$ 30,627
Spare parts*	28,632	46,496
Equity method investments	3,038	3,120
Interest rate contracts	5,724	4,876
Deferred debt issuance costs	1,719	3,439
Finance lease right-of-use assets	3,259	2,707
Other	2,132	2,755
	$ 68,135	$ 94,020

*As of December 31, 2024, spare parts account balances that are part of a disposal group that met the criteria for assets held for sale during the fourth quarter of 2024 were combined with other disposal group assets and presented as a separate line item "Assets Held For Sale" in our consolidated balance sheet (See Note 4:Assets Held For Sale).

NOTE 12. ACCRUED LIABILITIES AND OTHER LONG-TERM LIABILITIES

Accrued liabilities consist of the following (in thousands):

	As of December 31,	
	2024	2023
Salaries and benefits	$ 60,815	$ 52,250
Incentive compensation	59,445	37,992
Operating lease liability-ST	15,695	20,161
Accrued professional fees	3,167	2,803
Field service corrective action[(1)]	32,844	30,281
Italy medical device payback provision[(2)]	23,937	23,176
Legal accrual	3,425	1,874
Accrued sales taxes	4,449	6,748
Warranties and returns	4,094	3,682
Deferred revenue	30,358	31,640
Accrued other taxes	4,564	3,024
Distribution fees	16,548	13,049
Accrued freight	13,206	17,215
Restructuring accrual	9,945	3,568
Foreign exchange contracts	7,391	2,590
Accrued audit fees	4,395	5,492
Defined benefit plan	3,111	2,575
Accrued interest	667	1,431
Other	8,867	8,664
	$ 306,923	$ 268,215

(1) Primarily includes field corrective actions associated with certain products in connection with a 2021 Warning Letter (as defined below) received by Smiths Medical from the FDA following an inspection of Smiths Medical's Oakdale, Minnesota Facility (see Note 16: Commitments and Contingencies for further details).

(2) Related to potential payments associated with the IMDP (as defined below) as a result of 2015 legislation enacted requiring medical device companies to make payments to the Italian government based on regional expenditure ceilings (see Note 16: Commitments and Contingencies for further details).

As of December 31, 2024, certain accrued liability account balances that are part of a disposal group that met the criteria for assets held for sale during the fourth quarter of 2024 were presented as a separate line item "Liabilities held for sale" in our consolidated balance sheet (See Note 4:Assets Held For Sale).

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

	As of December 31,	
	2024	2023
Operating lease liability-LT	$ 40,777	$ 52,972
Finance lease liability-LT	2,332	1,954
Deferred revenue	9,045	10,585
Benefits	3,830	4,207
Field service corrective action[1]	6,401	26,056
Accrued rent	618	841
Other	3,742	3,882
	$ 66,745	$ 100,497

(1) Primarily related to field corrective actions associated with certain products in connection with a 2021 Warning Letter (as defined below) received by Smiths Medical from the FDA following an inspection of Smiths Medical's Oakdale, Minnesota Facility (see Note 16: Commitments and Contingencies for further details).

NOTE 13. LONG-TERM OBLIGATIONS

2022 Credit Agreement

In 2022, in connection with 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”) for $2.2 billion of senior secured credit facilities. The senior secured credit facilities include (i) a five-year Tranche A term loan of $850.0 million (the "Term Loan A"), (ii) a seven-year Tranche B term loan of $850.0 million (the "Term Loan B") and (iii) a five-year revolving credit facility of $500.0 million (the "Revolving Credit Facility"), with separate sub-limits of $50.0 million for letters of credit and swingline loans (collectively, the "Senior Secured Credit Facilities"). We used the proceeds from borrowings under the Term Loan A and the Term Loan B (collectively, the "Term Loans") to fund a portion of the cash consideration for the purchase of Smiths Medical and the related fees and expenses incurred in connection with the acquisition. We did not incur borrowings under the Revolving Credit Facility on the closing date of the acquisition. The proceeds from any future borrowings under the Revolving Credit Facility may be used for working capital and other general corporate purposes.

In connection with entering into the Credit Agreement, in 2022, we incurred $37.8 million in debt discount and issuance costs, which were allocated to the Term Loan A, the Term Loan B and the Revolving Credit Facility based on lender commitment amounts relative to each type of fees paid. The lender and third-party discount and issuance costs allocated to the Term Loan A and the Term Loan B were $15.8 million and $13.4 million, respectively, the current unamortized balances are reflected as a direct deduction from the face amount of the corresponding term loans on the consolidated balance sheet. These costs are being amortized to interest expense over the respective terms of the loans using the effective interest method. The issuance costs allocated to the Revolving Credit Facility were $8.6 million, which are capitalized and included in prepaid

expenses and other current assets and other assets on our consolidated balance sheets. These costs are being amortized to interest expense over the term of the Revolving Credit Facility using the straight-line method.

The net funds received from the Term Loan A and the Term Loan B, after deducting debt issuance costs, were $834.2 million and $836.6 million, respectively.

Maturity Dates

The maturity date for the Term Loan A and the Revolving Credit Facility is January 6, 2027 and the maturity date for the Term Loan B is January 6, 2029. Pursuant to the terms and conditions of the Credit Agreement, the maturity dates of the Term Loans and the Revolving Credit Facility may be extended upon our request, subject to the consent of the Lenders.

Interest Rate Terms

In general, the Term Loans and borrowings under the Revolving Credit Facility denominated in U.S. dollars bear interest, at our option, on either: (1) the Base Rate, as defined below, plus the applicable margin, as indicated below ("Base Rate Loans") or (2) the Adjusted Term Secured Overnight Financing Rate ("Adjusted Term SOFR"), as defined below, plus the applicable margin, as indicated below ("Term SOFR Loans").

The Base Rate is defined as the highest of (a) the Prime Rate, (b) the Federal Funds Rate plus 0.50% and (c) Adjusted Term SOFR (as defined below) for a one-month period plus, in each case, 1.00%.

