ARTIVION™

2024

2024 Annual Report to Stockholders

NYSE: AORT

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FORM 10-K

Included in this Annual Report to Stockholders is a copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, including certifications by the Chief Executive Officer and Chief Financial Officer, but excluding additional exhibits, as filed with the Securities and Exchange Commission. Additional copies of this Annual Report and the Form 10-K, without exhibits, are available at no charge. Please send requests to:

Corporate Secretary
Artivion, Inc.
1655 Roberts Boulevard, NW
Kennesaw, GA 30144

STOCKHOLDER COMMUNICATIONS

Directors may be contacted by mail, addressed c/o Corporate Secretary at the address provided above for requesting copies of the Form 10-K.

STOCK LISTINGS

Artivion, Inc. Common Stock is traded on the New York Stock Exchange under the symbol AORT.

NEW YORK STOCK EXCHANGE ANNUAL CEO CERTIFICATION

The Chief Executive Officer of Artivion, Inc. provided the New York Stock Exchange with an unqualified Annual CEO Certification last year.

TRANSFER AGENT

Communications regarding change of address, transfer of stock ownership, or lost stock certificates should be directed to:

Equinity Trust Company, LLC
55 Challenger Road
Floor 2
Ridgefield Park, NJ 07660
Phone: 800-468-9716

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP
Suite 1000
55 Ivan Allen Jr. Boulevard
Atlanta, GA 30308

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **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 number 1-13165

ARTIVION, INC.

(Exact name of registrant as specified in its charter)

Delaware	**59-2417093**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1655 Roberts Boulevard N.W., Kennesaw, GA 30144

(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code (770) 419-3355

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	AORT	New York Stock Exchange

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 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 emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one).

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 USC. 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 Exchange Act). Yes ☐ No ☒

As of June 30, 2024 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $1,016,967,660 computed using the closing price of $25.65 per share of Common Stock on June 30, 2024, the last trading day of the registrant's most recently completed second fiscal quarter, as reported by the New York Stock Exchange, based on management's belief that Registrant has no affiliates other than its directors and executive officers.

As of February 21, 2025 the number of outstanding shares of Common Stock of the registrant was 42,047,888.

Documents Incorporated By Reference

Document	**Parts Into Which Incorporated**
Proxy Statement for the Annual Meeting of Stockholders to be filed within 120 days after December 31, 2024	Part III

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Forward-Looking Statements

This Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Forward-looking statements give our expectations or forecasts of future events as of the date of this Form 10-K. In some cases, words such as "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future," "assume," and variations of these types of words or other similar expressions identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-K.

All statements included herein, other than statements of historical facts, that address activities, events, or developments that we expect or anticipate will or may occur in the future, or that reflect our beliefs about the future and/or expectations, are forward-looking statements, including statements about the following:

- Our belief that new products, new indications, global expansion, and business development are the four growth areas that will drive our business in the future;
- The potential impact that public health crises and geopolitical conflicts may have on demand for and sales of our products and services, business operations, manufacturing operations, supply chain, cash flow, workforce, clinical and regulatory timelines, and our research and development projects;
- The potential impact of general global, regional, or national economic downturns and macroeconomic trends, including heightened inflation, interest rate, currency fluctuations, and proposed tariffs, as well as general or localized economic slowdowns or recessions may have on demand for and sales of our products and services, including ordering trends for international distributors based on currency fluctuations against the US dollar, and our business operations, manufacturing operations, supply chain, and workforce;
- Our beliefs about the robustness of our global supply chain in light of current global and macroeconomic conditions and about the potential impact of supply chain disruptions, particularly disruptions to single and sole source suppliers and third-party manufacturing partners;
- Our beliefs about our R&D and product pipeline, including our beliefs about the timing and results of our clinical trials, approvals, and product commercialization and launches;
- Our beliefs and anticipation regarding the favorable attributes, benefits, and clinical advantages of our products and services, the basis on which our products and services compete, the benefits of our physician education activities, and the advantages of our relationships with organ and tissue procurement organizations and tissue banks;
- Our beliefs about the future regulatory status of our medical devices and processed tissues, our compliance with applicable laws and regulations, and our ability to make timely transitions to our Notified Bodies and obtain renewals for our Conformité Européenne Mark product certification impacted by Brexit and the transition to the Medical Device Regulation in Europe, and the impact these transitions, renewals, and related processes may have on our business, including any impact on our customers' ordering patterns and our ability to supply products;
- Our beliefs regarding our global expansion efforts, including the international growth opportunity provided by obtaining regulatory approval for BioGlue in China;
- Our beliefs about the potential impact on our business of changes to regulations, regulators, Notified Bodies, and related matters;
- Our beliefs about the advantages of our intellectual property and its significance to our segments and our business as a whole, and our beliefs about the present value and potential impairment of our intangible assets and leases;
- Our beliefs about our workforce, including our ability to attract and retain talent at all levels, and about our relationship with our workforce, including our works council in Germany and union in Brazil;
- Our beliefs about potential information security vulnerabilities, and the associated potential adverse effects on our business;
- Our beliefs about the business impact of, and expenses associated with the 2024 Cybersecurity Incident, and our beliefs about the cybersecurity threat environment;
- The dependencies affecting our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the agreements with Endospan and Baxter and our acquisition of Ascyrus, and our beliefs about the costs and timelines for certain regulatory approvals and clinical trial milestones;

- Our beliefs regarding the fair value of our acquisitions, divestitures, and other business development activities and the estimates and assumptions about the future achievements of milestones and future revenues and cash flows related to those business development activities, including our ability to achieve the milestones in the Ascyrus and Baxter transactions;
- Our belief that revenues for preservation services, particularly revenues for certain high-demand cardiac tissues, can vary from quarter-to-quarter and year-to-year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, staffing levels, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services;
- Our beliefs regarding the seasonal nature of the demand for some of our products and services and the reasons for such seasonality, if any, and regarding the impact of consignment inventory on product sales, if any;
- Our belief that our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months, our expectations regarding future cash requirements and expenditures, and the impact that our cash requirements might have on our cash flows for the next twelve months;
- Our expectation regarding the impact on cash flows of undertaking significant business development activities and the potential need to obtain additional debt financing or equity financing;
- Our belief that we will incur expenses for research and development projects, including for clinical research projects to gain regulatory approvals for products or indications, including existing products, and for new products and technologies which will likely require additional investment, research, and new clinical studies or data;
- Our beliefs about market opportunity and our ability to capture market share;
- Our beliefs about pending and potential legal or other governmental or regulatory proceedings;
- Our expectations regarding the timing and impact of clinical research work and regulatory approvals for certain products or indications, including On-X products, aortic stent grafts, and surgical sealants, and the CryoValve SG pulmonary heart valve if the US Food and Drug Administration ("FDA") reclassifies allograft heart valves as Class III medical devices;
- Our beliefs and expectations regarding the utilization of net operating loss carryforwards from our acquisitions of JOTEC GmbH, On-X Life Technologies, Inc., Hemosphere, Inc., and Cardiogenesis Corporation;
- Our beliefs about our operating results which may fluctuate significantly on a periodic basis as a result of internal and external factors, including reduced demand for our products, the potential impact of new therapies, healthcare workforce trends and labor disputes, regulatory challenges, the availability of products, materials, and supplies, strategic actions we take such as acquisitions or divestitures, unanticipated costs and expenses, market reception of our new or improved product offerings, and interest rate and currency fluctuations; and
- Other statements regarding projections of future financial and business performance; anticipated growth and trends in our business and the markets relevant to our business, including how our growth relates to our competitors; the robustness and reliability of our workforce and supply chain; future production capacity and product supply; the availability and benefits of our products in the future; and the expected timing and impact of our strategic initiatives.

These and other forward-looking statements reflect the views of management at the time such statements are originally made based on certain assumptions and analyses made by us in light of our experience and our perception of historical trends, current conditions, and expected future developments, as well as other factors we believe are appropriate in the circumstances and are subject to a number of risks, uncertainties, estimates, and assumptions. Whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially and adversely from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risk factors discussed in Item 1A of this Form 10-K and other factors, many of which are beyond our control. Consequently, all of the forward-looking statements made in this Form 10-K are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by us will be realized, or even if substantially realized, that they will have the expected consequences to, or effects on, us or our business or operations. Readers are urged to carefully review and consider the various disclosures made in this Form 10-K and in other documents we file from time to time with the SEC that disclose risks and uncertainties that may affect our business. Unless specifically indicated otherwise, the forward-looking statements in this Form 10-K do not reflect the potential impact of any divestitures, mergers, acquisitions, or other business combinations that have not been completed as of the date of this filing. We assume no obligation, and expressly disclaim any duty, to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

PART I

Item 1. Business.

Overview

Artivion, Inc. ("Artivion," the "Company," "we," or "us"), is a leader in the manufacturing, processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures for patients with aortic disease. We have four major product families: aortic stent grafts, surgical sealants, On-X® mechanical heart valves and related surgical products ("On-X" products), and implantable cardiac and vascular human tissues. Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, and synthetic vascular grafts. Aortic arch stent grafts include our E-vita® Open NEO, E-vita Open Plus, the Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, the NEXUS ONE™ ("NEXUS ONE"), NEXUS DUO™ ("NEXUS DUO"), and NEXUS TRE™ ("NEXUS TRE") aortic arch stent graft systems (the "NEXUS family of products"), and E-vita Thoracic 3G products. Abdominal stent grafts include our E-xtra Design Engineering (including Artivex™), E-nside™, E-tegra™, E-ventus™ BX, Tuva™ BX, and E-liac™ products. Surgical sealants include our BioGlue® Surgical Adhesive products ("BioGlue"). In addition to these four major product families, we sell or distribute PhotoFix® bovine surgical patches ("PhotoFix") and CardioGenesis® cardiac laser therapy (prior to our abandonment of the business as of June 30, 2023). We began to manufacture and supply PerClot® hemostatic powder ("PerClot") during the second quarter of 2023 (as part of the Transitional Manufacturing and Supply Agreement ("TMSA") of the Baxter Transaction, described below).

On January 1, 2022 we converted our state of incorporation from Florida to Delaware, and on January 18, 2022 we changed our name from CryoLife, Inc. to Artivion, Inc. Our common stock is listed on the New York Stock Exchange under the symbol of "AORT" and traded under the symbol "CRY" prior to January 24, 2022.

Corporate Structure

Our main operating subsidiaries include JOTEC GmbH ("JOTEC"), a Hechingen, Germany-based endovascular and surgical products company acquired on December 1, 2017, On-X Life Technologies, Inc. ("On-X LTI"), an Austin, Texas-based mechanical heart valve company acquired on January 20, 2016, Ascyrus Medical GmbH, a manufacturing entity founded in September 2020, as well as approximately twenty additional country entities to provide sales and marketing support throughout the world.

Segments and Geographic Information

We have two reportable segments organized according to our products and services: Medical Devices and Preservation Services. The Medical Devices segment includes revenues from sales of aortic stent grafts, surgical sealants, On-X products, and other product revenues. The Preservation Services segment includes services revenues from the preservation of cardiac and vascular implantable human tissues. See Part II, Item 8, Note 16 of the "Notes to Consolidated Financial Statements" for further information on our segments and for our geographic information.

Strategy

Artivion is committed to partnering with surgeons and cardiologists to deliver innovative technologies of unsurpassed quality that restore the health of patients with aortic disease. Our strategic plan is focused on four growth areas that we expect to drive our business in the future as follows:

- *New Products* – Through product development and commercialization of new and next-generation products and services focused on aortic repair;
- *New Indications* – Through regulatory approvals in new markets and for new products, and through approvals for expanded indications for our existing products and services;
- *Global Expansion* – By entering new international markets, establishing new international direct sales territories, and developing our commercial infrastructure in new markets, including emerging markets, such as China and Brazil; and

- *Business Development* – By pursuing select acquisitions, licensing, and distribution opportunities that are aligned to our objectives and complement our existing products, services, and infrastructure. Examples include our acquisitions of JOTEC, On-X LTI, and Ascyrus Medical LLC ("Ascyrus"), and our distribution agreement and purchase option for the NEXUS family of products. To the extent that we identify, develop, or acquire non-core products or applications, we may dispose of these assets or pursue licensing or distribution agreements with third-party partners for development or commercialization such as the sale of the PerClot product line.

Markets, Products, Services, and Competition

Our medical devices and preservation services are primarily used by cardiac and vascular surgeons to treat patients with aortic disease, including heart valve disease, aortic aneurysms and dissections, and, to a lesser extent, other conditions in cardiac and vascular surgery.

We face competition from several domestic and international medical device, pharmaceutical, and biopharmaceutical companies and from both for-profit and non-profit tissue processors. Many of our current and potential competitors have greater financial and personnel resources than we have. Some of these competitors might have greater experience in developing products, procuring tissues, conducting clinical trials, and obtaining regulatory approvals, and they might have large contracts with hospitals under which they can obtain purchase requirements that place our products at a disadvantage. Some of these competitors might obtain patent protection or approval or clearance by the FDA or foreign regulators sooner than we do. Some might have superior manufacturing efficiency, tissue processing capacity, and/or marketing capabilities. We cannot ensure that our current or future competitors will not succeed in developing alternative technologies, products, or services that have advantages over those that have been, or are being, developed by us or that would render our products or technologies obsolete or non-competitive. Any of these competitive disadvantages could materially, adversely affect us.

We discuss the disease states in which we compete and our products, services, and technologies that treat these diseases below.

Aortic Disease

Aortic Valve Disease

Patients with heart disease can experience valve insufficiency, regurgitation, or stenosis that may require heart valve repair or replacement surgery. Patients with congenital cardiac defects such as tetralogy of fallot, truncus arteriosus, and pulmonary atresia can require complex cardiac reconstructive surgery to repair the defect. A variety of tissues and synthetic materials are implanted in these cardiac procedures. Implantable human tissues (allografts) and animal tissues (xenografts) as well as other synthetic materials may be used in cardiac procedures. Implantable devices may be entirely synthetic, such as mechanical heart valves, or contain both synthetic materials and xenograft tissue components, such as bioprosthetic heart valves. These devices may be implanted surgically through open heart surgery, or in some cases, without sternotomy through transcatheter valve replacement.

Mechanical heart valves are durable and often last for the remainder of a patient's life without replacement, even for relatively young patients with long life expectancies. Mechanical heart valves are readily available and are a less expensive solution for those requiring a heart valve replacement. Patients who receive mechanical heart valves are required to undergo long-term blood thinning or anticoagulation drug therapy to minimize the risk of thromboembolism, stroke, or other complications from the formation of blood clots.

Bioprosthetic heart valves are readily available and are a relatively inexpensive solution for those requiring a valve replacement. Bioprosthetic heart valves contain bovine, equine, or porcine tissues that are typically processed with glutaraldehyde, which may result in progressive calcification, or hardening of the tissue over time, reducing the lifespan of the device. Bioprosthetic heart valves usually have a life of 7 to 15 years, after which the valve typically must be replaced. Patients receiving a bioprosthetic heart valve may not require long-term anticoagulation drug therapy, although some of these patients may require anticoagulation drug therapy for other heart or vascular conditions that are common in this patient population.

Multiple heart valve replacements, each requiring open heart surgery, can be a significant concern for patients, particularly younger patients that tend to choose mechanical heart valves over bioprosthetic heart valves. On the other hand, the requirement that mechanical heart valve recipients undergo long-term anticoagulation drug therapy can be a concern for patients that may lead some patients to choose bioprosthetic heart valves over mechanical heart valves.

Both mechanical heart valves and bioprosthetic heart valves contain a synthetic sewing ring to facilitate surgical implantation of the device. The sewing rings of both mechanical and bioprosthetic heart valves are synthetic materials that may harbor bacteria and lead to endocarditis and infection that can be difficult to treat with antibiotics. Patients with an infected mechanical or bioprosthetic heart valve may require valve replacement surgery. The 2013 Society of Thoracic Surgeons Guidelines, as published in the Annals of Thoracic Surgery, have increased the indication (from Class II to Class I) and broadened the scope for using an aortic allograft, or a human heart valve, during aortic valve replacement surgery due to endocarditis. The Class I indication means that an aortic allograft is the recommended course of treatment when endocarditis has functionally destroyed the aortic valve annulus. The previous Class II indication meant that it was an acceptable course of treatment.

Human heart valves are used in valve replacement procedures. Human heart valves allow for more normal blood flow, often provide higher cardiac output than mechanical and bioprosthetic heart valves, and do not require long-term anticoagulation drug therapy. Human tissue responds better to treatment for infections, and consequently, for many physicians, human heart valves are the preferred alternative to animal-derived and mechanical heart valves for patients who have, or are at risk to contract, endocarditis. Human tissue valves also are not as susceptible to progressive calcification as glutaraldehyde-fixed bioprosthetic tissues. A Ross Procedure may be a preferred surgical technique by physicians and patients, particularly for young patients, due to the human heart valve's long-term resistance to calcification and the patient's relative freedom from re-intervention surgery. In a Ross Procedure, a diseased aortic valve is replaced with a patient's own pulmonary valve, which is in turn replaced with a donated human pulmonary valve.

Human tissue patches are used in a variety of cardiac repair procedures. Human vascular tissues are used in cardiac and vascular bypass surgery. The transplant of any human tissue that has not been preserved, however, must be accomplished within extremely short time limits. Cryopreservation, or cooling and storing at extremely cold temperatures, expands the treatment options available by extending these timelines. Cryopreserved human tissue patches and human vascular tissues are available for use in a variety of cardiac and vascular procedures.

We currently market the On-X aortic and mitral mechanical heart valves for valve replacement procedures. We also market our cardiac preservation services, including our CryoValve® and CryoValve SG human tissues, for heart valve replacement surgeries and our CryoPatch® and CryoPatch SG human tissues for cardiac repair procedures. Our PhotoFix product is a bovine patch device used for cardiac and vascular repair.

Aortic Aneurysms

The aorta is the main artery that carries blood out of the heart from the aortic valve to the rest of the body. It extends upwards from the heart through the aortic arch and then down through the chest and into the abdomen, where it divides into arteries that supply each leg. The aorta is comprised of five segments: ascending, arch, thoracic, thoraco-abdominal, and abdominal. In some patients, part of the aorta can become abnormally large or bulge, referred to as an "aneurysm."

An aneurysm results from a weakening in the wall of an aorta, which causes the aorta to progressively "balloon" or expand in size. Although an aneurysm can develop anywhere along the aorta, most occur in the section running through the abdomen (abdominal aortic aneurysms or "AAA"). Others occur in the section that runs through the chest (thoracic aortic aneurysms or "TAA") or the area between the chest and the abdomen (thoraco-abdominal aortic aneurysms or "TAAA"). The precise cause of aortic aneurysms is uncertain, but risk factors include high blood pressure, high cholesterol, smoking, obesity, and being male. As an aneurysm grows, the wall of the aorta is progressively weakened until it can split or tear resulting in a ruptured aorta or an aortic dissection. Left untreated, aortic aneurysms can result in a ruptured aorta, leading to death.

There are two types of aortic aneurysm repair: open surgical repair and endovascular repair. Open surgical repair can result in reasonable long-term survival but carries risks especially in older patients and those with other serious medical conditions.

During open surgical repair, a vascular graft is implanted from above the aneurysm to below the aneurysm in the aorta. Blood will then flow through the graft. This surgery reinforces the diseased aorta and reduces the chance of vessel rupture.

Endovascular repair is a minimally invasive procedure, during which a stent graft is delivered through the femoral artery to the area in the aorta needing repair. The stent graft expands inside the aorta and becomes the new channel for blood flow. The stent graft shields the aneurysm and helps prevent more pressure from building on it, thus preventing it from rupturing.

Following our acquisition of JOTEC, we began commercialization of a broad portfolio of endovascular products for repair of aortic aneurysms. These include highly differentiated products, such as E-xtra Design Engineering, a portfolio of stent grafts tailor-made for a patient's anatomy for TAAA repair, and the E-liac™ for repair of aneurysms in the iliac arteries, as well as less differentiated products, including the E-vita® Thoracic 3G for TAA repair and the E-tegra™ for AAA repair.

Aortic Dissections

An aortic dissection occurs when the innermost layer of the aorta tears and blood surges through the tear separating the inner layer from the outer layers of the aorta. Younger patients with inherited connective tissue disorders, such as Marfan syndrome, and patients with bicuspid aortic valves (two leaflets on the valve instead of three) are more likely to develop aortic dissection. In addition, as an aneurysm grows, the wall of the aorta is progressively weakened until it can split or tear, resulting in a ruptured aorta or an aortic dissection. Left untreated, an aortic dissection often results in a ruptured aorta, leading to death.

Aortic dissections often begin in the ascending aorta or aortic arch and may also have an aneurysm or an aortic dissection extending down the descending thoracic aorta. Often, the dissection in the aortic arch and the condition in the descending thoracic aorta are repaired in a two-stage procedure, with one open surgical procedure to repair the arch followed by another procedure to repair the descending thoracic aorta. We sell the E-vita Open Plus, E-vita Open NEO, and AMDS as well as distribute the NEXUS family of products to treat these conditions impacting the aortic arch and thoracic aorta.

Other Disease States – Peripheral Vascular Disease and End Stage Renal Disease

Patients with peripheral vascular disease can experience reduced blood flow, usually in the arms and legs. This can result in poor circulation, pain, and sores that do not heal. Failure to achieve revascularization of an obstructed vessel may result in the loss of a limb or even death of the patient. When patients require peripheral bypass surgery, the surgeon's first choice generally is a graft of the patient's own tissue (an autograft). In cases of advanced vascular disease, however, patients may not have suitable vascular tissue for transplantation. Other vascular repair procedures include procedures related to infected abdominal aortic grafts, vascular access for dialysis patients, carotid endarterectomy, and vessel repair. These procedures may include the use of bioprosthetic grafts or patches, synthetic grafts or patches, or donated human vascular tissues. Alternative treatments may include the repair, partial removal, or complete removal of the damaged tissue.

End-stage renal disease ("ESRD") refers to the stage of renal disease when the kidneys do not work well enough for the patient to live without on-going dialysis or kidney transplant. Patients with ESRD often undergo hemodialysis through an access site with an implanted vascular graft. We market our CryoVein® femoral vein and CryoArtery® femoral artery vascular preservation services for vascular access.

Bioprosthetic vascular grafts and patches, including those made of bovine or porcine tissue, can be used for a variety of vascular repair procedures. Bioprosthetic grafts are readily available and are a relatively inexpensive solution for those requiring a vascular repair procedure. Bioprosthetic tissues are typically processed with glutaraldehyde, which may result in progressive calcification.

Synthetic vascular grafts and patches can be used for a variety of vascular repair procedures. Synthetic grafts are readily available and are a relatively inexpensive solution for those requiring a vascular repair procedure. Synthetic grafts and patches, however, are generally not suitable for use in infected areas because they may harbor bacteria and are difficult to treat with antibiotics. Synthetic vascular grafts have a tendency to obstruct over time, particularly in below-the-knee surgeries.

Human vascular tissues tend to respond better to treatment for infection and remain open and accessible for longer periods of time and, as such, are used in indications where synthetic grafts typically fail, such as in infected areas and for below-the-knee surgeries. Human vascular and arterial tissues are also used in a variety of other reconstruction procedures such as cardiac bypass surgery and as vascular access grafts for hemodialysis patients. The transplant of human tissue that has not been preserved must be accomplished within extremely short time limits. Cryopreservation expands the treatment options available by extending these timelines.

We market our vascular preservation services, including our CryoVein and CryoArtery tissues, and a synthetic surgical graft portfolio for peripheral vascular reconstruction surgeries.

Product Categories and Products

On-X Mechanical Heart Valves

The On-X product line includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis ("AAP"). We also distribute CarbonAid® CO_2 diffusion catheters and sell Chord-X® ePTFE sutures for mitral chordal replacement, and we offer pyrolytic carbon coating services to other medical device manufacturers as part of the On-X family of products.

On-X heart valves are bileaflet mechanical valves composed of a graphite substrate coated with our silicon-free pyrolytic carbon coating that provides a smooth microstructure surface. We believe that the smooth pyrolytic carbon surface and other characteristics of the valve, such as full, 90-degree leaflet opening of the valve and flared valve inlet, contribute to the flow dynamics of the On-X valve. The On-X AAP is an On-X aortic valve combined with a synthetic vascular graft to allow physicians to more conveniently treat patients requiring both an aortic valve replacement and replacement of a portion of the ascending aorta with an aortic graft. Each device is available in a range of valve sizes in a variety of sewing ring options to suit physicians' preferences, along with dedicated instruments to facilitate valve sizing and implantation. On-X heart valves are FDA approved for the replacement of diseased, damaged, or malfunctioning native or prosthetic heart valves in the aortic and mitral positions and are classified as a Class III medical device. We also hold a Conformité Européene Mark product certification ("CE Mark") for On-X heart valves.

All mechanical heart valve patients require long-term anticoagulation drug therapy with a drug called warfarin to reduce the risk of blood clots and stroke. Because warfarin can also cause a risk of harmful bleeding, dosage must be monitored and may require adjustment over time. Certain dietary restrictions may also be imposed on warfarin patients.

In 2015 the FDA approved the On-X aortic valve for use with a lower INR (International Normalized Ratio), which means that patients with On-X aortic heart valves can be managed on lower doses of warfarin for anticoagulation. This new indication was, and still is, unique to the On-X aortic valve and was based on a prospective, randomized, controlled clinical trial called PROACT comparing a reduced versus standard warfarin dose for On-X heart valve recipients. In the aortic valve replacement arm of the trial, the reduced warfarin dose group had 60% fewer bleeding events without an increased risk of stroke. The 2020 American Heart Association / American College of Cardiology guidelines specifically mentioned On-X aortic heart valves as the only mechanical aortic heart valve that can be managed at a low INR of 1.5-2.0. Recent real-world data presented at the 2023 Annual European Association for Cardio-Thoracic Surgery Conference showed one-year outcomes for 510 On-X aortic heart valve patients at low INR (1.5-2.0) reduces risk of major bleeding by more than 84%, proving safe for patients with no significant increase in thromboembolic events and no valve thrombosis. Furthermore, this was confirmed by the five-year outcomes from this cohort that determined in a real-world setting, the On-X aortic heart valve managed at a low INR of 1.5-2.0 (after 3 months of standard therapy) demonstrated an 87% reduction in major bleeding with no increase in thromboembolic events and no valve thrombosis when compared to standard INR of 2.0-3.0.

While use of a lower INR has been approved for the On-X aortic heart valve, such use in mechanical mitral heart valves has not been approved by the FDA.

On-X heart valves compete primarily with mechanical valves from Abbott Laboratories, Medtronic, plc. ("Medtronic"), and Corcym S.r.l. (who completed acquisition of the LivaNova heart valve business in June 2021) ("Corcym"). On-X heart valves

compete with these products based on their features and benefits, such as full, 90-degree leaflet opening, pure pyrolytic carbon, flared inlet, and approved labeling claim for reduced INR for aortic valves.

We began selling On-X heart valves in January 2016 following our acquisition of On-X LTI. We sell On-X heart valves throughout the world including North America, Europe, the Middle East, and Africa (collectively, "EMEA"), Asia Pacific ("APAC"), and Latin America ("LATAM").

Aortic Stent Grafts

Hybrid stent grafts, surgical grafts, and endovascular stent grafts can be used in the treatment of complex thoracic and abdominal aortic disease, such as aortic dissections and aortic aneurysms, as well as in other aortic and peripheral procedures.

Thoracic Stents and Stent Grafts

E-vita Open NEO

The E-vita Open NEO is the next generation of the E-vita Open Plus hybrid stent graft, with an updated delivery system and improved handling. We obtained a CE Mark for E-vita Open NEO in the first quarter of 2020 and began full product launch in the fourth quarter of 2020.

E-vita Open NEO is a hybrid stent graft system used in the treatment of patients with either an aneurysm or dissection in the aortic arch and in the descending thoracic aorta. The E-vita Open NEO stent graft system enables a one-stage treatment to repair this condition through a combined surgical and endovascular treatment, providing a more cost-effective solution for the healthcare system and allowing the patient to avoid an additional operation.

We obtained marketing approvals in addition to the CE Mark for the E-vita Open NEO in other countries throughout the world. The E-vita Open NEO competes outside the US with products from Terumo Medical Corporation ("Terumo", formerly Vascutek) and two smaller companies. We do not currently sell E-vita Open NEO in the US. The E-vita Open NEO competes in Europe primarily on its proven stent graft technology and long-term clinical data. The CE Mark for the E-vita Open Plus expired in 2022 and is only sold in limited countries including Brazil.

AMDS™

We acquired Ascyrus in September 2020. Ascyrus developed the AMDS hybrid prosthesis, the world's first aortic arch remodeling device for use in the treatment of acute Type A aortic dissection. Hemi-arch reconstruction is the standard of care for the treatment of acute Type A aortic dissection. AMDS is used as a complement to, and in conjunction with, hemi-arch reconstruction without adding technical complexity to this life-saving procedure. The design of the AMDS allows for rapid deployment of the graft in the aortic arch during a standard replacement of the ascending aorta, adding on average approximately five minutes for deployment with additional time for suturing to complete the standard procedure. The deployment of the AMDS preserves the native arch, potentially allowing for minimally invasive re-interventions as needed, including the repair of additional entry tears, rather than an invasive arch repair. In the Dissected Aorta Repair Through Stent clinical trial supporting its CE Mark and Health Canada approvals, the AMDS was shown to reduce mortality, complications, and reoperations compared to the standard of care, thereby improving the care of patients and offering significant cost savings for the health care system.

AMDS indirectly competes with other manufacturers' standard open surgical repair and hybrid procedures including aortic debranching and frozen elephant trunk technique for total arch replacement. We began selling AMDS in September 2020 following the acquisition of Ascyrus. We sell AMDS in EMEA, Canada, APAC, and LATAM. We had minimal sales of AMDS in the US in 2023 under the investigational device exemptions ("IDE") and through special grants of continued access in 2024 while waiting for PMA approval in the US. Enrollment for the PERSEVERE clinical trial to gain US approval was completed in November of 2023. In December 2024 the FDA granted a humanitarian device exemption ("HDE") for use of the AMDS™ Hybrid Prosthesis in acute DeBakey Type I dissections in the presence of malperfusion. The HDE allows for, subject to certain restrictions, commercial distribution of AMDS in the United States ("US") prior to the approval of a

Premarket Approval ("PMA") Application, which we currently anticipate receiving in 2026 allowing for full commercial distribution of AMDS in the US.

NEXUS Products

We distribute the NEXUS family of products in certain countries in Europe under an exclusive distribution agreement with Endospan Ltd. ("Endospan"), an Israeli corporation. Endospan holds a CE Mark for NEXUS ONE which is the only endovascular stent graft system approved for the repair of both aneurysms and dissections in the aortic arch and markets the NEXUS DUO as a custom-made alternative for flexible aortic arch repair. NEXUS DUO is a low profile, custom made aortic arch system designed to treat a range of aortic arch pathologies including chronic dissection, aortic aneurysm, penetrating aortic ulcer, as well as intramural hematoma. Unlike the NEXUS ONE off-the-shelf device, NEXUS DUO includes a secondary branch designed to minimize surgical preparation for patients undergoing endovascular repair of the aortic arch. While open surgical repair remains the standard of care for complete aortic arch replacement, endovascular repair offers an alternative, less invasive procedure to treat the aortic arch with decreased surgical morbidity and mortality. The ability to repair the aortic arch with an endovascular approach is especially advantageous for elderly patients who are not suited for open surgery and for patients who were previously treated for a Type A dissection in an open surgical approach. The addition of the NEXUS family of products to our highly differentiated aortic stent graft portfolio further strengthens our position as a leader in the aortic repair market.

Several other manufacturers are introducing competitive products through the custom-made device process in Europe and the early feasibility process within the US, including Cook, Gore, and Terumo. The NEXUS family of products also compete with other manufacturers' standard open repair and hybrid procedures including aortic debranching, frozen elephant trunk, and thoracic endovascular aortic repair with chimneys or snorkels.

We began distribution of NEXUS ONE in the fourth quarter of 2019 in EMEA. The first implant of the NEXUS DUO, the dual branch graft system in the NEXUS product line, occurred in the fourth quarter of 2022 as a limited market release. We began distribution of NEXUS TRE, the custom-made three branch graft, in the third quarter of 2024 as a limited market release.

We also entered into a securities purchase option agreement with Endospan ("Endospan Option") in September 2019 and subsequent amendment ("Endospan Option Amendment") in July 2024 (as described in Part II, Item 8, Note 4 of the "Notes to Consolidated Financial Statements") which provides us the option to purchase all the outstanding securities of Endospan from Endospan's securityholders at the time of acquisition (or the option to acquire all of Endospan's assets) up through a certain period of time after FDA approval of NEXUS ONE. Endospan completed patient enrollment in their US pivotal trial, TRIOMPHE in the fourth quarter of 2024.

E-vita Thoracic 3G

The E-vita Thoracic 3G is a stent graft system that enables endovascular treatment of TAAs. Its unique spring configuration gives the stent graft flexibility, helping the stent graft adapt to the vessel's shape and ensuring a good seal at the landing zone, even in the case of complex vascular anatomy. Compared to its competing products, its different proximal and distal stent graft configurations, as well as straight and conical designs, enable individual treatment of the diseased aorta. The product line includes a wide portfolio of tapered versions from proximal to distal. The wide variety ensures the possibility of adapting the stent graft to the native course of the descending aorta. The E-vita Thoracic 3G is sometimes used in conjunction with the E-vita Open NEO and E-xtra Design Engineering.

Until 2022 we held a CE Mark for the E-vita Thoracic 3G and additional marketing approvals have been granted in several other countries throughout the world. The E-vita Thoracic 3G competes primarily with products from Medtronic, Gore, Terumo, and Cook.

Thoraco-abdominal Stents and Stent Grafts

E-xtra Design Engineering

E-xtra Design Engineering is a comprehensive range of stent graft systems for the treatment of aortic vascular diseases that enables surgeons to quickly and efficiently respond to an individual patient's therapeutic requirements. E-xtra Design Engineering stent graft systems are tailor-made for individual patients based on imaging of the patient's own aorta. There are currently only limited off-the-shelf products to treat aneurysms in the thoraco-abdominal aorta due to the many side branches in this anatomy where blood flow to vital organs would be obstructed by unbranched stent grafts. We have pioneered a service whereby we can manufacture a customized thoraco-abdominal stent graft in approximately 22 working days. Our custom E-xtra Design Engineering stent graft system includes TAAA and Artivex™ Thoracic Extension Stent Graft System ("Artivex"). Our custom TAAA is often used in conjunction with E-vita Thoracic 3G, as well as the AAA offering, the E-tegra, or in combination with both. In December 2023 we launched Artivex as part of our E-xtra Design Engineering stent graft systems in EMEA. Artivex is indicated for use in both thoraco-abdominal aneurysms and dissections extending into the thoraco-abdominal aorta.

We sell custom TAAA and Artivex in EMEA and in a limited number of other countries around the world. TAAA competes with customized product offerings from Cook and Terumo. Artivex competes with other thoracic extension products marketed by Medtronic, Gore, Terumo, and Cook.

E-nside™

The E-nside TAAA multibranch stent graft system is an off-the-shelf stent graft with pre-cannulated inner branches indicated for treatment of patients with thoraco-abdominal disease. The E-nside's pre-cannulated inner branches are designed to reduce the overall procedure time which reduces the patient's exposure to radiation. The vast majority of patients with thoraco-abdominal disease are treated with risky, invasive open surgical procedures, characterized by lengthy hospitalization periods and prolonged recuperation, or with custom-made stent grafts which can take up to 90 days to manufacture. We believe the addition of E-nside positions us well to capture share in the European aortic stent graft market because E-xtra Design Engineering provides patient-specific solutions, and E-nside provides an off-the-shelf solution. Further, there are synergies between E-nside and our portfolio of thoracic and abdominal stent grafts. E-nside competes with products from Cook.

We obtained a CE Mark for E-nside in the fourth quarter of 2019 and began limited selling of E-nside in the second quarter of 2020. We fully launched E-nside in 2021.

Abdominal and Peripheral Stents and Stent Grafts

E-tegra™

The E-tegra is a AAA stent graft system with special stent design for secure sealing that makes difficult vascular anatomies treatable, thus expanding endovascular treatment options for infrarenal abdominal aortic aneurysms. The design of the E-tegra enables optimal fixation and sealing. It is a proximal laser cut stent with anchors for suprarenal stent graft fixation. Its asymmetric stent design and seamless cover ensure excellent adaptation to the vessel. The product also features a low-profile delivery system with its unique squeeze-to-release mechanism supporting the user by ensuring excellent control during each phase of the implantation. The E-tegra is often used in combination with E-xtra Design Engineering and the E-liac.

