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

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2021

OR

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

For the transition period from to
Commission file 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, $.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 x No o
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 o No x
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 x No o
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 x 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 x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
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. x
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes o No x
As of June 30, 2021 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $1,069,799,941 computed using the closing price of $28.40 per share of Common Stock on June 30, 2021, 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 18, 2022 the number of outstanding shares of Common Stock of the registrant was 40,115,521.

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, 2021	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 and reflect the views of management 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 of the COVID-19 pandemic on product demand and our product sales, business operations, manufacturing operations, supply chain, cash flow, workforce, clinical and regulatory timelines, and our research and development projects;
- Our belief that our distributors may delay or reduce purchases of products in US Dollars depending on the relative price of goods in their local currencies;
- Our beliefs that the use of surgical adhesives and sealants, with or without sutures and staples, for certain indications can enhance the efficacy and cost-effectiveness of certain procedures through more effective and rapid wound closure;
- Our beliefs and anticipation regarding the favorable attributes and benefits of our products, the basis on which our products compete, our physician education activities, the advantages of our relationships with organ and tissue procurement organizations and tissue banks, the FDA classification of our medical devices, our compliance with applicable laws and regulations, and the advantages of our intellectual property and its significance to our segments and our business as a whole, our relations with our employees, timelines regarding product launches and regulatory certifications, clearances, renewals, and approvals;
- Our beliefs about potential competition and competitive products, potential adverse regulatory consequences, potential security vulnerabilities, and the associated potential adverse effects on our business;
- Our beliefs about the impact of the contaminated saline solution and the tissue processed with contaminated saline solution we identified in the fourth quarter of 2020;
- Our beliefs regarding our global expansion efforts, including the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- 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 clinical trial milestones for the regulatory approvals of the NEXUS stent graft system in the US and the AMDS globally;
- 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 Baxter Transaction;
- Our beliefs about the anticipated benefits from our corporate reincorporation and rebranding and the risks posed by the same;
- Our beliefs about the present value and potential impairment of our intangible assets and leases;
- Our beliefs about the timing for handpiece availability and CardioGenesis cardiac laser therapy revenue;
- Our beliefs regarding the impact alternative anticoagulation therapy may and transcatheter heart valve replacement have on the number of patients choosing On-X mechanical heart valves;
- Our beliefs about our ability to make timely transitions to our notified bodies and obtain renewals for our CE Marks impacted by Brexit and the transition to the Medical Device Regulation (“MDR”) in Europe, our ability to obtain derogations related to the same, and the impact these renewals and derogations may have on our business;

- Our beliefs about our R&D and product pipeline, including our beliefs about the timing of our clinical trials and product launches;
- 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 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 On-X, aortic stents and stent grafts, and BioGlue products, and for research and development for new products despite reduced planned spending due to COVID-19 and that our efforts to develop new products and technologies will likely require additional investment, research, and new clinical studies or data;
- Our beliefs about pending and potential legal or other governmental or regulatory proceedings;
- Our expectations regarding the timing of clinical research work and regulatory approvals for and expected distribution of products or indications, including On-X, aortic stents and stent grafts, and BioGlue products, and CryoValve SGPV if the 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, On-X, 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, 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 as 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, however, 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 stents and stent grafts, surgical sealants, On-X® mechanical heart valves and related surgical products, and implantable cardiac and vascular human tissues. Aortic stents and stent grafts include JOTEC® stent grafts and surgical products (collectively, "JOTEC Products"), the Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, and the NEXUS® endovascular stent graft system ("NEXUS"). Surgical sealants include BioGlue® Surgical Adhesive ("BioGlue") products. In addition to these four major product families, we sell or distribute PhotoFix® bovine surgical patches, CardioGenesis® cardiac laser therapy, Therion® chorioamniotic allografts (previously marketed as NeoPatch®), and PerClot® hemostatic powder (prior to the sale to a subsidiary of Baxter International, Inc ("Baxter")).

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 and On-X Life Technologies, Inc. ("On-X"), an Austin, Texas-based, mechanical heart valve company acquired on January 20, 2016, as well as separate country entities to support direct sales operations in Brazil, Canada, France, Italy, Poland, Spain, Switzerland, and the UK. Additionally, we have entities in Australia, China, Korea, Singapore, Thailand, and Vietnam, to provide sales and marketing support for the Asia Pacific region.

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 stents and stent grafts, surgical sealants, On-X, 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 18 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. We plan to drive growth through:

- *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, and Ascyrus Medical LLC, ("Ascyrus") and our distribution agreement and purchase option for NEXUS. 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 with 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 US Food and Drug Administration ("FDA") or foreign regulators sooner than we do. Some might have superior manufacturing efficiency, tissue processing capacity, and/or marketing capabilities. We cannot assure 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 (homografts) 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 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 20 years, after which the valve typically must be replaced. These valves typically contain a synthetic sewing ring to facilitate surgical implantation. 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 tends to cause 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 homograft, or a human heart valve, during aortic valve replacement surgery due to endocarditis. The Class

I indication means that an aortic homograft 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. Consequently, for many physicians, human heart valves are the preferred alternative to animal-derived and mechanical valves for patients who have, or are at risk to contract, endocarditis.

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 are also 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 through 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 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 NEXUS 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 On-X's 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.

PROACT was a prospective, randomized, controlled clinical trial comparing a reduced versus standard warfarin dose for On-X heart valve recipients. In the aortic valve replacement arm of PROACT, the reduced warfarin dose group had 60% fewer bleeding events without an increased risk of stroke. As a consequence, 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 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. 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. While use of a lower INR has been approved for the On-X aortic heart valve, such use for the On-X mitral heart valve was submitted to the FDA in mid-2021 and is still under FDA review. We currently anticipate receiving FDA approval in 2022.

While patients with an On-X aortic heart valve can be safely maintained at a lower INR, patients with mechanical prosthetic heart valves would still benefit by elimination of the need for warfarin anticoagulation therapy, due to warfarin's significant drawbacks for patients including the need to frequently draw blood for monitoring and to observe certain dietary and alcohol restrictions. We believe that providing an acceptable alternative to warfarin anticoagulation may increase the number of patients choosing an On-X aortic heart valve not only due to the valve's existing durability and clinical superiority, but also due to the ability to avoid warfarin.

As a result, Artivion initiated the PROACT Xa clinical trial to determine if patients with an On-X aortic valve can be maintained safely and effectively on apixaban as an alternative to warfarin, given the drawbacks associated with warfarin. This prospective, randomized, controlled, parallel-arm clinical trial is on-going with enrollment anticipated to be completed in 2022.

On-X heart valves compete primarily with mechanical valves from Abbott Laboratories, Medtronic, plc. ("Medtronic"), and CORCYM (who completed acquisition of the LivaNova heart valve business in June 2021). 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. 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 Stents and Stent Grafts

Hybrid stent grafts, surgical grafts, and endovascular stent grafts can be used in the treatment of complex and 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 and E-vita Open Plus

E-vita Open Plus 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 Plus 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 hold a CE Mark for the E-vita Open Plus and additional marketing approvals have been granted in other countries throughout the world. The E-vita Open Plus competes outside the US with products from Terumo Medical Corporation ("Terumo") and two smaller competitors. We do not currently sell E-vita Open Plus in the US and we believe there are no competitive products currently being commercialized in the US. The E-vita Open Plus competes in the EU primarily on its proven stent graft technology and long-term clinical data.

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

AMDS

We acquired Ascyrus Medical LLC ("Ascyrus") in September 2020. Ascyrus has 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 less than five minutes to the procedure time. 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 ("DARTS") 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 outside of the US, including in EMEA, Canada, APAC, and LATAM. We have begun the PERSEVERE clinical trial to gain US approval and anticipate first enrollment in the first half of 2022.

NEXUS

We acquired the exclusive distribution rights in certain countries in Europe for NEXUS in September 2019 from Endospan Ltd., an Israeli corporation ("Endospan"). Endospan holds a CE Mark for NEXUS which is the only endovascular stent graft system approved for the repair of both aneurysms and dissections in 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 NEXUS 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 United States, including Cook, Gore, and Bolton Medical. NEXUS also competes with other manufacturers' standard open repair and hybrid procedures including aortic debranching, frozen elephant trunk, and thoracic endovascular aortic repair ("TEVAR") with chimneys or snorkels.