Adjusted Term SOFR is the rate per annum equal to (a) the Term SOFR plus (b) the Term SOFR Adjustment. Term SOFR is the forward-looking term rate based on SOFR and is calculated separately for Term SOFR Loans and Base Rate Loans, as specified in the Credit Agreement. The Term SOFR Adjustment is a percentage per annum of 0.10% for Base Rate Loans and between 0.10% to 0.25% for Term SOFR Loans based on the applicable interest period.

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. Effective on the first Adjustment Date, as defined in the Credit Agreement, occurring subsequent to our quarter ended June 30, 2022, the commitment fee is determined by reference to the leverage ratio in effect from time to time as set forth in the table below.

Applicable Interest Margins

The Term Loan A and borrowings under the Revolving Credit Facility have an initial applicable margin of 0.75% per annum for Base Rate Loans and 1.75% per annum for Term SOFR Loans.

Effective on the first Adjustment Date, as defined in the Credit Agreement, occurring subsequent to our quarter ended June 30, 2022, the applicable margin for the Term Loan A and borrowings under the Revolving Credit Facility is determined by reference to the leverage ratio in effect from time to time as set forth in the following table:

Leverage Ratio	Applicable Margin for Term SOFR Loans	Applicable Margin for Base Rate Loans	Commitment Fee Rate
Greater than 4.00 to 1.0	2.25%	1.25%	0.35%
Less than or equal to 4.00 to 1.0 but greater than 3.00 to 1.0	2.00%	1.00%	0.30%
Less than or equal to 3.00 to 1.0 but greater than 2.50 to 1.0	1.75%	0.75%	0.25%
Less than or equal to 2.50 to 1.0 but greater than 2.00 to 1.0	1.50%	0.50%	0.20%
Less than or equal to 2.00 to 1.0	1.25%	0.25%	0.15%

The Term Loan B has an initial applicable margin of 1.5% per annum for Base Rate Loans and 2.5% per annum for Term SOFR Loans.

Effective on the first Adjustment Date, as defined in the Credit Agreement, occurring subsequent to our quarter ended June 30, 2022, the applicable margin for the Term Loan B is determined by reference to the leverage ratio in effect from time to time as set forth in the following table:

Leverage Ratio	Applicable Margin for Term SOFR Loans	Applicable Margin for Base Rate Loans
Greater than 2.75 to 1.0	2.50%	1.50%
Less than 2.75 to 1.0	2.25%	1.25%

Principal Payments

Principal payments on the Term Loans are due on the last day of each calendar quarter commencing on June 30, 2022.

The Term Loan A amortizes in nineteen consecutive quarterly installments in an amount equal to 2.50% of the original principal amount in each of the first two years, 5.00% in each of the third and fourth years and 7.50% in the fifth year, with a final payment of the remaining outstanding principal balance due on the maturity date.

The Term Loan B matures in twenty-seven consecutive quarterly installments in an amount equal to 0.25% of the original principal amount, with a final payment of the remaining outstanding principal balance due on the maturity date.

We may borrow, prepay and re-borrow amounts under the Revolving Credit Facility, in accordance with the terms and conditions of the Credit Agreement, with all outstanding amounts due at maturity.

During March 2022, we prepaid $16.0 million in principal payments on the Term Loan A principal balance. For the years ended December 31, 2024, 2023 and 2022, total principal payments on both Term Loans was $51.0 million, $29.7 million and $22.4 million, respectively.

Interest Payments

Interest payments on Base Rate Loans are payable quarterly in arrears on the last business day of each calendar quarter and the applicable maturity date. Interest periods on Term SOFR Loans are determined, at our option, as either one, three or six months and will be payable on the last day of each interest period and the applicable maturity date. In the case of any interest periods of more than three months' duration, the interest payment are payable on each day prior to the last day of such interest period that occurs at three-month intervals.

The commitment fee on the Revolving Credit Facility is payable quarterly in arrears on the third business day following the last day of each calendar quarter and at the maturity date. The commitment fee is included in interest expense in our consolidated statements of operations.

Guarantors and Collateral

Our obligations under the Credit Agreement are unconditionally guaranteed, on a joint and several basis, by ICU Medical, Inc. and certain of our existing subsidiaries.

Debt Covenants

The Credit Agreement contains affirmative and negative covenants, including certain financial covenants. The negative covenants include restrictions regarding the incurrence of liens and indebtedness, certain merger and acquisition transactions, asset sales and other dispositions, other investments, dividends, share purchases and payments affecting

subsidiaries, changes in nature of business, fiscal year or organizational documents, prepayments and redemptions of subordinated and other junior debt, transactions with affiliates, and other matters.

The financial covenants include the Senior Secured Leverage Ratio and the Interest Coverage Ratio, both defined below, and pertain to the Term Loan A and the Revolving Credit Facility.

The Senior Secured Leverage Ratio is defined, at any measurement date, as the ratio of: (a) all Funded Debt, as defined in the Credit Agreement, that is secured by a lien on any asset or property minus the lesser of (i) all unrestricted cash and cash equivalents and (ii) $500.0 million, to (b) Consolidated EBITDA, as defined in the Credit Agreement, for the most recently completed four fiscal quarters, calculated on a pro forma basis. The maximum Senior Secured Leverage Ratio was 4.50 to 1.00 until June 30, 2024. Thereafter, the maximum Senior Secured Leverage Ratio is 4.00 to 1.00, with limited permitted exception.

The Interest Coverage ratio is defined, at any measurement date, as the ratio of Consolidated EBITDA, as defined in the Credit Agreement, to Consolidated Interest Expense, as defined in the Credit Agreement, paid or payable in cash, for the most recently completed four fiscal quarters. The minimum Interest Coverage ratio is 3.00 to 1.00.

We were in compliance with all financial covenants as of December 31, 2024.

The Credit Agreement contains customary events of default, including, among others: non-payments of principal and interest; breach of representations and warranties; covenant defaults; cross-defaults and cross-acceleration to certain other material indebtedness; the existence of bankruptcy or insolvency proceedings; 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 all amounts due and the termination of commitments under the Senior Secured Credit Facilities.