We hold a CE Mark for the E-tegra and additional marketing approvals have been granted in several other countries throughout the world. The E-tegra competes with products from several companies including Medtronic, Gore, Terumo, Endologix, and Cook.

E-ventus™ BX

E-ventus BX is a balloon-expandable peripheral stent graft indicated for the endovascular treatment of renal and pelvic arteries in cases of ruptures, dissections, and aneurysms. The E-ventus BX stent grafts have a combination of high flexibility together with high radial strength through the combination of the microporous single-layer ePTFE cover and the cobalt

chromium stent. The E-ventus BX stent grafts feature minimal recoil and foreshortening and enables secure fixation and positioning in the vessel. The E-ventus BX delivery system has a highly flexible catheter that allows easy advancement in the vessel and enables lesions to be reliably reached by the catheter. Radiopaque markers on the delivery system enable secure and accurate positioning of the stent graft. The E-ventus BX is often used in conjunction with E-xtra Design Engineering products, E-nside stent grafts, and the E-liac stent graft.

The E-ventus BX was manufactured by Bentley, who holds a CE Mark for that product and additional marketing approvals in several other countries throughout the world. The E-ventus BX competes with products from Maquet, Gore, BD, and Bentley InnoMed. We received the final production lots of E-ventus BX in May 2023 and we substantially depleted the remaining inventory during 2024.

Tuva™ BX

Tuva BX is a balloon-expandable peripheral stent graft indicated for the endovascular treatment of arterial ruptures, aneurysms and other peripheral vascular system pathologies. The Tuva BX stents are manufactured using a cobalt chromium alloy which is covered internally and externally with ePTFE so that the stent is completely encapsulated. The Tuva BX stent is designed for different artery diameters by adapting its open cell design with alternating connection bridges. The device also has enhanced visibility due to three radiopaque markers at each stent end that facilitate accurate placement in implantation and post-dilation. The Tuva BX is often used in conjunction with E-xtra Design Engineering products, E-nside stent grafts, and E-liac stent grafts.

The Tuva BX is manufactured by LVD Biotech SL, who hold a CE Mark for that product and additional marketing approvals in several other countries throughout the world. The Tuva BX competes with products from Maquet, Gore, BD, and Bentley InnoMed.

E-liac

The E-liac is a stent graft used to treat aneurysmal iliac arteries as well as aneurysmal iliac side branches. The E-liac is a self-expanding stent graft characterized by easy and safe handling, which makes it possible to safely reach the lesion and accurately position the stent graft in the vessel. We estimate that 20% of patients who have an AAA also have an aneurysmal iliac artery, and as such, the E-liac is often used in conjunction with the E-tegra AAA device as well as one or two E-ventus BX devices.

We hold a CE Mark for the E-liac and additional marketing approvals have been granted in several other countries throughout the world. The E-liac competes with products from Gore and Cook.

Synthetic Vascular Grafts

In addition to our endovascular stent graft offerings, we have a broad line of synthetic vascular grafts that are used in open aortic and peripheral vascular surgical procedures. Our offerings include ePTFE grafts and both woven and knitted polyester grafts. Not only are we able to manufacture and sell a broad line of synthetic vascular graft offerings, but also, we are able to manufacture our own nitinol stents, given our expertise incorporating nitinol in our synthetic graft systems.

Our synthetic surgical vascular grafts have CE Marks and additional marketing approvals have been granted in several other countries throughout the world. Our synthetic grafts compete with products from Bard, a subsidiary of BD, Gore, LeMaitre, Terumo, and Maquet.

Surgical Sealants

Closing internal wounds effectively following surgical procedures is critical to the restoration of the function of tissue and to the ultimate success of the surgical procedure. Failure to seal surgical wounds effectively can result in leakage of blood in cardiac surgeries, air in lung surgeries, and cerebrospinal fluid in neurosurgeries potentially resulting in prolonged hospitalization, greater post-operative pain, higher costs, and higher mortality rates.

Sutures and staples facilitate healing by joining wound edges to allow the body to heal naturally. Sutures and staples, however, cannot consistently eliminate air and fluid leakage at the wound site, particularly when used to close tissues containing air or fluids under pressure, such as in blood vessels, the lobes of the lung, and the dural membrane surrounding the brain and spinal cord. In some cases, the tissues may be friable, which complicates surgical wound closure. In addition, it can be difficult and time consuming for the physician to apply sutures and staples in minimally invasive surgical procedures where the physician must operate through small access openings. We believe that the use of surgical adhesives and sealants, with or without sutures and staples, in certain areas can enhance the efficacy of these procedures through more effective and rapid wound closure.

Our proprietary BioGlue is a polymer consisting of bovine blood protein and an agent for cross-linking proteins, which was developed for use in cardiac, vascular, neurologic, and pulmonary procedures. BioGlue is stronger than other cardiovascular sealants with a tensile strength that is four to five times that of fibrin sealants. BioGlue begins to polymerize within 20 to 30 seconds, reaches its bonding strength within two minutes, and it adheres to tissues in a wet field. BioGlue is dispensed through a controlled delivery system that consists of a disposable syringe and various applicator tips. BioGlue syringes are available in pre-filled 2ml, 5ml, and 10ml volumes with applicator tips suitable for various applications.

BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. We distribute BioGlue under CE Mark for repair of soft tissues (which include cardiac, vascular, and pulmonary). We also distribute BioGlue in Japan where it is approved for adhesion and support of hemostasis for aortotomy closure sites, suture/anastomosis sites (including aortic dissection and anastomosis sites with use of a prosthetic graft), and suture sites on the heart. Additional marketing approvals have been granted for specified applications in numerous other countries throughout the world. We received regulatory approval to commercialize BioGlue in China during the third quarter of fiscal year 2024. We currently expect to commercialize BioGlue in China during the second half of 2025.

BioGlue competes primarily with surgical sealants from Baxter, Ethicon, Grena Ltd, Integra LifeSciences, and Bard, a subsidiary of BD. BioGlue competes with these products based on its features and benefits, such as its strength and ease of use.

We sell BioGlue throughout the world including North America, EMEA, APAC, and LATAM.

Preservation Services

Cardiac Preservation Services

Our proprietary preservation process involves our dissection, processing, preservation, and storage of donated human tissues until they are shipped to a hospital where they are implanted by physicians. The cardiac tissues we currently preserve include aortic and pulmonary heart valves and cardiac patches in three primary pulmonary anatomic configurations: hemi-artery, trunk, and branch. These tissues more closely resemble in structure, and simulate the performance of, the patient's own tissue compared to non-human tissue alternatives. Our cardiac tissues are used in a variety of valve replacement and cardiac reconstruction surgeries. We believe the human tissues we distribute offer specific clinical advantages over mechanical, synthetic, and bioprosthetic alternatives. Depending on the alternative, the clinical advantages of our heart valves include more natural blood flow properties, better results in patients who have endocarditis, no requirement for long-term drug therapy to prevent excessive blood clotting, and a reduced risk of catastrophic failure, thromboembolism, stroke, or deterioration due to calcification.

Our cardiac tissues include the CryoValve® SG pulmonary heart valve ("CryoValve SGPV") and the CryoPatch® SG pulmonary cardiac patch ("CryoPatch SG") which are both processed with our proprietary SynerGraft® decellularization technology. A multi-center study showed that, at 10 years, freedom from conduit dysfunction was significantly better in patients receiving our proprietary SynerGraft SGPV valves (83%) compared with patients receiving standard allografts (58%).

We believe that the human heart valves preserved by us compare favorably with bioprosthetic and mechanical valves for certain indications and patient populations, and that the human cardiac patches preserved by us compare favorably with

xenograft small intestine submucosa ("SIS") and glutaraldehyde fixed bovine pericardial patches due to the benefits of human tissue discussed above. Human tissue is preferred by many physicians as the replacement alternative with respect to certain medical conditions, such as pediatric cardiac reconstruction, congenital cardiac defect repair, valve replacements for women in their child-bearing years, and valve replacements for patients with endocarditis. In addition, implantation of SynerGraft treated cardiac tissue reduces the risk for induction of Class I and Class II alloantibodies, based on Panel Reactive Antibody ("PRA") measured at up to one year, compared to standard processed cardiac tissues. We believe that this reduced risk may provide a competitive advantage for CryoValve SGPV and CryoPatch SG for patients who later need a whole organ transplant, because an increased PRA can decrease the number of possible donors for subsequent organ transplants and increase time on transplant waiting lists.

Two other domestic tissue processors, LifeNet Health ("LifeNet") and LeMaitre Vascular ("LeMaitre"), offer preserved human heart valves and patches in competition with us. We believe that we compete favorably on the basis of surgeon preference, documented clinical data, technology, and customer service, particularly with respect to the capabilities of our field representatives. Alternatives to human heart valves processed by us include valve repair and valve replacement with bioprosthetic valves or mechanical valves. We compete with bioprosthetic or mechanical valves from companies including Medtronic, Edwards Lifesciences, Corcym, and Abbott Laboratories. Alternatives to our human cardiac patches include xenograft SIS and glutaraldehyde fixed bovine pericardial patches. We compete with these xenograft products from companies including Edwards Lifesciences, Anteris Technologies, Abbott Laboratories, and Baxter.

We ship human cardiac tissues to implanting institutions throughout the US. Our CryoValve SGPV and CryoPatch SG are distributed under 510(k) clearance from the FDA. We also ship limited tissues in Canada and other countries under special access programs.

Vascular Preservation Services

Our proprietary preservation process involves our dissection, processing, preservation, and storage of donated human tissues until they are shipped to a hospital for implantation by a physician. The vascular tissues currently preserved by us include saphenous veins, aortoiliac arteries, and femoral veins and arteries. Each of these tissues maintains a structure which more closely resembles and simulates the performance of the patient's own tissue compared to non-human tissue alternatives. Our vascular tissues are used to treat a variety of vascular reconstructions, such as peripheral bypass, hemodialysis access, and aortic infections, which have saved the lives and limbs of patients. We believe the human tissues we distribute offer specific advantages over synthetic and bioprosthesis alternatives, particularly for the treatment of infection in hemodialysis and peripheral bypass patients. Human tissue is not as susceptible to infection as synthetic alternatives and more closely simulates the performance of the patient's own tissue and vasculature compared to non-human tissue alternatives.

Two other domestic human tissue processors, LifeNet and LeMaitre, offer preserved vascular tissue in competition with us. There are also a number of providers of synthetic and bioprosthetic alternatives to vascular tissues preserved by us and those alternatives are available primarily in medium and large diameters. Our vascular tissues compete with products from Gore, BD, LeMaitre, LifeNet, and Maquet.

We believe that we compete favorably with other entities that preserve human vascular tissues on the basis of surgeon preference, documented clinical data, technology, and customer service, particularly with respect to the capabilities of our field representatives.

Other Products

PhotoFix

PhotoFix is a bovine pericardial patch fixated using a dye-mediated photo-oxidation process without the use of glutaraldehyde. We hold FDA 510(k) clearance and previously held a CE Mark for PhotoFix which is indicated for use in intracardiac repair, great vessel repair, suture line buttressing, pericardial closure, and vascular repair and reconstruction (for example: the carotid, iliac, femoral, and tibial blood vessels as well as arteriovenous access revisions). We are currently transitioning our PhotoFix CE Mark to our new Notified Body, DEKRA. See Part I, Item 1A, "Risk Factors—Legal, Quality,

and Regulatory Risks—Our products and tissues are highly regulated and subject to significant quality and regulatory risks," for a discussion of the risks related to our PhotoFix CE Mark.

Our PhotoFix product line competes with bioprosthetic and synthetic cardiac and vascular patch offerings from several other companies, including Baxter, LeMaitre, and Abbott Laboratories, based on PhotoFix's features and benefits, such as the photo-oxidation cross-linking process that does not use glutaraldehyde.

We sell PhotoFix in North America, EMEA, and APAC.

CardioGenesis Cardiac Laser Therapy for Angina Treatment

The CardioGenesis cardiac laser therapy product line is FDA approved for treating patients with severe angina that are not responsive to conventional therapy. We began selling the CardioGenesis cardiac laser therapy product line in the US in May 2011 when we completed the acquisition of CardioGenesis Corporation. Due to supply-related factors outside of our control, we abandoned the business as of June 2023.

PerClot

PerClot is an absorbable powdered hemostat, consisting of plant starch modified into ultra-hydrophilic, adhesive-forming hemostatic polymers. PerClot granules are biocompatible, absorbable polysaccharides containing no animal or human components. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier to any further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) at the site of application. PerClot does not require additional operating room preparation or special storage conditions and is easy to apply. PerClot is readily dissolved by saline irrigation and is totally absorbed by the body within several days.

In September 2010 we entered into a distribution agreement and a license and manufacturing agreement with Starch Medical, Inc. ("SMI"), which allowed us to distribute PerClot, worldwide, except a few countries. In July 2021 we entered into an asset purchase agreement and other ancillary agreements related to the sale of PerClot to a subsidiary of Baxter and an agreement to terminate all of our material agreements with SMI related to PerClot (collectively the "Baxter Transaction"). Under the terms of the Baxter Transaction, we will continue to provide to Baxter certain transition, manufacturing, and supply services relating to the sale of SMI PerClot outside of the US and manufacture and supply of PerClot to Baxter in the US.

In May 2023 we obtained FDA PMA approval to commercialize PerClot in the US, which we transferred to Baxter, and began manufacturing and supplying PerClot for Baxter, as discussed further in "Research and Development and Clinical Research" below.

Marketing and Distribution

In the US and Canada, we market our products and preservation services primarily to physicians and sell our products through our approximately 50-person direct sales team to hospitals and other healthcare facilities. We also have a team of regional managers, national accounts managers, and sales and marketing management. Through our field representatives and our physician relations and education department, we conduct field training for surgeons regarding the surgical applications of our products and tissues.

In EMEA, we market our products through our European headquarters, based in Hechingen, Germany, as well as through several other subsidiaries based throughout Europe. We employ approximately 100 direct field service representatives and distributor managers across several countries in the EMEA region. We provide customer service, logistics, marketing, and clinical support to cardiac, vascular, thoracic, and general surgeons throughout the EMEA region.

In APAC and LATAM, we commercialize our products through our independent distributors and our subsidiaries through approximately 50 sales and clinical support specialists.

Our physician relations and education staff, clinical research staff, and field representatives assist physicians by providing educational materials, seminars, and clinics on methods for using our products and implanting tissue preserved by us, including virtual and remote programs. We sponsor programs, and work with other companies such as Endospan to sponsor programs, where surgeons train other surgeons in best-practice techniques. In addition, we host several workshops throughout the year that provide didactic and hands-on training to surgeons. We also produce educational videos for physicians and coordinate peer-to-peer training at various medical institutions. We believe that these activities enhance the medical community's understanding of the clinical benefits of the products and tissues offered by us and help to differentiate us from other medical device companies and tissue processors.

Our human tissues are obtained in the US through organ and tissue procurement organizations ("OPOs") and tissue banks. To assist OPOs and tissue banks, we provide educational materials and training on procurement, dissection, packaging, and shipping techniques. We produce educational videos and coordinate laboratory sessions for OPO and tissue bank personnel to improve their recovery techniques and increase the yield of usable tissue. We also maintain staff 24 hours per day, 365 days per year, for OPO and tissue bank support.

Suppliers, Sources, and Availability of Raw Materials and Tissues

We obtain a number of our raw materials and supplies from a global supply base. The materials and supplies used in our product manufacturing and tissue processing are subject to regulatory requirements and oversight. If materials or supplies used in our manufacturing or tissue processing fail to meet these requirements or are subject to regulatory enforcement action, they may have to be scrapped, or our products or tissues could be rejected during or after processing, recalled, or rejected by customers. In these cases, we may have to immediately scrap raw or in-process materials and expense the costs of manufacturing or preservation.

In addition, if these materials or supplies, or changes to them, do not receive regulatory approval or are recalled, if the related suppliers and/or their facilities are shut down temporarily or permanently, for any reason, or if the related suppliers are otherwise unable or unwilling to supply us, we may not have sufficient materials or supplies to manufacture our products or process tissues. In addition, we rely on contract manufacturers to manufacture some of our products or to provide additional manufacturing capacity for some products. If these contract manufacturers fail to meet our quality standards or other requirements or if they are unable or unwilling to supply these products, we may not be able to meet demand for these products. Our ability to fully recover all possible losses from these suppliers and contract manufacturers may have practical limitations imposed by factors like industry standard contractual terms or the financial resources of the adverse party.

Some of the materials, supplies, and services used in our product manufacturing and tissue processing, as well as some of our products, are sourced from single- or sole-source suppliers. As a result, our ability to negotiate favorable terms with those suppliers may be limited, and if those suppliers experience operational, financial, quality, or regulatory difficulties, or if those suppliers and/or their facilities refuse to supply us or cease operations temporarily or permanently, or if those suppliers take unreasonable business positions, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. Ongoing sustaining efforts are in process to find alternative suppliers for single- or sole-source raw materials, supplies, and services wherever feasible. The process of qualifying alternative suppliers and manufacturers could result in additional costs or lengthy delays or may not be possible.

Finally, the war in Ukraine and conflicts in the Middle East, and other macroeconomic factors have impacted the global supply chain; workforces, global mobility, material availability, demand, shipping, and reorder times, and may continue to do so in the future. Any of these adverse outcomes could have a material, adverse effect on our revenues or profitability.

We have established operating mechanisms in place to manage this increased risk and we will continue to adjust as necessary into the future. See also Part I, Item 1A, "Risk Factors – Operational Risks" for our disclosures of risks related to suppliers, sources, and availability of raw materials and tissues.

Operations, Manufacturing, and Tissue Preservation

We conduct our internal manufacturing operations at three facilities: Austin, Texas for On-X products, Hechingen, Germany for internally manufactured aortic stent grafts, and Kennesaw, Georgia for most other products and services. Certain aortic stent graft assemblies are manufactured for us by a contract manufacturer in Slovakia. The AMDS product is solely manufactured by a supplier in Charlotte, North Carolina, and the NEXUS family of products are solely manufactured by Endospan in Herzliya, Israel.

See Part I, Item 1A, "Risk Factors—Business and Economic Risks—We are subject to a variety of risks due to our international operations and continued global expansion," for a discussion of risks related to our global footprint.

We maintain a facility—which contains our corporate headquarters, manufacturing, and laboratory space—and an additional off-site warehouse, in Kennesaw, Georgia. We manufacture BioGlue, PhotoFix, and PerClot and process human tissues at this facility.

Our On-X facility consists of combined manufacturing, warehouse, and office space in Austin, Texas, where our On-X products, including On-X heart valves and AAPs, are manufactured.

Our aortic stent graft facility consists of combined manufacturing, warehousing, and office space in Hechingen, Germany and is our EMEA headquarters.

We also maintain sales offices, some of which have distribution operations, in Brazil, Greece, Italy, Poland, Singapore, Spain, Switzerland, and the UK. See also Part I, Item 2, "Properties."

In all of our facilities, we are subject to regulatory standards for good manufacturing practices, including current Quality System Regulations, which are the FDA regulatory requirements for medical device manufacturers, and current Good Tissue Practices ("cGTPs"), which are the FDA regulatory requirements for the processing of human tissue. We also operate according to International Organization for Standardization ("ISO") 13485 Quality System Requirements, an internationally recognized voluntary system of quality management for companies that design, develop, manufacture, distribute, and service medical devices. We maintain a Certification of Approval to ISO 13485.

We employ a comprehensive quality assurance program in our product manufacturing and tissue preservation activities. Raw materials, solutions, and other components utilized in our manufacturing and tissue processing operations as well as certain subassemblies and finished goods manufactured by third parties are received and inspected by trained quality control personnel according to written specifications and standard operating procedures. Those items found to comply with our standards are utilized in our operations. Raw materials, solution, components, subassemblies, and tissues are documented throughout manufacturing or processing to ensure traceability.

We evaluate and inspect both our manufactured and distributed products to ensure conformity to product specifications. Processes are validated to review whether products manufactured meet our specifications. Each process is documented along with inspection results, including final finished product inspection and acceptance. Records are maintained as to the consignees of products to track product performance and to facilitate product removals or corrections, if necessary.

We maintain controls over our tissue processing to ensure conformity with our procedures. OPOs and tissue banks must follow our procedures related to tissue recovery practices and are subject to periodic audits to confirm compliance. Samples are taken from donated tissue for microbiological testing, and tissue must be shown to be free of certain detectable microbial contaminants before being released for distribution. Tissue processing records and donor information are reviewed to identify characteristics that would disqualify the tissue for processing or implantation. Once tissue is released for distribution, it is moved from quarantine to an implantable status. Tissue is stored by us until it is shipped to a hospital, where the tissue is thawed and implanted immediately or held in a liquid nitrogen freezer pending implantation.

Backlog

As of December 31, 2024 we did not have a significant backlog of orders related to our medical devices. The limited supply of certain types or sizes of preserved tissue can result in a backlog of orders for these tissues. The amount of backlog fluctuates based on the tissues available for shipment and the surgical needs of specific cases. Our backlog of human tissue consists mostly of pediatric tissues and certain sizes of adult valves that have limited availability. Our backlog is generally not considered firm and must be confirmed with the customer before shipment. Certain aortic stent grafts products are specifically designed to meet specifications of a particular patient which can result in a limited backlog of these products.

Government Regulation

Medical devices and human tissues are subject to a number of regulations from various government bodies including US federal, state, and local governments, as well as various international governments and regulatory bodies. Government regulations are continually evolving, and requirements may change with or without notice. Changes in government regulations or changes in the enforcement of existing government regulations could have a material, adverse impact on us. See also Part I, Item 1A, “Risk Factors” for a discussion of risks related to government regulations.

US Federal Regulation of Medical Devices

The Federal Food, Drug, and Cosmetic Act (“FDCA”) provides that, unless exempted by regulation, medical devices may not be distributed in the US unless they have been approved or cleared by the FDA. Medical devices may receive clearance through either a pre-market notification (also known as the 510(k) process) or a PMA. Prior to approval, IDE's allow investigational devices to be used in clinical studies in order to collect safety and effectiveness data.

Under a 510(k) process, a medical device manufacturer provides the FDA with premarket notification that it intends to begin commercializing a product and demonstrates to the FDA that the product is substantially equivalent to another legally marketed predicate device. To be found substantially equivalent to a predicate device, the device must be for the same intended use and have either the same technological characteristics as the predicate or different technological characteristics that do not raise different questions of safety or effectiveness. In some cases, the submission must include data from clinical studies in order to demonstrate substantial equivalency to a predicate device. Commercialization may commence when the FDA issues a clearance letter finding such substantial equivalence.

FDA regulations require approval through the IDE/PMA process for all Class III medical devices and for medical devices not deemed substantially equivalent to a predicate device. An IDE authorizes distribution of devices that lack PMA or 510(k) clearance for clinical evaluation purposes. After a product is subjected to clinical testing under an IDE, we may file a PMA application. Once a PMA application has been submitted, the FDA’s review may be lengthy and may include requests for additional data, which may require us to undertake additional human clinical studies. Commercialization of the device may begin when the FDA approves the PMA.

The FDCA requires all medical device manufacturers and distributors to register with the FDA annually and to provide the FDA with a list of those medical devices they distribute commercially. The FDCA also requires manufacturers of medical devices to comply with labeling requirements and to manufacture devices in accordance with Quality System Regulations, which require that companies manufacture their products and maintain their documents in compliance with good manufacturing practices, including design, document production, process, labeling and packaging controls, process validation, and other applicable quality control activities. The FDA’s medical device reporting regulation requires that a device manufacturer provide information to the FDA on death or serious injuries alleged to have been associated with the use of its products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA further requires that certain medical devices that may not be sold in the US follow certain procedures before they are exported. The FDA periodically inspects our facilities to review our compliance with these and other regulations and has authority to seize non-complying medical devices, enjoin and/or impose civil penalties on manufacturers and distributors marketing non-complying medical devices, criminally prosecute violators, and order recalls in certain instances.

The following products are, or we believe would be, upon approval, classified as Class III medical devices: BioGlue, On-X heart valves, On-X AAP, PerClot, E-vita Open Plus, E-vita Open NEO, E-vita Thoracic 3G, E-tegra, E-liac, E-nside, the NEXUS family of products, and AMDS. CryoPatch SG is classified as a Class II medical device. We obtained 510(k) clearance from the FDA to commercialize the CryoValve SGPV; however, these tissues are not officially classified as Class II or III medical devices.

Beginning in December 2019 and most recently in the fall 2024, the FDA indicted that it was planning to issue a proposed rule for reclassification of more than minimally manipulated ("MMM") allograft heart valves, which could include our CryoValve SGPV, from unclassified medical devices reviewed through the 510(k) process to Class III (PMA) medical devices. Following any comment period and subsequent publication of a final rule, should the CryoValve SGPV be determined to be MMM or classified as a Class III device, we currently expect to have approximately thirty months to submit a PMA application, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers during its review of the PMA application. Although this proposed rule change has, to our knowledge, remained on the HHS's unified regulatory agenda since 2019, no final rule has been published at this time. See also Part I, Item 1A, "Risk Factors—Legal, Quality, and Regulatory Risks—Reclassification by the FDA of CryoValve SG pulmonary heart valve ("CryoValve SGPV") as a PMA device may make it commercially infeasible to continue processing the CryoValve SGPV."

US Federal Regulation of Human Tissue

The FDA regulates human tissues pursuant to Section 361 of the Public Health Services Act, which in turn provides the regulatory framework for regulation of human cellular and tissue products. The FDA regulations focus on donor screening and testing to prevent the introduction, transmission, and spread of HIV-1 and -2, Hepatitis B and C, and other communicable diseases and disease agents. The regulations set minimum requirements to prevent the transmission of communicable diseases from human tissue used for transplantation. The regulations define human tissue as any tissue derived from a human body which is (i) intended for administration to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease and (ii) recovered, preserved, stored, or distributed by methods not intended to change tissue function or characteristics. The FDA definition excludes, among other things, tissue that currently is regulated as a human drug, biological product, or medical device, and it also excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ. The current regulations applicable to human tissues include requirements for donor suitability, processing standards, establishment registration, product listing, testing, and screening for risks of communicable diseases. The FDA periodically audits our tissue preservation facilities for compliance with its requirements and has the authority to enjoin the distribution, force a recall, or require the destruction of tissues that do not meet its requirements.

Recently, the Center for Biologics Evaluation and Research ("CBER") of the FDA issued two "final" guidance documents directed at the reduction of the risk of transmission of tuberculousis (Mtb) in processed human tissue (the "Guidances"), which is already exceedingly low. These Guidances were issued without benefit of clinician or industry input and we believe could, if implemented as written, significantly reduce the supply of safe implantable human tissue without simultaneously reducing the risk of Mtb transmission. We also believe the Guidances are unnecessary in light of new Mtb screening criteria the American Association of Tissue Banks ("AATB") recently implemented. CBER recently paused implementation of the Guidances until May 4, 2025, and indicated that it would consider comments received on the Guidances. Industry and the clinician community are currently working with CBER and other federal agencies and stakeholders to rescind implementation of the Guidances or to reissue them.

NOTA Regulation

Our activities in preserving and transporting human hearts and certain other organs are also subject to federal regulation under the National Organ Transplant Act ("NOTA"), which makes it unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. NOTA excludes from the definition of "valuable consideration" reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ. The purpose of this statutory provision is to allow for compensation for legitimate services. We believe that, to the extent our activities are subject to NOTA, we meet this statutory provision relating to the reasonableness of our charges.

State Licensing Requirements

Some states have enacted statutes and regulations governing the manufacture, sale, marketing, or distribution of medical devices, and we believe we are in compliance with such applicable state laws and regulations.

Some states have enacted statutes and regulations governing the preservation, transportation, and storage of human organs and tissues. The activities we engage in require us to be either licensed or registered as a clinical laboratory or tissue bank under California, Delaware, Florida, Georgia, Illinois, Maryland, New York, and Oregon law. We have such licenses or registrations, and we believe we are in compliance with applicable state laws and regulations relating to clinical laboratories and tissue banks that store, preserve, and distribute donated human tissue designed to be used for medical purposes in human beings.

Some of our employees have obtained other required state licenses. The regulatory bodies of states may perform inspections of our facilities as required to ensure compliance with state laws and regulations.

International Approval Requirements

Sales of medical devices and shipments of human tissues outside the US are subject to international regulatory requirements that vary widely from country to country. Approval of a product by comparable regulatory authorities of other countries must be obtained and compliance with applicable regulations for tissues must be met prior to commercial distribution of the products or human tissues in those countries. The time required to obtain these approvals may be longer or shorter than that required for FDA approval. Countries in which we distribute products and tissue may perform inspections of our facilities to ensure compliance with local country regulations.

The European Economic Area ("EEA") recognizes a single medical device approval (the CE Mark) which allows for distribution of an approved product throughout the EEA without additional general applications in each country. Individual EEA members, however, reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third parties called "Notified Bodies" award the CE Mark. These Notified Bodies are approved and subject to review by the "Competent Authorities" of their respective countries. Our Notified Bodies perform periodic on-site inspections to independently review our compliance with systems and regulatory requirements. A number of countries outside of the EEA accept the CE Mark in lieu of marketing submissions as an addendum to that country's application process. We have CE Marks for BioGlue, On-X heart valves, On-X AAP, E-vita Open NEO, E-tegra, E-liac, E-nside, AMDS, and other devices. In addition, E-ventus BX, Tuva BX, and NEXUS ONE, which we distribute, have CE Marks.

The Medical Device Directive ("MDD") was the governing document for the EEA that detailed requirements for safety and risk of devices. The Medical Device Regulation ("MDR") replaced MDD on May 26, 2021 and places stricter requirements on manufacturers and the European Notified Bodies who have been designated by the various European Union Member States to perform assessments of compliance to the MDD and MDR. We work with a number of notified bodies and the transition from the MDD to the MDR is ongoing.

As a result of the UK's exit from the European Union, or "Brexit," the UK Medicines and Healthcare Products Regulatory Agency ("MHRA") announced in the third quarter of 2023 that the UK government (MHRA) extended the acceptance of CE marked medical devices beyond the original date of June 2023. CE Marking will continue to be recognized in the UK and certificates issued by EU-recognized Notified Bodies (with a valid declaration and CE marking under MDD) will continue to be valid in the UK market until June 30, 2028. General medical devices and custom-made devices under MDR compliance can be placed on the UK market until June 30, 2030. As of September 2023 the Swiss government (Swissmedic) declared that Class III and IIb devices with a valid CE Mark issued under the MDD can remain on the Swiss market until December 31, 2027 so long as the manufacturer maintains a QMS in compliance with EU MDR and has a formal application with a notified body for an MDR CE Mark by May 26, 2024. See Part I, Item 1A, "Risk Factors—Legal, Quality, and Regulatory Risks—Our products and tissues are highly regulated and subject to significant quality and regulatory risks," for a discussion of risks related to the transition to MDR.

On June 13, 2019 one of our notified bodies, Lloyd's Register Quality Assurance Limited ("LRQA") informed us that it would no longer provide Notified Body services for medical devices effective September 2019. The governing German competent authority, the Regierungspräsidium Tübingen, granted us an extended grace period until December 31, 2021 to transfer LRQA-issued certifications for BioGlue and PhotoFix to a new Notified Body. Although our BioGlue CE Mark has been successfully transferred to our new Notified Body, we are still in the process of transferring PhotoFix to DEKRA and currently expect to receive notice of such transfer in 2025. While progress has been made, failure to timely complete the transfer or any other delays in the MDR transition, may have a material, adverse effect on our ability to supply PhotoFix in affected jurisdictions and have a material, adverse impact on our business. See also Part I, Item 1A, "Risk Factors—Legal, Quality, and Regulatory Risks—Our products and tissues are highly regulated and subject to significant quality and regulatory risks," for a discussion of the risks related to LRQA's decision, the MDR transition, and Brexit.

Environmental Matters

Our tissue preservation activities generate some biomedical wastes, consisting primarily of human and animal pathological and biological wastes, including human and animal tissue and body fluids removed during laboratory procedures. The biomedical wastes generated by us are placed in appropriately constructed and labeled containers and are segregated from other wastes generated by us. We contract with third parties for transport, treatment, and disposal of biomedical waste.

Some of our products, including certain On-X products, are sterilized using ethylene oxide ("EtO"). Although we have a small-scale EtO facility in Austin, Texas, we rely primarily on large-scale EtO facilities to sterilize our products. In addition, some of our suppliers use, or rely upon third parties to use, EtO to sterilize some of our product components. Concerns about the release of EtO into the environment at unsafe levels have led to various regulatory enforcement activities and legal actions against EtO facilities, resulting in permanent and temporary closures, as well as proposals increasing regulations and increased regulations related to EtO. Although we believe we are in compliance with applicable laws and regulations, regarding the disposal of our waste resulting from tissue preservation activities, as well as in our other production and sterilization activities, the failure by us, or the companies with which we contract, to comply fully with any such regulations could result in an imposition of penalties, fines, or sanctions, which could materially, adversely affect our business. See also, Part I, Item 1A, "Risk Factors—Legal, Quality, and Regulatory Risks—Increased environmental regulations and private litigation activity relating to processes and materials used in our industry could have a material, adverse impact on us." We do not currently anticipate any material capital expenditures required for compliance with these laws and regulations relating to our waste disposal and sterilization activities.

Research and Development and Clinical Research

We use our technical and scientific expertise to identify market opportunities for new products and services, and to expand the use of our current products and services through expanded indications and product and tissue enhancements. Our research and development strategy is to allocate most of our available resources among our core market areas based on the potential market size, estimated development time and cost, and the expected efficacy for any potential product or service offering. To the extent we identify new non-core products or additional non-core applications for our core products, we may attempt to license these products to corporate partners for further development or seek funding from outside sources to continue commercial development. We may also attempt to acquire or license additional strategically complementary products or technologies from third-parties to supplement our product lines.

Research on these and other projects is conducted in our research and development department and at universities and clinics where we sponsor research projects. We also conduct preclinical and clinical studies at universities, medical centers, hospitals, and other third-party locations under contract with us. Research is inherently risky, and any potential products or services under development ultimately may not be deemed safe or effective or worth commercializing for other reasons and, therefore, may not generate a return on investment for us. Our clinical research department also collects and maintains clinical data on the use and effectiveness of our products and services. We use this data to gain regulatory approvals to market the products and services, to inform third parties on the benefits of our products and services, and to help direct our continuing improvement efforts.

In 2024, 2023 and 2022 we spent approximately $28.5 million, $28.7 million and $38.9 million, respectively, on research and development activities on new and existing products. These amounts accounted for approximately 7%, 8% and 12% of our revenues for each of 2024, 2023 and 2022, respectively.

We are in the process of developing and investigating several new products and technologies, as well as changes and enhancements to our existing products and services. Our strategies for driving growth include new product approvals and indications, global expansion, and business development. These activities will likely require additional research, new clinical studies, and/or compilation of clinical data.

We received regulatory approval from the National Medical Products Administration ("NMPA") to commercialize BioGlue in China during the third quarter of fiscal year 2024. We currently expect to commercialize BioGlue in China during the second half of 2025.

At the FDA's request, we are conducting a post-approval study to collect long-term clinical data for the On-X aortic heart valve managed with reduced warfarin therapy. This study is ongoing and data collection is expected to continue through 2027.

The FDA granted Breakthrough Device Designation in the third quarter of 2019 for the AMDS hybrid prosthesis. The Breakthrough Device Designation program is designed to provide timely access to medical devices that potentially provide a more effective treatment for life-threatening conditions by prioritizing review of its regulatory submissions, thereby expediting the device development process. We are conducting a pivotal clinical trial (PERSEVERE) to gain approval to commercialize the AMDS hybrid prosthesis in the US for treatment of acute DeBakey type I aortic dissections. We received IDE approval in the fourth quarter of 2021 and completed enrollment of the required patients in the fourth quarter of 2023. During the fourth quarter of 2024, the FDA granted HDE approval for use of AMDS in acute DeBakey Type I dissections in the presence of malperfusion. We are continuing to seek PMA approval, which we currently anticipate receiving in 2026.

The FDA granted Breakthrough Device Designation in the first quarter of 2020 for Arcevo LSA, and in the second quarter of 2020 for E-vita Open NEO, representing our next-generation hybrid stent graft system used in the treatment of patients with either an aneurysm or dissection in the aortic arch and in the descending thoracic aorta. The FDA granted Breakthrough Device Designation in the third quarter of 2019 for the E-nside and E-xtra Design Multibranch TAAA devices.