We began distribution of NEXUS in the fourth quarter of 2019 in EMEA.

We also entered into a securities purchase option agreement with Endospan in September 2019 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. Endospan is currently enrolling patients in their US pivotal IDE trial, TRIOMPHE.

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 Plus and E-xtra Design Engineering.

We hold 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.

E-nya

The E-nya is a thoracic stent graft system for the minimally invasive repair of lesions of the descending aorta, including thoracic aortic aneurysms and dissections. The E-nya system was designed to give physicians more options and control while treating both simple and challenging anatomies. The E-nya builds upon JOTEC's experience in the thoracic endovascular aortic repair market and increases the number of options to treat a broader range of patients. The system offers both bare spring and covered proximal configurations with tip capture technology, enhancing control and predictability during deployment while achieving optimal outcomes. The lower profile graft material leverages JOTEC's expertise in textile manufacturing and is designed for both flexibility in conformance and long-term durability. E-nya competes primarily with products from Medtronic, Gore, Cook, and Terumo.

We obtained a CE Mark for E-nya in the fourth quarter of 2019 and began limited distribution of E-nya in the second quarter of 2020. We have temporarily suspended this limited release while we implement modifications in response to customer feedback and hope to resume limited market release in early 2023.

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. JOTEC has pioneered a service whereby it manufactures a customized thoraco-abdominal stent graft within 3 weeks. E-xtra Design Engineering stent graft systems are often used in conjunction with E-vita Thoracic 3G, as well as the AAA offering, the E-tegra, or in combination with both.

We sell E-xtra Design Engineering stent graft systems in EMEA and in a limited number of other countries around the world. E-xtra Design Engineering competes with customized product offerings from Cook and Terumo.

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 and Terumo.

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.

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 graft has 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 graft features 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 graft, and the E-liac stent graft.

The E-ventus BX has a CE Mark 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.

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, Vascutek, 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 product 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 and 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) (See also, “Government Regulation – International Approval Requirements” and Part I, Item 1A, “Risk Factors—Industry Risks— Our products and tissues are highly regulated and subject to significant quality and regulatory risks.” for additional discussion about our BioGlue CE Mark). 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 several other countries throughout the world.

BioGlue competes primarily with surgical sealants from Baxter; Ethicon; 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 (60%).

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 and LeMaitre Vascular, 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 Life Sciences, CORCYM (who completed acquisition of the LivaNova heart valve business in June 2021), 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 Aziyo Biologics, Edwards Life Sciences, 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 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 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, 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 Technologies

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 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).

Our PhotoFix product line competes with bioprosthetic and synthetic cardiac and vascular patch offerings from several other companies, including Baxter, LeMaitre, Aziyo Biologics, 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

Angina consists of pressure, discomfort, or pain in the chest typically due to narrowed or blocked arteries that are also a cause of ischemic heart disease. Patients with severe angina are often treated with surgical procedures including angioplasty or coronary artery bypass or with medications such as aspirin, nitrates, beta-blockers, statins, or calcium channel blockers. Pain may be chronic or may become pronounced with exercise. Angina can also be treated with Transmyocardial Revascularization ("TMR"), a procedure that can be performed as an open surgical procedure or through a minimally invasive surgery either as a stand-alone procedure or concurrently with coronary artery bypass. During TMR, the surgeon uses a disposable handpiece to deliver precise bursts of laser energy directly to an area of heart muscle that is suffering from ischemic heart disease through a small incision or small ports with the patient under general anesthesia and without stopping the heart. TMR is typically performed with a CO_2 or Holmium: YAG laser. It takes approximately 6 to 10 pulses of the laser to traverse the myocardium and create channels of one millimeter in diameter. During a typical procedure, approximately 20 to 40 channels are made in the heart muscle. The external openings seal with little blood loss. Angina usually subsides with improved oxygen supply to the targeted areas of the damaged heart muscle. We currently sell the CardioGenesis cardiac laser therapy product line to perform TMR.

Our CardioGenesis cardiac laser therapy product line consists of Holmium: YAG laser consoles, related service and maintenance, and single-use, fiber-optic handpieces, which are used in TMR to treat patients with severe angina resulting from diffuse coronary artery disease. Patients undergoing TMR treatment with CardioGenesis products have been shown to have angina reduction, longer event-free survival, reduction in cardiac related hospitalizations, and increased exercise tolerance. Our SolarGen 2100s Console ("console") uses the solid-state technology of the Holmium: YAG laser system to provide a stable and reliable energy platform that is designed to deliver precise energy output. The console has an advanced electronic and cooling system technology, which allows for a smaller and lighter system, while providing 115V power capability. We also provide service plan options to ensure that the console is operating within the critical factory specifications. We sell the SoloGrip® III disposable handpieces ("handpieces"), which consist of multiple, fine fiber-optic strands in a one-millimeter diameter bundle and are designed to work with the console. The handpiece has an ergonomic design and is pre-calibrated in the factory to provide easy and convenient access for treating all regions of the left ventricle. See Part 1, Item I, "Business—Suppliers, Sources, and Availability of Raw Materials and Tissues," for a discussion of the limitations around our supply of handpieces and consoles.

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, primarily in the US, in May 2011 when we completed the acquisition of Cardiogenesis Corporation.

Our CardioGenesis cardiac laser therapy competes with other methods for the treatment of coronary artery disease, including drug therapy, percutaneous coronary intervention, coronary artery bypass surgery, and enhanced external counter pulsation. There is currently no directly competitive laser technology for the performance of TMR as Stryker discontinued the directly competitive CO_2 Heart Laser System. Currently, Laser Engineering Inc. services the Stryker laser system, but no more handpieces are being sold. Our CardioGenesis cardiac laser therapy product competes with other methods for the treatment of coronary artery disease on the basis of its ease of use, versatility, size of laser console, and improved access to the treatment area with a smaller fiber-optic system.

We did not have a supply of handpieces for cardiac laser therapy while we waited for the FDA to approve our supplier's change in manufacturing location through our Premarket Approval ("PMA")-supplement. In January 2021 we received PMA-S approval for this change in manufacturing site and we resumed limited sales of TMR handpieces in the fourth quarter of 2021.We sell handpieces and consoles primarily in the US.

PerClot

Hemostatic agents are frequently utilized as an adjunct to sutures and staples to control intraoperative bleeding. Hemostatic agents prevent excess blood loss and can help maintain good visibility of the operative site. These products may reduce operating room time and decrease the number of blood transfusions required in surgical procedures. Hemostatic agents are available in various forms including pads, sponges, liquids, and powders.

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.

PerClot has a CE Mark and additional marketing approvals have been granted in a number of other countries throughout the world. PerClot is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venular, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

PerClot competes with various topical absorbable hemostats including offerings from Pfizer, Baxter, Ethicon, Bard, and BioCer Entwicklungs. Other competitive products may include topical thrombin and fibrin sealants. A number of companies have surgical hemostat products under development. PerClot competes on the basis of safety, clinical efficacy, absorption rates, and ease of use.

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, a powdered hemostatic agent, 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 and manufacturing and supply services relating to the sale of SMI PerClot outside of the US and manufacture and supply of PerClot to Baxter post FDA PMA approval.

In January 2019 we completed enrolling patients in a clinical trial for the purpose of obtaining FDA PMA approval. In conjunction with Baxter, we submitted the PMA to the FDA in the third quarter of 2021, 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, a national accounts manager, 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 90 direct field service representatives and distributor managers in the EMEA region in Germany, the UK, France, Spain, Italy, Poland, Austria, Switzerland, Netherlands, Belgium, and Ireland. 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 30 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 in 2021. 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 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 or 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.

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 refuse to supply us or they and/or their facilities cease operations temporarily or permanently, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers can 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 ongoing global COVID-19 pandemic has continued to impact the global supply chain; the pandemic's impact on workforces, global mobility, material availability, demand, shipping, reorder time and reliability has reportedly continued or worsened in many cases. Any of these adverse outcomes could have a material, adverse effect on our revenues or profitability.
Additional attention has been applied to managing this increased risk and will continue 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 all of our own manufacturing operations at three facilities: Austin, Texas for On-X products, Hechingen, Germany for JOTEC Products, and Kennesaw, Georgia for all other products and services. The NEXUS product is solely manufactured by Endospan in Herzelia, Israel, and the AMDS product is solely manufactured by a contract manufacturer in Charlotte, North Carolina.