The carrying values of our long-term debt consist of the following (in thousands):

	2024 Effective Interest Rate	As of December 31, 2024	As of December 31, 2023	2023 Effective Interest Rate
Senior Secured Credit Facilities:				
Term Loan A — principal	8.03 %	$ 770,313	$ 812,813	7.67 %
Term Loan B — principal	8.38 %	826,625	835,125	8.00 %
Revolving Credit Facility — principal	— %	—	—	— %
Less unamortized debt issuance costs[(1)]		(14,080)	(19,168)	
Total carrying value of long-term debt		1,582,858	1,628,770	
Less current portion of long-term debt		51,000	51,000	
Long-term debt, net		$ 1,531,858	$ 1,577,770	

(1) In 2024, comprised of $6.1 million and $8.0 million relating to the Term Loan A and the Term Loan B, respectively. In 2023, comprised of $9.3 million and $9.9 million relating to the Term Loan A and the Term Loan B, respectively.

As of December 31 2024, the aggregate amount of principal repayments of our long-term debt (including any current portion) for each of the next five years is approximately (in thousands):

2025	$ 51,000
2026	72,250
2027	672,563
2028	8,500
2029	792,625
Thereafter	—
Total	$ 1,596,938

The following table presents the total interest expense related to our long-term debt (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Contractual interest	$ 125,012	$ 125,550	$ 66,770
Amortization of debt issuance costs	6,807	6,814	6,972
Commitment fee — Revolving Credit Facility	1,524	1,518	1,290
Total long-term debt-related interest expense	$ 133,343	$ 133,882	$ 75,032

NOTE 14. INCOME TAXES

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

	Year Ended December 31,		
	2024	2023	2022
United States	$ (116,024)	$ (136,980)	$ (135,646)
Foreign	50,012	58,681	21,237
	$ (66,012)	$ (78,299)	$ (114,409)

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

	Year Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ 16,589	$ (8,235)	$ 4,128
State	4,256	5,035	3,799
Foreign	25,164	24,500	12,924
	$ 46,009	$ 21,300	$ 20,851
Deferred:			
Federal	$ 1,294	$ (43,042)	$ (42,012)
State	14,850	(14,657)	(11,239)
Foreign	(10,477)	(12,245)	(7,723)
	5,667	(69,944)	(60,974)
	$ 51,676	$ (48,644)	$ (40,123)

We have accrued for tax contingencies for potential tax assessments, and in 2024 we recognized a $5.7 million net decrease, most of which related to federal, state, and foreign tax reserves net of the release of various federal 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,					
	2024		2023		2022	
	Amount	Percent	Amount	Percent	Amount	Percent
Federal tax at the expected statutory rate	$ (13,862)	21.0 %	$ (16,443)	21.0 %	$ (24,026)	21.0 %
State income tax, net of federal effect	701	(1.1)%	(6,057)	7.7 %	(5,050)	4.4 %
Tax credits	(10,985)	16.6 %	(9,824)	12.5 %	(3,636)	3.2 %
Global intangible low-taxed income	2,977	(4.5)%	(2,658)	3.4 %	2,303	(2.0)%
Foreign income tax differential	(4,231)	6.4 %	(2,506)	3.2 %	(2,943)	2.5 %
Stock-based compensation	2,824	(4.3)%	(289)	0.4 %	(3,721)	3.2 %
Foreign-derived intangible income	(3,756)	5.7 %	(3,299)	4.2 %	(2,269)	2.0 %
Transaction cost	—	— %	—	— %	2,299	(2.0)%
Contingent consideration	(838)	1.3 %	(3,407)	4.4 %	(6,830)	6.0 %
Section 162(m)	1,880	(2.8)%	3,268	(4.2)%	3,942	(3.4)%
Tax reserve releases	(2,216)	3.3 %	(6,884)	8.8 %	(1,834)	1.6 %
Legal Settlement	(2,100)	3.2 %	—	— %	—	— %
Valuation allowance	81,713	(123.8)%	—	— %	—	— %
Other	(431)	0.7 %	(545)	0.7 %	1,642	(1.4)%
	$ 51,676	(78.3)%	$ (48,644)	62.1 %	$ (40,123)	35.1 %

Tax credits in 2024, 2023 and 2022 consist principally of research and developmental tax credits.

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

	As of December 31,	
	2024	2023
Deferred tax asset:		
Accruals/other	$ 40,849	$ 30,190
Acquired future tax deductions	7,869	10,877
Stock-based compensation	3,940	6,987
Tax credits	17,068	15,095
Inventory reserves	25,015	25,592
Warranty reserve	1,098	13,788
Section 163(j) - interest expense limitation	27,078	25,467
Chargebacks, discounts, customer concessions	52,709	39,077
Capitalized research and development	56,975	43,313
Valuation allowance	(90,950)	(8,452)
	$ 141,651	$ 201,934
Deferred tax liability:		
State income taxes	$ 5,886	$ 4,465
Depreciation and amortization	160,368	212,429
Foreign currency translation and derivative instrument adjustments	—	3,630
	$ 166,254	$ 220,524
Deferred tax (liability) asset, net	$ (24,603)	$ (18,590)

The Company regularly assesses the realizability of deferred tax assets and records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. In assessing the realizability of our deferred tax assets, we weigh all available positive and negative evidence. This evidence includes, but is not limited to, historical earnings, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. Due to the weight of objectively verifiable negative evidence, the Company recorded a valuation allowance of $81.7 million tax expense and $3.9 million foreign currency translation and derivative instrument adjustments against certain U.S. federal and state deferred tax assets for the tax years ending December 31, 2024. The significant piece of objectively verifiable negative evidence evaluated was the recent U.S. cumulative losses. Our ability to use our deferred tax assets depends on the amount of taxable income in future periods.