Patents, Licenses, and Other Proprietary Rights

We rely on a combination of patents, trademarks, confidentiality agreements, and security procedures to protect our proprietary products, preservation technology, trade secrets, and know-how. We believe that our patents, trade secrets, trademarks, and licensing rights provide us with important competitive advantages. We currently own rights to numerous US and foreign patents and pending patent applications relating to our technology for various product lines. There can be no assurance that any pending applications will ultimately be issued as patents. We have also obtained rights through license and distribution agreements for additional products and technologies, including the NEXUS family of products. In the aggregate, these intellectual property assets and licenses are of material importance to our businesses; however, with the exception of BioGlue as discussed below, we believe that no single intellectual property asset or license is material in relation to any segment of our business or to our business as a whole.

The main patent for BioGlue expired in mid-2012 in the US and expired in mid-2013 in the majority of the rest of the world. Although the patents for BioGlue have expired, this technology is still protected by trade secrets and manufacturing know-how, as well as the time and expense to obtain regulatory approvals.

We have confidentiality agreements with our employees, our consultants, and our third-party vendors to maintain the confidentiality of trade secrets and proprietary information. There can be no assurance that the obligations of our employees, consultants, and third parties with whom we have entered into confidentiality agreements, will effectively prevent disclosure of our confidential information or provide meaningful protection for our confidential information if there is unauthorized use or disclosure, or that our trade secrets or proprietary information will not be independently developed by our competitors.

See Part I, Item 1A, "Risk Factors—Legal, Quality, and Regulatory Risks—Some of our products and technologies are subject to significant intellectual property risks and uncertainty," for a discussion of risks related to our patents, licenses, and other proprietary rights.

Seasonality

See Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Seasonality," regarding seasonality of our products and services.

Human Capital

Overview

As of December 31, 2024 we had approximately 1,600 employees. Most of our employees are located in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany. We have never experienced a work stoppage or interruption due to labor disputes. Our employees located in Hechingen, Germany have a Works Council, and our employees in Brazil are affiliated with a union in connection with compensation-related collective bargaining. We believe our relations with our employees worldwide and with the Works Council in Germany and union in Brazil are good.

Employee Talent and Retention

Our business and future operating results depend in significant part upon the continued contributions of our key personnel, including qualified personnel with medical device and tissue processing experience, and senior management with experience in the medical device or tissue processing space, many of whom would be difficult to replace. Our business and future operating results, including production at our manufacturing and tissue processing facilities, also depend in significant part on our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel for our operations.

Our main facilities are in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany, where the local supply of qualified personnel in the medical device and tissue processing industries is limited and competition for such personnel is intense and has become increasingly more so in recent years. We have programs and processes in place to help ensure that our compensation, benefits programs, and work environment attract and retain such personnel, and we strive to enhance those programs and processes to respond to the increasingly competitive market for talent. We also strive to offer competitive equitable pay, comprehensive benefits, and services that retain and meet the varying needs of our employees. The principal purposes of our equity and cash incentive plans and non-officer incentive plans are to attract, retain, motivate, and reward our employees.

Culture

Fostering and maintaining a strong and collaborative culture is a key strategic focus, as evidenced by our core values of collaboration, results driven, and customer focus. We also have ethics and compliance policies that instill a commitment to ethical behavior and legal compliance across our Company. Employees are encouraged to approach their supervisors if they believe violations of policies have occurred. Employees are also able to confidentially and anonymously report any such violations through an online form or telephone hotline hosted by a third-party provider.

The Company has employees in almost 30 different countries representing unique cultures, ethnicities, backgrounds, experiences and viewpoints. We believe that we are better able to achieve our business objectives, and maintain our core values of collaboration, results driven, and customer focus, when our workforce includes individuals with a variety of backgrounds and experiences, who are able to respectfully share different perspectives and work together to leverage them.

In early 2022 we appointed a Chief Diversity Officer to manage and oversee aspects of Company culture that facilitate these efforts. The Company strives to provide equal opportunity to all applicants and employees.

Training and Development

We provide internal training and development programs to employees globally. Such programs include leadership development, office safety, ethics, and various skill-based training programs.

Health and Safety

Protecting the health, safety, and well-being of our employees around the world is a priority. We continually strive to look for opportunities to provide a safer, healthier, work environment for our employees.

Employee Engagement

We solicit employee feedback to assess employee satisfaction and engagement and to identify opportunities for development. Employee feedback is also gathered through onboarding surveys, the employee review process, spot surveys, and exit surveys.

Risk Factors

Our business is subject to a number of risks. See Part I, Item 1A, "Risk Factors" below for a discussion of these and other risk factors.

Available Information

It is our policy to make all our filings with the Securities and Exchange Commission, including, without limitation, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, available free of charge on our website, *www.Artivion.com*, on the day of filing. All such filings made on or after November 15, 2002 have been made available on our website.

We also make available on the Corporate Governance portion of our website: (i) our Code of Conduct; (ii) our Corporate Governance Guidelines; (iii) the charter of each active committee of our Board of Directors; (iv) our Code of Ethics for Senior Financial Officers; (v) our Corporate Responsibility Report (ESG); and (vi) our Foreign Corrupt Practices Act ("FCPA") Policy. We also intend to disclose any amendments to our Codes of Conduct, or waivers of our Codes of Conduct on behalf of our Chief Executive Officer, Chief Financial Officer, or Chief Accounting Officer, on the Corporate Governance portion of our website. All of these corporate governance materials are also available free of charge in print to stockholders who request them in writing to: Jean F. Holloway, General Counsel, Chief Compliance Officer, and Corporate Secretary, 1655 Roberts Blvd NW, Kennesaw, GA 30144.

Item 1A. Risk Factors.

Risks Relating to Our Business

Our business involves a variety of risks and uncertainties, known and unknown, including, among others, the risks discussed below. These risks should be carefully considered together with the other information provided in this Annual Report on Form 10-K and in our other filings with the US Securities and Exchange Commission (the "SEC"). Our failure to adequately anticipate or address these risks and uncertainties may have a material, adverse impact on our business, reputation, revenues, financial condition, profitability, and cash flows. Additional risks and uncertainties not presently known or knowable to us, or that we currently believe to be immaterial, may also adversely affect our business.

Business and Economic Risks

We are subject to a variety of risks due to our international operations and continued global expansion.

Our international operations subject us to a number of risks, which may vary significantly from the risks we face in our US operations, including:

- Greater difficulties and costs associated with staffing at all levels, establishing and maintaining internal controls, managing foreign operations and distributor relationships, and selling directly to customers;
- Broader exposure to corruption and expanded compliance obligations, including under the Foreign Corrupt Practices Act, the UK Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, the European Union's General Data Protection Regulation and Corporate Sustainability Reporting Directive, and other emerging corruption, sustainability, and data privacy and cybersecurity regulations;
- Overlapping, ambiguous, and potentially conflicting, or unexpected changes in, international legal and regulatory requirements or reimbursement policies and programs;
- Longer and more expensive collection cycles in certain countries, particularly those in which our primary customers are government-funded hospitals;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the US Dollar and other inflationary pressures, given sensitivity to exchange rates that we experience from our product revenue streams and account balances;
- Potential exposure to adverse financial impact and negative erosion of our operating profit margin over time due to increasing inflationary pressures, including impact felt through our supply chain, and this exposure may be increased through our limited ability to raise prices and through global expansion where business occurs with, or pricing is set directly by, government entities, or we are party to long term pricing agreements with governments or local distributors, impacting our ability to pass on rising costs;
- Potential adverse tax consequences of overlapping tax structures or potential changes in domestic and international tax policy, laws, and treaties; and
- Potential adverse consequences from unexpected global regulatory and trade developments.

As an example of this risk, via a Ministerial Decree of July 6, 2022, published September 15, 2022, the Italian government stated that the spending ceiling for medical devices at the national and regional levels had been exceeded, requiring medical device companies to pay back alleged overpayments the government claims companies received between 2015 and 2018. Ultimately, we were subject to an immaterial payment obligation following the conclusion of judicial challenges and negotiations between us, industry, US government representatives, and the Italian government.

Our operations and performance have been, and may continue to be, impacted by regional and global geopolitical conditions, domestic and foreign trade and monetary policies, and other factors beyond our control, such as Russia's war with Ukraine and instability in the Middle East. To date, sanctions and other disruptions in the Eastern European region have not materially impacted our business or ability to supply products to Russia, Belarus, Ukraine, and the region generally; however, continuation or escalation of the wars in Ukraine or instability in the Middle East, or increased export controls or additional sanctions imposed on or by impacted countries, their allies, or related entities could adversely affect our financial performance. Although we do not have any direct operations in Russia, Ukraine, Israel, Gaza, or Syria, the NEXUS family of products are solely manufactured by Endospan in Herzliya, Israel. Although we have not experienced any material disruption of supply from Endospan, it is difficult to predict the ultimate course of these conflicts and we may face business operations and supply chain disruptions as a result, including disruptions related to shortages of materials and finished goods, higher costs of materials and freight, freight delays, increased energy costs or energy shortages, travel disruptions, currency fluctuation, and disruptions to banking systems or capital markets.

We operate in highly competitive market segments, face competition from large, well-established medical device companies and tissue service providers with greater resources and we may not be able to compete effectively.

The market for our products and services is competitive and affected by new product introductions and activities of other industry participants, including the introduction of novel products and therapies aimed at unrelated disease states or even overall patient health. In addition, such products and therapies like GLP-1 drugs, which we believe have or will have little to no actual impact on demand for our products, can lead to investor and customer confusion, can change investor focus, and can impact the perceived demand for our products, which may affect our stock price even if actual demand for our products is unaffected. We face intense competition in virtually all of our product lines. A significant percentage of market revenues from competitive products are generated by Baxter, Ethicon (a Johnson & Johnson Company), Medtronic, Abbott Laboratories, Edwards Lifesciences, C.R. Bard (a subsidiary of Becton, Dickinson and Company), Integra Life Sciences, LifeNet, Corcym, Anteris Technologies, Elutia (formerly Aziyo Biologics), Cook Medical, Gore & Associates, Terumo, LeMaitre Vascular, Maquet, Pfizer, and BioCer Entwicklungs-GmbH. Several of our competitors enjoy competitive advantages over us, including:

- Greater financial and other resources for research and development, commercialization, acquisitions, and litigation and to weather the impacts of global economic downturns and workforce competition;
- Greater name recognition as well as more recognizable trademarks for products similar to products that we sell;
- More established record of obtaining and maintaining regulatory product clearances or approvals;
- More established relationships with healthcare providers and payors along with better positioning to minimize the impact of consolidated purchasing and other consolidation within the healthcare industry;
- Lower cost of goods sold or preservation costs; and
- Larger direct sales forces and more established distribution networks.

Our established and early-stage competitors may have advantages over us in terms of cost structure, pricing, back-office automation, product development, marketing, supply chain, and sourcing, and if we are unable to compete effectively, our financial results will be adversely affected.

We are significantly dependent on our revenues from tissue preservation services and are subject to a variety of risks affecting them.

Tissue preservation services are a significant source of our revenues, and as such, we face risks if we are unable to:

- Source sufficient quantities of some human tissue or address potential excess supply of others. We rely primarily upon the efforts of third parties to educate the public and foster a willingness to donate tissue. Factors beyond our control such as supply, regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue;
- Capitalize on our clinical advantages that we rely on as competitive strengths; or
- Mitigate sufficiently the risk that tissue can become contaminated during processing; that processed tissue cannot be end-sterilized and hence carries an inherent risk of infection or disease transmission or that our quality controls can eliminate that risk.

In addition, US and foreign governmental authorities have adopted laws and regulations that restrict tissue preservation services and the avenues available to distribute processed tissues. Any of these laws or regulations could change, including becoming more restrictive, or our interpretation of them could be challenged by governmental authorities.

As an example of this risk, in January 2025, the Center for Biologics Evaluation and Research (“CBER”) of the FDA issued two “final” guidance documents directed at the reduction of the risk of transmission of tuberculousis (Mtb) in processed human tissue (the “Guidances”), which is already exceedingly low. We believe these Guidances, if implemented as written, could significantly reduce the supply of safe implantable human tissue without simultaneously reducing the risk of Mtb transmission. Although some industry advocates and health care practitioners have expressed strong opposition to these new Guidances, and their implementation has been paused until at least May 2025, if and how they may ultimately be implemented and enforced, and how they may actually impact the availability of our donated tissue, remains to be seen and is difficult to predict.

We are significantly dependent on our revenues from BioGlue and are subject to a variety of related risks.

BioGlue is a significant source of our revenues, and as such, any risk adversely affecting our BioGlue products or business would likely be material to our financial results. We face the following risks relating to BioGlue:

- We may be unable to obtain approval to commercialize BioGlue in certain non-US countries as fast as our competitors do or at all. We also may not be able to capitalize on new BioGlue approvals, including for new indications, in non-US countries; and
- BioGlue contains a bovine blood protein. Animal-based products are subject to increased scrutiny from the public and regulators, who may seek to impose additional regulations, regulatory hurdles or product bans in certain countries on such products; BioGlue is a mature product and other companies may use the inventions disclosed in expired BioGlue patents to develop and make competing products.

As an example of this risk, our regulatory approval for BioGlue in China took significantly longer and required significant additional investment, at least in part, due to BioGlue's animal of origin components. Although we received approval to market BioGlue in China during the third quarter of 2024, we do not expect any revenue until at least the second half of 2025.

We are significantly dependent on our revenues from aortic stent grafts and are subject to a variety of related risks.

Aortic stent grafts are a significant source of our revenues, and as such, any risk adversely affecting aortic stent grafts would likely be material to our financial results. We face risks relating to aortic stent grafts based on our ability to:

- Develop innovative, high quality, and in-demand aortic repair products;
- Respond adequately to enhanced regulatory requirements and enforcement activities, and particularly, our ability to obtain regulatory approvals and renewals globally;
- Drive timely adoption of new products in our aortic stent graft portfolio;
- Meet demand and manage inventory for aortic stent grafts as we seek to expand our business globally; and
- Maintain a productive working relationship with our Works Council in Germany.

We are significantly dependent on our revenues from On-X products and are subject to a variety of related risks.

On-X products are a significant source of our revenues, and as such, any risk adversely affecting our On-X products or business would likely be material to our financial results. We face risks based on our ability to:

- Take further market share in the mechanical heart valve market based on the FDA's approved lower INR indication for the On-X aortic heart valve or complete the associated FDA mandated post-approval studies;
- Address clinical trial data or changes in technology that may reduce the demand for mechanical heart valves, such as data regarding transcatheter aortic valve replacement, or "TAVR" devices;
- Keep up with increasing demand for our On-X products globally;
- Manage risks associated with less favorable contract terms for On-X products on consignment at hospitals; and
- Respond adequately to enhanced international regulatory requirements or enforcement activities.

Continued fluctuation of foreign currencies relative to the US Dollar could materially, adversely affect our business.

Most of our foreign revenues are denominated in Euros, making them sensitive to exchange rate changes. Some sales are made to customers who must convert local currencies into US Dollars or Euros. We hold balances in foreign currencies affected by exchange rates. Global inflation and currency crises could result in foreign currency controls, parallel exchange rates, or highly inflationary economies in certain countries. Fluctuations in exchange rates could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Some of our products and technologies are subject to significant intellectual property risks and uncertainty.

We own trade secrets, patents, patent applications, and licenses relating to our technologies and trademarks and goodwill related to our products and services, which we believe provide us with important competitive advantages. We cannot be certain that we will be able to maintain our trade secrets, that our pending patent applications will issue as patents, or that no one will challenge the validity or enforceability of any intellectual property that we adopt, own, or license. Competitors may independently develop our proprietary technologies or design non-infringing alternatives to patented inventions. We do not control the maintenance, prosecution, enforcement, or strategy for in-licensed intellectual property and as such are dependent in part on the owners of these rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit those technologies. Additionally, our technologies, products, or services could infringe intellectual property rights owned by others, or others could infringe our intellectual property rights.

If we become involved in intellectual property disputes, the costs could be expensive, and if we were to lose or decide to settle, the amounts or effects of the settlement or award by a tribunal could be costly.

Public health crises have, may continue to have, and could have a material, adverse impact on us.

Because of our role in the healthcare industry, we are particularly susceptible to the impact public health crises have on healthcare systems globally, including impacts on system capacity and procedure volumes, shortages in healthcare staffing, and restrictions on travel and non-critical hospital access. For example, we experienced negative impacts on our business operations and sales during the COVID-19 pandemic, particularly through reductions in demand for certain products and services due to reduced procedure volumes, or through downstream financial impact from delays or difficulty collecting outstanding receivables. If other public health crises emerge in the future, we may experience similar adverse effects on our business. This impact on healthcare system capacity may also affect our R&D pipeline by lengthening timelines for R&D and clinical research projects and timelines associated with regulatory reviews for new and updated devices, as well as affecting our workforce.

Operational Risks

We are heavily dependent on our suppliers and contract manufacturers to provide quality products.

The materials and supplies used in our product manufacturing and tissue processing are subject to regulatory requirements and oversight. If materials or supplies used in our processes fail to meet these requirements or are subject to regulatory enforcement action, they may have to be scrapped, or our products or tissues could be rejected during or after processing, recalled, or rejected by customers. In these cases, we may have to immediately scrap raw or in-process materials and expense the costs of manufacturing or preservation.

In addition, if these materials or supplies, or changes to them, do not receive regulatory approval or are recalled, if the related suppliers and/or their facilities are shut down temporarily or permanently, for any reason, or if the related suppliers are otherwise unable or unwilling to supply us, we may not have sufficient materials or supplies to manufacture our products or process tissues. In addition, we rely on contract manufacturers to manufacture some of our products or to provide additional manufacturing capacity for some products. If these contract manufacturers fail to meet our quality standards or other requirements or if they are unable or unwilling to supply the products, we may not be able to meet demand for these products. Our ability to fully recover all possible losses from these suppliers and contract manufacturers may have practical limitations imposed by factors like industry standard contractual terms or the financial resources of the adverse party.

Finally, the global supply chain is subject to disruption due to labor, geopolitical, trade and monetary issues, which may be exacerbated by ongoing instability in Ukraine and the Middle East. See Part I, Item 1A, “Risk Factors – Business and Economic Risks – We are subject to a variety of risks due to our international operations and continued global expansion.” Although we have yet to experience any material effects of this impact on our supply chain or operations, we face the potential risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after current conflicts have subsided.

We are dependent on single and sole-source suppliers and single facilities.

Some of the materials, supplies, and services used in our product manufacturing and tissue processing, as well as some of our products, are sourced from single- or sole-source suppliers. As a result, our ability to negotiate favorable terms with those suppliers may be limited, and if those suppliers experience operational, financial, quality, or regulatory difficulties, or if those suppliers and/or their facilities refuse to supply us or cease operations temporarily or permanently, or if those suppliers take unreasonable business positions, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We also could be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power.

As an example of these risks, in 2019 we lost our supply of handpieces for cardiac laser therapy resulting from a manufacturing location change at our supplier that ultimately required a Premarket Approval ("PMA") supplement and FDA approval before handpiece manufacturing and distribution could resume. Even though the FDA approved the PMA-S, due to supply-related factors outside of our control, we eventually abandoned the business as of June 2023 resulting in a write-off of all of our CardioGenesis cardiac laser therapy assets and a recorded expense of $0.4 million during the year ended December 31, 2023 in our Consolidated Statements of Operations and Comprehensive Loss.

By way of additional non-limiting examples, our BioGlue product has three main product components: bovine protein, a cross linker, and a molded plastic resin delivery device. The bovine protein and cross linker are obtained from a small number of qualified suppliers. The delivery devices are manufactured by a single supplier, using resin supplied by a different single supplier. We purchase grafts for our On-X AAP from a single supplier and various other components for our On-X valves come from single-source suppliers.

Our preservation services business and our ability to supply needed tissues is dependent upon donation of tissues from human donors by donor families. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations ("OPOs") and tissue banks. We must rely on the OPOs and tissue banks that we work with to educate the public on the need for donation, to foster a willingness to donate tissue, to follow our donor screening and procurement procedures, and to send donated tissue to us. We have active relationships with approximately 60 OPOs and tissue banks throughout the US. As with any vendor, we believe these relationships with our OPOs are critical in the preservation services industry and that the breadth of these existing relationships provides us with a significant advantage over potential new entrants to this market. We also use various raw materials, including medicines and solutions, in our tissue processing. Some of these raw materials are manufactured by single suppliers or by a small group of suppliers.

Our aortic stent graft systems consist of two main product components: the stent graft and the delivery system. The stent graft is manufactured from several different raw materials that are manufactured internally or at various external suppliers, including single suppliers. The delivery systems we manufacture are comprised of several different raw materials and subassemblies. Our internal manufacturing processes include machining of plastic parts, suturing of stent grafts, processing of Nitinol, and weaving of textiles. Our conventional polyester grafts consist of two main product components: polyester fabric and collagen coating. The polyester fabric is woven from a few different yarns that are supplied by an external supplier. The collagen suspension we manufacture is comprised of a collagenous tissue that is supplied by a single supplier. The conventional ePTFE grafts we manufacture are comprised of various raw materials supplied by several suppliers. For some products the ePTFE grafts are heparin coated. For these products, the heparin suspension we manufacture is comprised of a heparin solution that is also supplied by an external supplier.

We have three internal manufacturing facilities: Austin, Texas for On-X products, Hechingen, Germany for internally manufactured aortic stent grafts, and Kennesaw, Georgia for all other products and services. Certain aortic stent graft assemblies are manufactured for us by a contract manufacturer in Slovakia. The AMDS product is solely manufactured by a supplier in Charlotte, North Carolina, and the NEXUS family of products are solely manufactured by Endospan in Herzliya, Israel. If one of these suppliers or facilities ceases operations temporarily or permanently, for any reason including a pandemic, war, work stoppage, cybersecurity incident, infrastructure or equipment malfunction, or a natural disaster, our business could be substantially disrupted.

Although we work diligently to maintain adequate inventories of raw materials, components, supplies, subassemblies, and finished goods, there can be no assurance that we will be able to avoid all disruptions to our global supply chain, or disruptions to our sterilization or distribution networks. Any of these disruptions could have a material, adverse effect on our revenues, reputation, or profitability.

We are dependent on our specialized workforce.

Our business and future operating results depend in significant part upon the continued contributions of our specialized workforce, including key personnel, qualified personnel with medical device and tissue processing experience, and senior management with experience in the medical device or tissue processing space, some of whom would be difficult to replace. Our business and future operating results, including production at our manufacturing and tissue processing facilities, also depend in significant part on our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel. Our primary facilities are in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany, where the supply of qualified medical device and tissue processing and other personnel is limited, competition for such personnel is significant, and we cannot ensure that we will be successful in attracting or retaining them. We face risks if we lose any key employees to other employers or due to severe illness, death, or retirement, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees. Competition for talent and worker shortages at all levels have impacted supply chains and distribution channels and our ability to attract and retain the specialized workforce necessary for our business and operations.

We continue to evaluate expansion through acquisitions of, or licenses with, investments in, and distribution arrangements with, other companies or technologies, which may carry significant risks.

One of our growth strategies is to pursue select acquisitions, licensing, or distribution rights with companies or technologies that complement our existing products, services, and infrastructure. In connection with one or more of these transactions, we may:

- Issue additional equity securities that would dilute our stockholders' ownership interest;
- Use cash we may need in the future to operate our business;
- Incur debt, including on terms that could be unfavorable to us or debt we might be unable to repay;
- Structure the transaction resulting in unfavorable tax consequences, such as a stock purchase that does not permit a step-up in basis for the assets acquired;
- Be unable to realize the anticipated benefits of the transaction; or
- Assume material unknown liabilities associated with the acquired business.

Our charges resulting from acquisitions, divestitures, partnerships, and other business development activities may materially, adversely affect the market value of our common stock.

We account for the completion of acquisitions using the purchase method of accounting. Our financial results could be adversely affected by a number of financial adjustments required by purchase accounting such as:

- We may incur additional amortization expense over the estimated useful lives of some acquired intangible assets;
- We may incur additional depreciation expense as a result of recording purchased tangible assets;
- We may be required to incur material charges relating to any impairment of goodwill and intangible assets;
- Cost of sales may increase temporarily if acquired inventory is recorded at fair market value;
- If acquisition consideration consists of earnouts, our earnings may be affected by changes in estimates of future contingent consideration; or
- Earnings may be affected by transaction and integration costs, which are expensed immediately.

As an example of this risk, we fully impaired the value of our original securities purchase option agreement with Endospan ("Endospan Option") in the fourth quarter of 2021 and fully wrote-down the value of our loan to Endospan in the second

quarter of 2023, primarily driven by a decrease in forecasted operating results. Although the Endospan Option and our loan to Endospan were partially written back up to fair value in the third quarter of 2024, similar impairments, and other potential risks like those mentioned above, may adversely affect the market value of our common stock.

We may not realize all the anticipated benefits of our business development activities.

As part of our efforts to drive growth by pursuing select acquisition, license, and distribution opportunities that are aligned to our objectives and complement our existing products, services, and infrastructure or to divest non-core product lines, we have completed several transactions in recent years and may pursue similar additional transactions in the future.

Our ability to realize the anticipated business opportunities, growth prospects, cost savings, synergies, and other benefits of these and other transactions depends on a number of factors including our ability to:

- Leverage our global infrastructure to sell and cross-market the acquired products;
- Drive adoption of the NEXUS family of products and AMDS in the European and other markets, including our ability to manage the substantial product training, implant support, and proctoring requirements for NEXUS procedures;
- Bring acquired products to the US market, including our acquired aortic stent grafts;
- Harness the aortic stent graft product pipeline and our research and development capabilities;
- Obtain regulatory approvals in relevant markets, including our ability to timely obtain or maintain CE Mark product certifications for pipeline and current products;
- Execute on development and clinical trial timelines for acquired products;
- Manage global inventories, including our ability to manage inventories for product lines with large numbers of product configurations and manage manufacturing and demand cycles to avoid excess inventory obsolescence due to shelf life expiration, particularly for processed tissues and aortic stent grafts;
- Carry, service, and manage significant debt and repayment obligations; and
- Manage the unforeseen risks and uncertainties related to these transactions, including any related to intellectual property rights.

Additionally, our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of our 2019 Endospan transaction depends on a number of additional factors including Endospan's ability to: (a) comply with the Endospan Loan and other debt obligations, and avoid an event of default; (b) successfully commercialize the NEXUS family of products, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for the NEXUS family of products; (d) meet quality and regulatory requirements for the NEXUS family of products; (e) manage any intellectual property risks and uncertainties associated with the NEXUS family of products; (f) obtain FDA approval of the NEXUS family of products; (g) remain a going concern; and (h) develop the NEXUS family of products, and other product improvements to meet competitive threats and physician demand. As an example of this risk, the forecasted operating results related to NEXUS ONE decreased, resulting in an impairment to the carrying value of the Endospan Option, and a full write-down of the value of our original loan to Endospan, reflecting decreased expectations with respect to the anticipated benefits of the Endospan transaction. Similarly, our ability to realize the anticipated benefits of the Baxter Transaction depends on factors beyond our control, including Baxter's performance against Baxter's originally anticipated demand.

Many of these factors are outside of our control and any one of them could result in increased costs, decreased revenues, and diversion of management's time and energy. The benefits of these transactions may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share, decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our common stock. In addition, if we fail to realize the anticipated benefits of a transaction, we could experience an interruption or loss of momentum in our existing business activities.

Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business.

We rely upon a combination of information technology systems as well as traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including, but not limited to, information about our business, financial information, personnel data, intellectual property, and, in some instances, patient data and other personally identifiable information). Our business operations rely on critical information technology systems related to systems that power aspects of our Quality System (including our eQMS system) and our global operations (including our ERP systems).

We have experienced, and expect to continue to be subject to the risk of, cybersecurity threats and incidents. For example, we experienced a previously-disclosed cyber-attack in the fourth quarter of 2024 that temporarily disrupted our business operations, including our ERP systems, and had an impact on revenue, manufacturing, order processing, shipping, and other corporate operations (the "Cybersecurity Incident"). Our claims for reimbursement with our insurer remain outstanding and we continue to incur expenses in connection with improving our global infrastructure and cybersecurity posture, additionally, we remain subject to other risks and uncertainties as a result of the incident, including those related to scrap, inventory levels, and timely shipping releases, as well as the potential to incur additional expenses.

While we have invested, and continue to invest, in our information technology and information security systems and employee information security training, there can be no assurance that our efforts will prevent all security breaches, service interruptions, or data losses, particularly in light of rapid improvements in information processing technology accompanying developments in, among other areas, artificial intelligence platforms. In addition, a portion of our employees work remotely, and those employees may use outside technology and systems that are vulnerable to security breaches, service interruptions, data loss or malicious attacks, including by third parties.

We have limited cyber-insurance coverage that may not cover all possible events, or the financial expenses or losses associated with any particular event, and this insurance is subject to deductibles and coverage limitations. Any security breaches, service interruptions, or data losses could adversely affect our business operations or result in the loss of critical or sensitive confidential information or intellectual property, or in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities.

Our business could be impacted by environmental, social, and governance matters.

Governments, investors, customers, employees and other stakeholders are continuing to focus on areas of corporate responsibility, and particularly matters related to environmental, social, and governance ("ESG") factors. Stakeholders are looking to companies that demonstrate strong ESG and sustainability practices as an indicator of long-term resilience. Keeping up with and meeting these sometimes contradictory and evolving expectations can be difficult and expensive, and may disrupt our business and divert the attention of our management. We may be unable to make the investments in ESG programs that our competitors with greater financial resources are able to make or we may be challenged by governmental authorities if we choose to make such investments. Failure to meet the expectations of investors, other stakeholders, or certain governmental authorities in these areas may damage our reputation, impact employee retention, impact the willingness of our customers to do business with us, or otherwise impact our financial results and stock price.

Legal, Quality, and Regulatory Risks

Our products and tissues are highly regulated and subject to significant quality and regulatory risks.

The commercialization of medical devices and processing and distribution of human tissues are highly complex and subject to significant global quality and regulatory risks, including product recalls, and as such, we face the following risks:

- Our products and tissues allegedly have caused, and may in the future cause, patient injury, which has exposed, and could in the future expose, us to product recalls and/or liability claims that could lead to additional regulatory scrutiny;

- Our manufacturing and tissue processing operations are subject to regulatory scrutiny, inspections and enforcement actions, and regulatory agencies could require us to change or modify our operations or take other action, such as issuing product recalls or holds;
- Regulatory agencies could reclassify, re-evaluate, or suspend our clearances or approvals, or fail to, or decline to, issue or reissue our clearances or approvals that are necessary to sell our products and distribute tissues;
- Regulatory and quality requirements are subject to change, which could adversely affect our ability to sell our products or distribute tissues; and
- Adverse publicity associated with our products, processed tissues, or our industry could lead to a decreased use of our products or tissues, increased regulatory scrutiny, or product or tissue processing liability claims.

As an example of these risks, the European Union's Medical Device Regulation (the MDR), which was to be fully implemented on May 26, 2021, places stricter requirements on manufacturers and European Notified Bodies regarding, among other things, product classifications and pre- and post-market clinical studies for product clearances and approvals. The MDR could result in product reclassifications or the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the European Economic Area and other markets that require or rely on CE Marking as a basis for market authorization.

The transition to the MDR has been fraught with difficulties and uncertainty, including delays in audits and approvals. The European Parliament has extended the MDR transition period under Regulation (EU) 2023/607 but it is still unclear whether this extension will be able to mitigate transition challenges. As a result, we face increased risks related to:

- Our Custom Devices: Stricter requirements on manufacturers of custom-made devices may delay, impede, or otherwise impact the availability of our E-xtra Design Engineering services and custom-made products;
- Our Existing CE Marks: The extended timeline for the MDR transition has resulted in certain MDD-based CE Marks expiring prior to the completion of the transition. Our MDD-based CE Mark for BioGlue expired in December 2021, and for Chord-X in September 2022. We have since been able to successfully renew the CE Mark for BioGlue and Chord-X under the MDR;
- Our Notified Bodies: The combination of the increased regulatory framework under the MDR and the UK's exit from the European Union have both had an impact on notified bodies. The MDR has significantly increased the workload on existing notified bodies and as a result, many have elected to leave the space, including our Notified Body in the UK, LRQA. Although we were able to transition our LRQA-issued certification for BioGlue to a new notified body, DEKRA, we are still in the process of transitioning the LRQA-issue certification for PhotoFix; and
- New CE Marks: The increased workload on notified bodies and other uncertainties around the transition to the MDR will likely cause delays in the approval for any new products that we may wish to bring to the EU market.

While we continue to make progress on the MDR transition, the transition to new notified bodies, and the renewal of expired CE Marks, failure to timely complete any transfers or renewals, or to comply with transition to a newly designated UK Approved Body, or further delays in the MDR transition as a whole, may have a material, adverse effect on our ability to supply product in certain jurisdictions, have a material, adverse impact on our business, and may also impact our Medical Device Single Audit Program ("MDSAP") certifications. Failure to timely obtain new MDSAP certifications following their expiration may impact our ability to distribute covered products in Australia, Brazil, Canada, and Japan.

Reclassification by the FDA of CryoValve SG pulmonary heart valve ("CryoValve SGPV") may make it commercially infeasible to continue processing the CryoValve SGPV.

Beginning in December 2019 and most recently in the fall of 2024, the FDA indicated that it was planning to issue a proposed rule for reclassification of more than minimally manipulated ("MMM") allograft heart valves to Class III medical devices, which could include our CryoValve SGPV. Following any comment period and subsequent publication of a final rule, should the CryoValve SGPV be determined to be MMM or classified as a Class III device, we currently expect to have approximately thirty months to submit a PMA application, after which the FDA will determine if, and for how long, we may continue to

provide these tissues to customers during its review of the PMA application. Although this proposed rule change has, to our knowledge, remained on the HHS's unified regulatory agenda since 2019, no final rule has been published at this time.

If the FDA ultimately classifies our CryoValve SGPV as a Class III medical device, and if there are delays in obtaining the PMA, if we are unsuccessful in obtaining the PMA, or if the costs associated with these activities are significant, we could decide that the requirements for continued processing of the CryoValve SGPV are too onerous, leading us to discontinue distribution of these tissues.

We may not be successful in obtaining clinical results or regulatory clearances/approvals for new and existing products and services, and our approved products and services may not achieve market acceptance.

Our growth and profitability depend in part upon our ability to develop, and successfully introduce, new products and services, or expand upon existing indications, clearances, and approvals, requiring that we invest significant time and resources to obtain new regulatory clearances/approvals, including investment into pre- and post-market clinical studies. Although we believe certain products and services in our portfolio or under development may be effective in a particular application, we cannot be certain until we successfully execute on relevant clinical trials, and the results we obtain from pre- and post-market clinical studies may be insufficient for us to obtain or maintain any required regulatory approvals or clearances.

As an example of this risk, in September 2022 we halted the PROACT Xa clinical trial based on the recommendation of the trial's Data and Safety Monitoring Board ("DSMB") due to insufficient evidence to support non-inferiority of apixaban to warfarin for valve thrombosis and thromboembolism. Similarly, in November 2023 we announced that we were no longer pursuing a labeling change for our On-X mitral valve in connection with our PROACT Mitral trial due to additional investments that would be required to do so. Finally, although we recently received regulatory approval to market BioGlue in China, it was only after a significantly longer and more expensive regulatory approval process than likely could reasonably have been anticipated when the program began.

Each of our trials, studies, and approvals is subject to the risks outlined herein.

We cannot give assurance that regulatory agencies will clear or approve these products and services or indications, or any new products and services or new indications, on a timely basis, if ever, or that the products and services or new indications will adequately meet the requirements of the market or achieve market acceptance. Pre- and post-market clinical studies may also be delayed or halted due to many factors beyond our control.

If we are unable to successfully complete the development of a product, service, or application, or if we determine for any reason not to complete development or obtain regulatory approval or clearance of any product, service, or application, particularly in instances when we have expended significant capital, this could materially, adversely affect our financial performance. Halting R&D efforts and clinical trials prematurely may lead to accelerated or unanticipated wind down costs. Even the successful commercialization of a new product or service in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity, and continuing research and development and education costs, among other things. The introduction of new products or services may require significant physician training or years of clinical evidence in order to gain acceptance in the medical community.

Increased environmental regulations and private litigation activity relating to processes and materials used in our industry could have a material, adverse impact on us.

Some of our products, including certain On-X products, are sterilized using EtO, primarily by third-party large-scale EtO facilities. In addition, some of our suppliers use, or rely upon third parties to use, EtO to sterilize some of our product components. Concerns about the release of EtO into the environment at unsafe levels have led to increased activism and lobbying as well as various regulatory enforcement activities against EtO facilities, including closures and temporary closures, lawsuits against EtO service providers, and proposals increasing regulations related to EtO. The number of EtO

facilities in the US is limited, and any permanent or temporary closures or disruption to their operations for any reason could delay, impede, or prevent our ability to commercialize our products.