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 and PhotoFix and process human tissues at this facility. Our headquarters also includes a CardioGenesis cardiac laser therapy console maintenance and evaluation laboratory space.

We maintain a facility of combined manufacturing and office space in Atlanta, Georgia which we sublet to a third-party beginning in 2018.

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 JOTEC 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, the UK, Italy, Poland, Singapore, Spain, and Switzerland. 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.

The Medical Device Directive (“MDD”) is the governing document for the European Economic Area (“EEA”) that details requirements for safety and risk of devices. The Medical Device Regulation (“MDR”) replaced MDD on May 26, 2021 and imposes more stringent requirements on manufacturers and European Notified Bodies, who have already begun the transition to these new requirements. See Part I, Item 1A, “Risk Factors—Industry 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 and “Government Regulation – International Approval Requirements” for additional discussion about the MDR transition.

We employ a comprehensive quality assurance program in our product manufacturing and tissue preservation activities. Materials, solutions, and components utilized in our manufacturing and tissue processing 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. Materials, components, subassemblies, and tissues are documented throughout manufacturing or processing to assure 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, 2021, we did not have a firm 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 that have limited availability. Our backlog is generally not considered firm and must be confirmed with the customer before shipment. Certain JOTEC Products are specifically designed to meet specifications of a particular patient which can result in a limited backlog of these products. We did not have a supply of handpieces for cardiac laser therapy until the fourth quarter of 2021. We resumed limited sales of handpieces in the fourth quarter of 2021 following the FDA approval of our supplier's change in manufacturing location through our PMA-supplement.

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 510(k) process or an approval through an investigational device exemption ("IDE") and PMA process.

Under a Section 510(k) process, a medical device manufacturer provides premarket notification that it intends to begin commercializing a product and shows that the product is substantially equivalent to another legally marketed predicate product. 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 or different technological characteristics that do not raise new 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, CardioGenesis cardiac laser therapy, E-vita Open Plus, E-Vita Open Neo, E-vita Thoracic 3G, E-tegra, E-liac, E-nya, E-nside, NEXUS, 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.

In December 2019 we learned that the FDA is preparing 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 to Class III medical devices. Following a comment period and subsequent publication of a final rule, should the CryoValve SGPV be determined to be MMM, we 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 review of the PMA application. To date, the FDA has not issued a final rule. See also Part I, Item 1A, "Risk Factors—Industry Risks— Reclassification by the FDA of CryoValve SGPV 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.

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 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 On-X heart valves, On-X AAP, On-X Chord-X sutures, E-vita Open Plus, E-vita Open Neo, E-vita Thoracic 3G, E-tegra, E-liac, E-nya, E-nside, AMDS, and other devices. In addition, E-ventus and NEXUS, which we distribute, have CE Marks.

We work with a number of organizations officially designated as Notified Bodies by European Union Member States to perform assessments of compliance to the MDD and MDR for our various product lines. These organizations include LNE/G-Med ("G-Med"), Deutscher Kraftfahrzeug-Überwachungs-Verein ("DEKRA"), the British Standards Institute ("BSI"), and DQS Holding GmbH ("DQS"). These organizations as well as Lloyd's Register Quality Assurance Limited ("LRQA") also perform assessments and issue certifications affirming compliance to quality system standard ISO 13485:2016. In addition, we work with auditing organizations BSI and DEKRA to perform assessments affirming compliance to the Medical Device Single Audit Program ("MDSAP"), which certifies conformance to the regulations of five key jurisdictions: the US, Japan, Australia, Canada, and Brazil.

As a result of the UK's exit from the European Union, or "Brexit," the UK Medicines and Healthcare Products Regulatory Agency ("MHRA") has announced that CE Marking will continue to be recognized in the UK and certificates issued by EU-recognized Notified bodies will continue to be valid in the UK market until June 30, 2023. Going forward, all devices marketed in the UK will require UK Conformity Assessed ("UKCA") Marks certified by a UK Approved Body (the re-designation of the UK Notified Body).

On June 13, 2019 LRQA informed us that it would no longer provide Notified Body services for medical devices effective September 2019. The governing German competent authority, the Regierungspraesidium-Tubingen, granted us an extended grace period until December 31, 2021 to transfer LRQA-issued certifications for BioGlue and PhotoFix to a new Notified Body. We are currently in the process of transferring BioGlue and PhotoFix to our new Notified Body, DEKRA. While positive progress has been made, DEKRA has been unable to schedule and complete the last audit, a Phase 2 onsite audit, for our registration due to COVID-19 restrictions on travel, staffing shortages, and workload related to the transition to the MDR. We currently have sufficient inventory on the market in the EU to cover customer demand for a period of the transition. We also are currently requesting derogations from certain individual European countries to allow us to continue to commercialize BioGlue in those countries if our inventory is insufficient to cover demand and until we can complete the certification process with DEKRA. Failure to obtain such derogations may have a material adverse effect on our ability to supply demand in affected jurisdictions and have a material, adverse impact on our business. See also Part I, Item 1A, "Risk Factors—Industry 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.

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 our 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 against EtO facilities, including closures and temporary closures, as well as proposals increasing 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—Some of our products and technologies are subject to significant intellectual property risks and uncertainty," for additional discussion of risks related to our use of EtO sterilization. We do not currently anticipate compliance with these laws and regulations relating to our waste disposal and sterilization activities will require any material capital expenditures.

Research and Development and Clinical Research

We use our technical and scientific expertise to identify market opportunities for new products or services, or to expand the use of our current products and services, through expanded indications or product or 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 laboratory or at universities or 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 tissues 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 2021, 2020, and 2019 we spent approximately $35.5 million, $24.2 million, and $23.0 million, respectively, on research and development activities on new and existing products. These amounts accounted for approximately 12%, 10%, and 8% of our revenues for each of 2021, 2020, and 2019, respectively.

We are in the process of developing or 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 or indications, global expansion, and business development. These activities will likely require additional research, new clinical studies, and/or compilation of clinical data.

We are currently seeking regulatory approval for BioGlue in China. Enrollment was completed in the third quarter of 2018 and the submission for market approval was filed in March 2019 with Chinese regulatory authorities who have made additional requests, and expressed several concerns, related to the application. If we cannot satisfy the regulator’s requests and concerns and obtain approval in April 2022, the pending application will expire and no longer be eligible for allowance, requiring the Company to restart or decide to abandon the approval process.

We are currently conducting a clinical trial to assess reduced levels of required anticoagulation or warfarin for the On-X mitral heart valve. Trial results were submitted for regulatory review in 2021 with anticipated FDA and CE Mark approvals in 2022.

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 in 2022.

The PROACT Xa clinical trial is in its enrollment phase to determine if patients with an On-X aortic heart valve can be maintained safely and effectively on apixaban rather than on warfarin. The trial has enrolled more than half of the patients and we anticipate enrollment to be complete in 2022.

We completed our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the US. Enrollment was completed in January 2019 and, in conjunction with Baxter, we submitted the PMA to the FDA during the third quarter of 2021. See also Part I, Item 1A, “Risk Factors—Operational Risks—Our investment in PerClot is subject to significant risks, including our ability to fully realize our investment by obtaining FDA approval and to successfully commercialize PerClot in the US either directly or indirectly.”

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 will be conducting a pivotal clinical trial 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 anticipate study initiation and first patient enrollment in the first quarter of 2022.

The FDA granted Breakthrough Device Designation in the second quarter of 2020 for E-vita OPEN NEO, 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 technology 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 NEXUS. 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, 2021 we had approximately 1,300 employees. Most of our employees are located in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany. None of our employees are covered by a collective bargaining agreement, and we have never experienced a work stoppage or interruption due to labor disputes. Our employees located in Hechingen, Germany have a Works Council. We believe our relations with our employees worldwide and with the Works Council in Germany 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 over the past year. 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 the 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.