Tax Holidays and Carryforwards

Net operating loss ("NOL") carryforwards consist of: (a) federal NOL carryforwards of $1.3 million which will expire at various dates from 2031 to indefinite carryforward periods, (b) state NOL carryforwards of $2.6 million which has indefinite carryforward periods and (c) foreign NOL carryforwards of $114.3 million which will expire at various dates from 2025 to indefinite carryforward periods. We have recorded a net deferred tax asset of $6.8 million, $29.5 million gross deferred tax asset net of tax reserves of $22.7 million, related to our foreign NOL carryforwards. The deferred tax assets recognized for these foreign NOLs are presented net of tax reserves. We believe that it is more likely than not that the benefit from certain foreign NOL carryforwards will not be realized. In recognition of this risk, we have provided a valuation allowance of $5.9 million on the $6.8 million net deferred tax assets related to these foreign NOL carryforwards. 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 $23.9 million, the majority of 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 2029. 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 $11.1 million or $0.45 per diluted share in 2024 and by $8.0 million or $0.33 per diluted share in 2023.

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

As of December 31, 2024, we have estimated $322 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 2021 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, 2024 was $72.8 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, 2024, it is reasonably possible that the expiration of the U.S. federal statute of limitations will cause the gross amount of unrecognized tax benefits to decrease by $5.2 million within the next twelve months. It is not possible to estimate any other 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 recognized $0.8 million of interest expense and $0.1 million of penalties in income tax benefit during 2024 and released $1.1 million of interest expense and $0.5 million of penalties in 2024. In total, we have accrued for interest and penalties of $2.6 million and $1.6 million, respectively as of December 31, 2024, and $2.9 million and $2.0 million, respectively, as of December 31, 2023.

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

	Year Ended December 31,		
	2024	2023	2022
Beginning balance	$ 78,558	$ 54,053	$ 21,537
Increases to prior year tax positions	1,945	2,347	148
Increases due to acquisitions		—	29,606
Increases to current year tax positions	4,441	34,607	4,706
Decreases to prior year tax positions	(406)	(2,455)	(222)
Decrease related to lapse of statute of limitations	(10,062)	(9,591)	(1,722)
Decrease related to settlements with tax authorities	(1,133)	(403)	—
Decrease related to exchange rate fluctuations	(524)	—	—
Ending balance	$ 72,819	$ 78,558	$ 54,053

In December 2022, the European Union (EU) agreed to implement Pillar Two, the OECD's global minimum tax rate of 15% for multinationals that meet a global revenue threshold. All of the EU countries and some of the non-EU countries in which we operate have enacted or have announced plans to enact legislation to adopt Pillar Two. The Pillar Two legislation is effective for our fiscal year beginning January 1, 2024 and for fiscal year 2024, Pillar 2 did not have a material impact to our tax provision or effective tax rate. However, the Pillar Two rules continue to evolve and their application may alter our tax obligations in certain countries in which we operate for fiscal periods beyond 2024 as we continue to assess the impact of tax legislation in these jurisdictions.

NOTE 15. 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 2024, 2023 or 2022. We are limited on share purchases in accordance with the terms and conditions of our Senior Secured Credit Facilities (see Note 13: Long-Term Obligations).

In 2024, we withheld 114,787 shares of our common stock from employee vested restricted stock units in consideration for $12.0 million in payments for the employees' share award income tax withholding obligations. We had 571 shares remaining in treasury at December 31, 2024.

In 2023, we withheld 59,377 shares of our common stock from employee vested restricted stock units in consideration for $9.4 million in payments for the employees' share award income tax withholding obligations. We had 2,428 shares remaining in treasury at December 31, 2023.

In 2022, we withheld 47,664 shares of our common stock from employee vested restricted stock units in consideration for $10.9 million in payments for the employees' share award income tax withholding obligations. We had 1,633 shares remaining in treasury at December 31, 2022.

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, 2022	$ (19,045)	$ (237)	$ 13	$ (19,269)
Other comprehensive (loss) income before reclassifications	(103,928)	54,962	1,203	(47,763)
Amounts reclassified from AOCI	—	(13,946)	—	(13,946)
Other comprehensive (loss) income	(103,928)	41,016	1,203	(61,709)
Balance as of December 31, 2022	$ (122,973)	$ 40,779	$ 1,216	$ (80,978)
Other comprehensive income before reclassifications	46,189	12,096	603	58,888
Amounts reclassified from AOCI	—	(30,991)	—	(30,991)
Other comprehensive income (loss)	46,189	(18,895)	603	27,897
Balance as of December 31, 2023	$ (76,784)	$ 21,884	$ 1,819	$ (53,081)
Other comprehensive loss before reclassifications	(70,158)	14,042	—	(56,116)
Amounts reclassified from AOCI	—	(30,204)	—	(30,204)
Other comprehensive loss	(70,158)	(16,162)	—	(86,320)
Balance as of December 31, 2024	$ (146,942)	$ 5,722	$ 1,819	$ (139,401)

NOTE 16. 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 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 ended September 2024. The terms of the agreement included a contingent earn-out payment. The contingent earn-out payment could not exceed $6.0 million and was to 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. The estimated fair value of the contingent earn-out was calculated using a probability-weighted cash flow model based on historical revenue streams and the likelihood that the revenue targets will be met. As of December 31, 2023, the earn-out measurement period ended. The fair value of the contingent earn-out was determined to be $3.4 million and was paid out in the first quarter of 2024 (see Note 10: 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 obtaining certain product-related regulatory certifications by May 26, 2024. As of December 31, 2022, the measurement period related to the contingent earn-out based on certain revenue targets ended and based on the actual

revenue achieved during the measurement period, the fair value of the contingent earn-out was determined to be zero as the minimum threshold for earning the earn-out was not met. As of December 31, 2024, the earn-out measurement period related to certain product-related regulatory certifications had ended and the product-related regulatory certification had not been achieved, and accordingly, the estimated fair value for the contingent consideration was reduced to zero (see Note 10: Fair Value Measurements).

In January 2022, we acquired Smiths Medical. Total consideration for the acquisition included a potential earn-out payment of $100.0 million in cash contingent on our common stock achieving the Price Targets from the closing date to either the third or fourth anniversary of closing and provided Smiths beneficially owned at least 50.0% of the shares of common stock issued at closing at the time the Price Target is achieved. During 2024, Smiths sold all of their remaining shares of common stock of ICU Medical, Inc. The sale of these shares renders Smiths unable to achieve the contingent consideration based on certain price targets during the third and fourth anniversary of closing as Smiths no longer met the required minimum beneficial ownership percentage. Accordingly, the valuation of the contingent earn-out liability as of December 31, 2024 was zero (see Note 10: Fair Value Measurements).