In addition, any litigation, regulatory enforcement, or government regulation regarding the use of EtO could result in financial, legal, business, and reputational harm to us.

The per-and polyfluoroalkyl substances ("PFAS") are used in a wide variety of consumer and industrial products, including medical devices and product packaging. PFAS have been subject to increasing regulations, and in some cases bans, by the Environmental Protection Agency and numerous states. These requirements impose a high compliance burden, and further regulation of PFAS-containing products is expected. Although we have yet to experience any material impact from this activity or identify any of our products materially impacted by PFAS-related regulation, the ultimate impact and associated cost of current and future rulemaking cannot be predicted at this time.

We may be subject to fines, penalties, and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off-label, uses.

Our business and future growth depend on the continued use of our products for approved uses. Generally, regulators contend that, unless our products are approved or cleared by a regulatory body for alternative uses, we may not make claims about the safety or effectiveness of our products or promote them for such uses. Such limitations present a risk that law enforcement could allege that the nature and scope of our sales, marketing, or support activities, though designed to comply with all regulatory requirements, constitute unlawful promotion of our products for an unapproved use. We also face the risk that such authorities might pursue enforcement based on past activities that we discontinued or changed. Investigations concerning the promotion of unapproved uses and related issues are typically expensive, disruptive, and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant, and educational activities. In addition, we or our officers could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

We are subject to various US and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, any breach of which could cause a material, adverse effect on our business, financial condition, and profitability.

Our relationships with physicians, hospitals, government officials, healthcare providers, and others are subject to scrutiny under various US and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, often referred to collectively as "healthcare compliance laws." Healthcare compliance laws are broad, sometimes ambiguous, counterintuitive, complex, and subject to change and changing interpretations. Our global expansion into higher-risk regions and Russia's ongoing war with Ukraine and the instability of the Middle East, and the current and future sanctions imposed on Russia and others as a result may exacerbate these risks. See also Part I, Item 1A, "Risk Factors – Business and Economic Risks - We are subject to a variety of risks due to our international operations and continued global expansion." Possible sanctions for violation of these healthcare compliance laws include fines, civil and criminal penalties, exclusion from government healthcare programs, and despite our compliance efforts, we face the risk of an enforcement activity or a finding of a violation of these laws.

We have entered into consulting and product development agreements with healthcare professionals and healthcare organizations, including some who may order our products or make decisions to use them. We have also adopted the AdvaMed Code of Conduct, the MedTech Europe Code of Ethical Business Practice, and the APACMed Code of Ethical Conduct which govern our relationships with healthcare professionals to bolster our compliance with healthcare compliance laws. While our relationships with healthcare professionals, government officials, and organizations are structured to comply with such laws and we conduct training sessions on these laws and codes, it is possible that enforcement authorities may view our relationships as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties or debarment. In any event, any enforcement review of or action against us as a result of such review, regardless of outcome, could be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going-forward basis only.

United States policy changes may have a material, adverse effect on us.

The transition to a new presidential administration in the US brings several potential risks that could impact our business operations and financial performance. Changes in policy regarding international trade, including import and export regulation and international trade agreements, could negatively impact our business. The US has imposed tariffs and export controls on certain goods and products imported from abroad, which has resulted in retaliatory tariffs. Additional tariffs imposed by the US on a broader range of imports, or further retaliatory trade measures taken by other countries in response, could result in an increase in supply chain costs that we may not be able to offset or that otherwise adversely impact our results of operations. In addition, political tensions between the US and certain other countries have escalated in recent years between and among these countries. Changes in foreign policy and the imposition of new sanctions could impact our ability to distribute products in certain regions. This could limit our market reach and affect our revenue streams. The new administration may introduce regulatory changes that could impact the speed to market and our ability to obtain timely reviews for our products. This could delay clinical trials and product launches, impact the regulatory status of current products or services, or affect our competitive position. Changes in tax policy, including changes to corporate tax rates or changes in tax incentives that we currently benefit from, could negatively impact our results of operations and financial condition.

The new administration has already taken numerous steps impacting federal spending and the federal workforce. Policies relating to reductions in spending, reductions in staff, and mandated return-to-office policies, could impact the capabilities of regulatory agencies which could affect the timeliness and efficiency of regulatory reviews and approvals that are critical to our operations. Regulatory focus, particularly with respect to sustainability matters, may change, reducing or changing regulations relating to ethylene oxide (EtO), per- and polyfluoroalkyl substances (PFAs), or other sustainability initiatives, potentially requiring us to make additional expenditures to comply with new regulations, or abandon programs we have already invested in.

In response to perceived increases in healthcare costs in recent years, there have been, and continue to be, proposals by the governmental authorities, third-party payors, and elected office holders and candidates to impact public health, control healthcare costs and, more generally, to reform the healthcare systems. These changes may impact costs and reimbursement, as well as potential changes to the regulatory environment and healthcare generally. Many US healthcare laws, including the Affordable Care Act and the Federal Food, Drug, and Cosmetics Act, are complex, subject to change particularly during a change in administrations, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. Changes in federal funding or staffing at administrative agencies like the FDA may impact, for example, the speed at which we are able to obtain regulatory approvals, and changes in the focus of those administrative agencies may result in the repeal of applicable regulations or guidance or impact us in other ways we can not anticipate. The impact of this uncertainty on us, our customers, or the specific services and relationships we have with our customers is not always clear. Our failure to anticipate accurately these changes, or our failure to comply with changes to legal and regulatory frameworks, could create liability for us, result in adverse publicity and negatively affect our business, results of operations, and financial condition.

As a medical device manufacturer and tissue services provider we are exposed to risk of product liability claims and our existing insurance coverage may be insufficient, or we may be unable to obtain insurance in the future, to cover any resulting liability.

Our products and processed tissues allegedly have caused, and may in the future cause, injury or result in other serious complications that may result in product or other liability claims from our customers or their patients. If our products are defectively designed, manufactured, or labeled, or contain inadequate warnings, defective components, or are misused, or are used contrary to our warnings, instructions, and approved indications, we may become subject to costly litigation that can have unpredictable and sometimes extreme outcomes.

We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability and securities, claims, among others, that are reported to the insurance carrier while the policy is in effect. These policies do not include coverage for punitive damages. Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, if we are unsuccessful in arranging cost-effective acceptable resolutions of claims, it is

possible that our insurance program may not be adequate to cover any or all possible claims or losses, including losses arising out of natural disasters or catastrophic circumstances. Any significant claim could result in an increase in our insurance rates or jeopardize our ability to secure coverage on reasonable terms, if at all.

Any securities or product liability/tissue processing claim, even a meritless or unsuccessful one, could be costly to defend, and result in diversion of our management's attention from our business, adverse publicity, withdrawal of clinical trial participants, injury to our reputation, or loss of revenue.

Failure to comply with data privacy and security laws could have a material adverse effect on our business.

We are subject to an increasing number of federal, state, and foreign laws and regulations to address topics relating to data privacy, sustainability, and artificial intelligence. These regulations, some of which can be enforced by private parties or governmental entities, have been or are being promulgated and are constantly evolving and becoming increasingly complex and rigorous. These laws and regulations may include new compliance or disclosure requirements which increases our operating costs and requires significant management investment. Many of these laws and regulations, including the European Union's General Data Protection Regulation ("GDPR") also include significant penalties for noncompliance. Although our practices, policies, and procedures are intended to comply with relevant laws and regulations, there can be no assurance that regulatory or enforcement authorities will view our arrangements as being in compliance, or that one or more of our employees or agents will not disregard aspects of our compliance programs. Any resulting government enforcement activities may be costly, result in negative publicity, or subject us to significant penalties.

Risks Relating to Our Indebtedness

The agreements governing our indebtedness contain restrictions that limit our flexibility in operating our business.

The agreements currently governing our indebtedness contain, and any instruments governing future indebtedness of ours may contain, covenants that impose significant operating and financial restrictions on us and certain of our subsidiaries, including (subject in each case to certain exceptions) restrictions or prohibitions on our and certain of our subsidiaries' ability to, among other things:

- Incur or guarantee additional debt or create liens on certain assets;
- Pay dividends on or make distributions of our share capital, including repurchasing or redeeming capital stock, or make other restricted payments, including restricted junior payments;
- Enter into agreements that restrict our subsidiaries' ability to pay dividends to us, repay debt owed to us or our subsidiaries, or make loans or advances to us or our other subsidiaries;
- Enter into certain transactions with our affiliates including any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary;
- Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement;
- Amend, supplement, waive, or otherwise modify our or our subsidiaries' organizational documents in a manner that would be materially adverse to the interests of the lender, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lender;
- Make changes to our and our subsidiaries' fiscal year without notice to the administrative agent;
- Enter into agreements which restrict our ability to incur liens;
- Engage in any line of business substantially different from that in which we are currently engaged; and
- Make certain investments, including strategic acquisitions or joint ventures.

Our indebtedness could adversely affect our ability to raise additional capital to fund operations and execute our strategic plan, and limit our ability to react to changes in the economy or our industry.

We may need to seek additional debt or equity financing to execute our strategic plan. However, we may be unable to obtain any desired additional financing on terms favorable to us, if at all. Our current and future levels of indebtedness could adversely affect our ability to raise additional capital, limit our operational flexibility, and hinder our ability to react to changes in the economy or our industry. It may also limit our ability to borrow money, require us to dedicate substantial portions of our cash flow to repayment, and restrict our ability to invest in business opportunities. Because most of our borrowings are at a variable rate of interest, we are exposed to interest rate fluctuations.

We have pledged substantially all of our US assets as collateral under our existing Credit Agreement. If we default on the terms of such credit agreements and the holders of our indebtedness accelerate the repayment of such indebtedness, there can be no assurance that we will have sufficient assets to repay our indebtedness.

A failure to comply with the covenants in our existing Credit Agreement could result in an event of default, which, if not cured or waived, could have a material, adverse effect on our business, financial condition, and profitability. In the event of any such default, the holders of our indebtedness:

- Will not be required to lend any additional amounts to us; and
- Could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable.

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against their secured collateral to seek repayment out of proceeds from the sale or liquidation of our assets. If our indebtedness were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

Risks Relating to Ownership of our Common Stock

Our business could be negatively impacted as a result of stockholder activism.

In recent years, stockholder activists have become involved in the governance, strategic direction, and operations of companies. Such involvement with us may disrupt our business and divert the attention of our management, and any perceived uncertainties as to our future direction resulting from such involvement could result in the loss of business opportunities, be exploited by our competitors, cause concern for our current or potential customers, cause significant fluctuations in stock price, or make it more difficult to attract and retain qualified personnel and business partners.

We do not anticipate paying any dividends on our common stock for the foreseeable future.

In December 2015 our Board of Directors discontinued dividend payments on our common stock for the foreseeable future. If we do not pay cash dividends, our stockholders may receive a return on their investment in our common stock only through appreciation of shares of our common stock that they own. In addition, restrictions in our credit facility limit our ability to pay future dividends.

Provisions of Delaware law and anti-takeover provisions in our organizational documents may discourage or prevent a change of control, even if an acquisition would be beneficial to stockholders, which could affect our share price adversely and prevent attempts by stockholders to remove current management.

Effective January 1, 2022 we reincorporated in Delaware. Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay, or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, the

organizational documents adopted in connection with our reincorporation contain provisions that restrict persons who may call stockholder meetings, allow the issuance of blank-check preferred stock without the vote of stockholders, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Delaware law and our Certificate of Incorporation and Bylaws could prevent attempts by stockholders to remove current management, prohibit or delay mergers or other changes of control transactions, and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our stockholders.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things, operational risks; intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy or security laws and other litigation and legal risk; and reputational risks. We have established cybersecurity measures, technologies, and controls to aid in our efforts to assess, identify, and manage such material risks.

Our enterprise risk management framework assesses cybersecurity threats alongside other company risks as part of our overall risk assessment process. This approach involves collaboration between enterprise risk professionals and subject matter experts to identify and assess material cybersecurity threat risks, their severity, and potential mitigations. We leverage various tools and services, including network monitoring, vulnerability assessments, penetration testing, and tabletop exercises, to enhance our risk identification and assessment capabilities.

Our cybersecurity-specific risk assessment process benchmarks our practices against standards set by the National Institute of Standards and Technology (“NIST”), International Organization for Standardization (“ISO”), and the Center for Internet Security (“CIS”), and includes penetration tests to evaluate the security of our information systems, as such term is defined in Item 106(a) of Regulation S-K.

To safeguard critical data and systems, support regulatory compliance, manage our material risks from cybersecurity threats, and identify, assess and respond to potential cybersecurity incidents, as such term is defined in Item 106(a) of Regulation S-K, we:

- Monitor emerging data protection laws and adjust our processes and procedures as required or appropriate;
- Utilize Endpoint Detection and Response (EDR) tools to help us prevent, detect, and respond to endpoint threats with real-time visibility across our infrastructure and devices, enterprise-wide;
- Provide periodic, but no less than annual, training on cybersecurity, data privacy, and data handling to all employees and contractors with access to our systems;
- Conduct periodic, but no less than, annual cybersecurity management and incident response training for relevant personnel, utilizing Knowbe4 resources;
- Implement regular phishing simulations and processes for reporting phishing events and concerns to enhance staff awareness, vigilance, and responsiveness;
- Mandate that both employees and service providers treat sensitive data with utmost care, enforced through policies, practices, and contracts;
- Employ elements of the NIST incident handling framework for identifying, protecting, detecting, responding to, and recovering from cybersecurity incidents; and
- Maintain cybersecurity risk insurance to mitigate potential financial losses from incidents.

Our incident response plan outlines our approach to preparing for, detecting, responding to, and recovering from cybersecurity incidents, including severity assessment, containment, investigation, and remediation processes.

Our cybersecurity efforts involve regular engagement with external assessors, consultants, and auditors, including periodic reviews by an independent qualified security assessor to identify areas for improvement and support compliance, as well as assessments and audits by our insurer and our external auditing firm.

We address cybersecurity risks related to third-party service providers by incorporating these risks into our enterprise risk management and cybersecurity-specific risk assessment programs. We conduct due diligence on third parties with access to our systems or data and require them to adhere to specified cybersecurity standards and audits.

Our information systems have been subject to cybersecurity incidents in the past, including a cyber-attack identified and disclosed during the fourth quarter of 2024 (the "Cybersecurity Incident") that temporarily disrupted our business operations, including our ERP systems, and had an impact on manufacturing, order processing, shipping, and other corporate operations. Although we are continuing to work with our insurer to recoup covered losses, we do expect to continue to incur expenses in connection with improving our global cybersecurity infrastructure and cybersecurity posture.

As of the date of this Annual Report on Form 10-K, we believe that the Cybersecurity Incident has not materially impacted the Company, our overall financial condition or results of operations, and that the incident is not reasonably likely to materially impact the Company, our financial conditions or results of operations. In addition, we are not aware of any cybersecurity threats or cybersecurity incidents that have or would be reasonably likely to materially affect us, including our business strategy, results of operations or financial condition as of the date of this Annual Report on Form 10-K. This includes penalties and settlements, of which there were none. We are seeking reimbursement of costs, expenses and losses stemming from the Cybersecurity Incident by submitting claims to our cybersecurity insurer. The timing and amount of any such reimbursements are not known at this time. As discussed in more detail in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", the Cybersecurity Incident had a $4.6 million impact on our results for the year ended December 31, 2024.

To learn more about the risk and potential impact of cybersecurity threats on our business strategy, operations, and financial condition, including with respect to the Cybersecurity Incident, See Part I, Item 1A, "Risk Factors," "Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business".

Governance

Cybersecurity is integrated with our overall risk management strategy and is an area of focus for our Board and management, with oversight at the executive level led by our Chief Financial Officer. The Audit Committee, and where applicable, other directors or the entire Board, are involved in overseeing cybersecurity risks. They receive quarterly and bi-annual updates, respectively, on our cybersecurity threat risk management and strategy processes, and may meet more frequently in response to specific threats or incidents. These updates, provided by our Chief Financial Officer and/or our global head of Information Technology, cover various cybersecurity topics, including data security posture, third-party assessment results, progress on risk mitigation goals, incident response plans, and select cybersecurity threat risks or incidents. The Board and Audit Committee also have discussions with our global head of Information Technology and engage in separate meetings to consider cybersecurity risks in the context of broader corporate matters.

Our cybersecurity risk management and strategy processes are led by our global head of Information Technology who reports directly to our Chief Financial Officer and focus on preventing, mitigating, detecting and remediating cybersecurity incidents, as well as threat risks and related matters. The global head of Information Technology is part of our operating team and is responsible for implementing our cybersecurity risk management and strategy processes and the operation of our incident response and business continuity plan. Management uses information provided by our global head of Information Technology, along with feedback from external experts, the Audit Committee, and our Board, as part of the cyber-specific and enterprise-wide risk management process described above.

Our information technology and cybersecurity team has approximately 35 years of collective experience in information security and cybersecurity strategy, with various roles in significant organizations. Team members' relevant degrees and certifications include but are not limited to Certified Information Security Manager, Certified Information Systems Security Professional, Certified Ethical Hacker, Certified Penetration Tester, among others.

Item 2. Properties.

Our corporate headquarters consist of approximately 190,400 square feet of leased manufacturing, administrative, laboratory, and warehouse space located on a 21.5-acre setting, with an additional 14,400 square feet of off-site warehouse space both located in Kennesaw, Georgia. The manufacturing and tissue processing space includes approximately 20,000 square feet of class 10,000 clean rooms and 8,000 square feet of class 100,000 clean rooms. This extensive clean room environment provides a controlled aseptic environment for manufacturing and tissue preservation. Two back-up emergency generators assure continuity of our manufacturing operations and liquid nitrogen freezers maintain preserved tissue at or below –135°C. We manufacture products from our Medical Devices segment, including BioGlue and PhotoFix, and process and preserve tissues from our Preservation Services segment at our headquarters facility.

Our corporate complex includes the Ronald C. Elkins Learning Center, a 3,600 square foot auditorium that holds 225 participants, and a 1,500 square foot training lab, both equipped with closed-circuit and satellite television broadcast capability allowing live worldwide broadcasts. The Ronald C. Elkins Learning Center provides visiting surgeons with a hands-on training environment for surgical and implantation techniques for our technology platforms.

Our primary European subsidiary, JOTEC, located in Hechingen, Germany, maintains facilities that consist of approximately 156,000 square feet of leased manufacturing, administrative, laboratory, and warehouse space where we manufacture aortic stent grafts.

Our On-X facility consists of approximately 75,000 square feet of combined manufacturing, administrative, laboratory, warehouse, and office space leased in Austin, Texas.

We lease small amounts of ancillary office and warehouse space in various countries in which we operate direct sales subsidiaries, including in Brazil, Greece, Italy, Poland, Spain, Switzerland, and the United Kingdom. In April 2022 we opened a distribution center in Singapore to support sales activities in the APAC region.

Item 3. Legal Proceedings.

From time to time, we are involved in legal proceedings concerning matters arising in connection with the conduct of our business activities. We regularly evaluate the status of legal proceedings in which we are involved in order to assess whether a loss is probable or there is a reasonable possibility that a loss or additional loss may been incurred, and to determine if accruals are appropriate. We further evaluate each legal proceeding to assess whether an estimate of possible loss or range of loss can be made.

Based on current knowledge, management does not believe that there are any pending legal proceedings that will have a material, adverse effect on our business, financial condition, results of operations, or cash flows. However, we are engaged in various legal actions in the normal course of business. There can be no assurances in light of the inherent uncertainties involved in any potential legal proceedings, some of which are beyond our control, and an adverse outcome in any legal proceeding could be material to our results of operations or cash flows for any particular reporting period.

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 Price of Common Stock

Our common stock is traded on the New York Stock Exchange ("NYSE") under the symbol "AORT". The following table sets forth, for the periods indicated, the intra-day high and low sale prices per share of common stock on the NYSE.

2024	High	Low
First quarter	$ 21.82	$ 16.48
Second quarter	25.74	19.36
Third quarter	29.24	23.79
Fourth quarter	30.45	24.82

2023	High	Low
First quarter	$ 15.18	$ 11.44
Second quarter	17.69	12.57
Third quarter	17.97	14.58
Fourth quarter	19.00	12.16

As of February 21, 2025 we had 157 stockholders of record.

Dividends

No dividends were paid in 2024, 2023, or 2022.

Issuer Purchases of Equity Securities

Neither the Company nor any affiliate or other party acting on behalf of the Company repurchased any of the Company's equity securities during the three months ended December 31, 2024.

Under our Credit Facilities, we are prohibited from repurchasing our common stock, except for the repurchase of stock from our employees or directors when tendered in payment of taxes or the exercise price of stock options, upon the satisfaction of certain requirements.

Item 6. [Reserved]

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

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this filing. The discussion contains forward-looking statements that involve known and unknown risks and uncertainties, including those set forth under Part I, Item 1A."*Risk Factors*" *of this Form 10-K. The following discussion and analysis do not include certain items related to the year ended December 31, 2022, including year-to-year comparisons between the year ended December 31, 2023 and the year ended December 31, 2022. For a comparison of our results of operations for the fiscal years ended December 31, 2023 and December 31, 2022, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 23, 2024.*

Overview

Artivion, Inc. ("Artivion," the "Company," "we," or "us"), is a leader in the manufacturing, processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures for patients with aortic disease. We have four major product families: aortic stent grafts, On-X mechanical heart valves and related surgical products, surgical sealants, and implantable cardiac and vascular human tissues. Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, and synthetic vascular grafts. Aortic arch stent grafts include our E-vita Open NEO, E-vita Open Plus, AMDS, NEXUS ONE, NEXUS DUO, and NEXUS TRE, and E-vita Thoracic 3G products. Abdominal stent grafts include our E-xtra Design Engineering, E-nside, E-tegra, E-ventus BX, Tuva™ BX, and E-liac products. Surgical sealants include BioGlue Surgical Adhesive ("BioGlue") products. In addition to these four major product families, we sell or distribute PhotoFix bovine surgical patches ("PhotoFix") and CardioGenesis cardiac laser therapy (prior to our abandonment of that business as of June 2023). We began to manufacture and supply PerClot® hemostatic powder ("PerClot") during the second quarter of 2023 (as part of the Transitional Manufacturing and Supply Agreement ("TMSA") of the Baxter Transaction, described below).

For the year ended December 31, 2024 we reported annual revenues of $388.5 million, increasing 10% over the prior year. Excluding the effects of foreign exchange, revenues increased 9% over the prior year. The increase in revenues was due to increases in revenues from aortic stent grafts, On-X products, surgical sealants, and preservation services, partially offset by a decrease in revenues from other products and certain limited impacts resulting from the Cybersecurity Incident. For the year ended December 31, 2024 we reported a net loss of $13.4 million. See the "Results of Operations" section below for additional analysis of the full year 2024 results. See Part I, Item 1, "Business," for further discussion of our business and activities during 2024.

Critical Accounting Policies

A summary of our significant accounting policies is included in Part II, Item 8, Note 1 of the "Notes to Consolidated Financial Statements." We believe that the consistent application of these policies enables us to provide users of the financial statements with useful and reliable information about our operating results and financial condition. The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the US, which require us to make estimates and assumptions. The following are accounting policies that we believe are most important to the portrayal of our financial condition and results of operations and may involve a higher degree of judgment and complexity.

Deferred Preservation Costs

Deferred preservation costs include costs of cardiac and vascular tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status. By federal law, human tissues cannot be bought or sold; therefore, the tissues we preserve are not held as inventory. The costs we incur to procure and process cardiac and vascular tissues are instead accumulated and deferred. Deferred preservation costs are stated at the lower of cost or net realizable value on a first-in, first-out basis and are deferred until revenue is recognized. Upon shipment of tissue to an implanting facility, revenue is recognized, and the related deferred preservation costs are expensed as cost of preservation services. Cost of preservation services also includes, as applicable, lower of cost or net realizable value write-downs and impairments for tissues not deemed to be recoverable, and includes, as incurred, idle facility expense, excessive spoilage, extra freight, and re-handling costs.

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations ("OPOs") and tissue banks that provide the tissue to us for processing, preservation, and distribution. Deferred preservation costs consist primarily of the procurement fees charged by the OPOs and tissue banks, direct labor and materials (including salary and fringe benefits, laboratory supplies and expenses, and freight-in charges), and indirect costs (including allocations of costs from support departments and facility allocations). Fixed production overhead costs are allocated based on actual tissue processing levels, to the extent that they are within the range of the facility's normal capacity.

These costs are then allocated among the tissues processed during the period based on cost drivers, such as the number of donors or number of tissues processed. We apply a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. We estimate quarantine and in process yields based on our historical yield experience with similar tissues and re-evaluate these estimates periodically. Actual yields could differ significantly from our estimates, which could result in a change in tissues available for shipment and could increase or decrease the balance of deferred preservation costs. These changes could result in additional cost of preservation services expense or could increase per tissue preservation costs, which would impact gross margins on tissue preservation services in future periods.

We regularly evaluate our deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or net realizable value. We also evaluate our deferred preservation costs for costs not deemed to be recoverable, including tissues not expected to ship prior to the expiration date of their packaging. Lower of cost or net realizable value write-downs are recorded if the tissue processing costs incurred exceed the estimated market value of the tissue services, based on recent average service fees at the time of the evaluation. Impairment write-downs are recorded based on the book value of tissues deemed to be impaired. Actual results may differ from these estimates. Write-downs of deferred preservation costs are expensed as cost of preservation services, and these write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if our estimates change.

Fair Value Measurements - Contingent Consideration

Contingent consideration represents a recurring fair value estimate of potential future payments. The fair value of the contingent consideration liability is estimated by discounting to present value the contingent payments expected to be made based on a probability-weighted scenario approach. A discount rate is applied based on our unsecured credit spread and the term commensurate risk-free rate to the additional consideration to be paid, and then we apply a risk-based estimate of the probability of achieving each scenario to calculate the fair value of the contingent consideration. This fair value measurement was based on unobservable inputs, including management estimates and assumptions about the future achievement of milestones and future estimate of revenues, and is, therefore, classified as Level 3 within the fair value hierarchy.

New Accounting Pronouncements

See Part II, Item 8, Note 1 of “Notes to Consolidated Financial Statements” for further discussion of new accounting standards that have been adopted or are being evaluated for future adoption.

Results of Operations

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

($ in thousands)

Revenues

	Revenues for the Year Ended December 31,			Revenues as a Percentage of Total Revenues for the Year Ended December 31,	
	2024	2023	Percent Change	2024	2023
Products:					
Aortic stent grafts	$ 123,081	$ 107,469	15%	32%	31%
On-X	83,982	74,528	13%	22%	21%
Surgical sealants	73,898	68,016	9%	19%	19%
Other	9,269	11,172	(17)%	2%	3%
Total products	**290,230**	**261,185**	**11%**	**75%**	**74%**
Preservation services	98,307	92,819	6%	25%	26%
Total	**$ 388,537**	**$ 354,004**	**10%**	**100%**	**100%**

Revenues increased 10% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase in revenues for the year ended December 31, 2024 was due to an increase in revenues from aortic stent grafts, On-X products, surgical sealants, and preservation services, partially offset by a decrease in revenues from other products. Excluding the effects of foreign exchange, revenues increased 9% for the year ended December 31, 2024, as compared to the year ended December 31, 2023.

The following table reconciles revenues to constant currency revenues for the periods presented:

	Revenues for the Year Ended December 31,				Percent Change From Prior Year
	2024	2023			
	US GAAP	US GAAP	Exchange Rate Effect	Constant Currency	Constant Currency
Products:					
Aortic stent grafts	$ 123,081	$ 107,469	$ 1,052	$ 108,521	13%
On-X	83,982	74,528	(8)	74,520	13%
Surgical sealants	73,898	68,016	39	68,055	9%
Other	9,269	11,172	8	11,180	(17)%
Total products	**290,230**	**261,185**	**1,091**	**262,276**	**11%**
Preservation services	98,307	92,819	(34)	92,785	6%
Total	**$ 388,537**	**$ 354,004**	**$ 1,057**	**$ 355,061**	**9%**
North America	197,940	187,603	(75)	187,528	6%
Europe, the Middle East, and Africa	131,518	114,814	1,838	116,652	13%
Asia Pacific	37,202	33,577	—	33,577	11%
Latin America	21,877	18,010	(706)	17,304	26%
Total	**$ 388,537**	**$ 354,004**	**$ 1,057**	**$ 355,061**	**9%**

A detailed discussion of the changes in product revenues and preservation services revenues for the year ended December 31, 2024 is presented below.

Products

Revenues from products increased 11% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase was due to an increase in revenues from aortic stent grafts, On-X products, and surgical sealants, partially offset by a decrease in revenues from other products and certain limited impacts resulting from the Cybersecurity Incident. A discussion of the changes in product revenues for aortic stent grafts, On-X products, surgical sealants, and other product revenues is presented below.

Sales of certain products through our direct sales force and distributors across Europe and various other countries are denominated in a variety of currencies including Euros, Brazilian Reals, Polish Zlotys, British Pounds, Canadian Dollars, and Swiss Francs with a concentration denominated in Euros. Each currency is subject to exchange rate fluctuations. For the year ended December 31, 2024, as compared to the year ended December 31, 2023, the US Dollar weakened in comparison to major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into US Dollars. Future changes in these exchange rates could have a material, adverse effect on our revenues denominated in these currencies. Additionally, our sales to many distributors around the world are denominated in US Dollars, and although these sales are not directly impacted by currency exchange rates, we believe that some of our distributors may delay or reduce purchases of products in US Dollars depending on the relative price of these goods in their local currencies.

Aortic Stent Grafts

Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, synthetic vascular grafts, and original equipment manufacturing ("OEM") aortic stent graft products. Aortic arch stent grafts include our E-vita Open NEO, E-vita Open Plus,

AMDS, the NEXUS family of products, and E-vita Thoracic 3G products. Abdominal stent grafts include our E-xtra Design Engineering, E-nside, E-tegra, E-ventus BX, Tuva™ BX, and E-liac products. Aortic stent grafts are used in endovascular and open vascular surgery for the treatment of complex aortic arch, thoracic, and abdominal aortic diseases. Our aortic stent grafts are primarily distributed in international markets.

Revenues from the sales of aortic stent grafts increased 15% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. This increase was primarily due to a change in the volume and mix of units sold, and to a lesser extent, an increase in average sales prices, and the effect of foreign exchange rates.

Constant currency revenues from the sales of aortic stent grafts increased 13% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. Revenues for the year ended December 31, 2024 increased primarily in Europe, the Middle East, and Africa (collectively, "EMEA") and, to a lesser extent, in Latin America and Asia Pacific ("APAC"). The revenue increase in EMEA for the year ended December 31, 2024 was primarily due to an increase in volume of higher priced products within the aortic stent graft product line in direct (to hospitals) markets.

On-X Products

The On-X products include the On-X aortic and mitral heart valves and the On-X ascending aortic prosthesis ("AAP") for heart valve replacement. Revenues from the sales of On-X products include revenues from the distribution of CarbonAid® CO_2 diffusion catheters and from the sale of Chord-X® ePTFE sutures for mitral chordal replacement. On-X product revenue also includes revenue generated from pyrolytic carbon coating services for OEM customers.

Revenues from the sales of On-X products increased 13% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. This increase was primarily due to an increase in the volume of units sold and, to a lesser extent, an increase in average sales prices.

Constant currency revenues from the sales of On-X products increased 13% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. Revenues for the year ended December 31, 2024 increased in all geographies, with the most significant increase in North America. The increase in revenues in North America for the year ended December 31, 2024 was impacted by recent gains in the market share. On-X OEM sales accounted for less than 1% of product revenues for the year ended December 31, 2024 and 2023.

Domestic revenues from the sales of On-X products accounted for 61% and 60% of total On-X revenues for the year ended December 31, 2024 and 2023, respectively.

Surgical Sealants

Surgical sealants include BioGlue products used as an adjunct to standard methods of achieving hemostasis (such as sutures and staples) in adult patients in open surgical repair of large vessels (such as aorta, femoral, and carotid arteries).

Revenues from the sales of surgical sealants increased 9% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. This increase was primarily due to an increase in the volume of milliliters sold and, to a lesser extent, an increase in average sales prices.

Constant currency revenues from the sales of surgical sealants increased 9% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase in revenues was primarily due to revenue increases in EMEA, North America, and Latin America, with the most significant increase in EMEA. The increase in revenues in EMEA for the year ended December 31, 2024 was primarily due to an increase in unit sales in direct markets.

Domestic revenues from surgical sealants accounted for 47% and 48% of total surgical sealant revenues for the year ended December 31, 2024 and 2023, respectively.

Other

Other revenues are comprised of revenues from PhotoFix and PerClot (as part of the TMSA of the Baxter Transaction described below), and CardioGenesis cardiac laser therapy (prior to our abandonment of that business as of June 2023).

Other revenues decreased 17% for the year ended December 31, 2024, as compared to the year ended December 31, 2023.

The decrease in other revenues for the year ended December 31, 2024 was primarily due to an decrease in PerClot product revenues and, to a lesser extent, a decrease in CardioGenesis revenues as a result of our abandonment of the CardioGenesis cardiac laser therapy business as of June 30, 2023, partially offset by an increase in PhotoFix revenues due to a change in mix of units sold and an increase in average sales prices.

On July 28, 2021 we entered into an asset purchase agreement, TMSA, and other ancillary agreements related to the sale of PerClot, a polysaccharide hemostatic agent used in surgery, to a subsidiary of Baxter International, Inc. ("Baxter"), and an agreement to terminate all of our material agreements with Starch Medical, Inc. ("SMI") related to PerClot (collectively the "Baxter Transaction"). On May 23, 2023 the FDA granted Premarket Approval ("PMA") of PerClot for use to control bleeding in certain open and laparoscopic surgical procedures. Pursuant to the terms of the TMSA of the Baxter Transaction, we transferred the ownership of the PMA to Baxter following approval and began manufacturing and supplying PerClot for Baxter for a period of 21 months, subject to short-term renewal provisions.

Preservation Services

Preservation services include service revenues from processing cardiac and vascular tissues. Our cardiac valves are primarily used in cardiac replacement and reconstruction surgeries, including the Ross procedure, for patients with endocarditis or congenital heart defects. Our cardiac tissues are primarily distributed in domestic markets. The majority of our vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. Competition with synthetic product alternatives and the availability of tissues for processing are key factors affecting revenue volume that can fluctuate from quarter to quarter. Our vascular tissues are primarily distributed in domestic markets.

We continue to evaluate modifications to our tissue processing procedures in an effort to improve tissue processing throughput, reduce costs, and maintain quality across our tissue processing business. Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors, including quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues for implant, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services.

Revenues from tissue processing increased 6% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase in revenues was primarily due to an increase in average sales prices.

Cost of Products and Preservation Services

Cost of Products

	Year Ended December 31,	
	2024	2023
Cost of products	$ 99,385	$ 84,595

Cost of products increased 17% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. Cost of products for the year ended December 31, 2024 and 2023 included costs related to aortic stent grafts, On-X, surgical sealants, and other products.

Cost of products for the year ended December 31, 2024 included a $2.0 million idle capacity charge resulting from the previously disclosed cybersecurity incident that occurred during the fourth quarter of 2024. The remaining increase in cost

of products as compared to the year ended December 31, 2023 was primarily due to an increase in volume of On-X and aortic stent grafts shipped and an increase of the cost of certain aortic stent grafts and other products shipped, partially offset by favorable product mix.

Cost of Preservation Services

	Year Ended December 31,	
	2024	2023
Cost of preservation services	$ 40,371	$ 40,233

Cost of preservation services remained flat for the year ended December 31, 2024, as compared to the year ended December 31, 2023. Cost of preservation services included costs for cardiac and vascular tissue preservation services. Cost of preservation services for the year ended December 31, 2024 was negatively impacted by an increase in cost of certain tissues shipped, offset by a decrease in volume of certain tissues shipped.

Gross Margin

	Year Ended December 31,	
	2024	2023
Gross margin	$ 248,781	$ 229,176
Gross margin as a percentage of total revenues	64 %	65 %

Gross margin increased 9% for the year ended December 31, 2024, as compared to the year ended December 31, 2023.