Diversity and Inclusion

We believe that a culture of inclusion and diversity enables us to create, develop, and fully leverage the strengths of our workforce to achieve our business objectives. Approximately 58% of our global employees are female, and approximately 35% of our US based employees are from an underrepresented ethnic community.

We believe that bringing together different perspectives and experiences is fundamental to innovation. In early 2022 we appointed a Global Diversity Officer to manage and oversee the Company’s diversity and inclusion efforts and goals.

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 safety, health, and well-being of our employees around the world is a key priority. Throughout the COVID-19 pandemic, we have remained focused on the health and safety of our employees by implementing and enforcing safety protocols. We provided employees with protective equipment, required the wearing of masks, increased cleaning procedures, provided cleaning supplies, implemented remote work where possible, enhanced our IT systems to facilitate remote work, and improved our cybersecurity protocols.

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.

See also Part II, Item 7, “Effects of COVID-19” for discussion about COVID-19’s impact on our employees, and Part I, Item 1A, “Risk Factors—Operational Risks—We are dependent on our specialized workforce” for discussion about Human Capital risks.

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 this 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; and (iv) our Code of Ethics for Senior Financial Officers. 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 shareholders 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 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

COVID-19, and similar outbreaks, could have a material, adverse impact on us.

Since early 2020, businesses, communities, and governments worldwide have taken, and continue to take, a wide range of actions to mitigate the spread and impact of COVID-19, leading to an unprecedented impact on the global economy. Hospitals and other healthcare providers have adopted differing approaches to address the surge and resurgence of COVID-19 cases, including their impact on healthcare workers, such as postponing elective and non-emergent procedures, restricting access to their facilities, cancelling elective procedures, or re-allocating scarce resources to some critically ill patients. Although some areas have seen a decline in COVID-19 cases, the potential for additional impact from new variants of COVID-19 and longer than anticipated timelines for widespread therapeutic and vaccine availability and acceptance remain. These conditions have and could continue to impact our activities, including:

- Our product sales. Certain regions experienced an impact on revenues in 2021 due to the COVID-19 pandemic. In addition to COVID-19's impact on procedure volumes, including an impact on procedure volumes due in part to COVID-19-related healthcare staffing shortages, we have begun to observe additional downstream effects on our business, including an increase in delays or difficulty in collecting certain outstanding receivables, particularly with certain governmental payors in regions heavily impacted by COVID-19. The extent to which our financial performance will be impacted by the pandemic in 2022 and beyond will depend largely on future developments, including changes in hospital utilization rates and staffing, the prevalence and severity of new variants, global availability and acceptance of COVID-19 vaccines and their effectiveness against variants, and the prevalence of public and private vaccine mandates. COVID-19's continued or increased impact on our financial performance may also increase the risks we face with respect to managing our indebtedness.
- Our business operations. In 2020 we took several steps to address the impact of COVID-19 on our employees, cash consumption, and operations, including reducing expenditures and delaying investments. The reductions and delays we adopted could adversely impact our business operations or delay our recovery from the effects of the pandemic. Although we have begun to scale back many of these steps in most geographies, the COVID-19 virus and its variants remain highly contagious and our efforts to contain the spread of COVID-19 and its variants among our employees, including our key personnel, and to protect our supply chain, may not succeed. COVID-19 also continues to impact our business partners, including the various regulators and notified bodies that we rely on, which increases the regulatory risks we face, and specifically, the risks we face with respect to timely review and approval of new and renewal certifications, clearances, and approvals for our products.

- Our manufacturing operations. The COVID-19 pandemic has continued to impact the global supply chain; the pandemic's impact on workforces, global mobility, material availability, demand, and shipping and reorder time and reliability has reportedly continued or worsened in many cases. Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after COVID-19's risk as a global pandemic has subsided.
- Our workforce. As some global economies have begun to emerge from the COVID-19 downturn, the expiration of COVID-related hiring freezes, increased opportunities for remote work, the Great Resignation and increasing compensation pressure have resulted in a war for talent and an unprecedent number of career changes. The resulting worker shortages at all levels have impacted supply chains and distribution channels and employers' ability to adequately staff their operations. This has impacted not only our own ability to attract and retain employees, but also the ability of our customers who face increasing staffing pressures throughout their healthcare organizations.
- Our research and development projects. In 2020 and parts of 2021 we reduced spending on research and development projects, including clinical research projects. These reductions could adversely impact future revenue, and additional reductions in spending could be implemented, further impacting future revenue. In addition, our ability to conduct our ongoing research and development projects in markets that are affected by COVID-19 has been, and could continue to be, adversely impacted. Enrollment and timelines for our clinical trials have been, and might continue to be, impacted as healthcare providers reprioritize resources, address staffing shortages, and limit access to healthcare facilities or as patients decline to participate or are hesitant to voluntarily visit healthcare facilities. In addition, staffing shortages and COVID-19-related impacts on government and regulatory agencies have slowed and might continue to slow timelines for regulatory actions, including approvals.

If COVID-19 or its variants continue to spread, if efforts to contain COVID-19 or its variants continue or are unsuccessful, if we experience new outbreaks of COVID-19 in areas previously successful in containing its spread, if staffing shortages impact us, governmental or regulatory bodies, or our customers, if vaccine mandates become more prevalent, or if COVID-19, its variants, or disruptions to the global supply chain impact our supply chain or employee productivity, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows. The nature and extent of these developments are highly uncertain and unpredictable and may vary greatly by region. These adverse developments or a prolonged period of uncertainty could adversely affect our financial performance.

We are subject to a variety of risks due to our 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, 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 other emerging corruption and data privacy regulations;
- Overlapping 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;
- Potential adverse financial impact and negative erosion of our operating profit margin over time due to increasing inflationary pressures, particularly through our supply chain; our 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; and
- Potential adverse financial and regulatory consequences resulting from the exit of the UK from the European Union, or "Brexit."

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. We face intense competition in virtually all of our product lines. A significant percentage of market revenues from competitive products are generated by Baxter International, Inc.; Ethicon (a Johnson & Johnson Company); Medtronic, Inc.; Abbott Laboratories; Edwards Lifesciences Corp.; C.R. Bard, Inc., a subsidiary of Becton, Dickinson and Company; Integra Life Sciences Holdings; LifeNet; CORCYM (completed acquisition of the LivaNova heart valve business in June 2021); Anteris Technologies, Inc.; Aziyo Biologics; Cook Medical; Gore & Associates; Terumo Aortic Corp.; LeMaitre Vascular, Inc.; Maquet, Inc.; Pfizer, Inc.; 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 COVID-19 and increased 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;
- Lower cost of goods sold or preservation costs; and
- Larger direct sales forces and more established distribution networks.

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;
- Compete effectively, as we may be unable to capitalize on our clinical advantages or our competitors may have advantages over us in terms of cost structure, pricing, back-office automation, marketing, and sourcing; 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.

As an example of this risk, in the fourth quarter of 2020 we became aware that a supplier shipped to us a lot of saline solution that we use in our tissue processing that contained some contamination. The contamination was identified by our routine quality controls. While we were able to mitigate the impact of this contamination through our own efforts and additional testing that was reviewed with the FDA, the contaminated solution impacted a small percentage of the tissue processed with this lot of solution, requiring us to write-off approximately $826,000 in contaminated tissues in the fourth quarter of 2020. The written off and temporarily quarantined tissue impacted our ability to fully meet demand for certain tissues and sizes in the fourth quarter of 2020, the first quarter of 2021, and to a lesser extent the second quarter of 2021. Our inability to meet some demand for tissue in the third quarter resulted in part from a shortage of trained staff capable of meeting the increased demand for releasing this quarantined tissue. See also, Part I, Item 1A, “Risk Factors—Operational Risks— We are dependent on our specialized workforce.”

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

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

BioGlue Surgical Adhesive (“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 related to BioGlue:

- Competing effectively with our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;

- We may be unable to obtain approval to commercialize BioGlue in certain non US countries as fast as our competitors do of their products or at all. We also may not be able to capitalize on new BioGlue approvals, including for new indications, in non US countries;
- 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; and
- BioGlue faces potential adverse regulatory consequences resulting from the exit of the UK from the European Union, or "Brexit." See Part I, Item 1A, "Risk Factors—Industry Risks— Our products and tissues are highly regulated and subject to significant quality and regulatory risks."