Prior to being acquired, during 2021, Smiths Medical received a Warning Letter from the FDA following an inspection of Smiths Medical’s Oakdale, Minnesota Facility (the "2021 Warning Letter"). The 2021Warning Letter cited, among other things, failures to comply with FDA's medical device reporting requirements and failures to comply with applicable portions of the Quality System Regulation. A provision for the estimated costs related to the field service corrective actions identified as of the closing date of the acquisition was recorded on the opening acquired balance sheet of Smiths Medical. The initial estimate recorded was based on a probability-weighted estimate of the costs required to settle the obligation related to known field corrective actions. The actual costs to be incurred are dependent upon the scope of the work necessary to achieve regulatory clearance, including potential additional field corrective actions, and could differ from the original estimate. For the years ended December 31, 2024 and 2023, we recorded a net reversal to the provision of $5.2 million and a provision of $20.3 million, respectively, to adjust the estimated cost to complete the field corrective actions to the amounts expected to be incurred based on historical experience. As of December 31, 2024, approximately $31.7 million of the $39.2 million of accrued field service corrective action recorded was related to the 2021 Warning Letter.

In 2015, legislation was enacted in Italy which requires medical device companies to make payments to the Italian government if Italy's medical device expenditures for certain years exceeded annual regional expenditure ceilings. Since its enactment, the legislation has been subject to appeals in the Italy court system. In the third quarter of 2024, Italy's Constitutional Court issued two judgments, one of which confirmed the legitimacy of the legislation on the Italy Medical Device Payback ("IMDP"). However, litigation proceedings are still pending and the ultimate resolution remains unknown. The timing and amount of payments could ultimately differ from our current expectations (see Note 12: Accrued Liabilities and Other Long-Term Liabilities for details on amounts accrued for potential payments related to the IMDP).

Commitments

We have non-cancelable operating lease agreements where we are contractually obligated to pay certain lease payment amounts (see Note 7: Leases).

NOTE 17. COLLABORATIVE AND OTHER ARRANGEMENTS

On February 3, 2017, we entered into two Manufacturing and Supply Agreements ("MSAs") whereby (i) Pfizer would 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. We no longer purchase products from Pfizer under the MSA as described in (i) above.

The MSA described in (ii) above provides each party with mutually beneficial interests and is jointly managed by both Pfizer and ICU. 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. The MSA was amended on January 24, 2025 to extend the term through 2027 for certain Solutions products. Changes to the terms of the MSA include (i) amendments to our level of supply of products to Pfizer and (ii) updates to our supply price for 2025.

NOTE 18: ACCOUNTS RECEIVABLE PURCHASE PROGRAM

On January 19, 2023, we entered into a revolving $150 million uncommitted receivables purchase agreement with Bank of The West ("BOW"), which was subsequently acquired by BMO in February 2023. This agreement provided for a less expensive form of capital. The discount rate applied to sold receivables equals a rate per annum equal to the sum of (i) an applicable margin, plus (ii) Term SOFR for a period equal to the discount period which is calculated with respect to the payment terms of the specific receivable. The accounts receivable sold have payment terms ranging between 30 and 60 days, and are related to customer accounts with good credit history. The transfer of the purchased accounts receivable under the agreement is intended to be an absolute and irrevocable transfer constituting a true sale as the transferred receivables have been isolated beyond the reach of the Company and our creditors, even in bankruptcy or other receivership. We do not retain effective control over the sold receivables and BMO has the right upon purchase to pledge and/or exchange the transferred assets without restrictions. The Company acts as collection agent for BMO and collection services are undertaken by our accounts receivable personnel in their normal course of business and collected funds are remitted to BMO. We do not have any continuing involvement with the sold receivables other than the collection services which does not provide us with more than a trivial benefit. The discount rate has been negotiated net of consideration for the collection services, the cost of collection is immaterial to the Company; therefore, we did not separately record any related servicing assets or liabilities related to the sold receivables.

The following table presents information in connection with the purchase program (in thousands):

	Year Ended December 31,	
	2024	2023
Trade receivables sold[1]	$ 435,438	$ 629,065
Cash received in exchange for trade receivables sold[2]	432,803	625,341
Loss on sale of receivables[3]	2,635	3,724

(1) Represents carrying value of trade receivables sold to BMO.
(2) Cash proceeds received from BMO.
(3) Reflected in other expense, net in our condensed consolidated statement of operations.

As of December 31, 2024, we are not actively utilizing the program and there are no outstanding balances to be collected on behalf of BMO. At December 31, 2023, cash remaining to be collected on behalf of BMO was $75.9 million which has been removed from our consolidated balance sheet as of December 31, 2023, and is reflected as cash provided by operating activities in the consolidated statement of cash flows in the same period. There were no such balances at December 31, 2022. The carrying value of the sold receivables approximated the fair value at December 31, 2023.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 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. Disclosure controls and procedures are designed to ensure that the information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities Exchange Commission, and that such information 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. Based upon that evaluation, our principal executive officer and our principal financial officer concluded that, as of December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

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 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, 2024.

Our independent registered public accounting firm that audited the December 31, 2024 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 can be found in Part II, Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

(a) None

(b) During the three months ended December 31, 2024, none of the Company's directors or "officers" (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" intended to satisfy the affirmative defense of Rule 10b5-1(c) or a “non-Rule 10b5-1 trading arrangement,” each as defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table lists the names, ages, certain positions and offices held by our executive officers and directors as of January 31, 2025:

Name	Age	Office Held
Vivek Jain	52	Chief Executive Officer ("CEO") and Chairman of the Board
Brian Bonnell	51	Chief Financial Officer ("CFO") and Treasurer
Christian Voigtlander	56	Chief Operating Officer ("COO")
Daniel Woolson	48	President
Virginia Sanzone	50	Corporate Vice President, General Counsel ("CVP, GC")
David C. Greenberg	58	Director
Elisha Finney	63	Director
David Hoffmeister	70	Director
Donald Abbey	58	Director
Laurie Hernandez	67	Director
Kolleen T. Kennedy	65	Director

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

Mr. Christian Voigtlander has served as our Chief Operating Officer since January 2018. From February 2017 to January 2018, Mr. Voigtlander served as the Company’s Corporate Vice President, Business Development and General Manager, Infusion Solutions. From June 2015 to February 2017, Mr. Voigtlander served as the Company’s Vice President, Business Development. Prior to May 2015, Mr. Voigtlander held various roles at CareFusion and last served as Senior Vice President, Business Development and Strategy.