The increase in gross margin for the year ended December 31, 2024, as compared to the year ended December 31, 2023 was due to an increase in the volume of all products shipped as well as favorable pricing of certain aortic stent grafts, surgical sealants, On-X products, and tissues shipped during 2024. This increase was partially offset by an increase in the cost of certain aortic stent grafts, including an idle capacity charge resulting from the cybersecurity incident that occurred in the fourth quarter of 2024, and certain tissues shipped as well as unfavorable geography mix of On-X products and certain aortic stent grafts shipped during 2024. Gross margin as a percentage of total revenues decreased for the year ended December 31, 2024, as compared to the year ended December 31, 2023. Gross margin as a percentage of total revenues was negatively impacted by an increase in the cost of certain aortic stent grafts, largely due to an idle capacity charge resulting from the fourth quarter cybersecurity incident, and other products, unfavorable geography mix of On-X products shipped, partially offset by favorable pricing of certain tissues, favorable product mix of certain aortic stent grafts, and On-X products shipped during the year ended December 31, 2024.

Operating Expenses

General, Administrative, and Marketing Expenses

	Year Ended December 31,	
	2024	2023
General, administrative, and marketing expenses	$ 181,455	$ 208,977
General, administrative, and marketing expenses as a percentage of total revenues	47 %	59 %

General, administrative, and marketing expenses decreased 13% for the year ended December 31, 2024, as compared to the year ended December 31, 2023, which includes the impact of the Ascyrus contingent consideration fair value adjustment gain of $11.0 million and loss of $23.5 million for the year ended December 31, 2024 and 2023, respectively. The remaining general, administrative, and marketing expenses for the year ended December 31, 2024 increased $7.0 million as a result of higher personnel-related expenses due to an increase in headcount and $2.6 million of expenses associated with the fourth quarter cybersecurity incident.

Research and Development Expenses

	Year Ended December 31,	
	2024	2023
Research and development expenses	$ 28,452	$ 28,707
Research and development expenses as a percentage of total revenues	7 %	8 %

Research and development expenses decreased 1% for the year ended December 31, 2024, as compared to the year ended December 31, 2023. Research and development spending for the year ended December 31, 2024 and 2023 was primarily focused on clinical work to gain regulatory approvals for certain aortic stent grafts, and, to a lesser extent, On-X products.

Gain from Sale of Non-Financial Assets

Gain from sale of non-financial assets for the year ended December 31, 2023 consisted of the net $14.3 million received as part of the Baxter Transaction upon receipt of the PerClot PMA in May 2023.

Interest Expense

Interest expense was $34.3 million and $25.3 million for the year ended December 31, 2024 and 2023, respectively. The increase in interest expense for the year ended December 31, 2024, as compared to the year ended December 31, 2023, was primarily due to an increase in the interest rates and higher unused commitment fees on our new credit facilities as a result of our debt refinancing in January 2024 as well as an increase in non-cash amortization of debt discounts and debt issuance costs.

Loss on Extinguishment of Debt

During the year ended December 31, 2024 we recorded a loss on extinguishment of debt of $3.7 million in connection with the extinguishment of our previously existing credit facilities. See Part II, Item 8, Note 10 of the “Notes to Consolidated Financial Statements” for further discussion of our new credit facilities.

Other Expense, Net

Other expense, net was $9.9 million and $3.1 million for the year ended December 31, 2024 and 2023, respectively. Other expense, net for the year ended December 31, 2024 primarily included a net $5.4 million loss from realized and unrealized effects of foreign currency gains and losses and a $4.5 million loss associated with fair value adjustments to loans issued pursuant to our Endospan agreements. Other expense, net for the year ended December 31, 2023 primarily included a $5.0 million loss associated with fair value adjustments to loans issued pursuant to our Endospan agreements, partially offset by a $2.1 million gain from realized and unrealized effects of foreign currency gains and losses. See Part II, Item 8, Note 4 - “Agreements with Endospan” of the “Notes to Consolidated Financial Statements” for further information on our agreements with Endospan.

Income Tax Expense

Our effective income tax rate was an expense of 78% and 42% for the year ended December 31, 2024 and 2023, respectively. The increase in the effective income tax rate for the year ended December 31, 2024 was primarily due to changes in the jurisdictional mix of our earnings and valuation allowance, higher nondeductible executive compensation, state taxes and provision to return adjustments.

Non-GAAP Measures of Financial Performance

To supplement our Consolidated Financial Statements presented in accordance with US GAAP, we use constant currency revenues, which is a non-GAAP financial measure. We define constant currency revenues as revenues minus the exchange rate effect. We define exchange rate effect as the year-over-year impact of foreign currency movements using current period foreign currency rates applied to prior period transactional currency amounts.

We have provided non-GAAP financial measures in this report as we believe that these figures are helpful in allowing management and investors to more accurately assess the ongoing nature of our operations and measure our performance more consistently across periods. Management uses constant currency revenues internally to assess the operational performance of the Company, as a component in compensation metrics, and as a basis for strategic planning.

We believe the provided non-GAAP measures are meaningful in addition to the information contained in the US GAAP presentation of financial performance. Investors should consider this non-GAAP information in addition to, and not as a substitute for, financial measures prepared in accordance with US GAAP. In addition, this non-GAAP financial information may not be the same as similar measures presented by other companies.

Seasonality

Historically, we believe the demand for most of our aortic stent grafts is seasonal, with a decline in demand generally occurring in the third quarter due to the summer holiday season in Europe.

Historically, we believe the demand for surgical sealants is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. We believe that this trend may be due to the summer holiday season in Europe and the US.

We do not believe the demand for our On-X and other products is seasonal.

Demand for our cardiac preservation services has traditionally been seasonal, with peak demand generally occurring in the third quarter. We believe this trend for cardiac preservation services is primarily due to the high number of surgeries scheduled during the summer months for school-aged patients. Based on experience in recent years, we believe that this trend is lessening as we are distributing a higher percentage of our tissues for use in adult populations.

Demand for our vascular preservation services has also traditionally been seasonal, with lowest demand generally occurring in the fourth quarter. We believe this trend for vascular preservation services is primarily due to fewer vascular surgeries being scheduled during the winter holiday months.

Liquidity and Capital Resources

Our primary uses of liquidity include the payment of operating expenses, capital expenditures, servicing of debt and the funding of acquisitions or other collaborative arrangements. Our primary sources of funding are operating cash flows and borrowings under our debt facilities. As of December 31, 2024 we had approximately $320.2 million of total nominal indebtedness outstanding.

Our liquidity as of December 31, 2024 consisted of cash and cash equivalents of $53.5 million, unused commitments of $30.0 million under a revolving credit facility and unused commitments of $100.0 million on delayed draw term loan facility (see “Credit Facilities” below). As of December 31, 2024 approximately 48% of our cash and cash equivalents were held in foreign jurisdictions. Our practice is to maintain sufficient liquidity through cash from operations and our revolving credit facility to mitigate the impacts of any adverse financial market conditions on our operations. We believe that cash generated from operations, together with amounts available under the revolving credit facility will be sufficient to meet working capital requirements and anticipated capital expenditures, and other strategic uses of cash, if any, and debt payments, if any, over the next twelve months.

Our future cash requirements are expected to include interest payments under our credit facilities, expenditures for clinical trials, research and development expenditures, general working capital needs, capital expenditures, other corporate purposes and may include cash to fund business development activities including obligations pursuant to arrangements with Endopsan and the acquisition of Ascyrus. These items may have a significant effect on our future cash flows during the next twelve months. Subject to the terms of our credit facilities, we may seek additional borrowing capacity or financing, pursuant to our current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If we undertake any further significant business development activity, we may need to finance such activities by obtaining additional debt financing or using a registration statement to sell equity securities. There can be no assurance that we will be

able to obtain any additional debt or equity financing at the time needed or that such financing will be available on terms that are favorable or acceptable to us.

Significant Sources and Uses of Liquidity

Credit Facilities

On January 18, 2024 we entered into a credit and guaranty agreement with Ares Management Credit funds (the "Ares Credit Agreement") for $350.0 million of senior secured, interest-only, credit facilities, consisting of a $190.0 million secured term loan facility (the "Term Loan Facility"), a $100.0 million secured delayed draw term loan facility (the "Delayed Draw Term Loan Facility" and, together with the Term Loan Facility, the "Term Loan Facilities") and a $60.0 million "senior-priority" secured revolving credit facility with a priority claim ahead of the other secured facilities (the "Revolving Credit Facility" and, together with the Term Loan Facilities, the "Credit Facilities"). Upon closing, we borrowed $190.0 million under the Term Loan Facility and $30.0 million under the Revolving Credit Facility. The proceeds of the initial borrowings were used along with cash on hand to pay off our previously existing credit agreement and pay related fees and expenses. The $100.0 million of undrawn availability under the Delayed Draw Term Loan Facility was established solely to make funds available in the event of a repurchase or repayment of the Convertible Senior Notes on or prior to a scheduled maturity date of July 1, 2025 (see below).

The final scheduled maturity date of the Credit Facilities is January 18, 2030. There are no scheduled repayments of principal required to be made prior to the final maturity date. We have the right to prepay loans under the Ares Credit Agreement in whole or in part at any time, subject to certain premium payment requirements. Amounts repaid in respect of loans under the Term Loan Facilities may not be reborrowed. The Credit Facilities currently bear interest at the Adjusted Term Secured Overnight Financing Rate ("Adjusted Term SOFR") plus applicable margins. As of December 31, 2024 the aggregate interest rate was 11.09% and 8.59% per annum for the Term Loan Facilities and Revolving Credit Facility, respectively. See Part II, Item 8, Note 10 of the "Notes to Consolidated Financial Statements" for further discussion of our new Ares Credit Agreement.

Convertible Senior Notes

On June 18, 2020 we issued $100.0 million aggregate principal amount of 4.25% Convertible Senior Notes with a maturity date of July 1, 2025 (the "Convertible Senior Notes"). The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. The initial conversion rate of the Convertible Senior Notes is 42.6203 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $23.46 per share, subject to adjustments. We use the if-converted method for assumed conversion of the Convertible Senior Notes for the diluted earnings per share calculation.

We became eligible to redeem the Convertible Senior Notes beginning on July 5, 2023, following the expiration of their non-redemption period. We are able to redeem the Convertible Senior Notes in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. As of December 31, 2024 we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes.

On December 23, 2024 in accordance with an Indenture (the "Indenture") dated June 23, 2020, between Artivion, Inc. (formerly CryoLife, Inc.) and U.S. Bank Trust Company, National Association, as Trustee, relating to our Convertible Senior Notes, we gave notice to the Trustee, the Conversion Agent, and the Holders (each as defined in the Indenture) that we elected to change the "Default Settlement Method" (as defined in the Indenture) for conversions of the Convertible Senior Notes to "Physical Settlement" (as defined in the Indenture). As a result, all conversions after the date of the notice will be settled by delivery of shares of our common stock using Physical Settlement in accordance with the Indenture.

Cash Flows

The following table summarizes cash flows from operating activities, investing activities, and financing activities for the periods indicated (in thousands):

	Year Ended December 31,	
	2024	2023
Cash flows provided by (used in):		
Operating activities	$ 22,236	$ 18,825
Investing activities	(28,188)	(502)
Financing activities	2,203	865
Effect of exchange rate changes on cash and cash equivalents	(1,728)	401
(Decrease) increase in cash and cash equivalents	**$ (5,477)**	**$ 19,589**

Operating Activities

Net cash provided by operating activities increased $3.4 million during the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to an increase in cash collections resulting from a 10% increase in revenues, partially offset by higher personnel-related costs associated with an increase in headcount, an increase in cash paid for taxes, and higher inventory purchases and increased preservation costs related to the increase in revenues.

Investing Activities

Net cash used in investing activities was $28.2 million and $0.5 million for the year ended December 31, 2024 and 2023, respectively. During the year ended December 31, 2024 cash flows used in investing activities primarily included $11.2 million of cash used for capital expenditures and $17.0 million for the funding of loans made pursuant to the Endospan agreements. Cash flows used in investing activities during the year ended December 31, 2023 included $9.8 million of cash used for capital expenditures and $5.0 million for the funding of loans made pursuant to the Endospan agreements, which were partially offset by $14.3 million of proceeds received as part of the Baxter transaction from the sale of non-financial assets.

Financing Activities

Net cash provided by financing activities was $2.2 million and $0.9 million for the year ended December 31, 2024 and 2023, respectively. The current year cash provided by financing activities was primarily due to $5.7 million of proceeds from exercise of stock options and issuances of common stock and $0.7 million of net proceeds received on our new credit facilities after repaying and extinguishing all obligations on our old credit facilities, all of which were partially offset by payments of $2.5 million for debt issuance costs and $1.0 million for repayments of short-term notes payable.

Scheduled Contractual Obligations and Future Payments

Our long-term debt obligations and interest payments include $320.0 million of scheduled principal payments and $119.2 million in anticipated interest payments related to our Initial Term Loan Facility, Revolving Credit Facility, and Convertible Senior Notes. While interest payments will be settled in cash, we plan to settle the $100.0 million principal outstanding on our Convertible Senior Notes due July 1, 2025 by issuing shares of our common stock.

We have contingent payment obligations that include up to $100.0 million to be paid to the former shareholders of Ascyrus upon the achievement of certain milestones. As part of the transaction with Baxter, we may be required to pay up to $3.0 million if certain milestones are met. Pursuant to the Amended and Restated Loan Agreement with Endospan Ltd. (“Endospan”) dated July 1, 2024, we anticipate making the remaining $8.0 million tranche payment subject to Endospan’s achievement of milestones related to its pursuit of regulatory approval for NEXUS ONE in the US.

Our operating and finance lease obligations result from the lease of land and buildings that comprise our corporate headquarters and our various manufacturing facilities; leases related to additional manufacturing, office, and warehouse space; leases on company vehicles; and leases on a variety of office and other equipment.

Capital Expenditures

Capital expenditures for the year ended December 31, 2024 and 2023 were $11.2 million and $9.8 million, respectively. Capital expenditures in the year ended December 31, 2024 were primarily related to routine purchases of computer software, manufacturing and tissue processing equipment, leasehold improvements needed to support our business and computer equipment.

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

Interest Rate Risk

We have a significant amount of indebtedness with a mix of fixed and variable rates of interest. Floating rate debt carries interest based generally on Secured Overnight Financing Rate ("SOFR") plus an applicable margin. Increase in interest rates could therefore significantly increase the associated interest payments that we are required to make on this debt. See Part II, Item 8, Note 10 of the "Notes to Consolidated Financial Statements" for a further discussion.

We have assessed our exposure to changes in interest rates by analyzing the sensitivity to our operating results assuming various changes in market interest rates. Assuming a hypothetical increase of one percentage point in interest rates on our variable rate debt portfolio, cash equivalents, and investments as of December 31, 2024, our pre-tax operating results would decrease by an estimated $2.0 million over a twelve-month period.

Foreign Currency Exchange Rate Risk

We have exposure to foreign currency exchange rate fluctuations worldwide resulting from intercompany transactions, other cross currency obligations and certain intercompany loans. Specifically, a portion of our international aortic stent grafts, surgical sealants, On-X products, and other product revenues are denominated in Euros, Brazilian Reals, Polish Zlotys, British Pounds, Canadian Dollars, and Swiss Francs and a portion of our General, administrative, and marketing expenses are denominated in Euros, Brazilian Reals, Polish Zlotys, British Pounds, Canadian Dollars, Swiss Francs, and Singapore Dollars. We manage our foreign currency exchange risk primarily by incurring, to the extent practicable, operating and financing expenses in the local currency in the countries in which we operate. We do not hedge our operating results against currency movement as they are primarily translational in nature.

Assuming a hypothetical 10% change to the foreign currency exchange rates in effect as of December 31, 2024 on our operating results, intercompany trade, and certain intercompany loan and interest balances, our pre-tax operating results would decrease by an estimated $8.0 million over a twelve-month period.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Management's Annual Report on Internal Controls over Financial Reporting

The management of Artivion, Inc. and subsidiaries ("Artivion" or "we") is responsible for establishing and maintaining adequate internal controls over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Artivion's internal control system was designed to provide reasonable assurance to Artivion's management and Board of Directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

Artivion management assessed the effectiveness of Artivion's internal controls over financial reporting as of December 31, 2024. In making this assessment, we used the criteria set forth in the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, we have determined that, as of December 31, 2024, our internal controls over financial reporting was effective based on those criteria.

Artivion's independent registered public accounting firm, Ernst & Young, LLP, has issued an audit report on the effectiveness of Artivion's internal controls over financial reporting as of December 31, 2024.

Artivion, Inc.
February 28, 2025

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Artivion, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Artivion, Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at 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 U.S. generally accepted accounting principles.

We also have 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 issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2025 expressed an unqualified opinion thereon.

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 the critical audit matter does not alter in any way our opinion on the consolidated 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 account or disclosure to which it relates.

Deferred Preservation Costs

Description of the Matter

At December 31, 2024, the Company's deferred preservation costs, net, balance was $51.7 million. As discussed in Note 1 to the consolidated financial statements, the calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations ("OPOs") and tissue banks, that provide the tissue to the Company for processing, preservation, and distribution. Deferred preservation costs consist primarily of the procurement fees charged by the OPOs and tissue banks, direct labor and materials (including salary and fringe benefits, laboratory supplies and expenses, and freight-in charges), and indirect costs (including allocations of costs from support departments and facility allocations). Fixed production overhead costs are allocated based on actual tissue processing levels, to the extent that they are within the range of the facility's normal capacity. These costs are then allocated among the tissues processed during the period based on cost drivers, such as the number of donors or number of tissues processed. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Estimated yields are based on the Company's historical yield experience with similar tissues and these estimates are evaluated periodically to determine whether the appropriate historical volume and time periods are being used to calculate the yields applied to in-process tissues to determine the equivalent units on hand at each period end.

Auditing management's deferred preservation costs was complex and required judgment due to the detailed calculations within the Company's costing model to determine the amount of preservation costs deferred, including the estimation of the number of in-process tissue equivalent units based on historical volumes and yields by tissue type that is utilized to determine the number of tissues in process that will ultimately become implantable to which the deferred costs will be applied.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the process used by management to calculate the Company's deferred preservation costs, including controls over management's review of the completeness and accuracy of the deferred preservation cost model and key inputs such as the historical yield information used to estimate the in-process tissue equivalent units as a component of the deferred preservation costs, as discussed above.

To test the appropriateness of the amounts recorded as deferred preservation costs, we performed audit procedures that included, among others, testing the nature of costs being deferred and the accuracy of the calculation of deferred preservation costs by agreeing the amounts to and testing the underlying reports and analyses supporting the calculation of costs to be deferred. We tested the yield estimates applied to determine the equivalent units of in-process tissues by understanding and testing the historical information utilized and comparing the yields utilized in the period end model to those historical results. We also compared the reconciliation of the ending balance of deferred preservation costs as calculated in the Company's deferred preservation cost calculation model to amounts recorded in the general ledger.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2013.
Atlanta, Georgia
February 28, 2025

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Artivion, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Artivion, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Artivion, Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations and 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 our report dated February 28, 2025 expressed an unqualified opinion thereon.

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 Controls 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/ Ernst & Young LLP
Atlanta, Georgia
February 28, 2025

Artivion, Inc. and Subsidiaries
Consolidated Balance Sheets
In Thousands

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,463	$ 58,940
Trade receivables, net	79,462	71,796
Other receivables	6,431	2,342
Inventories	79,766	81,976
Deferred preservation costs	51,701	49,804
Prepaid expenses and other	19,257	15,810
Total current assets	**290,080**	**280,668**
Goodwill	240,958	247,337
Acquired technology, net	128,051	142,593
Operating lease right-of-use assets, net	39,726	43,822
Property and equipment, net	36,403	38,358
Other intangibles, net	28,332	29,638
Deferred tax assets, net	1,068	1,087
Other long-term assets	24,483	8,894
Total assets	**$ 789,101**	**$ 792,397**

Artivion, Inc. and Subsidiaries
Consolidated Balance Sheets
In Thousands, Except Par Value

	December 31,	
	2024	**2023**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,971	$ 13,318
Accrued compensation	18,342	18,715
Accrued expenses	11,834	10,449
Accrued interest	8,170	2,283
Taxes payable	2,934	3,840
Accrued procurement fees	1,704	1,439
Current maturities of operating leases	4,489	3,395
Current portion of finance lease obligations	601	582
Current portion of long-term debt, net	195	1,451
Other current liabilities	583	2,390
Total current liabilities	**66,823**	**57,862**
Long-term debt, net	314,152	305,531
Contingent consideration	52,880	63,890
Non-current maturities of operating leases	39,988	43,977
Deferred tax liabilities, net	20,183	21,851
Deferred compensation liability	7,977	6,760
Non-current finance lease obligations	2,833	3,405
Other long-term liabilities	8,065	7,341
Total liabilities	**512,901**	**510,617**
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued	—	—
Common stock $0.01 par value per share, 75,000 shares authorized, 43,432 and 42,569 shares issued as of December 31, 2024 and 2023, respectively	434	426
Additional paid-in capital	376,607	355,919
Retained deficit	(61,266)	(47,907)
Accumulated other comprehensive loss	(24,927)	(12,010)
Treasury stock at cost, 1,487 shares as of December 31, 2024 and 2023	(14,648)	(14,648)
Total stockholders' equity	**276,200**	**281,780**
Total liabilities and stockholders' equity	**$ 789,101**	**$ 792,397**

See accompanying Notes to Consolidated Financial Statements.

Artivion, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
In Thousands, Except Per Share Data

	Year Ended December 31,		
	2024	**2023**	**2022**
Revenues:			
Products	$ 290,230	$ 261,185	$ 230,353
Preservation services	98,307	92,819	83,436
Total revenues	**388,537**	**354,004**	**313,789**
Cost of products and preservation services:			
Products	99,385	84,595	72,166
Preservation services	40,371	40,233	39,100
Total cost of products and preservation services	**139,756**	**124,828**	**111,266**
Gross margin	**248,781**	**229,176**	**202,523**
Operating expenses:			
General, administrative, and marketing	181,455	208,977	157,443
Research and development	28,452	28,707	38,879
Total operating expenses	**209,907**	**237,684**	**196,322**
Gain from sale of non-financial assets	—	(14,250)	—
Operating income	**38,874**	**5,742**	**6,201**
Interest expense	34,277	25,299	18,224
Interest income	(1,467)	(1,077)	(147)
Loss on extinguishment of debt	3,669	—	—
Other expense, net	9,909	3,106	3,108
Loss before income taxes	**(7,514)**	**(21,586)**	**(14,984)**
Income tax expense	5,845	9,104	4,208
Net loss	**$ (13,359)**	**$ (30,690)**	**$ (19,192)**
Loss per share:			
Basic	**$ (0.32)**	**$ (0.75)**	**$ (0.48)**
Diluted	**$ (0.32)**	**$ (0.75)**	**$ (0.48)**
Weighted-average common shares outstanding:			
Basic	41,676	40,743	40,032
Diluted	41,676	40,743	40,032
Net loss	**$ (13,359)**	**$ (30,690)**	**$ (19,192)**
Other comprehensive loss:			
Foreign currency translation adjustments, net of tax	(12,917)	9,599	(11,722)
Comprehensive loss	**$ (26,276)**	**$ (21,091)**	**$ (30,914)**

See accompanying Notes to Consolidated Financial Statements.

Artivion, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
In Thousands

	Year Ended December 31,		
	2024	**2023**	**2022**
Net cash flows from operating activities:			
Net loss	$ (13,359)	$ (30,690)	$ (19,192)
Adjustments to reconcile net loss to net cash from operating activities:			
Depreciation and amortization	24,205	23,076	22,442
Non-cash compensation	14,242	14,422	12,344
Non-cash lease expense	4,915	4,541	4,666
Write-down of inventories and deferred preservation costs	4,434	4,785	4,374
Non-cash interest expense	3,866	1,858	1,832
Deferred income taxes	(1,511)	(1,385)	(1,717)
Change in fair value of contingent consideration	(11,010)	23,490	(9,000)
Endospan fair value adjustments	4,329	5,000	—
Loss on extinguishment of debt	3,669	—	—
Gain on sale of non-financial assets	—	(14,250)	—
Other	5,699	1,358	2,268
Changes in operating assets and liabilities:			
Receivables	(15,395)	(4,050)	(13,340)
Inventories and deferred preservation costs	(6,137)	(14,360)	(8,404)
Prepaid expenses and other assets	(5,209)	535	(2,234)
Accounts payable, accrued expenses, and other liabilities	9,498	4,495	808
Net cash flows provided by (used in) operating activities	**22,236**	**18,825**	**(5,153)**
Net cash flows from investing activities:			
Capital expenditures	(11,188)	(9,752)	(10,715)
Payments under Endospan agreements	(17,000)	(5,000)	—
Proceeds from sale of non-financial assets, net	—	14,250	—
Net cash flows used in investing activities	**(28,188)**	**(502)**	**(10,715)**
Net cash flows from financing activities:			
Proceeds from issuance of long-term debt	184,000	—	—
Proceeds from revolving credit facility	28,500	—	—
Repayment of debt	(211,831)	(2,772)	(2,753)
Proceeds from exercise of stock options and issuance of common stock	5,728	3,955	3,368
Payment of debt issuance costs	(2,544)	(249)	—
Proceeds from financing insurance premiums	—	3,558	—
Principal payments on short-term notes payable	(1,027)	(2,531)	—
Redemption and repurchase of stock to cover tax withholdings	—	(559)	(1,795)
Other	(623)	(537)	(459)
Net cash flows provided by (used in) financing activities	**2,203**	**865**	**(1,639)**
Effect of exchange rate changes on cash and cash equivalents	(1,728)	401	1,848
(Decrease) increase in cash and cash equivalents	**(5,477)**	**19,589**	**(15,659)**
Cash and cash equivalents, beginning of year	58,940	39,351	55,010
Cash and cash equivalents, end of year	**$ 53,463**	**$ 58,940**	**$ 39,351**

See accompanying Notes to Consolidated Financial Statements.

Artivion, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
In Thousands

	Common Stock		Additional Paid In Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2021	**41,397**	**$ 414**	**$ 322,874**	**$ 1,975**	**$ (9,887)**	**(1,487)**	**$ (14,648)**	**$ 300,728**
Net loss	—	—	—	(19,192)	—	—	—	(19,192)
Other comprehensive loss, net of tax	—	—	—	—	(11,722)	—	—	(11,722)
Equity compensation	282	3	12,939	—	—	—	—	12,942
Exercise of options	151	1	1,788	—	—	—	—	1,789
Employee stock purchase plan	95	1	1,578	—	—	—	—	1,579
Redemption and repurchase of stock to cover tax withholdings	(95)	(1)	(1,794)	—	—	—	—	(1,795)
Balance at December 31, 2022	**41,830**	**$ 418**	**$ 337,385**	**$ (17,217)**	**$ (21,609)**	**(1,487)**	**$ (14,648)**	**$ 284,329**
Net loss	—	—	—	(30,690)	—	—	—	(30,690)
Other comprehensive income, net of tax	—	—	—	—	9,599	—	—	9,599
Equity compensation	412	4	15,142	—	—	—	—	15,146
Exercise of options	226	3	2,499	—	—	—	—	2,502
Employee stock purchase plan	141	2	1,451	—	—	—	—	1,453
Redemption and repurchase of stock to cover tax withholdings	(40)	(1)	(558)	—	—	—	—	(559)
Balance at December 31, 2023	**42,569**	**$ 426**	**$ 355,919**	**$ (47,907)**	**$ (12,010)**	**(1,487)**	**$ (14,648)**	**$ 281,780**
Net loss	—	—	—	(13,359)	—	—	—	(13,359)
Other comprehensive loss, net of tax	—	—	—	—	(12,917)	—	—	(12,917)
Equity compensation	513	5	14,963	—	—	—	—	14,968
Exercise of options	232	2	3,965	—	—	—	—	3,967
Employee stock purchase plan	118	1	1,760	—	—	—	—	1,761
Balance at December 31, 2024	**43,432**	**$ 434**	**$ 376,607**	**$ (61,266)**	**$ (24,927)**	**(1,487)**	**$ (14,648)**	**$ 276,200**

See accompanying Notes to Consolidated Financial Statements.

Artivion, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

1. Basis of Presentation and Summary of Significant Accounting Policies

Nature of Business

Artivion, Inc. ("Artivion," the "Company," "we," or "us"), is a leader in the manufacturing, processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures for patients with aortic disease. We have four major product families: aortic stent grafts, On-X mechanical heart valves and related surgical products ("On-X" products), surgical sealants, and implantable cardiac and vascular human tissues. Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, and synthetic vascular grafts. Aortic arch stent grafts include our E-vita Open NEO, E-vita Open Plus, the Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, the NEXUS ONE™ ("NEXUS ONE"), NEXUS DUO™ ("NEXUS DUO"), and the NEXUS TRE™ ("NEXUS TRE") aortic arch stent graft systems (the "NEXUS family of products"), and E-vita Thoracic 3G products. Abdominal stent grafts include our E-xtra Design Engineering (including Artivex), E-nside, E-tegra, E-ventus BX, Tuva BX, and E-liac products. Surgical sealants include our BioGlue Surgical Adhesive products ("BioGlue"). In addition to these four major product families, we sell or distribute PhotoFix bovine surgical patches ("PhotoFix") and CardioGenesis cardiac laser therapy (prior to our abandonment of that business as of June 2023). We began to manufacture and supply PerClot hemostatic powder ("PerClot") during the second quarter of 2023 (as part of the Transitional Manufacturing and Supply Agreement ("TMSA") of the Baxter Transaction, described in more detail in Note 2 below).

Basis of Presentation and Principles of Consolidation

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). The accompanying consolidated financial statements include the accounts of the Company and our wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. Certain prior-year amounts have been reclassified to conform to the current year presentation.

Foreign Currency Translation and Transactions

Assets and liabilities of international subsidiaries whose functional currency is the local currency are translated at the rate of exchange in effect on the balance sheet date; income and expenses are translated at the average exchange rates throughout the year. The related translation adjustments, including the effects of foreign exchange rate changes on intra-entity foreign currency transactions that are of a long-term investment nature, net of tax, are reflected in Accumulated other comprehensive loss in the stockholders' equity section of our Consolidated Balance Sheets. Foreign currency exchange rate realized and unrealized gains and losses resulting from transactions are included in Other expense, net in our Consolidated Statements of Operations and Comprehensive Loss and resulted in a net loss of $5.4 million, a net gain of $2.1 million and a net loss of $3.1 million for the years ended December 31, 2024, 2023 and 2022, respectively. Currency translation adjustments resulting from intra-entity loans that are of a long-term investment nature, net of tax, are included in Accumulated other comprehensive loss and resulted in a net loss of $8.6 million, a net gain of $6.6 million and a net loss of $5.7 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with US GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Estimates and assumptions are used when accounting for trade receivables allowances, inventories, deferred preservation costs, acquired assets or businesses, intangible assets, deferred income taxes, valuation of loan receivables and purchase options, commitments and contingencies (including product and tissue processing liability claims, claims incurred but not reported, and amounts recoverable from insurance companies), non-cash

compensation, certain accrued liabilities (including accrued procurement fees, income taxes, and financial instruments including contingent consideration), and other items as appropriate.

Revenue Recognition

Contracts with Customers

We routinely enter into contracts with customers that include general commercial terms and conditions, notification requirements for price increases, shipping terms and, in most cases, prices for the products and services that we offer. These agreements, however, do not obligate us to provide goods or services to the customer, and there is no consideration promised to us at the onset of these arrangements. For customers without separate agreements, we have a standard list price established by geography and by currency for all products and services, and our invoices contain standard terms and conditions that are applicable to those customers where a separate agreement is not controlling. Our performance obligations are established when a customer submits a purchase order notification (in writing, electronically or verbally) for goods and services, and we accept the order. We identify performance obligations as the delivery of the requested product or service in appropriate quantities and to the location specified in the customer's contract and/or purchase order. We generally recognize revenue upon the satisfaction of these criteria when control of the product or service has been transferred to the customer at which time we have an unconditional right to receive payment. Our prices are fixed and are not affected by contingent events that could impact the transaction price. We do not offer price concessions and do not accept payment that is less than the price stated when we accept the purchase order. We do not have any material performance obligations where we are acting as an agent for another entity.

Revenues for products, including: aortic stent grafts, surgical sealants, On-X products, and other medical devices, are typically recognized at the time the product is shipped, at which time the title passes to the customer, and there are no further performance obligations. Revenues from consignment are recognized when we receive a notification of implantation. We recognize revenues for preservation services when tissue is shipped to the customer.

Significant Judgments

There are no significant judgments associated with the satisfaction of our performance obligations. We generally satisfy performance obligations upon shipment of the product or service obligation to the customer. This is consistent with the time in which the customer obtains control of the product or service. Performance obligations are also generally settled quickly after the purchase order acceptance, therefore, the value of unsatisfied performance obligations at the end of any reporting period is immaterial.

We consider variable consideration in establishing the transaction price. Forms of variable consideration potentially applicable to our arrangements include sales returns, rebates, volume-based bonuses, and prompt pay discounts. We use historical information along with an analysis of the expected value to properly calculate and to consider the need to constrain estimates of variable consideration. Such amounts are included as a reduction to revenue in the periods in which the related revenue is recognized and adjusted in future periods as necessary.

Commissions and Contract Costs

Sales commissions are earned upon completion of each performance obligation, and therefore, are expensed when incurred. These costs are included in General, administrative, and marketing expenses in the Consolidated Statements of Operations and Comprehensive Loss. We generally do not incur incremental charges associated with securing agreements with customers which would require capitalization and recovery over the life of the agreement.

Practical Expedients

Our payment terms for sales direct to customers are substantially less than the one-year collection period that falls within the practical expedient in the determination of whether a significant financing component exists.

Shipping and Handling Charges

Fees charged to customers for shipping and handling of products and tissues are included in Product and preservation service revenues. The costs for shipping and handling of products and tissues are included as a component of Cost of products and cost of preservation services.

Taxes Collected from Customers

Taxes collected on the value of transaction revenue are excluded from Revenues and Cost of products and preservation services and are included in Accrued expenses until remitted to governmental authorities.

Advertising Costs

The costs to develop, produce, and communicate our advertising are expensed as incurred and are reflected as General, administrative, and marketing expenses. The total amount of advertising costs included in our Consolidated Statements of Operations and Comprehensive Loss was $1.7 million, $1.9 million and $1.6 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Stock-Based Compensation

We have stock option and stock incentive plans for employees and non-employee directors that provide for grants of restricted stock awards ("RSA"s), restricted stock units ("RSU"s), performance stock units ("PSU"s), and options to purchase shares of our common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. We also maintain a stockholder approved Employee Stock Purchase Plan (the "ESPP") for the benefit of our employees. The ESPP allows eligible employees the right to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period. The RSAs, RSUs, PSUs, and stock options typically vest over a one to three-year period. The stock options typically expire within seven years of the grant date.

We value our RSAs, RSUs, and PSUs based on the stock price on the date of grant. We expense the related compensation cost of RSAs and RSUs using the straight-line method over the vesting period. We expense the related compensation cost of PSUs based on the number of shares expected to be issued, if achievement of the performance component is probable, using a straight-line method over each vesting tranche of the award which results in accelerated recognition of expenses. The amount of compensation costs expensed related to PSUs is adjusted as needed if we deem that achievement of the performance component is no longer probable or if our expectation of the number of shares to be issued changes. We use a Black-Scholes model to value our stock option grants and expense the related compensation cost using the straight-line method over the vesting period. The fair value of our ESPP options is also determined using a Black-Scholes model and is expensed over the vesting period.

The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, volatility, dividend yield, and the risk-free interest rate. The expected term is primarily based on the contractual term of the option and our data related to historic exercise and post-vesting forfeiture patterns, which is adjusted based on our expectations of future results. Our anticipated volatility level is primarily based on the historic volatility of our common stock, adjusted to remove the effects of certain periods of unusual volatility not expected to recur, and adjusted based on our expectations of future volatility, for the life of the option or option group. Our model includes a zero-dividend yield assumption and we do not anticipate paying dividends in the future. The risk-free interest rate is based on recent US Treasury note auction results with a similar life to that of the option. Our model does not include a discount for post-vesting restrictions, as we have not issued awards with such restrictions.

The period expense for our stock compensation is determined based on the valuations discussed above and forfeitures are accounted for in the period awards are incurred.

Income (Loss) Per Common Share

Income (loss) per common share is computed using the two-class method, which requires us to include unvested RSAs that contain non-forfeitable rights to dividends (whether paid or unpaid) as participating securities in the income per common share calculation.

Under the two-class method, net income is allocated to the weighted-average number of common shares outstanding during the period and the weighted-average participating securities outstanding during the period. The portion of net income that is allocated to the participating securities is excluded from basic and dilutive net income per common share. Diluted net income per share is computed using the weighted-average number of common shares outstanding plus the dilutive effects of outstanding stock options and awards and other dilutive instruments as appropriate.