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

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

- Compete effectively with our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;
- 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;
- Meet demand for aortic stents and 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:

- Compete effectively with some of our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;
- Take market share in the mechanical heart valve market based on the FDA's approved lower International Normalized Ratio ("INR") indication 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 transcatheter aortic valve replacement, or "TAVR" devices;
- Manage risks associated with less favorable contract terms for On-X products on consignment at hospitals;
- Respond adequately to enhanced international regulatory requirements or enforcement activities; and
- Receive timely renewal certifications in certain markets.

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

The majority of our foreign product revenues are denominated in Euros and, as such, are sensitive to changes in exchange rates. In addition, a portion of our dollar-denominated and euro-denominated product sales are made to customers in other countries who must convert local currencies into US Dollars or Euros in order to purchase these products. We also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Fluctuations in exchange rates of Euros or other local currencies in relation to the US Dollar 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.

Our charges resulting from acquisitions, restructurings, and integrations 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 added 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 earn-outs, 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, in the fourth quarter of 2021, we fully impaired the value of the Endospan Option and fully wrote-down the value of the Endospan Loan, primarily driven by a decrease in forecasted operating results. This impairment, and other potential risks like those mentioned above, may adversely affect the market value of our common stock.

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 or expense the costs of manufacturing or preservation.

As an example of this risk, in the fourth quarter of 2020 we became aware that a supplier shipped to us a lot of saline solution that we use in our tissue processing that contained some contamination. The contamination was identified by our routine quality controls. While we were able to mitigate the impact of this contamination through our own efforts and additional testing that was reviewed with the FDA, the contaminated solution impacted a small percentage of the tissue processed with this lot of solution, requiring us to write-off those contaminated tissues in the fourth quarter of 2020 and impacting our ability to fully meet demand for certain tissues and sizes in the fourth quarter of 2020, the first quarter of 2021, and to a lesser extent the second quarter of 2021.

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. As a further example of this risk, our supplier of TMR handpieces was informed in the fourth quarter of 2021 that the sole-source manufacturer of tubing used in the handpiece assembly had gone out of business, requiring us to work with our supplier to identify and qualify a new supplier before a disruption in handpiece availability occurs.

Finally, the COVID-19 pandemic has continued to impact the global supply chain; the pandemic's impact on workforces, global mobility, material availability, demand, and shipping and reorder time and reliability has reportedly continued or worsened in many cases. Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after COVID-19's risk as a global pandemic has 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 could also 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, our supplier has been unable to fully resume production due to factors outside of our control. Due to these and other supplier issues, we had virtually no supply of handpieces during the first three quarters of 2021. Although handpiece supply resumed on a limited basis during the last quarter of 2021, we remain dependent on a sole-source manufacturer for these handpieces.

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 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 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 59 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 endovascular stent graft systems consist of two main product components: the stent graft and the delivery system. The stent graft is manufactured out of several different raw materials that are manufactured by JOTEC and various external suppliers, including single suppliers. The delivery systems are manufactured by JOTEC from several different raw materials with different processing techniques. Primary processes are the assembly of injection molded parts and machine drilled 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 manufactured by JOTEC out of a few different yarns that are supplied by an external supplier. The collagen suspension is manufactured by JOTEC out of a collagenous tissue that is supplied by a single supplier. Our conventional ePTFE grafts are manufactured by JOTEC out of various raw materials supplied by several suppliers. For some products the ePTFE grafts are heparin coated. For these products, the heparin suspension is manufactured by JOTEC out of a heparin solution that is also supplied by an external supplier.

We also conduct all of our own manufacturing operations at three facilities: Austin, Texas for On-X products, Hechingen, Germany for JOTEC Products, and Kennesaw, Georgia for all other products and services. The NEXUS product is solely manufactured by Endospan in Herzelia, Israel, and the AMDS product is solely manufactured by a supplier in Charlotte, North Carolina. If one of these facilities ceases operations temporarily or permanently, for any reason including a pandemic or climate change related event, 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 field-based workforce is increasingly being subject to public and private vaccine mandates, including mandates without exception, which may impact unvaccinated personnel's ability to fulfill or stay in their roles. 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. This risk was exacerbated during 2021, and is expected to continue, as the competition for talent in the medical device industry and in the workforce generally has intensified substantially. As some global economies have begun to emerge from the COVID-19 downturn, the expiration of COVID-19 related hiring freezes, the Great Resignation, increased opportunities for remote work, and increasing compensation pressure have resulted in a war for talent and an unprecedent number of career changes. The resulting competition 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.

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. Examples of these activities include the following:

- On December 1, 2017 we acquired JOTEC AG, a Swiss entity that we converted to JOTEC GmbH and subsequently merged with our Swiss acquisition entity, Jolly Buyer Acquisition GmbH and its subsidiaries;
- On September 11, 2019 we entered into various agreements with Endospan, Ltd. ("Endospan"), an Israeli medical device manufacturer (the "Endospan Transaction"). The Endospan Transaction included an exclusive distribution agreement for the NEXUS stent graft system ("NEXUS") in Europe; an agreement ("Endospan Loan") for a secured loan from Artivion to Endospan; and a security purchase option agreement for Artivion to purchase all the then outstanding Endospan securities from Endospan's existing securityholders upon FDA approval of NEXUS;
- On September 2, 2020 we acquired 100% of the outstanding shares of Ascyrus Medical LLC ("Ascyrus"), the developer of the Ascyrus Medical Dissection Stent ("AMDS");
- On July 28, 2021 we entered into various agreements with Baxter International, Inc. ("Baxter") and Starch Medical, Inc. ("SMI") related to the sale of our PerClot assets to Baxter and the termination of our existing material agreements with SMI.

Our ability to realize the anticipated business opportunities, growth prospects, cost savings, synergies, and other benefits of these 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 NEXUS and AMDS in the European and other markets, including our ability to manage the substantial requirements for NEXUS procedures for product training, implant support, and proctoring;
- Bring acquired products to the US market, including AMDS and the JOTEC Products;
- Harness the JOTEC product pipeline and research and development capabilities;
- Obtain regulatory approvals in relevant markets, including our ability to timely obtain FDA PMA for PerClot as contemplated under the terms of the Baxter Transaction, to obtain Conformité Européene Mark ("CE Mark") product certification for pipeline products, and to obtain or maintain certification for pipeline and current products at all;
- 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 and stent graft products;
- 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 the 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 NEXUS, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for NEXUS; (d) meet quality and regulatory requirements; (e) manage any intellectual property risks and uncertainties associated with NEXUS; (f) obtain FDA approval of NEXUS; and (g) develop NEXUS product improvements to meet competitive threats and physician demand. As an example of this risk, the forecasted operating results related to NEXUS decreased in the fourth quarter of 2021, resulting in an impairment in the value of the Endospan Option, and a full write-down the value of the Endospan Loan, reflecting decreased expectations with respect to the anticipated benefits of the Endospan Transaction.

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.

We may not realize all the anticipated benefits of our corporate rebranding and it may result in unanticipated disruptions to our on-going business.

In order to reflect our evolution to focus on providing innovative technologies to surgeons who treat patients with aortic disease, we changed our name to Artivion, Inc., effective January 18, 2022 (the "Corporate Rebrand"). The Corporate Rebrand also involved the adoption of a new ticker symbol on the New York Stock Exchange, "AORT." We may face unanticipated disruptions to our business arising from the Corporate Rebrand, and it may expose us to additional risks, including:

- Disruptions to our day-to-day business operations including disruptions to our ability to receive or our customers' ability to make timely payments;
- Disruptions to access to certain markets or segments due to delays or other issues with regulatory approvals or updates arising from the Corporate Rebrand;
- Unanticipated delays or other impact on our pending regulatory applications or clinical trials arising from the Corporate Rebrand;
- Confusion within the marketplace, particularly with multiple points of contact in our downstream product flow involving purchasing and accounts payable departments and end users;
- Intellectual property risks associated with the adoption of a new corporate identity and trade dress; and
- Loss of goodwill associated with our legacy brands, including our CryoLife and JOTEC brands that will become less prominent over time.