Mr. Brian Bonnell has served as our Chief Financial Officer and Treasurer since March 3, 2020. From May 2018 until March 2020, Mr. Bonnell served as the Company’s Corporate Vice President, Finance. Prior to joining the Company, Mr. Bonnell served as Treasurer and Head of Financial Planning and Analysis at Alere Inc. from May 2015 until December 2017. Prior to May 2015, Mr. Bonnell held various roles at CareFusion Corporation in Finance and last served as Senior Vice President, Tax and Treasurer.

Mr. Daniel Woolson has served as our President since October 2024. Prior to becoming President, Mr. Woolson served as our Corporate Vice President, General Manager - Infusion Systems from January 2017 to October 2024. Mr. Woolson served

as President, Respiratory Solutions for Becton Dickinson from March 2015 to November 2016. Prior to March 2015, Mr. Woolson held various roles at CareFusion and last served as Vice President/General Manager, Specialty Disposables.

Ms. Virginia Sanzone has served as our Corporate Vice President, General Counsel and Secretary since January 2018. Ms. Sanzone also serves as our Compliance Officer. Ms. Sanzone served as the Company's Vice President, General Counsel from August of 2015 to January 2018. Prior to August of 2015, Ms. Sanzone held various roles at CareFusion and last served as Senior Vice President, Associate General Counsel - Business Segments & Americas.

Mr. David C. Greenberg has been a director since 2015, serves as Lead Independent Director and Chair of the Compensation Committee and is a member of the Audit Committee. Mr. Greenberg is currently serving as Chief Executive Officer of HomeThrive, Inc. Mr. Greenberg joined HomeThrive, Inc. in October 2018. Mr. Greenberg was Executive Vice President, Strategy of Medline Industries, Inc. ("Medline") from June 2008 to October 2018. Medline is a privately held manufacturer and distributor of medical supplies uniquely positioned to provide products, education and support across the continuum of care. In that capacity, Mr. Greenberg was a member of Medline's Executive Board and advised top leadership/ ownership on all aspects of the business. Mr. Greenberg was responsible for Strategy, Business Development and M&A. Additionally, Mr. Greenberg was a Group President and had responsibility for Medline's distribution business and several manufacturing and marketing divisions. Mr. Greenberg has served on the board of directors for Amendia, Inc., a spinal implant company. Previously, Mr. Greenberg spent thirteen years in a variety of leadership positions within Aon Corporation, including Chief Financial Officer of its Aon Global subsidiary. Mr. Greenberg previously served as a director at Potrero Medical, Inc., the latest spinout of medical device incubator Theranova, LLC. Currently Mr. Greenberg serves on the board of directors of HomeThrive, Inc. since October 2018, Canadian Hospital Specialties, a privately held medical device manufacturer and specialty distributor, since April 2021 and Access & Integrated Practice Holdings, LLC a comprehensive variable access medical services platform since 2023. The Board believes Mr. Greenberg should serve as a director due to his extensive knowledge and experience in the medical industry, demonstrated executive leadership in business and insight into financial matters.

Ms. Elisha W. Finney has been a director since January 2016, and serves as Chair of the Nominating and Governance Committee and is a member of the Audit Committee. Ms. Finney, now retired, was named Vice President, Finance and CFO of Varian Medical Systems in April 1999. In January 2005, she was promoted to Senior Vice President and given additional management responsibility for the Corporate Information Systems group. She was named Executive Vice President in February 2012. Varian Medical Systems is a leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, proton therapy and brachytherapy. Ms. Finney managed a worldwide staff of 400. Her management responsibilities included corporate accounting; corporate communications and investor relations; internal financial and compliance audit; risk management; tax and treasury, and corporate information systems. Ms. Finney joined Varian as risk manager in 1988 and has assumed a wide variety of finance functions over her last 29 years with the company. Prior to joining Varian, Ms. Finney was with the Fox Group in Foster City, CA, and Beatrice Foods, a major food processing company, in Chicago, IL. Ms. Finney has served on the boards of: Mettler Toledo, a multinational manufacturer of scales and analytical instruments, since November 2017; and Viatris, a global pharmaceutical and healthcare corporation, since December 2022. Ms. Finney previously served on the boards of directors of: Nanostring Technologies from May 2017 to June 2024; Laserscope from August 2005 until July 2006 when Laserscope was sold to American Medical Systems; Thoratec, a developer, manufacturer and marketer of proprietary medical devices for mechanical circulatory support from July 2007 to May 2013; Altera Corporation, a manufacturer of programmable logic devices from September 2011 until December 2015, when Altera was sold to Intel; Cutera, Inc. a global provider of laser and other energy-based aesthetic systems, from November 2017 to May 2019; and iRobot Corporation, a robotics technology company, from January 2017 to November 2021. The Board believes Ms. Finney should serve as a director due to her extensive knowledge and experience in the medical industry and her financial knowledge and experience, particularly with respect to her service on the Audit Committee.

Mr. David F. Hoffmeister has been director since January 2018 and serves as Chair of the Audit Committee and a member of the Compensation Committee. Mr. Hoffmeister served as Senior Vice President and Chief Financial Officer of Life Technologies Corp. from 2004 to 2014. Prior to joining Life Technologies, Mr. Hoffmeister was a senior partner with McKinsey & Co., focusing on health care, private equity and chemicals industries. Before joining McKinsey, Mr. Hoffmeister held financial positions at GTE Corp. and W.R. Grace and Co. Mr. Hoffmeister currently serves on the boards of Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals and has since November of 2014. Mr. Hoffmeister currently serves on the Board of Directors of Glaukos Corp. and has since 2014; Celanese Corp., since 2005; and Stepstone Group, Inc. since 2020. Mr. Hoffmeister received a bachelor's of science degree from University of Minnesota and a M.B.A. from University of Chicago. The Board believes Mr. Hoffmeister should serve as a director due to his strong finance background and extensive experience as a chief financial officer of a global biotechnology company.