Financial Instruments

Our financial instruments include cash equivalents, accounts receivable, notes receivable, accounts payable, and debt obligations. The carrying values of financial assets and liabilities, such as receivables and accounts payable, approximate their fair value due to their short-term duration, and the carrying value of debt obligations approximate their fair value as they contain variable interest rates that approximate market values. Other financial instruments are recorded as discussed in the sections below.

Fair Value Measurements

We record certain financial instruments, including cash equivalents, at fair value on a recurring basis. We may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

We also measure certain assets and liabilities at fair value on a non-recurring basis. These non-recurring valuations include evaluating assets such as certain financial assets, long-lived assets, and indefinite lived intangible assets for impairment, allocating value to assets in an acquired asset group, applying accounting for business combinations, and the initial recognition of liabilities such as contingent consideration. We use the fair value measurement framework to value these assets and liabilities and report these fair values in the periods in which they are recorded or written down.

The fair value measurement framework includes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;
- Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted in active markets, but corroborated by market data; and
- Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available.

The determination of fair value and the assessment of a measurement's placement within the hierarchy requires judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Level 3 valuations may require the use of various cost, market, or income valuation methodologies applied to our unobservable estimates and assumptions. Our assumptions could vary depending on the asset or liability value and the valuation method used. Such assumptions could include: estimates of prices, earnings, costs, actions of market participants, market factors, or the weighting of various valuation methods. We may also engage external advisors to assist in determining fair value as appropriate.

Although we believe that the recorded fair values of our financial instruments are appropriate, these fair values may not be indicative of future fair values.

Fair Value Measurements - Contingent Consideration

Contingent consideration represents a recurring fair value estimate of potential future payments. The fair value of the contingent consideration liability is estimated by discounting to present value the contingent payments expected to be made

based on a probability-weighted scenario approach. A discount rate is applied based on our unsecured credit spread and the term commensurate risk-free rate to the additional consideration to be paid, and then we apply a risk-based estimate of the probability of achieving each scenario to calculate the fair value of the contingent consideration. This fair value measurement is based on unobservable inputs, including management estimates and assumptions about the future achievement of milestones and future estimate of revenues, and is, therefore, classified as Level 3 within the fair value hierarchy. See Notes 3 and 5 for further discussion.

Fair Value Measurements - Loan Receivables

We elect to account for certain loan receivables under the fair value option on a recurring basis, resulting in increases and decreases in the fair value of such loans being recorded to Other expense, net for each reporting period. This fair value measurement is based on unobservable inputs, including management estimates and assumptions about the probability of future achievement of milestones, and is, therefore, classified as Level 3 within the fair value hierarchy. See Notes 4 and 5 for further discussion.

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of highly liquid investments at the time of acquisition. The carrying value of cash equivalents approximates fair value. We maintain depository accounts with certain financial institutions. Although these depository accounts may exceed government insured depository limits, we have evaluated the credit worthiness of these applicable financial institutions and determined the risk of material financial loss due to the exposure of such credit risk to be minimal.

Supplemental Cash Flow Information

Supplemental cash flow information is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cash paid during the year for:			
Interest	$ 24,523	$ 23,332	$ 14,243
Income taxes	$ 13,702	$ 4,865	$ 9,244
Non-cash investing and financing activities:			
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 2,067	$ 6,181	$ 1,803

Accounts Receivable and Allowances

Our accounts receivable are primarily from hospitals and distributors that either use or distribute our products and tissues. We assess the likelihood of collection based on a number of factors, including past transaction history and the credit worthiness of the customer, as well as the potential increased risks related to international customers and large distributors. We determine the allowance for uncollectible accounts based upon specific reserves for known collection issues, as well as a non-specific reserve based upon historical aging trends. We charge off uncollectible amounts against the reserve in the period in which we determine they are uncollectible. Our accounts receivable balances are reported net of allowances of $1.6 million and $1.9 million as of December 31, 2024 and 2023, respectively.

Inventories

Inventories are comprised of finished goods for our product lines including: aortic stent grafts; surgical sealants; On-X products; other medical devices; work-in-process; and raw materials. Inventories for finished goods are valued at the lower of cost or net realizable value on a first-in, first-out basis and raw materials are valued on a moving average cost basis. Typically, upon shipment or upon notification of implant of a medical device on consignment, revenue is recognized, and the

related inventory costs are expensed as cost of products. Cost of products also includes, as applicable, lower of cost or net realizable value of write-downs and impairments for products not deemed to be recoverable and, as incurred, idle facility expense, excessive spoilage, extra freight, and re-handling costs.

Inventory costs for manufactured products consist primarily of direct labor and materials (including salary and fringe benefits, raw materials, and supplies) and indirect costs (including allocations of costs from departments that support manufacturing activities and facility allocations). The allocation of fixed production overhead costs is based on actual production levels, to the extent that they are within the range of the facility's normal capacity. Inventory costs for products purchased for resale or manufactured under contract consist primarily of the purchase cost, freight-in charges, and indirect costs as appropriate.

We regularly evaluate our inventory to determine if the costs are appropriately recorded at the lower of cost or net realizable value. We also evaluate our inventory for costs not deemed to be recoverable, including inventory not expected to ship prior to its expiration. Lower of cost or net realizable value write-downs are recorded if the book value exceeds the estimated net realizable value of the inventories, based on recent sales prices at the time of the evaluation. Impairment write-downs are recorded based on the book value of inventory deemed to be impaired. Actual results may differ from these estimates. Write-downs of inventories are expensed as Cost of products, and these write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if our estimates change. Write-downs to our inventories totaled $3.8 million, $4.4 million and $4.0 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Deferred Preservation Costs

Deferred preservation costs include costs of cardiac and vascular tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status. By federal law, human tissues cannot be bought or sold; therefore, the tissues we preserve are not held as inventory. The costs we incur to procure and process cardiac and vascular tissues are instead accumulated and deferred. Deferred preservation costs are stated at the lower of cost or net realizable value on a first-in, first-out basis and are deferred until revenue is recognized. Upon shipment of tissue to an implanting facility, revenue is recognized, and the related deferred preservation costs are expensed as cost of preservation services. Cost of preservation services also includes, as applicable, lower of cost or net realizable value write-downs and impairments for tissues not deemed to be recoverable, and includes, as incurred, excessive spoilage, extra freight, and re-handling costs.

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations ("OPOs") and tissue banks that provide the tissue to us for processing, preservation, and distribution. Deferred preservation costs consist primarily of the procurement fees charged by the OPOs and tissue banks, direct labor and materials (including salary and fringe benefits, laboratory supplies and expenses, and freight-in charges), and indirect costs (including allocations of costs from support departments and facility allocations). Fixed production overhead costs are allocated based on actual tissue processing levels, to the extent that they are within the range of the facility's normal capacity.

These costs are then allocated among the tissues processed during the period based on cost drivers, such as the number of donors or number of tissues processed. We apply a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. We estimate quarantine and in process yields based on our historical yield experience with similar tissues and re-evaluate these estimates periodically. Actual yields could differ significantly from our estimates, which could result in a change in tissues available for shipment and could increase or decrease the balance of deferred preservation costs. These changes could result in additional cost of preservation services expense or could increase per tissue preservation costs, which would impact gross margins on tissue preservation services in future periods.

We regularly evaluate our deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or net realizable value. We also evaluate our deferred preservation costs for costs not deemed to be recoverable, including tissues not expected to ship prior to the expiration date of their packaging. Lower of cost or net realizable value write-downs are recorded if the tissue processing costs incurred exceed the estimated market value of the tissue services, based on recent

average service fees at the time of the evaluation. Impairment write-downs are recorded based on the book value of tissues deemed to be impaired. Actual results may differ from these estimates. Write-downs of deferred preservation costs are expensed as cost of preservation services, and these write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if our estimates change. Write-downs to our deferred preservation costs totaled $0.6 million, $0.4 million and $0.4 million for the years ended December 31, 2024, 2023 and 2022, respectively, primarily due to tissues not expected to ship prior to the expiration date of the packaging.

Property and Equipment, net

Property and equipment, net is stated at cost less depreciation. Depreciation expense is recorded over the estimated useful lives of the assets, generally three to ten years, on a straight-line basis. Leasehold improvements are depreciated on a straight-line basis over the remaining lease term at the time the assets are capitalized or the estimated useful lives of the assets, whichever is shorter.

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

	December 31,	
	2024	2023
Equipment and software	$ 67,125	$ 66,618
Leasehold improvements	51,213	49,107
Furniture and fixtures	7,233	7,555
Total property and equipment	**125,571**	**123,280**
Less: Accumulated depreciation	(89,168)	(84,922)
Property and equipment, net	**$ 36,403**	**$ 38,358**

Depreciation expense was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Depreciation expense	$ 8,350	$ 7,878	$ 7,132

Goodwill and Other Intangible Assets

Our intangible assets consist of goodwill, acquired technology, customer lists and relationships, patents, and other intangible assets, as discussed in Note 7. Our goodwill is attributable to a segment or segments of our business, as appropriate, as the related acquired business that generated the goodwill is integrated into our operations.

We evaluate goodwill and other indefinite lived intangible assets for impairment on an annual basis during the fourth quarter of the year, and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of October 31, 2024 and 2023 our indefinite lived intangible assets consisted of goodwill, in-process research and development, and acquired procurement contracts and agreements. We performed a qualitative analysis of our indefinite lived intangible assets as of October 31, 2024 and determined that the fair value of the asset groups and the fair value of the reporting unit more likely than not exceeded their associated carrying values and were, therefore, not impaired. No impairment indicators were identified from the date of our annual assessment through December 31, 2024.

Our definite lived intangible assets consist of acquired technologies, customer lists and relationships, distribution and manufacturing rights and know-how, patents, and other intangible assets. We amortize our definite lived intangible assets over their expected useful lives using the straight-line method, which we believe approximates the period of economic benefits of the related assets. Our indefinite lived intangible assets do not amortize but are instead subject to periodic impairment testing as discussed below.

Impairments of Long and Indefinite Lived Intangible Assets

We assess the potential impairment of our: (i) net property and equipment, (ii) amortizing intangible long-lived assets to be held and used and (iii) operating lease right-of-use assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include, but are not limited to, the following:

- Significant underperformance relative to expected historical or projected future operating results;
- Significant negative industry or economic trends;
- Significant decline in our stock price for a sustained period; or
- Significant decline in our market capitalization relative to net book value.

If we determine that an impairment review is necessary, we will evaluate the assets or asset groups by comparing their carrying values to the sum of the undiscounted future cash flows expected to result from their use and eventual disposition. If the carrying values exceed the future cash flows, then the asset or asset group is considered impaired, and we will write down the value of the asset or asset group to its concluded fair value. We determined that no impairments existed for the years ended December 31, 2024, 2023 and 2022.

Accrued Procurement Fees

Donated tissue is procured from deceased human donors by OPOs and tissue banks that provide the tissue to us for processing, preservation, and distribution. We reimburse the OPOs and tissue banks for their costs to recover the tissue and include these costs as part of deferred preservation costs, as discussed above. We accrue estimated procurement fees due to the OPOs and tissue banks at the time tissues are received based on contractual agreements between us and the OPOs and tissue banks.

Leases

We have operating and finance lease obligations resulting from the lease of land and buildings that comprise our corporate headquarters and various manufacturing facilities; leases related to additional manufacturing, office, and warehouse space; leases on vehicles; and leases on certain office and other equipment, as discussed in Note 9. Certain of our leases contain escalation clauses, rent concessions, and renewal options for additional periods.

We exercise judgment in the determination of whether a financial arrangement includes a lease and in determining the appropriate discount rates to be applied to leases based on our general collateralized credit standing and the geographical market considerations impacting lease rates across all locations. When available, we use the implicit discount rate in the lease contract to discount lease payments to present value. If an implicit discount rate is not available in the lease contract, we use our incremental borrowing rate. We elected the package of practical expedients that allow us to omit leases with initial terms of 12 months or less from our balance sheet, which are expensed on a straight-line basis over the life of the lease. We have elected not to separate lease and non-lease components for future leases.

Our leases do not include terms or conditions which would result in variable lease payments other than for small office equipment leases with an additional charge for volume of usage. These incremental payments are excluded from our calculation of lease liability and the related right-of-use asset. We do not include option terms in the determination of lease liabilities and the related right-of-use assets unless we determine at lease commencement that the exercise of the option is reasonably certain. Our leases do not contain residual value guarantee provisions or other restrictions or financial covenant provisions.

Debt Discounts and Debt Issuance Costs

Direct costs incurred in connection with the issuance of debt and debt discounts are deferred and amortized to interest expense over the term of the debt. Debt issuance costs and debt discounts associated with term loans and convertible debt are amortized to Interest expense using the effective interest method and are reflected as reductions of the loan balances in the Consolidated Balance Sheets. Debt issuance costs and debt discounts associated with revolving credit facilities are amortized

to Interest expense on a straight-line basis and are reflected as a component of Other long-term assets in the Consolidated Balance Sheets.

Liability Claims

In the normal course of business, we are made aware of adverse events involving our products and tissues. Future adverse events could ultimately give rise to a lawsuit against us, and liability claims may be asserted against us in the future based on past events that we are not aware of at the present time. We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. Any punitive damage components of claims are uninsured.

We accrue our estimate of unreported product and tissue processing liability claims as a component of Other long-term liabilities and record the related recoverable insurance amounts as a component of Other long-term assets. The amounts recorded represent our estimate of the probable losses and anticipated recoveries for unreported claims related to products sold and services performed prior to the balance sheet date.

Legal Contingencies

We accrue losses from a legal contingency when the loss is both probable and reasonably estimable. The accuracy of our estimates of losses for legal contingencies is limited by uncertainties surrounding litigation. Therefore, actual results may differ significantly from the amounts accrued, if any. We accrue for legal contingencies as a component of Accrued expenses and/or Other long-term liabilities in our Consolidated Balance Sheets. Gains from legal contingencies are recorded when the contingency is resolved.

Uncertain Tax Positions

We periodically assess our uncertain tax positions and recognize tax benefits if they are “more-likely-than-not” to be upheld upon review by the appropriate taxing authority. We measure the tax benefit by determining the maximum amount that has a “greater than 50 percent likelihood” of ultimately being realized. We reverse previously accrued liabilities for uncertain tax positions when audits are concluded, statutes expire, administrative practices dictate that a liability is no longer warranted, or in other circumstances, as deemed necessary. These assessments can be complex, and we often obtain assistance from external advisors to make these assessments. We recognize interest and penalties related to uncertain tax positions in interest expense, net in our Consolidated Statements of Operations and Comprehensive Loss. See Note 8 for further discussion of our liabilities for uncertain tax positions.

Deferred Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. We assess the recoverability of our deferred tax assets and provide a valuation allowance against our deferred tax assets when, as a result of this analysis, we believe it is more likely than not that some portion or all of our deferred tax assets will not be realized.

Assessing the recoverability of deferred tax assets involves judgment and complexity including the consideration of prudent and feasible tax planning. Estimates and judgments used in the determination of the need for a valuation allowance and in calculating the amount of a needed valuation allowance include, but are not limited to, the following:

- The ability to carry back deferred tax asset attributes to a prior tax year;
- Timing of the anticipated reversal of book/tax temporary differences;
- Projected future operating results;
- Anticipated future state tax apportionment;
- Timing and amounts of anticipated future taxable income;
- Evaluation of statutory limits regarding usage of certain tax assets; and

- Evaluation of the statutory periods over which certain tax assets can be utilized.

Significant changes in the factors above, or other factors, could affect our ability to use our deferred tax assets. Such changes could have a material, adverse impact on our profitability, financial position, and cash flows. We will continue to assess the recoverability of our deferred tax assets, as necessary, when we experience changes that could materially affect our prior determination of the recoverability of our deferred tax assets.

New Accounting Pronouncements

Recently Adopted

In November 2023 the Financial Accounting Standards Board (the "FASB") issued Accounting Standard Update ("ASU") 2023-07, Segment Reporting Topic 280 - Improvements to Reportable Segment Disclosures ("ASU 2023-07"). This amendment requires disclosure of incremental segment information on an annual and interim basis, primarily through enhanced disclosures about significant segment expenses that are regularly provided to the chief operating decision maker. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. We adopted ASU 2023-07 on a retrospective basis in fiscal year December 31, 2024. The adoption of ASU 2023-07 did not have a material impact on our financial condition or results of operations.

Not Yet Effective

In December 2023 the FASB issued ASU 2023-09, Income Taxes Topic 740 - Improvements to Income Tax Disclosures. This amendment is expected to enhance the transparency and decision usefulness of income tax disclosures by requiring public business entities, on an annual basis, to disclose specific categories in the rate reconciliation, additional information for reconciling items that meet a quantitative threshold and certain information about income taxes paid. This revised guidance is effective for financial statements issued for fiscal years beginning after December 15, 2024. We are currently evaluating the impacts of the new standard.

In November 2024 the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses to improve the disclosures about a public business entity's expenses for more detailed information about the types of expenses in commonly presented expense captions such as cost of sales; selling, general, and administrative expenses; and research and development. The updated accounting guidance, among other things, requires quantitative disclosures for employee compensation, selling expenses, and purchases of inventory. The updated guidance is effective for financial statements issued for fiscal years beginning after December 15, 2026. We are currently evaluating the impacts of the new standard.

2. Sale of PerClot

Overview

On July 28, 2021 we entered into an asset purchase agreement, Transitional Manufacturing and Supply Agreement ("TMSA"), and other ancillary agreements related to the sale of PerClot®, a polysaccharide hemostatic agent used in surgery ("PerClot"), to a subsidiary of Baxter International, Inc. ("Baxter") and an agreement to terminate all of our material agreements with Starch Medical, Inc. ("SMI") related to PerClot (collectively the "Baxter Transaction"). Under the terms of the Baxter Transaction, Baxter will pay an aggregate of up to $54.5 million in consideration (we will receive up to $41.0 million and SMI will receive up to $13.5 million), consisting of (i) $25.0 million we received at closing, of which $6.0 million was paid to SMI; (ii) $18.8 million upon our receipt of Premarket Approval ("PMA") from the US Food and Drug Administration (the "FDA") for PerClot and our transfer of the PMA to Baxter, of which $4.5 million was paid to SMI; and (iii) up to $10.0 million upon Baxter's achievement of certain cumulative worldwide net sales of PerClot prior to December 31, 2026 and December 31, 2027, of which up to $3.0 million would be payable to SMI. In addition, at the conclusion of our manufacturing and supply services for Baxter, Baxter will pay $0.8 million upon transfer of our PerClot manufacturing equipment. Under the terms of the Baxter Transaction, we will continue to provide to Baxter certain transition services

relating to the sale of SMI PerClot outside of the US. Within the terms of the TMSA, we will manufacture and supply PerClot for Baxter post PMA for a contractual period of 21 months, subject to short-term renewal provisions.

PerClot PMA

On May 23, 2023 the FDA granted PMA of PerClot for use to control bleeding in certain open and laparoscopic surgical procedures. Pursuant to the terms of the TMSA of the Baxter Transaction, we transferred the ownership of the PMA to Baxter following approval. In May 2023 we received a payment of $18.8 million from Baxter, of which $4.5 million was paid to SMI. As a result, we recorded a pre-tax gain of $14.3 million as the assets were previously derecognized upon closing of the Baxter Transaction in fiscal year 2021, which was included as Gain from sale of non-financial assets within the Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2023.

Following receipt of the PMA, under the terms of the TMSA, we began manufacturing and supplying PerClot for Baxter and recorded $3.3 million and $5.1 million of PerClot revenues in the Consolidated Statements of Operations and Comprehensive Loss during the year ended December 31, 2024 and 2023, respectively.

We accounted for the TMSA in accordance with the provision of ASU 2016-02, *Leases Topic 842* ("ASC 842") by bifurcating the lease and non-lease components and recognizing each component based on ASC 842 and ASU 2014-09, *Revenue from Contracts with Customers Topic 606*. The amount of lease revenue was $0.5 million and $0.3 million for the year ended December 31, 2024 and 2023, respectively.

3. Acquisition of Ascyrus

Overview

On September 2, 2020 we entered into a Securities Purchase Agreement (the "Ascyrus Agreement") to acquire 100% of the outstanding equity interests of Ascyrus Medical LLC ("Ascyrus"). Ascyrus developed the AMDS, the world's first aortic arch remodeling device for use in the treatment of acute Type A aortic dissections.

Under the terms of the Ascyrus Agreement, we will pay an aggregate of up to $200.0 million in consideration, consisting of: (i) a cash payment of approximately $60.0 million and the issuance of $20.0 million in shares of Artivion common stock, in each case, that were delivered at the closing of the acquisition, (ii) a cash payment of $10.0 million and the issuance of $10.0 million in shares of Artivion common stock upon FDA approval of the Investigational Device Exemption ("IDE") application for the AMDS in 2021, (iii) if the FDA approves PMA application submitted for the AMDS, a cash payment of $25.0 million, (iv) if regulatory approval of the AMDS is obtained in Japan on or before June 30, 2027, a cash payment of $10.0 million, (v) if regulatory approval of the AMDS is obtained in China on or before June 30, 2027, a cash payment of $10.0 million and (vi) a potential additional consideration cash payment capped at $55.0 million (or up to $65.0 million to $75.0 million if the Japanese or Chinese approvals are not secured on or before June 30, 2027 and those approval milestone payments are added to the potential additional consideration cash payment cap) calculated as two times the incremental worldwide sales of the AMDS (or any other acquired technology or derivatives of such acquired technology) outside of the European Union during the three-year period following the date the FDA approves a PMA application submitted for the AMDS.

Accounting for the Transaction

As part of the acquisition, we may be required to pay additional consideration up to $100.0 million to the former shareholders of Ascyrus upon the achievement of certain milestones and the sales-based additional earnout described above. On September 2, 2020 the fair value of the total potential purchase consideration of $200.0 million included the total purchase consideration, as well as the contingent consideration liability discussed below. Our allocation of the purchase consideration was allocated to Ascyrus's tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of September 2, 2020.

The contingent consideration represents the estimated fair value of future potential payments. The fair value of the contingent consideration liability was estimated by discounting to present value the contingent payments expected to be made based on

a probability-weighted scenario approach. We applied a discount rate based on our unsecured credit spread and the term commensurate risk-free rate to the additional consideration to be paid, and then applied a risk-based estimate of the probability of achieving each scenario to calculate the fair value of the contingent consideration. This fair value measurement was based on unobservable inputs, including management estimates and assumptions about the future achievement of milestones and future estimate of revenues, and is, therefore, classified as Level 3 within the fair value hierarchy presented in Note 5. We used a discount rate of approximately 17% and estimated future achievement of milestone dates between 2025 and 2026 to calculate the fair value of contingent consideration as of December 31, 2024. We remeasure this liability at each reporting date and record changes in the fair value of the contingent consideration in General, administrative, and marketing expenses in the Consolidated Statements of Operations and Comprehensive Loss. Increases or decreases in the fair value of the contingent consideration liability can result from changes in the passage of time, discount rates, the timing and amount of our revenue estimates, and the timing and expectation of regulatory approvals.

We perform quarterly assessments of the fair value of the contingent consideration and recorded a net fair value gain of $11.0 million and a net fair value loss of $23.5 million for the year ended December 31, 2024 and 2023, respectively, in General, administrative, and marketing expenses in the Consolidated Statements of Operations and Comprehensive Loss. The reduction in the fair value of liability for the year ended December 31, 2024 was primarily due to an increase in the credit risk spread resulting from the change in the inputs related to the newly issued Credit Facilities in the first quarter of 2024, as further discussed in Note 10. The contingent consideration liability reflected in the Consolidated Balances Sheets was $52.9 million and $63.9 million as of December 31, 2024 and 2023.

In December 2021 the FDA approved our IDE application for AMDS. Upon the approval, we funded a cash payment of $10.0 million and issued $10.0 million in shares of Artivion common stock pursuant to the Ascyrus Agreement.

In December 2024 the FDA granted a Humanitarian Device Exemption (“HDE”) for use of the AMDS™ Hybrid Prosthesis in acute DeBakey Type I dissections in the presence of malperfusion. The HDE allows for commercial distribution of AMDS in the US prior to anticipated approval of a Premarket Approval (“PMA”) Application which we continue to pursue and anticipate receiving in 2026.

4. Agreements with Endospan

On September 11, 2019 Artivion’s wholly owned subsidiary, JOTEC, entered into an exclusive distribution agreement (“Endospan Distribution Agreement”) with Endospan Ltd. (“Endospan”), an Israeli corporation, pursuant to which JOTEC obtained exclusive distribution rights for NEXUS ONE, and under subsequent amendments, the NEXUS DUO and NEXUS TRE (collectively the “NEXUS family of products”) and accessories in certain countries in Europe in exchange for a fixed distribution fee of $9.0 million paid in September 2019 which has been reflected in “Other intangibles, net” in our Consolidated Balance Sheets. We also entered into a loan agreement to provide Endospan a secured loan of up to $15.0 million (“Endospan Loan”).

We also entered into a securities purchase option agreement (“Endospan Option”) with Endospan for $1.0 million paid in September 2019. The Endospan Option Agreement prior to amendment described below provided Artivion the option to purchase all the outstanding securities of Endospan from Endospan’s securityholders at the time of acquisition, or the option to acquire all of Endospan’s assets, in each case, for a price between $350.0 and $450.0 million before, or within a certain period of time after FDA approval of NEXUS, with such option expiring if not exercised within 90 days after receiving notice that Endospan has received approval from the FDA for NEXUS.

On July 1, 2024 Artivion and Endospan entered into an amendment to the Endospan Option (“Endospan Option Amendment”) which amended the terms of the previously existing Endospan Option. Under the terms of the Endospan Option Amendment, the price to acquire all of Endospan’s outstanding securities from Endospan’s securityholders at the time of acquisition, or the option to acquire all of Endospan’s assets under the Endospan Option was reduced from $250.0 million to $175.0 million, resulting in an upfront acquisition purchase price of $135.0 million, inclusive of the loan off-set. There is no longer a minimum earnout payment of $100.0 million and the maximum earnout payment of $200.0 million remains the same. We also agreed to fund Endospan additional secured loans of up to $25.0 million (“Additional Endospan Loan” and

together with the Endospan Loan, the "Endospan Loans").

Variable Interest Entity Assessment

We consolidate the results of a variable interest entity ("VIE") when it is determined that we are the primary beneficiary. Based on our initial evaluation of Endospan and the related agreements with Endospan, we determined that Endospan is a VIE. Although the arrangement with Endospan resulted in our holding a variable interest, it did not empower us to direct those activities of Endospan that most significantly impact the VIE economic performance. Therefore, we are not the primary beneficiary, and we have not consolidated Endospan into our financial results. We evaluated Endospan for VIE classification as of December 31, 2024, 2023 and 2022 and determined that Endospan meets the criteria of a non-consolidating VIE.

Valuation

The agreements with Endospan were entered into concurrently and had certain terms that are interrelated. In our evaluation of the initial relative fair value of each of the Endospan agreements to determine the amount to record, we utilized discounted cash flows to estimate the fair market value for the Endospan Loan and for the Endospan Distribution Agreement. We estimated the fair value of the Endospan Option utilizing a Monte Carlo simulation model. Inputs in our valuation of the Endospan agreements included cash payments and anticipated payments based on the executed agreements with Endospan, projected discounted cash flows in connection with the Endospan transaction, our expected internal rate of return and discount rates, and our assessed probability and timing of receipt of certification of certain approvals and milestones in obtaining FDA approval.

Endospan Option

Utilizing a Monte Carlo simulation model, we determined that the fair value of the Endospan Option in 2019 was $4.9 million. As a result of a decrease in forecasted operating results, we fully impaired the value of the Endospan Option primarily during the fourth quarter of December 31, 2021.

Due to the revised terms in the Endospan Option Amendment in July 2024, we performed another fair value measurement utilizing a Monte Carlo simulation model and revalued the Endospan Option. We determined that the fair value of the Endospan Option was $3.1 million which is reflected in Other long-term assets in our Consolidated Balance Sheet as of December 31, 2024.

Endospan Loans

Artivion and Endospan entered into the Endospan Loan, dated September 11, 2019, in which Artivion agreed to provide Endospan a secured loan of up to $15.0 million to be funded in three tranches of $5.0 million each in 2019, 2020 and 2023, respectively.

We elected the fair value option for recording the Endospan Loan. We assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics, and adjust the amount recorded to its current fair market value at each reporting period. We performed an assessment of the fair value of the Endospan Loan and determined that the fair value of the first two tranches decreased and had no value as of December 31, 2021. In 2023 we funded the $5.0 million third tranche payment and determined that the loan continued to have no fair value. Consequently, we recorded an expense of $5.0 million during the year ended December 31, 2023. After entering into an amendment to the Endospan Loan in July 2024 (the "Endospan Loan Amendment"), we determined that the Endospan Loan had a fair value of $0.3 million as of December 31, 2024.

As a part of the Endospan Loan Amendment, Artivion agreed to fund the Additional Endospan Loan up to $25.0 million. The Additional Endospan Loan is contracted to be funded in three tranches of $7.0 million, $10.0 million and $8.0 million, subject to Endospan's achievement of milestones related to its pursuit of regulatory approval for NEXUS ONE that are specified in the Endospan Loan Amendment. The first two tranches totaling $17.0 million were funded during the year ended December 31, 2024. We performed a fair value assessment of the Additional Endospan Loan and determined that the fair value was $9.2 million as of December 31, 2024 which is reflected in Other long-term assets in the Consolidated Balance Sheets as of December 31, 2024.

Distribution Agreement

The Endospan Distribution Agreement, reflected in Other intangibles, net in the Consolidated Balance Sheets and amortized on a straight-line basis, was $1.8 million as of December 31, 2023 and was fully amortized as of December 31, 2024.

5. Financial Instruments

A summary of financial instruments measured at fair value was as follows (in thousands):

December 31, 2024	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 18,182	$ —	$ —	$ 18,182
Certificates of deposit	5,069	—	—	5,069
Endospan Loans	—	—	9,535	9,535
Total assets	**$ 23,251**	**$ —**	**$ 9,535**	**$ 32,786**
Long-term liabilities:				
Contingent consideration	$ —	$ —	$ 52,880	$ 52,880
Total liabilities	**$ —**	**$ —**	**$ 52,880**	**$ 52,880**

December 31, 2023	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 22,802	$ —	$ —	$ 22,802
Certificates of deposit	3,968	—	—	3,968
Total assets	**$ 26,770**	**$ —**	**$ —**	**$ 26,770**
Long-term liabilities:				
Contingent consideration	$ —	$ —	$ 63,890	$ 63,890
Total liabilities	**$ —**	**$ —**	**$ 63,890**	**$ 63,890**

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds. The estimated market value of all cash equivalents is equal to cost basis as there were no gross realized gains or losses on cash equivalents for the years ended December 31, 2024, 2023 and 2022.

The fair value of the contingent consideration component of the Ascyrus acquisition and Endospan Loans were updated using Level 3 inputs. We recorded the Endospan Loans, classified as Level 3, as a result of the Endospan Option Amendment in July 2024. See Note 4 for further discussion of the Endospan Option Amendment. Changes in fair value of Level 3 assets and liabilities are listed in the tables below (in thousands):

	Endospan Loans
Balance as of December 31, 2023	$ —
Initial value of Additional Endospan Loan	8,912
Change in valuation of Endospan Loans	623
Balance as of December 31, 2024	**$ 9,535**

	Contingent Consideration
Balance as of December 31, 2023	$ 63,890
Change in valuation	(11,010)
Balance as of December 31, 2024	**$ 52,880**

6. Inventories and Deferred Preservation Costs

Inventories consist of the following (in thousands):

	December 31,	
	2024	2023
Raw materials and supplies	$ 35,295	$ 36,907
Work-in-process	13,926	12,687
Finished goods	30,545	32,382
Inventories	**$ 79,766**	**$ 81,976**

Deferred preservation costs consist of the following (in thousands):

	December 31,	
	2024	2023
Cardiac tissues	$ 26,489	$ 24,823
Vascular tissues	25,212	24,981
Deferred preservation costs	**$ 51,701**	**$ 49,804**

To facilitate product usage, we maintain consignment inventory of our On-X heart valves at domestic hospital locations and On-X heart valves, aortic stent grafts, and AMDS products at international hospital locations. We retain title and control over this consignment inventory until we receive a notification of implantation, at which time we invoice the hospital and recognize revenue. As of December 31, 2024 we had $12.2 million in consignment inventory, with approximately 39% in domestic locations and 61% in foreign locations. As of December 31, 2023 we had $10.7 million in consignment inventory, with approximately 44% in domestic locations and 56% in foreign locations.

7. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

The carrying values of our indefinite lived intangible assets were as follows (in thousands):

	December 31,	
	2024	2023
Goodwill	$ 240,958	$ 247,337
In-process R&D	$ 2,026	$ 2,154
Procurement contracts and agreements	$ 2,013	$ 2,013

We monitor the phases of development of our acquired in-process research and development projects, including the risks associated with further development and the amount and timing of benefits expected to be derived from the completed projects. Incremental costs associated with development are charged to expense as incurred. Capitalized costs are amortized over the estimated useful life of the developed asset once completed. Our in-process research and development projects are reviewed for impairment annually, or more frequently, if events or changes in circumstances indicate that the asset might be

impaired. We evaluate our goodwill and indefinite lived intangible assets for impairment on an annual basis during the fourth quarter of the year, and, if necessary, during interim periods if factors indicate that an impairment review is warranted. We did not record any impairment of indefinite lived intangible assets, including goodwill, during the years ended December 31, 2024, 2023 and 2022. In-process research and development, procurement contracts and agreements are included in Other intangibles, net in the Consolidated Balance Sheets as of December 31, 2024 and 2023.

Based on our experience with similar agreements, we believe that our acquired procurement contracts and agreements have indefinite useful lives, as we expect to continue to renew these contracts for the foreseeable future.