The Corporate Rebrand involved significant financial and resource investment and will continue to do so as we complete our global brand transitions over the coming years. The anticipated benefits of the Corporate Rebrand may not be achieved within the anticipated timeframe, without additional near or long-term investment, or at all. Any of these factors could negatively impact our revenues, earnings per share, decrease or delay the expected accretive effect of the Corporate Rebrand, and negatively impact the price of our common stock.

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

We rely upon a combination of sophisticated 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, personal data, intellectual property, and, in some instances, patient data). Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, data loss, or malicious attacks resulting from inadvertent or intentional actions by our employees, vendors, or other third parties. In addition, due to the COVID-19 pandemic, we have implemented remote work arrangements for some employees, 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.

As an example of these risks, on November 1, 2019 we were notified that we had become a victim of a business e-mail compromise. During the fourth quarter of 2019, a company email account was compromised by a third-party impersonator and a payment intended for one of our US vendors in the amount of $2.6 million was fraudulently re-directed into an individual bank account controlled by this third-party impersonator. Our cyber-insurance covered all but $25,000 of the unrecovered losses from this compromise.

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. We have limited cyber-insurance coverage that may not cover all possible events, 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.

Industry 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 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 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, 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.

Further, on May 25, 2017 the European Union adopted a new Medical Device Regulation (MDR 2017/745) ("MDR"), which was fully implemented on May 26, 2021. The MDR 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 which 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 ("EEA") and other markets that require CE Marking. Additionally, to the extent the MDR places stricter requirements on manufacturers of custom-made devices, those new requirements could delay, impede, or otherwise impact the availability of our E-xtra Design Engineering products. Finally, COVID-19 has impacted the predictability and timelines associated with the MDR transition.

Since the implementation of the MDR, Notified Bodies must review any proposed changes to determine if they require evaluation under the MDR or if they can still be evaluated under currently held MDD certifications. Our inability to obtain certifications for changes under the transitional provisions of the MDR's Article 120 or successfully submit proposed changes requiring MDR evaluation will delay implementation of those changes which could adversely impact our ability to obtain or renew certifications, clearances, or approvals for our products.

Finally, we anticipate additional regulatory impact as a result of the United Kingdom's exit from the European Union ("Brexit"). The UK Medicines and Healthcare Products Regulatory Agency ("MHRA") has announced that CE Marking will continue to be recognized in the UK and certificates issued by EU-recognized Notified Bodies will continue to be valid in the UK market until June 30, 2023. Going forward, all devices marketed in the UK will require UK Conformity Assessed Marks certified by a UK Approved Body (the re-designation of the UK Notified Body).
In 2019, our notified body in the UK, 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 Regierungspraesidium-Tubingen, granted us an extended grace period until December 31, 2021 to transfer LRQA-issued certifications for BioGlue and PhotoFix to a new Notified Body. We are currently in the process of transferring BioGlue and PhotoFix to our new Notified Body, DEKRA. While positive progress has been made, DEKRA has been unable to complete the last audit, a Phase 2 onsite audit, for our registration due to COVID-19 restrictions on travel, staffing shortages, and workload related to the transition to the MDR. We currently have sufficient inventory on the market in the EU to cover customer demand for a period of the transition. We also are currently requesting derogations from certain individual European countries to allow us to continue to commercialize BioGlue in those countries until we can complete the certification process with DEKRA. Failure to obtain such derogations before our inventory is depleted, or any other delays in this transition, may have a material adverse effect on our ability to supply demand in affected 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.

In December 2019 we learned that the FDA is preparing 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 a comment period and subsequent publication of any final rule, should the CryoValve SGPV be determined to be MMM, we expect to have approximately thirty months to submit an FDA PMA application, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers during review of the PMA application. To date, the FDA has not issued such a proposed final rule.

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 depends 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.

We are currently seeking regulatory approval for BioGlue in China, where the Chinese regulatory body has made additional requests, and expressed several concerns, related to the application. If we cannot satisfy the regulator's requests and concerns and obtain approval or an extension in April 2022, the pending application will expire and no longer be eligible for allowance, requiring the Company to restart or decide to abandon the approval process.

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. Research and development efforts are time consuming and expensive, and we cannot be certain that these efforts will lead to commercially successful products or services. 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.

Regulatory enforcement activities regarding Ethylene Oxide, which is used to sterilize some of our products and components, could have a material, adverse impact on us.

Some of our products, including our 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 increased activism and lobbying as well as various regulatory enforcement activities against EtO facilities, including closures and temporary closures, as well as 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 could delay, impede, or prevent our ability to commercialize our products. In addition, any regulatory enforcement activities against us for our use of EtO could result in financial, legal, business, and reputational harm to us.

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.

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

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. Additional uncertainty is anticipated as debates about healthcare, vaccines, and public health continue in light of the COVID-19 pandemic which may have an impact on US law relating to the healthcare industry. Many US healthcare laws, such as the Affordable Care Act, are complex, subject to change, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. The application of these laws to us, our customers, or the specific services and relationships we have with our customers is not always clear. Our failure to anticipate accurately any changes to, or the repeal or invalidation of all or part of the Affordable Care Act and similar or future laws and regulations, or our failure to comply with them, could create liability for us, result in adverse publicity and negatively affect our business, results of operations, and financial condition. As an example, the Executive Branch of the US government recently issued three vaccine mandates that may cover all, or groups of, our US workforce. While the temporary mandate has been withdrawn by the executive branch because the US Supreme Court stayed it, the Executive Branch of the US government has indicated that it intends to issue a similar permanent mandate and it may issue other such mandates. We are currently evaluating the applicability of the remaining two mandates to us. In addition, states and local authorities have begun to issue various forms of vaccine mandates and other COVID-19 related restrictive measures, while others have issued bans of such measures. If we determine that any of these COVID-19 related restrictions apply to us or that they are in conflict with one another, attempted compliance with such laws could cause disruption to our business and in our workforce that could have an impact on our ability to attract or retain talent and increase our costs or could otherwise adversely affect our business and profitability.

Further, the growth of our business, results of operations and financial condition rely, in part, on customers in the healthcare industry that receive substantial revenues from governmental and other third-party payer programs. A reduction or less than expected increase in government funding for these programs or a change in reimbursement or allocation methodologies, or a change in reimbursement related to products designated as “breakthrough devices” by the FDA, could negatively affect our customers’ businesses and, in turn, negatively impact our business, results of operations and financial condition. Any changes that lower reimbursement for our products or reduce medical procedure volumes, could adversely affect our business and profitability.

Legal, Quality, and Regulatory Risks

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.

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, and other healthcare providers 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, complex, and subject to change and changing interpretations. 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 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.

The proliferation of new and expanded data privacy laws, including the General Data Protection Regulation in the European Union, could adversely affect our business.

An increasing number of federal, state, and foreign data privacy laws and regulations, which can be enforced by private parties or governmental entities, have been or are being promulgated and are constantly evolving. These laws and regulations may include new requirements for companies that receive or process an individual's personal data (including employees), which increases our operating costs and requires significant management time and energy. Many of these laws and regulations, including the European Union's General Data Protection Regulation ("GDPR") also include significant penalties for noncompliance. Although our personal data practices, policies, and procedures are intended to comply with GDPR and other data privacy laws and regulations, there can be no assurance that regulatory or enforcement authorities will view our arrangements as being in compliance with applicable laws, or that one or more of our employees or agents will not disregard the rules we have established. Any privacy related government enforcement activities may be costly, result in negative publicity, or subject us to significant penalties.

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.

Risks Relating to Our Indebtedness

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

The agreements 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 lenders, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lenders;
- Make changes to our and our subsidiaries' fiscal year without notice to the administrative agent under the agreement;
- 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 limit our ability to react to changes in the economy or our industry.

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 Related to Ownership of our Common Stock

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

In recent years, shareholder activists have become involved in numerous public companies. Shareholder activists from time to time propose to involve themselves in the governance, strategic direction, and operations of a company. Such involvement 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.

Our business could be impacted by increased shareholder emphasis on environmental, social, and governance matters.