Mr. Donald M. Abbey has been a director since January 2018 and is a member of the Nominating Governance Committee and the Compensation Committee. Mr. Abbey is currently serving as Executive Vice President, Global Business Services, IT, Quality and Regulatory Affairs at Dexcom, Inc. ("Dexcom"). Mr. Abbey joined Dexcom in May of 2016. Prior to joining Dexcom, Mr. Abbey was with Becton Dickinson (who acquired CareFusion Corporation in 2015 and which was spun out of Cardinal Health in 2009 (collectively, "BD") from 2007. Mr. Abbey served in many roles over his years at BD including most recently as the Senior Vice President, Quality and Regulatory. Prior to his time at BD, Mr. Abbey held senior quality and regulatory affairs and general management positions with Respironics, Welch Allyn and Philips Healthcare. Mr. Abbey began his career at Varian Medical and Boston Scientific holding positions with increasing responsibility in research and development and quality. Mr. Abbey received a B.S.E.E from Washington State University and a M.B.A from University of Washington. The Board believes Mr. Abbey should serve as a director due to his extensive knowledge and experience in the medical industry and particularly, his knowledge of compliance and regulatory requirements.

Ms. Laurie Hernandez has been a director since July 2021 and is a member of the Nominating and Governance Committee. Ms. Hernandez is a retired healthcare executive with over 25 years of strategic healthcare experience. Ms. Hernandez joined Baxter Healthcare Corporation ("Baxter") in November of 2007 and has assumed a wide variety of strategic positions over her 10 years with that company. Prior to joining Baxter, Ms. Hernandez was with Hospira Inc. in Lake Forest, Illinois. Ms. Hernandez previously served on the boards of Sinai Health System in Chicago, Illinois and Lambs Farm in Libertyville, Illinois. The Board believes Ms. Hernandez should serve as a director due to her extensive experience in the medical industry.

Ms. Kolleen T. Kennedy has been a director since December 2021 and recently retired as President, Proton Solutions & Chief Growth Officer at Varian Medical Systems ("Varian") in December 2021. Ms. Kennedy joined Varian in 1997 as Marketing Manager for radiation therapy delivery systems, and assumed other strategic roles over 24 years including Executive Vice President of Varian Oncology Systems, the market leading radiation therapy business division with nearly 7,000 employees worldwide. Prior to joining Varian, Ms. Kennedy was with Siemens Medical Systems and Radiation Oncology Computer Systems in oncology product sales and marketing. Ms. Kennedy received BS degrees in Radiation Oncology and Psychology from Wayne State University as well as an MS degree in Medical Physics from the University of Colorado. Ms. Kennedy currently serves on the boards of IPG Photonics since 2023 and Wayne State University Foundation since 2018, served on the board of the City Cancer Challenge Foundation from 2018 to 2022, and served on the board of the Radiation Oncology Institute from 2018 to 2021. The Board believes Ms. Kennedy should serve as a director due to her relevant knowledge and history in the medical industry.

Corporate Governance

We have a Code of Business Conduct and Ethics applicable to all our directors, officers, and other employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy is available on our website, www.icumed.com in the "Investors" section. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any future amendments to, or waiver from, a provision of our Code of Business Conduct and Ethics, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified above.

Additional information as required by this Item 10 of Form 10-K will be 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 2025 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

We have adopted an insider trading policy governing the purchase, sale and other dispositions of our securities that applies to all personnel of ICU Medical, Inc. and its subsidiaries, including directors, officers and employees. We also follow procedures for the repurchase of our securities. We believe that our insider trading policy and repurchase procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations, as well as applicable listing standards. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 of Form 10-K will be 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 2025 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 will be 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 2025 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 will be set forth under the caption *Transactions with Related Persons*, *Policies and Procedures Regarding Transactions with Related Persons* and *Corporate Governance-Director Independence* in our definitive Proxy Statement to be filed in connection with our 2025 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 will be set forth under the caption *Ratification of Auditors* in our definitive Proxy Statement to be filed in connection with our 2025 Annual Meeting of Stockholders, and such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

		Form 10-K Page No.
	The following documents are filed as part of this report:	
1.	Consolidated Financial Statements. See Index to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K.	58
2.	Exhibits. The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Form 10-K.	118
3.	Financial Statement Schedules. The Financial Statement Schedules required to be filed as a part of this Report are:	
	Schedule II — Valuation and Qualifying Accounts	121

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Filed/ Furnished Herewith
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 on September 8, 2021 (File No. 001-34634).	
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 on September 8, 2021 (File No. 001-34634).	
2.3	Purchase Agreement, dated November 12, 2024, by and between ICU Medical, Inc., a Delaware corporation, ICU Medical Sales, Inc., a Delaware corporation and Otsuka Pharmaceutical Factory America, Inc., a Delaware corporation. Filed as an Exhibit to Registrant's Current Report on Form 10-Q filed on November 12, 2024 (File No. 001-34634)	
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 (File No. 001-34634).	
3.2	Registrant's Bylaws, as amended and restated. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed on November 3, 2023 (File No. 001-34634).	
4.1	Description of Securities Registered Under Section 12 of the Exchange Act. Filed as an Exhibit to Registrant's Annual Report on Form 10-K for the year ended December 31, 2019, filed on March 2, 3020 (File No. 001-34634).	
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 on October 22, 2010 (File No. 001-34634).	
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).	
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).	
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 (File No. 001-34634).	
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 on March 2, 2020 (File No.001-34634).	
10.8	Plan. Filed as an Exhibit to Registrant's Current Report on Form 8-K filed on May 22, 2023 (File No. 001-34634).	
10.9	Amended and Restated Executive Employment Agreement, dated as of April 15, 2022, by and between ICU Medical, Inc. and Vivek Jain.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed on April 20, 2022 (File No. 001-34634).	
10.10	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 (File No. 001-34634).	
10.11	ICU Medical, Inc. Executive Severance Plan.* Filed as an Exhibit to Registrant's Current Report on Form 8-K filed on January 6, 2017 (File No. 001-34634).	
10.12	First Amendment to the ICU Medical, Inc. Executive Severance Plan. *Filed as an Exhibit to Registrant's Current Report on Form 8-K filed on January 6, 2020 (File No. 001-34634).	
10.13	Exhibit to Registrant's Current Report on Form 8-K filed on January 3, 2023 (File No. 001-34634).	
10.14	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 (File No. 001-34634).	
10.15	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 on January 7, 2022 (File No. 001-34634).	
19.1	ICU Medical, Inc. Insider Trading Policy	*
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	**
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation. Filed as an Exhibit to Registrant's Annual Report on Form 10-K for the Year ended December 31, 2023 filed on February 27, 2024 (File No. 001-34634).	