Changes in the carrying value of our goodwill, all of which was related to our Medical Devices segment, was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Balance as of January 1,	$ 247,337	$ 243,631
Foreign currency translation	(6,379)	3,706
Balance as of December 31,	**$ 240,958**	**$ 247,337**

Definite Lived Intangible Assets

The definite lived intangible assets balance includes balances related to acquired technology, customer relationships, distribution and manufacturing rights and know-how, patents, and other definite lived intangible assets. The major intangible asset classes consist of the following (in thousands, except weighted average useful life):

December 31, 2024	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 195,912	$ 67,861	$ 128,051	18.3
Other intangibles:				
Customer lists and relationships	$ 28,611	$ 11,617	$ 16,994	21.6
Distribution and manufacturing rights and know-how	9,033	9,033	—	5.0
Patents	4,428	3,460	968	17.0
Other	11,776	5,445	6,331	5.0
Other intangibles, net	**$ 53,848**	**$ 29,555**	**$ 24,293**	**9.4**

December 31, 2023	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 201,897	$ 59,304	$ 142,593	18.2
Other intangibles:				
Customer lists and relationships	$ 28,729	$ 10,334	$ 18,395	21.6
Distribution and manufacturing rights and know-how	9,608	7,807	1,801	5.0
Patents	4,365	3,225	1,140	17.0
Other	7,815	3,680	4,135	5.0
Other intangibles, net	**$ 50,517**	**$ 25,046**	**$ 25,471**	**10.0**

Amortization Expense

Amortization expense recorded in General, administrative, and marketing expenses in our Consolidated Statements of Operations and Comprehensive Loss was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Amortization expense	$ 15,855	$ 15,198	$ 15,310

The estimated future amortization expense of intangible assets with definite lives as of December 31, 2024 for the next five years is as follows (in thousands):

	2025	2026	2027	2028	2029	Total
Amortization expense	$ 13,190	$ 12,833	$ 12,730	$ 12,542	$ 12,342	$ 63,637

8. Income Taxes

Income Tax Expense

The components of loss before income taxes are as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Domestic	$ 4,559	$ (24,658)	$ (13,798)
Foreign	(12,073)	3,072	(1,186)
Loss before income taxes	**$ (7,514)**	**$ (21,586)**	**$ (14,984)**

Income tax expense consists of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ 5,857	$ 5,573	$ 1,606
State	834	1,004	367
Foreign	665	3,851	3,120
	7,356	**10,428**	**5,093**
Deferred:			
Federal	538	222	236
State	277	157	234
Foreign	(2,326)	(1,703)	(1,355)
	(1,511)	**(1,324)**	**(885)**
Income tax expense	**$ 5,845**	**$ 9,104**	**$ 4,208**

Effective Tax Rate Reconciliation

The income tax expense in the accompanying Consolidated Statements of Operations and Comprehensive Loss differs from the income tax benefit computed by applying the US federal statutory income tax rate of 21% to loss before income taxes due to the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Income tax benefit at statutory rate	$ (1,578)	$ (4,533)	$ (3,147)
Increase (reduction) in income taxes resulting from:			
Valuation allowance change	4,091	9,964	4,779
Nondeductible executive compensation	1,432	989	878
State income taxes, net of federal benefit	936	281	484
Equity compensation	577	872	472
Provision to return adjustments	536	(937)	336
Research and development credit	(425)	(800)	(961)
Foreign income taxes	(323)	2,969	415
Nondeductible entertainment expenses	201	262	117
Foreign derived intangible income deduction	(60)	(501)	(133)
Net change in uncertain tax positions	(56)	652	527
Foreign interest disallowance	—	—	151
Foreign deferred items	—	—	(112)
Other	514	(114)	402
Income tax expense	**$ 5,845**	**$ 9,104**	**$ 4,208**

Deferred Taxes

The tax effects of temporary differences which give rise to deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2024	**2023**
Deferred tax assets:		
Finance and operating leases	$ 11,774	$ 13,254
Excess interest carryforward	9,203	6,438
Loan revaluation	5,240	3,859
Property	2,974	1,786
Loss carryforwards	2,880	3,205
Non-cash compensation	2,545	2,761
Inventory and deferred preservation costs write-downs	2,441	302
Deferred compensation	2,055	1,790
Unrealized gains and losses	1,119	5,424
Debt costs	475	—
Credit carryforwards	323	336
Accrued expenses	165	2,567
Other	672	1,422
Total deferred tax assets	41,866	43,144
Less: Valuation allowance	(32,607)	(32,860)
Total deferred tax assets, net	**9,259**	**10,284**
Deferred tax liabilities:		
Intangible assets	(14,746)	(16,106)
Finance and operating leases	(11,972)	(12,777)
Prepaid items	(455)	(370)
Debt costs	—	(626)
Other	(1,201)	(1,169)
Total deferred tax liabilities	**(28,374)**	**(31,048)**
Total deferred tax liabilities, net	**$ (19,115)**	**$ (20,764)**

We regularly assess the realizability of deferred tax assets and establish valuation allowances if it is more likely than not that some or all deferred tax assets will not be realized. The following table reflects changes in the valuation allowance (in thousands):

	Year Ended December 31,		
	2024	**2023**	**2022**
Beginning balance	$ 32,860	$ 17,942	$ 13,282
Additions charged to income tax expense	4,091	9,964	4,779
(Reductions) additions related to Other comprehensive income, net	(4,081)	5,109	—
Currency translation and other	(263)	(155)	(119)
Ending balance	**$ 32,607**	**$ 32,860**	**$ 17,942**

As of December 31, 2024 and 2023 we maintained a net deferred tax liability of $19.1 million and $20.8 million, respectively. As of December 31, 2024 and 2023 we maintained valuation allowances against our deferred tax assets of $32.6 million and $32.9 million, respectively, primarily related to net operating loss carryforwards and disallowed excess interest carryforwards.

As of December 31, 2024 we had $4.6 million of federal net operating loss carryforwards related to prior acquisitions for which we have a full valuation allowance against and will fully expire at the end of 2032, $17.5 million of state net operating loss carryforwards, the majority of which will expire in 2025, $7.0 million of foreign net operating loss carryforwards, the majority of which have an indefinite carryforward period, and $0.3 million in research and development tax credit carryforwards, the majority of which will expire in 2032.

As of December 31, 2024 we had a deferred tax asset of $9.2 million of disallowed interest expense deduction carryforwards as a result of the interest deductibility rule imposed by the "Tax Cuts and Jobs Act" of 2017 ("Tax Act"), and later modified by the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). This deferred tax asset can be carried forward indefinitely. This rule disallows interest expense to the extent it exceeds 30% of adjusted taxable income. For the years ended December 31, 2024 and 2023 our interest deduction was limited to $18.5 million and $20.4 million, respectively.

Reinvestment of Unremitted Earnings

We intend to reinvest substantially all of the unremitted earnings of our non-US subsidiaries to fund working capital, strategic investments, and debt repayment and postpone their remittance indefinitely. Accordingly, no provision for state and local taxes or foreign withholding taxes was recorded on these unremitted earnings in the accompanying Consolidated Statements of Operations and Comprehensive Loss. The Company is permanently reinvested with respect to the outside basis differences in its significant non-US subsidiaries.

Uncertain Tax Positions

The following table reflects changes in our uncertain tax position liability, excluding interest and penalties (in thousands):

	Year Ended December 31,		
	2024	**2023**	**2022**
Beginning balance	$ 4,832	$ 4,508	$ 4,089
Decrease related to prior year tax positions	(467)	(508)	(103)
Increase related to current year tax positions	338	2,728	847
(Decrease) increase for foreign exchange differences	(267)	116	(145)
Increase related to prior year tax positions	199	26	20
Decrease due to the lapsing of statutes of limitations	(175)	(158)	(200)
Decrease due to settlements of prior year tax positions	—	(1,880)	—
Ending balance	**$ 4,460**	**$ 4,832**	**$ 4,508**

We recorded non-current liabilities of $0.6 million and $0.4 million related to interest and penalties on uncertain tax positions in our Consolidated Balance Sheets as of December 31, 2024 and 2023, respectively. We included expense of less than $0.1 million for December 31, 2024 and 2023, and expense of $0.1 million for December 31, 2022, for interest and penalties related to unrecognized tax benefits in our Consolidated Statements of Operations and Comprehensive Loss.

As of December 31, 2024 our uncertain tax liability of $5.1 million, including interest and penalties, was recorded as a reduction to deferred tax assets of $0.5 million, and a non-current liability of $4.6 million in our Consolidated Balance Sheets. The amount of uncertain tax liabilities that are expected to affect our tax rate if recognized were $4.0 million, $4.4 million and $3.6 million for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2023 our total uncertain tax liability, including interest and penalties of $5.2 million, was recorded as a reduction to deferred tax assets of $0.1 million and as a non-current liability of $5.1 million in our Consolidated Balance Sheets.

We believe it is reasonably possible that approximately $0.2 million of our uncertain tax liability will be recognized in 2025 due to the lapsing of various federal and state and foreign statutes of limitations, of which substantially all would affect the tax rate.

Other

Our tax years 2019 and forward generally remain open to examination by the major taxing jurisdictions to which we are subject. However, certain returns from years prior to 2019, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

9. Leases

We have operating and finance lease obligations resulting from the lease of land and buildings that comprise our corporate headquarters and various manufacturing facilities; leases related to additional manufacturing, office, and warehouse space; leases on company vehicles; and leases on a variety of office and other equipment.

Balance sheet information related to leases consists of the following (in thousands, except lease term and discount rate):

	December 31,	
Operating leases:	**2024**	**2023**
Operating lease right-of-use assets, net	$ 39,726	$ 43,822
Current maturities of operating leases	$ 4,489	$ 3,395
Non-current maturities of operating leases	39,988	43,977
Total operating lease liabilities	**$ 44,477**	**$ 47,372**
Finance leases:		
Property and equipment, at cost	$ 6,746	$ 6,862
Accumulated depreciation	(3,557)	(3,136)
Property and equipment, net	**$ 3,189**	**$ 3,726**
Current portion of finance lease obligations	$ 601	$ 582
Non-current finance lease obligations	2,833	3,405
Total finance lease liabilities	**$ 3,434**	**$ 3,987**
Weighted average remaining lease term (in years):		
Operating leases	9.6	10.4
Finance leases	5.7	6.8
Weighted average discount rate:		
Operating leases	6.3%	6.3%
Finance leases	2.3%	2.2%

The components of lease expense included in General, administrative, and marketing expenses in our Consolidated Statements of Operations and Comprehensive Loss consists of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Depreciation of property and equipment	$ 627	$ 542	$ 518
Interest expense on finance leases	89	84	89
Total finance lease expense	**716**	**626**	**607**
Operating lease expense	7,822	7,354	7,432
Sublease income	(465)	(278)	(306)
Total lease expense	**$ 8,073**	**$ 7,702**	**$ 7,733**

Supplemental cash flow information related to leases consists of the following (in thousands):

	Year Ended December 31,		
Cash paid for amounts included in the measurement of lease liabilities:	2024	2023	2022
Operating cash flows for operating leases	$ 6,627	$ 7,263	$ 6,927
Financing cash flows for finance leases	623	539	507
Operating cash flows for finance leases	89	84	90

Future maturities of lease liabilities are as follows (in thousands):

	Finance Leases	Operating Leases
2025	$ 677	$ 7,111
2026	653	6,976
2027	642	6,316
2028	608	5,904
2029	541	5,812
Thereafter	531	27,872
Total lease payments	**$ 3,652**	**$ 59,991**
Less: Amount representing interest	(218)	(15,514)
Present value of lease liabilities	3,434	44,477
Less: Current maturities of lease liabilities	(601)	(4,489)
Lease liabilities, less current maturities	**$ 2,833**	**$ 39,988**

10. Debt

Debt consists of the following (in thousands):

	December 31,	
	2024	**2023**
Term Loan Facility	$ 190,000	$ —
Revolving Credit Facility	30,000	—
Convertible Senior Notes	100,000	100,000
Old Term Loan Facility	—	211,500
2.45% Sparkasse Zollernalb (KFW Loan 1)	—	61
1.40% Sparkasse Zollernalb (KFW Loan 2)	195	484
Total principal debt	**320,195**	**312,045**
Less: Unamortized debt issuance costs[(a)]	(5,848)	(5,063)
Total debt	**314,347**	**306,982**
Less: Current portion of long-term debt	(195)	(1,451)
Long-term debt, net	**$ 314,152**	**$ 305,531**

(a) Additional unamortized debt issuance costs totaling $1.7 million related to the Revolving Credit Facility as of December 31, 2024 are included in "Other long-term assets" in the Consolidated Balance Sheets.

Maturities

The aggregate principal amount of maturities of debt for the next five years and thereafter are as follows (in thousands):

	2025	**2026**	**2027**	**2028**	**2029**	**Thereafter**	**Total**
Maturities	$ 100,195	$ —	$ —	$ —	$ —	$ 220,000	$ 320,195

Our liquidity needs arise from the funding of our cost of operations and capital expenditures and from debt service on our indebtedness. We believe that cash generated from operations, together with amounts available under our Revolving Credit Facility and our intent to settle our $100.0 million Convertible Senior Notes by issuing common stock shares (see “Convertible Senior Notes” discussion below) will be adequate to permit us to meet our obligations over the next twelve months from the date of this report.

Credit Facilities

On January 18, 2024 we entered into a credit and guaranty agreement with Ares Management Credit funds for $350.0 million of senior secured, interest-only, credit facilities, consisting of a $190.0 million secured term loan facility (the “Term Loan Facility”), a $100.0 million secured delayed draw term loan facility (the “Delayed Draw Term Loan Facility” and, together with the Term Loan Facility, the “Term Loan Facilities”) and a $60.0 million “senior-priority” secured revolving credit facility which has a priority claim ahead of the other secured facilities (the “Revolving Credit Facility” and, together with the Term Loan Facilities, the “Credit Facilities”). Upon closing, we borrowed $190.0 million under the Term Loan Facility and $30.0 million under the Revolving Credit Facility. The proceeds of the borrowings were used along with cash on hand to pay off our previously existing credit agreement (the “Old Credit Facilities” as defined below) and pay related fees and expenses.

The remaining $30.0 million of undrawn availability under the Revolving Credit Facility as of December 31, 2024 may be drawn for working capital, capital expenditures, and other general corporate purposes. The proceeds from borrowings under

the Delayed Draw Term Loan Facility, which remains undrawn as of December 31, 2024, may be used solely to repurchase or repay our outstanding 4.25% Convertible Senior Notes due July 1, 2025 and to pay related fees and expenses. Subject to the satisfaction of a specified maximum total net leverage ratio and other customary conditions, we may borrow under the Delayed Draw Term Loan Facility at any time and from time to time on or prior to the maturity date of the convertible bonds on July 1, 2025. Loans borrowed under the Delayed Draw Term Loan Facility generally have the same terms as the loans under the Term Loan Facility. See Convertible Senior Notes below for additional details.

Ranking; Guarantees

The Credit Facilities are secured by a security interest in substantially all existing and after-acquired real and personal property (subject to certain exceptions and exclusions) of us and the Guarantors.

Maturity and Redemption

The final scheduled maturity date of the Credit Facilities is January 18, 2030. There are no scheduled repayments of principal required to be made prior to the final maturity date. We have the right to prepay loans under the Ares Credit Agreement in whole or in part at any time, provided that any prepayment of loans under the Term Loan Facilities (or loans under the Revolving Credit Facility to the extent of reducing the balance of outstanding loans below $30.0 million) will be subject to a prepayment premium of 5.00% if the prepayment occurs prior to January 18, 2025 and 1.00% if the prepayment occurs thereafter and prior to January 18, 2026. Amounts repaid in respect of loans under the Term Loan Facilities may not be reborrowed.

Covenants

The Credit Facilities contain certain customary affirmative and negative covenants, including covenants that limit our ability and the ability of our subsidiaries to, among other things, grant liens, incur debt, dispose of assets, make loans and investments, make acquisitions, make certain restricted payments (including cash dividends), merge or consolidate, change business or accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. The covenants include a financial maintenance covenant that requires the company's total net leverage ratio, as defined in the agreement, to be not greater than 6.25x for the test periods from the second quarter of fiscal year 2024 through the fourth quarter of fiscal year 2024 and not greater than 5.75x from the first quarter of fiscal year 2025 and thereafter. As of December 31, 2024 we are in compliance with our debt covenants.

Interest

The Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate plus a margin of 3.00%, or the Adjusted Term Secured Overnight Financing Rate ("Adjusted Term SOFR") plus a margin of 4.00%. In addition, we will be required to pay fees of 0.50% per annum on the daily unused amount of the Revolving Credit Facility and 1.00% per annum on the daily unused amount of the Delayed Draw Term Loan Facility. The Term Loan Facilities initially bear interest, at our option, at a floating annual rate equal to either the base rate plus a margin of 5.50%, or the Adjusted Term SOFR plus a margin of 6.50%. If, after the second quarter of fiscal year 2025, the company reports total net leverage ratio, as defined in the Credit Facilities, of less than or equal to 3.75x the interest margins applicable to the Term Loan Facilities will be reduced by 25 basis points, to 5.25% and 6.25%, for base rate and Adjusted Term SOFR loans, respectively. As of December 31, 2024 the stated and effective interest rate for the Term Loan Facility was 11.09% and 11.86%, respectively. As of December 31, 2024 the stated interest rate was 8.59% per annum for the Revolving Credit Facility.

Convertible Senior Notes

On June 18, 2020 we issued $100.0 million aggregate principal amount of 4.25% Convertible Senior Notes with a maturity date of July 1, 2025 (the "Convertible Senior Notes"). The net proceeds from this offering, after deducting initial purchasers' discounts and costs directly related to this offering, were approximately $96.5 million. On January 1, 2021 we adopted ASU 2020-06 and adjusted the carrying balance of the Convertible Senior Notes to notional. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. The initial conversion rate of the Convertible

Senior Notes is 42.6203 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $23.46 per share, subject to adjustments. We use the if-converted method for assumed conversion of the Convertible Senior Notes for the diluted earnings per share calculation. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. The fair value and the effective interest rate of the Convertible Senior Notes as of December 31, 2024 was approximately $128.8 million and 5.05%, respectively. The fair value was based on market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy.

Interest expense recognized on the Convertible Senior Notes includes approximately $5.0 million, $5.0 million and $4.9 million for the aggregate of the contractual coupon interest and the amortization of the debt issuance costs during the years ended December 31, 2024, 2023 and 2022, respectively. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. There were approximately $0.4 million and $1.1 million of unamortized debt issuance costs related to convertible senior notes as of December 31, 2024 and 2023, respectively.

Holders of the Convertible Senior Notes may convert their notes at their option at any time prior to January 1, 2025 but only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on September 30, 2020 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (iii) we give a notice of redemption with respect to any or all of the notes, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date; or (iv) upon the occurrence of specified corporate events. On or after January 1, 2025 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing circumstances.

We became eligible to redeem the Convertible Senior Notes beginning on July 5, 2023, following the expiration of their non-redemption period. We are able to redeem the Convertible Senior Notes in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. We may redeem for cash all or part of the Convertible Senior Notes at a redemption price equal to 100% of the principal amount of the redeemable Convertible Senior Notes, plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the Convertible Senior Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the Convertible Senior Notes do not contain any financial covenants and do not restrict us from conducting significant restructuring transactions or issuing or repurchasing any of our other securities. As of December 31, 2024 and 2023 we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes.

On December 23, 2024 in accordance with the Indenture (the “Indenture”) dated June 23, 2020, between Artivion, Inc. (formerly CryoLife, Inc.) and U.S. Bank Trust Company, National Association, as Trustee, relating to our Convertible Senior Notes, we gave notice to the Trustee, the Conversion Agent, and the Holders (each as defined in the Indenture) that we elected to change the “Default Settlement Method” (as defined in the Indenture) for conversions of Notes to “Physical Settlement” (as defined in the Indenture). As a result, all conversions of Notes after the date of the notice will be settled by delivery of shares of our common stock using Physical Settlement in accordance with the Indenture.

Old Credit Facilities and Loss on Extinguishment of Debt

Our Old Credit Facilities, entered into on December 1, 2017, provided for a $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility (the “Old Term Loan Facility”) and a $30.0 million secured revolving credit facility (the “Old Revolving Credit Facility”). On June 2, 2021 we entered into an amendment to our Credit Agreement to extend the maturity dates of both our Term Loan and its Revolving Credit Facility. As part of the amendment, the maturity

dates of both our Term Loan and Revolving Credit Facility were each extended by two and one-half years, until June 1, 2027 and June 1, 2025, respectively, subject to earlier springing maturities as defined.

In connection with the proceeds received from our new Credit Facilities, we repaid all outstanding amounts under the Old Credit Facilities and recorded a loss on extinguishment of debt of $3.7 million, primarily comprised of the write-off of unamortized debt issuance costs, in our Consolidated Statements of Operations and Comprehensive Loss for year ended December 31, 2024.

Debt Discount and Debt Issuance Costs

In connection with the debt issued under the Credit Facilities, we capitalized $2.7 million in debt issuance costs. The Credit Facilities were also issued at an original issue discount of $7.5 million. Non-cash amortization of debt issuance costs and debt discounts for our Credit Facilities, Convertible Senior Notes, and Old Credit Facilities totaled $3.9 million, $1.9 million and $1.8 million for the years ended 2024, 2023 and 2022, respectively. Due to our intent to settle the Convertible Senior Notes with common shares instead of cash drawn on our Delayed Draw Term Loan Facility, non-cash amortization for the year ended December 31, 2024 includes full amortization of the $1.7 million associated with the Delayed Draw Term Loan Facility.

Other Borrowings

Government Supported Bank Debt

In April 2014 JOTEC obtained the first loan Sparkasse Zollernalb, which is government sponsored by the Kreditanstalt für Wiederaufbau Bank (KFW). The first loan bears an interest rate of 2.45% and matured during the first quarter of 2024. In December 2015 JOTEC obtained the second loan Sparkasse Zollernalb sponsored by KFW. The second loan bears an interest rate of 1.40% and is scheduled to mature during the third quarter of 2025.

Financed Insurance Premiums

On April 19, 2023 we issued notes payable in the aggregate of $3.6 million to finance our insurance premiums. The notes payable had a term of one year at an interest rate of 6.65% per annum. The notes payable balance of $1.0 million, reflected in Other current liabilities in the Consolidated Balance Sheet as of December 31, 2023, was fully repaid in the first quarter of 2024.

11. Commitments and Contingencies

Liability Claims

In the normal course of business, we are made aware of adverse events involving our products and tissues. Future adverse events could ultimately give rise to a lawsuit against us, and liability claims may be asserted against us in the future based on past events that we are not aware of at the present time. We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. The amounts recorded in these Consolidated Financial Statements as of December 31, 2024 and 2023 represent our estimate of the probable losses and anticipated recoveries for incurred but not reported claims related to products sold and services performed prior to the balance sheet date.

PROACT Xa Clinical Trial Termination

On September 23, 2022 we announced that we were stopping the PROACT Xa clinical trial as recommended by the trial's independent Data and Safety Monitoring Board. The PROACT Xa clinical trial was a prospective, randomized, trial designed to determine if patients with On-X mechanical aortic valves could be maintained safely and effectively on apixaban rather than on warfarin. As a result of PROACT Xa's early termination, we recorded $4.5 million of termination and wind-down expenses that are included in Research and development operating expenses in the Consolidated Statements of Operations

and Comprehensive Loss for the year ended December 31, 2022. The majority of these costs include administrative costs, that we paid during the fourth quarter of 2022 and the first quarter of 2023, as well as the estimated cost of clinical drugs purchased for patients participating in the study that are not expected to be recovered.

12. Employee Benefit Plans

401(k) Plan

We have a 401(k) savings plan ("401(k) Plan") providing retirement benefits to all US employees who have completed at least three months of service. We made matching contributions of each participant's contribution up to 4.0% of each participant's salary in 2024, 2023 and 2022. Our contributions approximated $2.8 million, $2.6 million and $2.6 million for the years ended 2024, 2023 and 2022, respectively. We may make discretionary contributions to the 401(k) Plan; however, no discretionary contributions were made in any of the past three years.

Deferred Compensation Plan

Our Deferred Compensation Plan ("Deferred Plan") allows certain of our US employees to defer receipt of a portion of their salary and cash bonus. The Deferred Plan provides for tax-deferred growth of deferred compensation. Pursuant to the terms of the Deferred Plan, we agree to return the deferred amounts plus gains and losses, based on investment fund options chosen by each respective participant, to the plan participants upon distribution. All deferred amounts and deemed earnings thereon are vested at all times. We have no current plans to match any contributions. Amounts owed to plan participants are unsecured obligations of the Company. We have established a rabbi trust in which it will make contributions to fund our obligations under the Deferred Plan. Pursuant to the terms of the trust, we will be required to make contributions each year to fully match our obligations under the Deferred Plan. The trust's funds are primarily invested in Company Owned Life Insurance ("COLI"), and we plan to hold the policies until the deaths of the insured.

Deferred compensation liabilities are reflected in the Consolidated Balance Sheets based on the anticipated distribution dates. Deferred compensation liabilities of $0.3 million and $8.0 million are reflected in Other current liabilities and Deferred compensation liability, respectively, as of December 31, 2024 in the Consolidated Balance Sheets. Deferred compensation liabilities of $0.5 million and $6.8 million are reflected in Other current liabilities and Deferred compensation liability, respectively, as of December 31, 2023 in the Consolidated Balance Sheets. The cash surrender value of COLI reflected in Other long-term assets in the Consolidated Balance Sheets was $7.8 million and $6.9 million as of December 31, 2024 and 2023, respectively. Changes in the value of participant accounts and changes in the cash surrender value of COLI are recorded as part of our operating expenses and are subject to our normal allocation of expenses to inventory and deferred preservation costs.

13. Revenue Recognition

Disaggregation of Revenue

Revenues are disaggregated by following geographic regions:

- North America: consists of US and Canada. We market our medical device products and preservation services (predominantly in the US), primarily to physicians through our direct sales representatives who are managed by region managers.
- Europe, the Middle East, and Africa ("EMEA"): in certain countries, we market approved medical device products to physicians, hospitals, and distributors through our direct sales force. In countries where we have no direct sales forces, regional sales managers market to distributors who buy medical device products directly from us and sell to hospitals in their respective countries.
- Asia Pacific ("APAC"): we market medical device products that are approved in each country to distributors in the region.
- Latin America ("LATAM"): we market medical device products that are approved in each country to distributors in the region except for Brazil where we sell directly to end customers and distributors.

Net revenues by geographic location based on the location of the customer were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
North America	197,940	187,603	167,542
EMEA	131,518	114,814	104,119
APAC	37,202	33,577	27,973
LATAM	21,877	18,010	14,155
Total revenue	**$ 388,537**	**$ 354,004**	**$ 313,789**

Also see segment disclosure in Note 16 below.

14. Stock Compensation

Overview

We are currently authorized to grant and have available for grant the following number of shares under our stock plans as of December 31, 2024:

Plan	Authorized Shares	Available for Grant	
		2024	2023
1996 Discounted Employee Stock Purchase Plan, as amended	2,900,000	709,000	826,000
2020 Equity and Cash Incentive Plan	7,145,000	2,033,000	3,281,000
Total	**10,045,000**	**2,742,000**	**4,107,000**

During 2020 the Stockholders approved a new 2020 Equity and Cash Incentive Plan ("ECIP") and funded it with 2.7 million of newly issuable shares. On August 11, 2020 4.1 million shares were registered under the 2020 ECIP, consisting of the newly issuable shares as well as 1.4 million of the shares that remained available for grant under the 2009 ECIP as of that date. On May 16, 2023 the Stockholders approved additional 3.0 million shares to be registered under the 2020 ECIP.

Stock Awards

In 2024 the Compensation Committee of our Board of Directors (the "Committee") authorized awards from approved stock incentive plans of RSAs to non-employee directors and RSUs and PSUs to certain employees and Company officers, which, assuming that performance under the PSUs at target levels, together totaled 781,000 shares and had an aggregate grant date market value of $16.2 million. The PSUs granted in 2024 ("2024 Annual PSU") have a one-year performance period and are based on attaining specified levels of revenue growth and specified levels of EBITDA, as defined in the PSU grant documents, for the 2024 calendar year. If the highest performance threshold was met, the 2024 Annual PSU represented the right to receive up to 150% of the target number of shares of common stock. The 2024 Annual PSU earned approximately 104% of the target number of shares and was subsequently modified during February 2025 to earn approximately 130% of the target number of shares.

In 2023 the Committee authorized awards from approved stock incentive plans of RSAs to non-employee Directors and RSUs and PSUs to certain employees and Company officers, which, counting PSUs at target levels, together totaled 681,000 shares and had an aggregate grant date market value of $9.7 million. Two types of PSUs were granted in 2023, an annual grant ("2023 Annual PSU") with a one-year performance period and an LTIP PSU grant ("2023 LTIP PSU") with a one-year performance period. If the highest performance threshold was met, the 2023 Annual PSU represented the right to receive up to 150% of the target number of shares of common stock. The performance component of the 2023 Annual PSU was based on attaining specified levels of revenue growth and specified levels of EBITDA, as defined in the PSU grant documents, for the 2023 calendar year. The 2023 Annual PSU earned approximately 148% of the target number of shares. If the highest

performance threshold was met, the 2023 LITP PSU grant represented a right to receive up to 200% of the target number of shares of common stock. The 2023 LTIP PSU grant earned approximately 200% of target number of shares.

In 2022 the Committee authorized awards from approved stock incentive plans of RSAs to non-employee Directors and RSUs and PSUs to certain employees and Company officers, which, counting PSUs at target levels, together totaled 871,000 shares and had an aggregate grant date market value of $13.5 million. Two types of PSUs were granted in 2022, an annual grant ("2022 Annual PSU") with a one-year performance period and an LTIP PSU grant ("2022 LTIP PSU") with a one-year performance period. If the highest performance threshold was met, the 2022 Annual PSU represented the right to receive up to 150% of the target number of shares of common stock. The performance component of the 2022 Annual PSU was based on attaining specified levels of revenue growth and specified levels of EBITDA, as defined in the PSU grant documents, for the 2022 calendar year. The 2022 Annual PSU earned approximately 51% of the target number of shares and was subsequently modified on February 13, 2023 to earn approximately 89% of the target number of shares. If the highest performance threshold was met, the 2022 LITP PSU grant represented a right to receive up to 200% of the target number of shares of common stock. The 2022 LTIP PSU grant earned approximately 140% of target number of shares.

A summary of the RSA activity for the year ended December 31, 2024 is presented below:

RSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	156,000	$ 20.11
Granted	50,000	23.85
Vested	(156,000)	20.11
Forfeited	—	—
Unvested at December 31, 2024	50,000	$ 23.85

The weighted average per share grant date fair value of RSAs granted during 2023 and 2022 were $15.45 and $17.91, respectively. The total fair value of RSAs that vested during 2024, 2023 and 2022 was $3.3 million, $1.8 million and $1.8 million, respectively.

A summary of the RSU activity for the year ended December 31, 2024 is presented below:

RSUs	Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	879,000	$ 14.75
Granted	500,000	20.55
Vested	(178,000)	17.67
Forfeited	(30,000)	17.31
Unvested at December 31, 2024	1,171,000	$ 16.72

The weighted average per share grant date fair value of RSUs granted during 2023 and 2022 were $14.59 and $14.55, respectively. The total fair value of RSUs that vested during 2024, 2023 and 2022 was $3.7 million, $1.7 million and $1.9 million, respectively.

A summary of the PSU activity for the year ended December 31, 2024 is presented below:

PSUs	Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	266,000	$ 16.94
Granted	341,000	19.79
Vested	(285,000)	18.67
Forfeited	(3,000)	13.39
Unvested at December 31, 2024	319,000	$ 18.48

The weighted average per share grant date fair value of PSUs granted during 2023 and 2022 was $14.43 and $18.93, respectively. The total fair value of PSUs that vested during 2024, 2023 and 2022 was $5.6 million, $2.8 million and $2.1 million, respectively.

Stock Options

The Committee did not authorize any grants of stock options during 2024. The Committee authorized grants of stock options from approved stock incentive plans to certain Company officers and employees totaling 110,000, and 1,031,000 shares in 2023 and 2022, respectively, with exercise prices equal to the stock prices on the respective grant dates.

A summary of stock option activity for the year ended December 31, 2024 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2023	1,878,000	$ 18.16		
Granted	—	—		
Exercised	(232,000)	17.15		
Forfeited	—	—		
Expired	(19,000)	28.27		
Outstanding at December 31, 2024	1,627,000	$ 18.19	3.6	$ 17,048,000
Vested and expected to vest	1,627,000	$ 18.19	3.6	$ 17,048,000
Exercisable at December 31, 2024	1,242,000	$ 19.44	3.3	$ 11,490,000

The weighted average per share grant date fair value of stock options granted during 2023 and 2022 was $7.87 and $5.31, respectively. The total intrinsic value of options exercised during 2024, 2023 and 2022 was $0.3 million, $0.7 million, and $1.1 million, respectively. The intrinsic value is the difference between the market value of the shares on the exercise date and the exercise price of the option.

Employees purchased common stock totaling 118,000, 141,000 and 95,000 shares in 2024, 2023 and 2022, respectively, through our ESPP.

Stock Compensation Expense

The following weighted-average assumptions were used to determine the fair value of options:

	Year Ended December 31,					
	2024		2023		2022	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	0.5 Years	5.0 Years	0.5 Years	5.0 Years	0.5 Years
Expected stock price volatility	N/A	43%	45%	57%	40%	40%
Risk-free interest rate	N/A	5.30%	4.11%	5.03%	3.58%	1.34%

The following table summarizes stock compensation expense and the associated income tax benefits recognized (in thousands):

	Year Ended December 31,		
	2024	2023	2022
RSA, RSU, and PSU expense	$ 12,543	$ 11,875	$ 10,351
Stock option and ESPP option expense	2,425	3,271	2,591
Total stock compensation expense	**$ 14,968**	**$ 15,146**	**$ 12,942**

For the years ended December 31, 2024, 2023 and 2022, we recognized tax benefits on total stock compensation expense, which are reflected in Income tax expense in the Consolidated Statements of Operations and Comprehensive Loss, of $2.4 million, $3.2 million, and $2.7 million, respectively.

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to our ESPP. These amounts were recorded as stock compensation expense and were subject to our normal allocation of expenses to inventory costs and deferred preservation costs. We capitalized $0.7 million, $0.7 million, and $0.6 million in the years ended December 31, 2024, 2023 and 2022, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of December 31, 2024 we had total unrecognized compensation expense of $12.4 million related to RSAs, RSUs, and PSUs and $1.3 million related to unvested stock options. As of December 31, 2024 this expense is expected to be recognized over a weighted-average period of 1.32 years for RSUs, 0.86 years for stock options, 0.85 years for PSUs, and 0.41 years for RSAs.

15. Loss Per Common Share

The following table sets forth the computation of basic and diluted loss per common share (in thousands, except per share data):

	Year Ended December 31,		
Basic loss per common share	**2024**	**2023**	**2022**
Net loss	$ (13,359)	$ (30,690)	$ (19,192)
Net loss allocated to participating securities	24	123	98
Net loss allocated to common stockholders	**$ (13,335)**	**$ (30,567)**	**$ (19,094)**
Basic weighted-average common shares outstanding	**41,676**	**40,743**	**40,032**
Basic loss per common share	**$ (0.32)**	**$ (0.75)**	**$ (0.48)**
Diluted loss per common share	**2024**	**2023**	**2022**
Net loss	$ (13,359)	$ (30,690)	$ (19,192)
Net loss allocated to participating securities	24	123	98
Net loss allocated to common stockholders	**$ (13,335)**	**$ (30,567)**	**$ (19,094)**
Diluted weighted-average common shares outstanding	**41,676**	**40,743**	**40,032**
Diluted loss per common share	**$ (0.32)**	**$ (0.75)**	**$ (0.48)**

We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to loss per common share. For the years ended December 31, 2024, 2023 and 2022 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive to the net loss.

16. Segment and Geographic Information

We have two reportable segments organized according to our products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of aortic stent grafts, On-X, surgical sealants, and other product revenues. Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, and synthetic vascular grafts. Aortic arch stent grafts include our E-vita® Open NEO, E-vita Open Plus, AMDS™, NEXUS ONE™, NEXUS DUO™, NEXUS TRE™, E-vita Thoracic 3G, and Artivex™. Abdominal stent grafts include our E-xtra Design Engineering, E-nside™, E-tegra™, E-ventus™ BX, Tuva BX, and E-liac™ products. Surgical sealants include BioGlue® Surgical Adhesive products. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

Our Chief Operating Decision Maker ("CODM") is the Company's Chairman, President, and CEO. The CODM reviews financial information to assess segment performance and determine how to allocate resources across segments.

The primary measure of segment performance, as assessed by our CODM, is segment gross margin or net external revenues less cost of products and preservation services. The CODM regularly reviews these costs, recognizing them as significant segment expenses. We do not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below.

The following table summarizes revenues, cost of products and preservation services, and gross margins for our reportable segments (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Revenues:			
Medical devices	$ 290,230	$ 261,185	$ 230,353
Preservation services	98,307	92,819	83,436
Total revenues	**388,537**	**354,004**	**313,789**
Cost of products and preservation services:			
Medical devices	99,385	84,595	72,166
Preservation services	40,371	40,233	39,100
Total cost of products and preservation services	**139,756**	**124,828**	**111,266**
Gross margin:			
Medical devices	190,845	176,590	158,187
Preservation services	57,936	52,586	44,336
Total gross margin	**$ 248,781**	**$ 229,176**	**$ 202,523**

Net revenues by product were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Products:			
Aortic stent grafts	$ 123,081	$ 107,469	$ 92,752
On-X	83,982	74,528	63,904
Surgical sealants	73,898	68,016	65,379
Other	9,269	11,172	8,318
Total products	**290,230**	**261,185**	**230,353**
Preservation services:	98,307	92,819	83,436
Total revenues	**$ 388,537**	**$ 354,004**	**$ 313,789**

Net revenues by geographic location attributed to countries based on the location of the customer were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
US	$ 189,994	$ 179,485	$ 161,113
International	198,543	174,519	152,676
Total revenues	**$ 388,537**	**$ 354,004**	**$ 313,789**

Revenues attributed to customers in Germany accounted for 9%, 8% and 9% of total revenues for the years ended December 31, 2024, 2023 and 2022, respectively.

As of December 31, 2024 and 2023, $18.4 million and $17.5 million of our long-lived assets were held in the US, respectively, where the corporate headquarters and a portion of our manufacturing facilities are located. Our long-lived international assets were $18.0 million and $20.9 million as of December 31, 2024 and 2023, respectively, of which 96% were located in Hechingen, Germany. As of December 31, 2024 and 2023, $241.0 million and $247.3 million, respectively, of our goodwill was allocated entirely to our Medical Devices segment.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures ("Disclosure Controls") as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934. These Disclosure Controls are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms, and that such information is accumulated and communicated to management, including the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosures.

Our management, including our President and CEO and our CFO and Executive Vice President, Finance do not expect that its Disclosure Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake. Our Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

Management's Annual Report on Internal Controls over Financial Reporting

Our management utilizes the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of December 31, 2024, the CEO and CFO have concluded that our Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by us in our periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

The report called for by Item 308(a) of Regulation S-K is incorporated herein by reference to "Management's Annual Report on Internal Controls over Financial Reporting" on page 577 of this report.