Investors and other key stakeholders are increasingly focusing on areas of corporate responsibility, and particularly matters related to environmental, social, and governance ("ESG") factors. Institutional investors have expressed expectations with respect to ESG matters that they use to guide their investment strategies and may, in some cases, choose not to invest in us if they believe our ESG policies are lagging or inadequate. Other stakeholders also have expectations regarding ESG factors, such as employees or potential employees who desire to work for a company that reflects their personal values. These areas of focus are continuing to evolve, as are the criteria that investors assess companies' performance in these areas. Investors are increasingly looking to companies that demonstrate strong ESG and sustainability practices as an indicator of long-term resilience, especially in light of events such as the COVID-19 pandemic. Keeping up with and meeting these expectations may disrupt our business and divert the attention of our management, and we may be unable to make the investments in ESG that our competitors with greater financial resources are able to make. Failure to meet the expectations of investors and other stakeholders 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.

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 shareholders 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 shareholders, which could affect our share price adversely and prevent attempts by shareholders 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 shareholder meetings, allow the issuance of blank-check preferred stock without the vote of shareholders, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Delaware law and our articles of incorporation and bylaws could prevent attempts by shareholders 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 shareholders. The effects of reincorporation in Delaware are detailed in our 2021 Special Proxy Statement and Notice of Special Meeting filed with the SEC on October 7, 2021.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters and laboratory facilities 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 headquarters also includes a CardioGenesis cardiac laser therapy maintenance and evaluation laboratory space.

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 broadcasts from and to anywhere in the world. 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 80,000 square feet of leased manufacturing, administrative, laboratory, and warehouse space. In 2021 we opened an additional 76,000 square foot manufacturing, administrative, laboratory, and warehouse space.

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

We also lease a facility, which consists of 15,600 square feet of combined manufacturing and office space in Atlanta, Georgia, which we sublet to a third-party. This facility was sublet beginning in 2018.

We lease small amounts of ancillary additional office and warehouse space in various countries in which we operate direct sales subsidiaries, including in Brazil, Italy, Poland, Spain, Switzerland, and the United Kingdom.

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 matters that potentially could 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." Prior to January 24, 2022 our common stock was traded on the NYSE under the symbol "CRY." 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.

2021	High	Low
First quarter	$ 26.60	$ 21.65
Second quarter	32.34	21.86
Third quarter	29.13	22.16
Fourth quarter	23.20	16.95

2020	High	Low
First quarter	$ 31.77	$ 12.63
Second quarter	25.52	15.95
Third quarter	21.93	16.13
Fourth quarter	24.10	16.60

As of February 18, 2022 we had 210 shareholders of record.

Dividends

No dividends were paid in 2021, 2020, or 2019.

On December 1, 2017 we entered into a Credit and Guaranty Agreement (the "Credit Agreement"), among Artivion, as borrower, CryoLife International, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., AuraZyme Pharmaceuticals, Inc., as guarantor subsidiaries, the financial institutions party thereto from time to time as lenders, and Deutsche Bank AG New York Branch, as administrative agent and collateral agent. The Credit Agreement prohibits the payment of certain restricted payments, including cash dividends. See also Part II, Item 8, Note 11 of the "Notes to Consolidated Financial Statements" for further discussion of the Credit Agreement.

Issuer Purchases of Equity Securities

The following table provides information about purchases we made during the quarter ended December 31, 2021 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934.

Issuer Purchases of Equity Securities

Common Stock

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
10/01/21 - 10/31/21	--	$ --	--	$ --
11/01/21 - 11/30/21	422	21.21	--	--
12/01/21 - 12/31/21	423	18.37	--	--
Total	845	$ 19.79	--	$ --

The common shares purchased during the quarter ended December 31, 2021 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

Under our Credit Agreement, 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. Selected Financial Data.

On November 19, 2020 the SEC adopted certain amendments to Regulation S-K, which are intended to modernize, simplify, and enhance certain financial disclosure requirements. Among other topics of focus, the amendments eliminated the requirements of Item 301, Selected Financial Data, which required certain public companies to provide the last five years of selected financial data in tabular form. We have elected to comply with the provision of the amendment allowing certain registrants to stop providing selected financial data.

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 does not include certain items related to the year ended December 31, 2019, including year-to-year comparisons between the year ended December 31, 2020 and the year ended December 31, 2019. For a comparison of our results of operations for the fiscal years ended December 31, 2020 and December 31, 2019, 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, 2020, filed with the SEC on February 23, 2021.

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 stents and stent grafts, surgical sealants, On-X® mechanical heart valves and related surgical products, and implantable cardiac and vascular human tissues. Aortic stents and stent grafts include JOTEC® stent grafts and surgical products (collectively, "JOTEC Products"), the Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, and the NEXUS® endovascular stent graft system ("NEXUS"). Surgical sealants include BioGlue® Surgical Adhesive ("BioGlue") products. In addition to these four major product families, we sell or distribute PhotoFix® bovine surgical patches, CardioGenesis® cardiac laser therapy, Therion® chorioamniotic allografts (previously marketed as NeoPatch®), and PerClot® hemostatic powder (prior to the sale to a subsidiary of Baxter International, Inc ("Baxter")).

For the year ended December 31, 2021 we reported annual revenues of $298.8 million, increasing 18% over the prior year, largely due to increases in revenues from all products and preservation services. For the year ended December 31, 2021 we reported a net loss of $14.8 million. See the "Results of Operations" section below for additional analysis of the fourth quarter and full year 2021 results. See Part I, Item 1, "Business," for further discussion of our business and activities during 2021.

Sale of PerClot

On July 28, 2021 we entered into an asset purchase agreement and other ancillary agreements related to the sale of PerClot, a polysaccharide hemostatic agent used in surgery ("PerClot") to 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 $60.8 million in consideration (we will receive up to $45.8 million and SMI will receive up to $15.0 million), consisting of (i) $25.0 million at closing, of which $6.0 million was paid to SMI; (ii) up to $25.0 million upon our receipt of Premarket Approval ("PMA") approval from the US Food and Drug Administration (the "FDA") for PerClot and our transfer of the PMA to Baxter, of which up to $6.0 million is payable to SMI, subject to certain reductions for delay in PMA approval; 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 is payable to SMI. In addition, at the conclusion of our manufacturing and supply services for Baxter, Baxter will pay us $780,000 upon transfer of our PerClot manufacturing equipment. Under the terms of the Baxter Transaction, we will continue to provide to Baxter certain transition and manufacturing and supply services relating to the sale of SMI PerClot outside of the US and manufacture and supply of PerClot to Baxter post PMA approval.

Effects of COVID-19

In December 2019 an outbreak of a respiratory illness caused by a new coronavirus named "2019-nCoV" ("COVID-19") was detected, and by March 11, 2020, the World Health Organization ("WHO") declared the COVID-19 outbreak a "pandemic."

Beginning in March 2020 we took steps to address the potential impact of COVID-19 on our employees and operations, and to preserve cash, including reducing expenditures and delaying investments. These steps included, but were not limited to, implementing specific protocols to minimize workplace exposures to COVID-19 by our employees; implementing remote work arrangements for most employees we deemed able to do so; restricting business travel; implementing hiring restrictions; reducing planned expenditures on some pending clinical trials; imposing senior management cash salary reductions in exchange for cash payments in the second quarter of 2021; requiring our Board of Directors to accept Artivion stock instead of cash compensation for a six month period through October 2020; and suspending management merit increases for seven months in 2020.

Our efforts to protect our supply chain and reduce the spread of COVID-19 among our employees, including our work-from-home arrangements, were successful in 2020 and 2021 as we continued to operate all manufacturing sites at full production. These efforts have not materially affected our ability to maintain our business operations, including the operation of financial reporting systems, internal control over financial reporting, or disclosure controls and procedures; however, there is no guarantee that these efforts and arrangements, if they are continued, will continue to be successful in the future. Further, our reductions or delays in expenditures slowed our progress on certain key R&D initiatives and could in the future continue to adversely impact our business operations or further delay our recovery from the pandemic.