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).

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* Filed herewith.

** Furnished herewith.

Annexes, schedules and exhibits have been omitted pursuant to Item 601(a)(5)(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

SCHEDULE II

ICU MEDICAL, INC.

VALUATION AND QUALIFYING ACCOUNTS

(Amounts in thousands) Description	Balance at Beginning of Period	Additions (Reductions) Charged to Costs and Expenses	Additions (Reductions) Charged to Other Accounts	Write-off/ Disposals	Balance at End of Period
For the year ended December 31, 2022:					
Allowance for doubtful accounts	$ 7,038	$ 1,036	$ 456	$ —	$ 8,530
Warranty and return reserve - accounts receivable[(1)]	$ 2,485	$ (364)	$ 3,742	$ —	$ 5,863
Warranty and return reserve - inventory/accrued[(2)]	$ (1,883)	$ 5,266	$ 47,436	$ —	$ 50,819
Deferred tax asset valuation allowance	$ 2,934	$ —	$ 8,232	$ —	$ 11,166
For the year ended December 31, 2023:					
Allowance for doubtful accounts	$ 8,530	$ 838	$ 1,696	$ —	$ 11,064
Warranty and return reserve - accounts receivable	$ 5,863	$ 1,627	$ 15	$ —	$ 7,505
Warranty and return reserve - inventory/accrued[(3)]	$ 50,819	$ 20,290	$ (13,313)	$ —	$ 57,796
Deferred tax asset valuation allowance	$ 11,166	$ —	$ (2,714)	$ —	$ 8,452
For the year ended December 31, 2024:					
Allowance for doubtful accounts[(4)]	$ 11,064	$ 5,800	$ (5,394)	$ —	$ 11,470
Warranty and return reserve - accounts receivable	$ 7,505	$ (1,441)	$ 806	$ —	$ 6,870
Warranty and return reserve - inventory/accrued[(5)]	$ 57,796	$ 2,571	$ (18,146)	$ —	$ 42,221
Deferred tax asset valuation allowance[(6)]	$ 8,452	$ 78,592	$ 3,906	$ —	$ 90,950

[(1)] Includes an acquired balance of $3.8 million related to the Smiths Medical acquisition.
[(2)] Includes an acquired balance of $55.2 million in short-term and long-term accrued warranty reserve related to the Smiths Medical acquisition.
[(3)]Additional charges to expense were primarily related to additional field corrective actions identified and initiated during the period related to the Smiths Medical business FDA warning letter (See Note: 16 Commitments and Contingencies in our accompanying consolidated financial statements).
[(4)] The charged to other accounts includes a $2.0 million reclassification to assets held for sale related to the IV Solutions business (See Note 4: Assets held For Sale in our accompanying consolidated financial statements).
[(5)] Primarily includes payments for expenses related to our field corrective actions.
[(6)] Primarily relates to valuation allowance against certain U.S. federal and state deferred tax assets (See Note 14: Income Taxes in our accompanying consolidated financial statements).

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 27, 2025

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 27, 2025
/s/ Brian M. Bonnell Brian M. Bonnell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2025
/s/ David C. Greenberg David C. Greenberg	Director	February 27, 2025
/s/ Elisha W. Finney Elisha W. Finney	Director	February 27, 2025
/s/ David F. Hoffmeister David F. Hoffmeister	Director	February 27, 2025
/s/ Donald M. Abbey Donald M. Abbey	Director	February 27, 2025
/s/ Laurie Hernandez Laurie Hernandez	Director	February 27, 2025
/s/ Kolleen T. Kennedy Kolleen T. Kennedy	Director	February 27, 2025

Board of Directors

Donald M. Abbey
Elisha W. Finney
David C. Greenberg
Laurie Hernandez
David F. Hoffmeister
Vivek Jain
Kolleen T. Kennedy

Executive Management

Vivek Jain*
Chairman of the Board and
Chief Executive Officer

Brian Bonnell*
Chief Financial Officer

Christian Voigtlander*
Chief Operating Officer

Virginia Sanzone*
Corporate Vice President,
General Counsel

Ben Sousa*
Chief Information Officer

Olivia Barrall
Vice President,
Human Resources

Krishna Uppugonduri
Corporate Vice President,
Quality, Medical, and Regulatory Affairs

Dan Woolson*
President

Jim Paloyan
Corporate Vice President
and General Manager, Consumables

Dante Tisci
Corporate Vice President,
IV Solutions, Pain Management, Distribution
Management, Alternate Site Sales

Chad Jansen
Corporate Vice President,
Infusion Systems

Henrik Schwerdt
Vice President,
Respiratory & Anesthesia

*"Executive Officer" under the Securities Exchange Act of 1934

We Connect Patients and Caregivers

through safe, life-saving, life-enhancing medical devices.

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human connections

Auditors

Deloitte & Touche LLP
695 Town Center Drive Suite 1000
Costa Mesa, CA 92626-7188

Transfer Agent and Registrar

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Phone: 800.937.5449
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Email: HelpAST@equiniti.com

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General Communications:
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Newark, NJ 07101

Common Stock

Symbol: ICUI
The Nasdaq Global Select Market

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