The attestation report called for by Item 308(b) of Regulation S-K is incorporated herein by reference to "Report of Independent Registered Public Accounting Firm" on page 588 of this report.

During the quarter ended December 31, 2024 there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, terminated, or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The response to Item 10 is incorporated herein by reference to the information to be set forth in the definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2024, with the exception of information concerning executive officers listed below.

The following table lists the executive officers of Artivion as of December 31, 2024 and their ages, positions with Artivion, and the dates from which they have continually served as executive officers with Artivion. Each of the executive officers of Artivion was elected by the Board of Directors to serve until the Board of Directors' meeting immediately following the next annual meeting of stockholders or until his or her earlier removal by the Board of Directors or his or her resignation.

Name	Service as Executive	Age	Position
J. Patrick Mackin	Since 2014	58	Chairman, President, and Chief Executive Officer
Lance A. Berry, CPA	Since 2023	52	Chief Financial Officer, Executive Vice President, Finance
John E. Davis	Since 2015	60	Senior Vice President, Global Sales and Marketing
Matthew A. Getz	Since 2019	56	Vice President, Human Resources
Andrew M. Green	Since 2021	56	Vice President, Regulatory Affairs
Jean F. Holloway, Esq.	Since 2015	67	Senior Vice President, General Counsel, Chief Compliance Officer, and Corporate Secretary
Amy D. Horton, CPA	Since 2006	54	Vice President, Chief Accounting Officer
Rochelle L. Maney	Since 2021	48	Vice President, Global Quality
Marshall S. Stanton, M.D.	Since 2021	68	Senior Vice President, Clinical Research and Chief Medical Officer
Robert C. Thomson	Since 2023	55	Vice President, Research and Development
Florian Tyrs	Since 2023	43	Vice President, Global Operations

J. Patrick Mackin assumed the position of President and Chief Executive Officer in September 2014, was appointed to the Board of Directors in October 2014 and was appointed Chairman in May 2015. Mr. Mackin has more than 30 years of experience in the medical device industry. Prior to joining Artivion, Mr. Mackin served as President of Cardiac Rhythm Disease Management, the then largest operating division of Medtronic, Inc. At Medtronic, he previously held the positions of Vice President, Vascular, Western Europe and Vice President and General Manager, Endovascular Business Unit. Prior to joining Medtronic in 2002, Mr. Mackin worked for six years at Genzyme, Inc. serving as Senior Vice President and General Manager for the Cardiovascular Surgery Business Unit and as Director of Sales, Surgical Products division. Before joining Genzyme, Mr. Mackin spent four years at Deknatel/Snowden-Pencer, Inc. in various roles and three years as a First Lieutenant in the US Army. Mr. Mackin received an MBA from Northwestern University's Kellogg Graduate School of Management and is a graduate of the US Military Academy at West Point.

Lance A. Berry, CPA commenced service as Chief Financial Officer and Executive Vice President, Finance of Artivion on December 4, 2023. Prior to that, Mr. Berry served as the Executive Vice President, Chief Financial and Operations Officer of Wright Medical Group N.V., from January 2019 until November 2020, when Wright was acquired by Stryker NV. Before becoming Executive Vice President, Chief Financial and Operations Officer, Mr. Berry served in the following roles at Wright Medical: Senior Vice President, Chief Financial Officer (2009-2018) and Vice President, Corporate Controller (2002-2009). Mr. Berry was employed as a Certified Public Accountant with Arthur Anderson from 1995 to 2002. Mr. Berry currently serves on the Board of Treace Medical Concepts (NASDAQ: TCMI). Mr. Berry received both his Masters and Bachelor's in Accounting from the University of Mississippi.

John E. Davis was appointed to the position of Senior Vice President, Global Sales and Marketing in September 2015. He has over 25 years of experience in Sales and Marketing and Executive Leadership. Prior to joining Artivion, he served as Executive Vice President, Global Sales and Marketing at CorMatrix, a privately held medical device company creating innovative biomaterial devices to repair damaged heart tissue from March 2012 to September 2015. Prior to CorMatrix, he served four years as a Vice President of Sales in the Cardiac Rhythm Management business at St. Jude Medical, now part of Abbott Laboratories. Before St. Jude Medical, he served 14 years with Medtronic in the Cardiac Rhythm Disease Management division including 7 years as Vice President Southeast. In his early career he held sales and leadership roles with Roche Diagnostics and Ciba-Geigy Corporation. Mr. Davis received a Bachelor's degree from Western Carolina University.

Matthew A. Getz was appointed to the position of Vice President, Human Resources in August 2019. Mr. Getz brings more than 25 years of human resources leadership experience in media, banking, and technology industries, and oversees the company's global human resources practice and strategy. Prior to joining Artivion, he served as the Chief Human Resources Officer of Encompass Digital Media and has held senior human resources roles at SunTrust Bank, Xiocom Wireless, Earthlink and BlessingWhite. Mr. Getz holds an MBA with a concentration in organizational management and international business from Georgia State University and a BBA in accounting from Mercer University.

Andrew M. Green was appointed to the position of Vice President, Regulatory affairs in March 2021. Mr. Green has more than 30 years of regulatory, clinical, quality, and business experience in the medical device and biologics industry. More specifically, he spent 3 years at the FDA as a scientific reviewer in the cardiovascular devices branch, almost 10 years at Novoste Corporation as the Vice President of Regulatory, Clinical, and Quality, and five years providing regulatory, clinical, and quality consulting services to medical device companies. Mr. Green also has broad business experience, having served as the President and COO of CorMatrix Cardiovascular for several years before ultimately serving as its CEO. After the acquisition of the CorMatrix assets by Aziyo Biologics, Mr. Green continued with Aziyo in several roles, including as the Executive Vice President of Regulatory and Medical Affairs. He started his career serving as a combat medic in the US Army and Army Reserves. Mr. Green has a Bachelor in Biological Sciences and a Master's in Bioengineering, both from Clemson University.

Jean F. Holloway, Esq. was appointed to the position of Senior Vice President, General Counsel, Chief Compliance Officer, and Secretary in January 2016. She previously served as Vice President, General Counsel, and Secretary beginning in April 2015 and was subsequently appointed to the additional position of Chief Compliance Officer in October 2015. Prior to joining Artivion, she held various positions, including Vice President, General Counsel and Secretary of Bard, Deputy General Counsel, Medtronic, Inc., Vice President, Litigation, Boston Scientific, Inc., and Deputy General Counsel, Guidant Corporation. Ms. Holloway also spent nearly 15 years in private practice as a trial lawyer at Dorsey & Whitney, Faegre & Benson and Sidley & Austin. She clerked for two years on the Seventh Circuit Court of Appeals for the Honorable Luther M. Swygert. Ms. Holloway has a JD/MBA from the University of Chicago and two undergraduate degrees from Yale University in engineering and political science.

Amy D. Horton, CPA was appointed to the position of Vice President and Chief Accounting Officer in January 2016 and had previously served as Chief Accounting Officer of Artivion since 2006. Ms. Horton has been with the Company since January 1998, serving as Controller from April 2000 to August 2006, and as Assistant Controller prior to that. From 1993 to 1998, Ms. Horton was employed as a Certified Public Accountant with Ernst & Young, LLP. She received her Bachelor's and Master's degrees in Accounting from Brigham Young University in Provo, Utah.

Rochelle L. Maney was appointed to the position of Vice President, Global Quality in March of 2021. She has over 25 years of experience in the medical device and tissue industries and has been with the Company since 2000 serving in multiple leadership roles, most recently as Vice President, Quality for the Kennesaw, Georgia manufacturing facility. She is the lead executive for Quality in strategy, diligence, and acquisitions and is responsible for all quality functions at the Company's three manufacturing facilities in Georgia, Texas, and Hechingen, Germany. Ms. Maney is a member of the American Society of Quality and serves on the Quality Council and Tissue Policy Group for the American Association of Tissue Banks. She received her Bachelor of Science in Biology degree from Berry College.

Marshall S. Stanton, MD was appointed to the position of Senior Vice President, Clinical Research and Chief Medical Officer in March of 2021. Dr. Stanton has over 20 years of experience in the medical device industry and over 30 years of advancing healthcare. Before joining Artivion, he held various senior management positions at Medtronic including Senior Vice President and President of the Pain Therapies Business Unit, General Manager of the Implantable Defibrillator Business, and leader of the Clinical Research department of the Cardiac and Vascular Group. While there, he served on the leadership team of the Medtronic Women's Network. Prior to Medtronic, he practiced cardiology for a decade at the Mayo Clinic. Dr. Stanton received his MD degree from the Medical College of Virginia and Bachelor of Arts from the University of Pennsylvania.

Robert C. Thomson, Ph.D. was appointed to the position of Vice President, Research and Development in June of 2023. Dr. Thomson brings more than 25 years of diverse R&D, technology, marketing, and business experience in the medical device industry. During his career at W.L. Gore, he successfully developed and globally commercialized several cardiovascular devices, including combination products. Dr. Thomson served as a senior director leading Peripheral vascular device R&D teams and businesses for several years before transitioning into the development of Aortic therapies. During this period, he held a senior management position leading teams focused on the development of an endovascular product portfolio. Prior to joining Artivion, he most recently led cardiac and vascular R&D and service development teams while also serving on an executive medical device review board. Dr. Thomson has held 2 US patents and has authored 15 peer-reviewed scientific publications. He received his Ph.D. in Biomedical Engineering from Rice University, where he currently serves as a Bioengineering Advisory Board Member and holds a Bachelor of Science in Chemical Engineering from the University of Edinburgh in Scotland.

Florian Tyrs was appointed to the position of Vice President, Global Operations in June 2023. Mr. Tyrs has more than 15 years of experience in the medical device industry. Mr. Tyrs has been with Artivion since March 2006. He has served as General Manager of the Hechingen Site since July 2020. Mr. Tyrs has also served as a Vice President Hechingen Operations from January 2023 to June 2023; as Director Operations from January 2018 to December 2022; as Director Production from May 2011 to December 2017; as Director Facility Management and Manufacturing Engineering from November 2011 to December 2017, as Deputy Director Production from April 2010 to April 2011, as Lean Production Manager from April 2009 to April 2011. From March 2006 to March 2009, Mr. Tyrs was employed as an R&D Engineer for the Endovascular Stentgraft Portfolio of Artivion. Mr. Tyrs holds a Diploma in Pharmaceutical Engineering of the State University of Applied Science in Albstadt-Sigmaringen, Germany.

Item 11. Executive Compensation.

The response to Item 11 is incorporated herein by reference to the information to be set forth in the definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management, and Related Stockholder Matters.

The response to Item 12 is incorporated herein by reference to the information to be set forth in the definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The response to Item 13 is incorporated herein by reference to the information to be set forth in the definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2024.

Item 14. Principal Accounting Fees and Services.

The response to Item 14 is incorporated herein by reference to the information to be set forth in the definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2024.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

- ***Financial Statements.***

The following are consolidated financial statements of Artivion, Inc. and subsidiaries are filed as part of this report under Item 8 – Financial Statements and Supplementary Data:

1. Financial Statements.

Consolidated Financial Statements begin on page 61.

- Financial Statement Schedules.

All financial statement schedules are omitted, as the required information is immaterial, not applicable, or the information is presented in the consolidated financial statements or related notes.

- Exhibits

The information required by this Item is set forth on the exhibit index that follows the signature page of this Annual Report on Form 10-K.

SIGNATURES

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

ARTIVION, INC.

By /s/ J. PATRICK MACKIN

February 28, 2025

J. Patrick Mackin
President, Chief Executive Officer, and
Chairman of the Board of Directors

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

Signature	Title	Date
/s/ J. PATRICK MACKIN **J. Patrick Mackin**	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	February 28, 2025
/s/ LANCE A. BERRY **Lance A. Berry**	Chief Financial Officer, Executive Vice President, Finance (Principal Financial Officer)	February 28, 2025
/s/ AMY D. HORTON **Amy D. Horton**	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 28, 2025
/s/ THOMAS F. ACKERMAN **Thomas F. Ackerman**	Director	February 28, 2025
/s/ DANIEL J BEVEVINO **Daniel J Bevevino**	Director	February 28, 2025
/s/ MARNA P. BORGSTROM **Marna P. Borgstrom**	Director	February 28, 2025
/s/ JAMES W. BULLOCK **James W. Bullock**	Director	February 28, 2025
/s/ JEFFREY H. BURBANK **Jeffrey H. Burbank**	Director	February 28, 2025
/s/ ELIZABETH A. HOFF **Elizabeth A. Hoff**	Director	February 28, 2025
/s/ JON W. SALVESON **Jon W. Salveson**	Director	February 28, 2025
/s/ ANTHONY B. SEMEDO **Anthony B. Semedo**	Director	February 28, 2025

Exhibit Number	Description
2.1	Securities Purchase Agreement, dated September 2, 2020, by and among Artivion, Inc., Ascyrus Medical LLC, the securityholders of Ascyrus Medical LLC and the Securityholder Representative (as defined therein). (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed September 2, 2020.)
2.2	Asset Purchase Agreement dated July 28, 2021, by among Artivion, Inc., and Baxter Healthcare Company. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed July 29, 2021.)
2.3	Plan of Conversion, effective January 1, 2022. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed January 4, 2022.)
3.1	Delaware Amended and Restated Certificate of Incorporation, effective May 15, 2024. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed May 16, 2024.)
3.2	Amended and Restated Bylaws of Artivion, Inc., effective May 15, 2024, a Delaware Corporation (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed May 17, 2024.)
4.1	Form of Certificate for our Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.)
4.2*	Description of Artivion, Inc.'s Securities under Section 12 of the Exchange Act.
4.3	Indenture, dated June 23, 2020, by and between Artivion, Inc. and US Bank National Association, as trustee. (Incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 23, 2020.)
4.4	Form of Note filed as Exhibit A to Indenture, dated June 23, 2020, by and between Artivion, Inc. and US Bank National Association, as trustee. (Incorporated herein by reference to Exhibit A of Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 23, 2020.)
10.1†	Artivion, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed July 30, 2009.)
10.1(a)†	Amended and Restated Artivion, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 99.1 to the Registrant's Form S-8 filed June 22, 2012.)
10.1(b)†	First Amendment to the Amended and Restated Artivion, Inc. 2009 Stock Incentive Plan, dated July 24, 2012. (Incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q filed October 30, 2012.)
10.1(c)†	Second Amended and Restated Artivion Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Appendix B to the Registrant's Definitive Proxy Statement filed April 8, 2014.)
10.1(d)†	Form of Non-Qualified Stock Option Grant Agreement pursuant to the Artivion, Inc. 2009 Employee Stock Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed April 29, 2010.)
10.2†	Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q filed July 28, 2015.)
10.2(a)†	Artivion, Inc. Equity and Cash Incentive Plan, as amended. (Incorporated herein by reference to Exhibit 10.2(a) to Registrant's Report on Form 10-K for the year ended December 31, 2018.)
10.2(b)†	Form of 2019 Performance Share Award Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(b) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019.)

Exhibit Number	Description
10.2(c)†	Form of 2019 Long Term Incentive Program Performance Share Award Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(c) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019.)
10.2(d)†∞	Form of 2018 Officer Restricted Stock Award Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(c) to Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.2(e)†∞	Form of 2018 Non-Employee Director Restricted Stock Award Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(d) to Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.2(f)†∞	Form of 2018 Grant of Non-Qualified Stock Option pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(e) to Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.3	Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Appendix B to the Registrant's 2020 Proxy Statement filed on March 31, 2020.)
10.3(a)†	Form of 2022 Grant of Non-Employee Director Restricted Stock Award Agreement pursuant to the Artivion, Inc. 2020 Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.3(a) to the Registrant's Annual Report on Form 10-K filed February 23, 2023.)
10.3(b)	Form of Non-Qualified Stock Option Grant Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan Option Award Agreement. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed May 6, 2022.)
10.3(c)	Form of PSU Award Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed May 6, 2022.)
10.3(d)	Form of Restricted Stock Unit Award Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed May 6, 2022.)
10.3(e)	Form of Special PSU Award Agreement pursuant to the Artivion, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed May 6, 2022.)
10.3(f)	Form of 2023 Long Term Incentive Program Performance Share Award Agreement pursuant to the 2020 Artivion, Inc. Equity and Cash Incentive Plan, adopted February 2023. (Incorporated herein by reference to Exhibit 10.3(f) to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.3(g)	Form of 2023 Performance Share Award Agreement pursuant to the 2020 Artivion, Inc. Equity and Cash Incentive Plan, adopted February 2023. (Incorporated herein by reference to Exhibit 10.3(g) to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.3(h)	Form of 2023 Restricted Stock Unit Award Agreement pursuant to the 2020 Artivion, Inc. Equity and Cash Incentive Plan, adopted February 2023. (Incorporated herein by reference to Exhibit 10.3(h) to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.3(i)	Form of 2023 Performance Share Award Agreement pursuant to the 2020 Artivion, Inc. Equity and Cash Incentive Plan, adopted August 2023. (Incorporated herein by reference to Exhibit 10.3(i) to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)

Exhibit Number	Description
10.3(j)	Form of 2023 Restricted Stock Unit Award Agreement pursuant to the 2020 Artivion, Inc. Equity and Cash Incentive Plan, adopted August 2023. (Incorporated herein by reference to Exhibit 10.3(j) to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.4	Artivion, Inc. Amended and Restated Employee Stock Purchase Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed May 20, 2022.)
10.5†	Artivion, Inc. Executive Deferred Compensation Plan. (Incorporated herein by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010.)
10.6†	Summary of Compensation Arrangements with Non-Employee Directors. (Incorporated herein by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.7†	Employment Agreement between Artivion, Inc. and J. Patrick Mackin, dated July 7, 2014. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 11, 2014.)
10.8†	Stock Option Grant Agreement by and between Artivion, Inc. and J. Patrick Mackin, dated September 2, 2014. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed October 28, 2014.)
10.9†	Form of Indemnification Agreement for Non-Employee Directors and Executive Officers. (Incorporated herein by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed November 4, 2022.)
10.10†	Change of Control Severance Agreement between Artivion, Inc. and John E. Davis, dated August 2, 2022. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed November 4, 2022.)
10.11†	Change of Control Severance Agreement between Artivion, Inc. and Jean F. Holloway, dated August 2, 2022 (Incorporated herein by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q filed November 4, 2022.)
10.12+	Clinical Research Agreement, dated October 10, 2019, by and between Artivion, Inc. and Duke University. (Incorporated herein by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019.)
10.12(a)+	First Amendment to Clinical Research Agreement, dated October 10, 2019, by and between Artivion, Inc. and Duke University. (Incorporated herein by reference to Exhibit 10.23(a) to the Annual Report on Form 10-K filed February 23, 2021.)
10.12(b)+	Second Amendment to Clinical Research Agreement, dated January 20, 2022, by and between Artivion, Inc. and Duke University (Incorporated herein by reference to Exhibit 10.13(b) to the Registrant's Annual Report on Form 10-K filed February 23, 2023.)
10.12(c)+	Third Amendment to Clinical Research Agreement, dated November 18, 2022, by and between Artivion, Inc. and Duke University (Incorporated herein by reference to Exhibit 10.13(c) to the Registrant's Annual Report on Form 10-K filed February 23, 2023.)
10.13	Credit and Guaranty Agreement, dated December 1, 2017, by and among Artivion, Inc., CryoLife International, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., AuraZyme Pharmaceuticals, Inc., the financial institutions party thereto from time to time as lenders, and Deutsche Bank AG New York Branch, as administrative agent and collateral agent. (Incorporated herein by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed December 1, 2017.)

Exhibit Number	Description
10.13(a)	First Amendment to Credit and Guaranty Agreement by and among Artivion, Inc., CryoLife International, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., AuraZyme Pharmaceuticals, Inc., the financial institutions party thereto from time to time as lenders, and Deutsche Bank AG New York Branch, as administrative agent and collateral agent, dated October 26, 2018. (Incorporated herein by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed October 31, 2018.)
10.13(b)	Second Amendment to Credit and Guaranty Agreement by and among Artivion, Inc., CryoLife International, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., AuraZyme Pharmaceuticals, Inc., the financial institutions party thereto from time to time as lenders, and Deutsche Bank AG New York Branch, as administrative agent and collateral agent, dated April 29, 2020. (Incorporated herein by reference to Exhibit 10.3 of Registrant's Quarterly Report on Form 10-Q filed July 31, 2020.)
10.13(c)	Third Amendment to Credit and Guaranty Agreement between Artivion, Inc. and Deutsche Bank AG New York Branch as administrative agent and collateral agent, dated June 2, 2021. (Incorporated herein by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed July 30, 2021.)
10.13(d)	Fourth Amendment to Credit and Guaranty Agreement between Artivion, Inc. (f/k/a CryoLife, Inc.), the Guarantor Subsidiaries defined therein, the financial institutions party thereto from time to time as lenders, and Deutsche Bank AG New York Branch, as Administrative Agent. (Incorporated herein by reference to Exhibit 10.14(d) to the Registrant's Annual Report on Form 10-K filed February 23, 2023.)
10.14	Lease Agreement between Artivion, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to Amli Land Development—I Limited Partnership, dated April 18, 1995. (Incorporated herein by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007.)
10.14(a)	First Amendment to Lease Agreement between Artivion, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to Amli Land Development—I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.)
10.14(b)	Restatement and Amendment to Funding Agreement between Artivion, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to Amli Land Development—I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(b) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.)
10.14(c)	Second Amendment to Lease Agreement between Artivion, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to P&L Barrett, L.P., dated May 10, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed July 29, 2010.)
10.14(d)++	Third Amendment to Lease Agreement between Artivion, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to P&L Barrett, L.P., dated May 10, 2020. (Incorporated herein by reference to Exhibit 10.15(d) to the Registrant's Quarterly Report on Form 10-Q filed April 30, 2021.)
10.15++	Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated March 2, 2009. (Incorporated herein by reference to Exhibit 10.14 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.15(a)++	First Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated November 15, 2012. (Incorporated herein by reference to Exhibit 10.14(a) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)

Exhibit Number	Description
10.15(b)++	Second Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated January 29, 2015. (Incorporated herein by reference to Exhibit 10.14(b) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.15(c)++	Third Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated January 29, 2015. (Incorporated herein by reference to Exhibit 10.14(c) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.15(d)+	Fourth Amendment to Lease Agreement between Artivion, Inc. and 1300 E. Anderson Lane, Ltd., dated March 8, 2019. (Incorporated herein by reference to Exhibit 10.3(d) to the Registrant's Quarterly Report on Form 10-Q filed November 3, 2023.)
10.15(e)+	Fifth Amendment to Lease Agreement between Artivion, Inc. and 1300 E. Anderson Lane, Ltd., dated September 1, 2023. (Incorporated herein by reference to Exhibit 10.3(e) to the Registrant's Quarterly Report on Form 10-Q filed November 3, 2023.)
10.16	Lease Agreement between JOTEC GmbH and Lars Sunnanväder for Lotzenäcker 23, dated October 27, 2017 and November 2, 2017. (Incorporated herein by reference to Exhibit 10.15 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.16(a)	First Amendment to Lease Agreement between JOTEC GmbH and Lars Sunnanväder for Lotzenäcker 23, dated December 28, 2017 and January 1, 2018. (Incorporated herein by reference to Exhibit 10.15(a) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.17++	Lease Agreement between JOTEC GmbH and Lars Sunnanväder for Lotzenäcker 25, dated October 27, 2017 and November 2, 2017. (Incorporated herein by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.17(a)++	First Amendment to Lease Agreement between JOTEC GmbH and Lars Sunnanväder for Lotzenäcker 25, dated April 27, 2018. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2018.)
10.18++	Lease Agreement between JOTEC GmbH and Frau Annika Sunnanväder for an objected located on the leased property at Lotzenäcker 25, dated October 28, 2020. (Incorporated herein by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K filed February 23, 2021.)
10.19	Loan Agreement, dated September 11, 2019, by and between Artivion, Inc., as lender, and Endospan Ltd., as borrower. (Incorporated herein by reference to Exhibit 10.1 of Registrant's Quarterly Report on Form 10-Q filed October 31, 2019.)
10.20+	Exclusive Distribution Agreement, dated September 11, 2019, by and between JOTEC GmbH, as distributor, and Endospan Ltd., as manufacturer. (Incorporated herein by reference to Exhibit 10.2 of Registrant's Quarterly Report on Form 10-Q filed October 31, 2019.)
10.20(a)+	First Amendment to Exclusive Distribution Agreement, by and between JOTEC GmbH, as distributor, and Endospan Ltd., as manufacturer, dated August 31, 2020. (Incorporated herein by reference to Exhibit 10.21(a) to the Annual Report on Form 10-K filed February 23, 2021.)
10.20(b)+	Second Amendment to Exclusive Distribution Agreement, by and between JOTEC GmbH, as distributor, and Endospan Ltd., as manufacturer, dated December 30, 2022. (Incorporated herein by reference to Exhibit 10.21(b) to the Registrant's Annual Report on Form 10-K filed February 23, 2023.)
10.20(c)+	Third Amendment to Exclusive Distribution Agreement, by and between JOTEC GmbH, as distributor, and Endospan Ltd., as manufacturer, dated October 1, 2023. (Incorporated herein by reference to Exhibit 10.21(c) to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)

Exhibit Number	Description
10.20(d)+*	Fourth Amendment to Exclusive Distribution Agreement, by and between JOTEC GmbH, as distributor, and Endospan Ltd., as manufacturer, dated July 22, 2024.
10.21	Purchase Agreement, dated June 18, 2020, by and between Artivion, Inc. and Morgan Stanley & Co. LLC, as the initial purchaser. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 23, 2020.)
10.22†+	Consulting Agreement, dated January 1, 2024, by and between Artivion, Inc. and D. Ashley Lee. (Incorporated herein by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.23†+	Offer Letter, dated December 4, 2023, by and between Artivion, Inc. and Lance A. Berry. (Incorporated herein by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.24†	Change of Control Severance Agreement, dated November 10, 2023, by and between Artivion, Inc. and Lance A. Berry. (Incorporated herein by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.25†+	Performance and Retention Bonus Letter Agreement, dated December 6, 2023, by and between Artivion, Inc. and Amy D. Horton. (Incorporated herein by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
10.26	Credit and Guaranty Agreement, dated January 18, 2024, by and among Artivion, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc. and Ascyrus Medical, LLC, as subsidiary guarantors, the lenders from time to time party thereto and Ares Capital Corporation, as administrative agent and collateral agent. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 18, 2024.)
10.27	First Amendment to Credit and Guaranty Agreement by and among Artivion, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., and Ascyrus Medical, LLC, as subsidiary guarantors, the lenders from time to time party thereto and Ares Capital Corporation, as administrative agent and collateral agent, dated June 13, 2024. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed August 9, 2024.)
10.28	Amended and Restated Loan Agreement, dated July 1, 2024, by and between Artivion, Inc., as lender, and Endospan Ltd., as borrower. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 9, 2024.)
19.1*	Artivion, Inc. Insider Trading Policy
21.1*	Subsidiaries of Artivion, Inc.
23.1*	Consent of Ernst & Young LLP
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Lance A. Berry pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002.
97.1	Artivion, Inc., Updated Clawback Policy, as amended August 2023. (Incorporated herein by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K filed February 23, 2024.)
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

Exhibit Number	Description
104	Cover Page Interactive Data File – formatted as Inline XBRL and contained in Exhibit 101

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* Filed herewith.

** Furnished herewith.

† Indicates management contract or compensatory plan or arrangement.

∞ Indicates that the 2018 form was used in 2019, and 2020, except otherwise indicated.

+ The Registrant has redacted exhibit provisions or terms that are both not material and would likely cause competitive harm to the Registrant if publicly disclosed.

++ The Registrant has been granted confidential treatment for certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 21.1

SUBSIDIARIES OF ARTIVION, INC.

Subsidiary	Jurisdiction
Artivion Chile SpA	Chile
Artivion Colombia SAS	Colombia
Artivion Cyprus Limited	Cyprus
Artivion EMEA GmbH	Germany
Artivion France S.A.S.	France
Artivion Hellas Single Member Ltd.	Greece
Artivion Hong Kong, Limited	Hong Kong
Artivion India Private Limited	India
Artivion Italy s.r.l.	Italy
Artivion LATAM Holdings Spain, SLU	Spain
Artivion Malaysia, Sdn. Bhd.	Malaysia
Artivion New Zealand	New Zealand
Artivion Polska Sp. z.o.o.	Poland
Artivion Taiwan Co. Limited	Taiwan
Artivion UK Ltd.	England and Wales
Ascyrus Medical GmbH	Germany
Ascyrus Medical LLC	Florida
AuraZyme Pharmaceuticals, Inc.	Florida
CryoLife Asia Pacific, PTE. Ltd	Singapore
CryoLife Beijing Medical Device Ltd.	China
CryoLife Canada, Inc.	Canada
CryoLife Germany HoldCo GmbH	Germany
CryoLife Germany TopCo GmbH	Germany
CryoLife International, Inc.	Florida
CryoLife Korea Co., Ltd.	Korea
CryoLife Medical (Australia) Co. Pty, Ltd.	Australia
CryoLife Medical (Thailand) Co., Ltd.	Thailand
CryoLife Vietnam Co., Ltd.	Vietnam
Jolly Buyer Acquisition GmbH	Switzerland
JOTEC Cardiovascular S.L.	Spain
JOTEC do Brasil Ltda.	Brazil
JOTEC GmbH	Germany
JOTEC Sales GmbH	Switzerland
JOTEC UK Ltd.	England
On-X Life Technologies Holdings, Inc.	Delaware
On-X Life Technologies, Inc.	Delaware
Valve Special Purpose Co., LLC	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement No. 333-277561 on Form S-3 filed on March 1, 2024,
2. Registration Statement No. 333-272557 on Form on S-8 pertaining to the Artivion, Inc. 2020 Equity and Cash Incentive Plan,
3. Registration Statement No. 333-265161 on Form on S-8 pertaining to the Artivion, Inc. Amended and Restated Employee Stock Plan,
4. Registration Statement No. 333-258716 on Form S-3 filed on August 11, 2021,
5. Registration Statement No. 333-244319 on Form S-8 pertaining to the CryoLife, Inc. 2020 Equity and Cash Incentive Plan,
6. Registration Statement No. 333-229881 on Form S-8 pertaining to the CryoLife, Inc. Equity and Cash Incentive Plan,
7. Registration Statement No. 333-227473 on Form S-3 filed on September 21, 2018,
8. Registration Statement No. 333-197545 on Form S-8 pertaining to the CryoLife, Inc. Second Amended and Restated 2009 Stock Incentive Plan,
9. Registration Statement No. 333-182296 on Form S-8 pertaining to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan,
10. Registration Statement No. 333-182297 on Form S-4 filed on June 22, 2012,
11. Registration Statement No. 333-167065 on Form S-8 pertaining to the CryoLife, Inc. Employee Stock Purchase Plan,
12. Registration Statement No. 333-159608 on Form S-8 pertaining to the CryoLife, Inc. 2009 Employee Stock Incentive Plan,
13. Registration Statement No. 333-119137 on Form S-8 pertaining to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, and
14. Registration Statement No. 333-104637 on Form S-8 pertaining to the CryoLife, Inc. 2002 Stock Incentive Plan;

of our reports dated February 28, 2025, with respect to the consolidated financial statements of Artivion, Inc. and subsidiaries and the effectiveness of internal control over financial reporting of Artivion, Inc. and subsidiaries included in this Annual Report (Form 10-K) of Artivion, Inc. and subsidiaries for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Atlanta, Georgia
February 28, 2025

Exhibit 31.1

I, J. Patrick Mackin, certify that:

1. I have reviewed this annual report on Form 10-K of the registrant, Artivion, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 28, 2025

/s/ J. PATRICK MACKIN

Chairman, President, and

Chief Executive Officer

Exhibit 31.2

I, Lance A. Berry, certify that:

1. I have reviewed this annual report on Form 10-K of the registrant, Artivion, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 28, 2025

/s/ LANCE A. BERRY
Chief Financial Officer and
Executive Vice President, Finance

Exhibit 32

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

In connection with the Annual Report of Artivion, Inc. (the "Company") on Form 10-K for the year ending December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of J. Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and Lance A. Berry, the Chief Financial Officer and Executive Vice President, Finance of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

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

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

/s/ J. PATRICK MACKIN	/s/ LANCE A. BERRY
J. PATRICK MACKIN	LANCE A. BERRY
Chairman, President, and	Chief Financial Officer and
Chief Executive Officer	Executive Vice President, Finance
February 28, 2025	February 28, 2025

BOARD OF DIRECTORS

Thomas F. Ackerman (1),(3)
Retired
Former Senior Financial Advisor Charles River Laboratories International, Inc.
(Research tools and services for drug and medical device development)
Wilmington, Massachusetts

Daniel J. Bevevino (1),(2)
Independent Consultant and Former Vice President and Chief Financial Officer Respironics, Inc.
(Medical devices for sleep and respiratory disorders)
Murrysville, Pennsylvania

Marna P. Borgstrom (3),(4)
Retired
Former President and Chief Executive Officer, Yale New Haven Health and Yale New Haven Hospital
New Haven, Connecticut

James W. Bullock (2),(3)
Retired
Former President and CEO Zyga Technology, Inc.
(Medical devices for minimally invasive treatment of the lumbar spine)
Minnetonka, Minnesota

Jeffrey Burbank (1),(4),(5)
Retired
Former Chief Technology Officer Fresenius Medical Care North America
(Medical devices for treatment of renal diseases)
Lawrence, Massachusetts

J. Patrick Mackin
President, Chief Executive Officer, and Chairman
Artivion, Inc.
Kennesaw, Georgia

Elizabeth A. Hoff (3),(4)
President and Chief Executive Officer at SOMAVAC Medical Solutions, Inc.
(Medical devices for post-surgical recovery)
Houston, Texas

Jon W. Salveson (3),(4)
Vice Chairman Investment Banking and Chairman of the Healthcare Investment Banking Group at Piper Jaffray Companies
(Investment banking firm)
Minneapolis, Minnesota

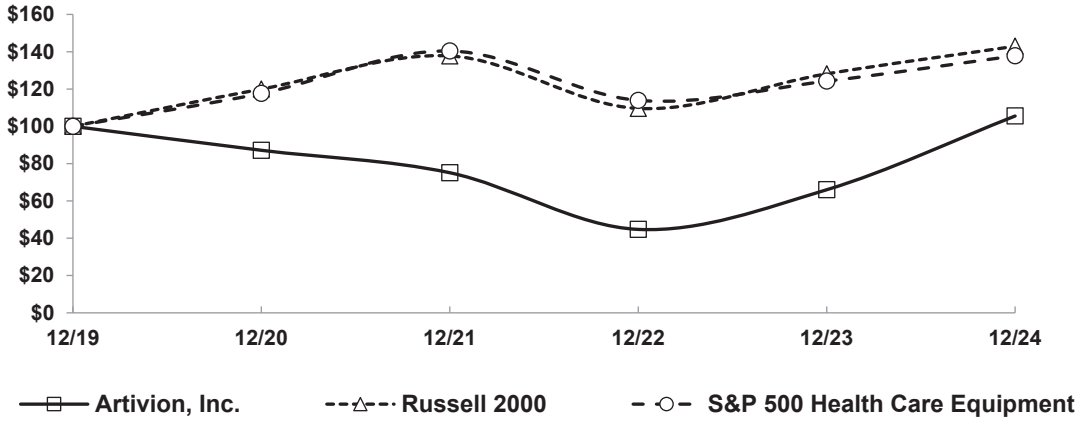
Anthony B. Semedo (2),(3)
Retired
Former Senior Vice President Medtronic
The Sea Ranch, California

Committee Members as of December 31, 2024
(1) Audit Committee
(2) Compensation Committee
(3) Innovation and Healthcare Compliance Committee
(4) Corporate Governance Committee
(5) Lead Director

The graph below matches Artivion, Inc.'s cumulative 5-Year total shareholder return on common stock with the cumulative total returns of the Russell 2000 index and the S&P 500 Health Care Equipment index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from 12/31/2019 to 12/31/2024.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Artivion, Inc., the Russell 2000 Index
and the S&P 500 Health Care Equipment Index



*$100 invested on 12/31/19 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/19	12/20	12/21	12/22	12/23	12/24
Artivion, Inc.	**100.00**	**87.15**	**75.12**	**44.74**	**66.00**	**105.54**
Russell 2000	**100.00**	**119.96**	**137.74**	**109.59**	**128.14**	**142.93**
S&P 500 Health Care Equipment	**100.00**	**117.63**	**140.40**	**113.92**	**124.22**	**137.81**

The stock price performance included in this graph is not necessarily indicative of future stock price performance.