Although we have scaled back many of our COVID-19 mitigation efforts, we continue to monitor the impact of the COVID-19 pandemic and the emergence of new variants on our business and recognize that COVID-19 and its effects could continue to negatively impact our business and results of operations beyond 2021. As an example, the COVID-19 pandemic reportedly has impacted the global supply chain. Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur or worsen. As global economies continue to recover from the COVID-19 downturn, the expiration of COVID-19 related hiring freezes, increased opportunities for remote work, and increasing compensation pressure have resulted in a war for talent and an unprecedent number of retirements or career changes. The resulting worker shortages at all levels have impacted supply chains and distribution channels and employers' and our own ability to adequately staff operations. Impact from these shortages during 2021, including a shortage of trained staff capable of meeting the increased demand associated with releasing quarantined tissue, have impacted, and may impact our operations going forward. Hospitals and other healthcare providers have also experienced staffing shortages impacting our business including increased restrictions on elective and non-emergent procedures, restrictions on access to healthcare facilities, cancellation of elective procedures, and the re-allocation of scarce resources to some critically ill patients. Portions of our operations are being impacted by public and private vaccine mandates, which can impact hospital staffing, impact our specialized workforce, and impact the global supply chain, all of which can directly or indirectly impact our product sales, business operations, manufacturing operations, workforce, and research and development projects.

The extent to which our operations and financial performance will be impacted by the pandemic in and beyond 2022 will depend largely on future developments, including changes in hospital utilization rates and staffing, prevalence and severity of new variants, the impact of vaccine mandates or vaccine encouragement programs on the spread of COVID-19 and its variants, global availability and acceptance of vaccines and their effectiveness against variants, the prevalence of vaccine mandates generally, disruptions to workforce availability, and any continuing impact on the global supply chain. If COVID-19 or its variants become more contagious, if efforts to further contain the effects of COVID-19 or its variants, including vaccine mandates or adoption, are unsuccessful, if COVID-19, its variants, or disruptions to the global supply chain impact our supply chain or employee availability or productivity, or if we continue to experience periods of uncertainty due to COVID-19 or its variants, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

See the "Risk Factors" identified in Part I, Item 1A of this form 10-K for risks related to COVID-19.

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 market 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 market 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 experience and reevaluate 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 market 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 market 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.

We recorded write-downs to our deferred preservation costs totaling $575,000, $1.7 million, and $787,000 for the years ended December 31, 2021, 2020, and 2019, respectively, due primarily to tissues not expected to ship prior to the expiration date of the packaging. In addition, write-offs during the year ended December 31, 2020 included $826,000 of non-conforming tissues resulting from the contaminated saline solution. See "Results of Operations," for further discussion of contaminated saline solution.

Fair Value Measurements

We record certain financial instruments at fair value on a recurring basis, including cash equivalents, and certain restricted securities. 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 non-amortizing intangible assets for impairment, allocating value to assets in an acquired asset group and 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 valued 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 value of our financial instruments is appropriate, these fair values may not be indicative of net realizable value or reflective of future fair values.

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 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.

Valuation of Acquired Assets or Businesses

As part of our corporate strategy, we are seeking to identify and capitalize upon acquisition opportunities of complementary product lines and companies. We evaluate and account for acquired patents, licenses, distribution rights, and other tangible or intangible assets as the purchase of an asset or asset group, or as a business combination, as appropriate. The determination of whether the purchase of a group of assets should be accounted for as an asset group or as a business combination requires judgment based on the weight of available evidence.

For the purchase of an asset group, we allocate the cost of the asset group, including transaction costs, to the individual assets purchased based on their relative estimated fair values. In-process research and development acquired as part of an asset group is expensed upon acquisition. We account for business combinations using the acquisition method. Under this method, the allocation of the purchase price is based on the fair value of the tangible and identifiable intangible assets acquired and the liabilities assumed as of the date of the acquisition. The excess of the purchase price over the estimated fair value of the tangible net assets and identifiable intangible assets is recorded as goodwill. Transaction costs related to a business combination are expensed as incurred. In-process research and development acquired as part of a business combination is accounted for as

an indefinite-lived intangible asset until the related research and development project gains regulatory approval or is discontinued.

We typically engage external advisors to assist in determining the fair value of acquired asset groups or business combinations, using valuation methodologies such as: the excess earnings, the discounted cash flow, or the relief from royalty methods. The determination of fair value in accordance with the fair value measurement framework requires significant judgments and estimates, including, but not limited to: timing of product life cycles, estimates of future revenues, estimates of profitability for new or acquired products, cost estimates for new or changed manufacturing processes, estimates of the cost or timing of obtaining regulatory approvals, estimates of the success of competitive products, and discount rates. We, in consultation with our advisor(s), make these estimates based on our prior experiences and industry knowledge. We believe that our estimates are reasonable, but actual results could differ significantly from our estimates. A significant change in our estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by us and could, therefore, materially impact our financial position and profitability. If the value of the liabilities assumed by us, including contingent liabilities, is determined to be significantly different from the amounts previously recorded in purchase accounting, we may need to record additional expenses or write-downs in future periods, which could materially impact our financial position and profitability.

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, 2021 Compared to Year Ended December 31, 2020

(In thousands)

Revenues

	Revenues for the Twelve Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2021	2020	Percent Change	2021	2020
Products:					
Aortic stents and stent grafts	$ 85,387	$ 61,663	38%	28%	24%
Surgical sealants	70,714	62,068	14%	24%	25%
On-X	57,363	48,053	19%	19%	19%
Other	8,133	7,515	8%	3%	3%
Total products	221,597	179,299	24%	74%	71%
Preservation services	77,239	73,928	4%	26%	29%
Total	$ 298,836	$ 253,227	18%	100%	100%

Revenues increased 18% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. The increase in revenues for the twelve months ended December 31, 2021 was due to increases in revenues from all products and preservation services. On a constant currency basis, revenues increased 16% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. Revenues for the twelve months ended December 31, 2021 and 2020 were negatively impacted in certain regions by delays or cancellations of some surgical procedures as a result of reduced hospital capacity and staffing and hospital restrictions due to the COVID-19 pandemic. Additionally, reduced hospital staffing and restricted access resulting from COVID-19 have impacted the adoption rates for newly acquired or newly released products. The revenue impact from COVID-19 was smaller and varied regionally during the three and twelve months ended December 31, 2021 as compared to the three and twelve months ended December 31, 2020 with the largest negative impact during the three months ended June 30, 2020.

A detailed discussion of the changes in product revenues and preservation services revenues for the twelve months ended December 31, 2021 is presented below.

Products

Revenues from products increased 24% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. The increase in revenues for the twelve months ended December 31, 2021 was due to increases in revenues from all products. A discussion of the changes in product revenues for aortic stents and stent grafts, surgical sealants, On-X, 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, British Pounds, Polish Zlotys, Swiss Francs, Brazilian Reals, and Canadian Dollars, with a concentration denominated in Euros. Each currency is subject to exchange rate fluctuations. For the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020, 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 Stents and Stent Grafts

Aortic stents and stent grafts, including JOTEC, AMDS, and NEXUS products, are used in endovascular and open vascular surgery as well as for the treatment of complex aortic arch and thoracic aortic diseases. Our aortic stents and stent grafts are primarily distributed in international markets.

On September 11, 2019 Artivion and its wholly-owned subsidiary JOTEC entered into exclusive distribution and loan agreements with Endospan Ltd. (“Endospan”), an Israeli corporation, under which JOTEC obtained exclusive distribution rights for Endospan’s NEXUS products and accessories in certain countries in Europe.

On September 2, 2020 Artivion entered into an agreement to acquire all of the equity interests of Ascyrus Medical LLC (“Ascyrus”). Ascyrus developed the AMDS, an aortic arch remodeling device used for the treatment of acute Type A aortic dissections. The AMDS is currently distributed in Europe, the Middle East, and Africa (collectively, “EMEA”), Canada, Asia Pacific (“APAC”), and Latin America (“LATAM”), and is included as a component of aortic stents and stent grafts revenues from the date of the acquisition.

Aortic stents and stent grafts revenues increased 38% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020.

Aortic stents and stent grafts revenues, excluding OEM, increased 38% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. This increase was primarily due to an increase in volume of units sold, which increased revenues by 37%, and the effect of foreign exchange rates, which increased revenues by 4%, partially offset by a decrease in average sales prices of certain products in certain regions, which decreased revenues by 3%.

On a constant currency basis, revenues for aortic stents and stent grafts, excluding OEM, increased 33% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. The increase in revenues was partially due to improved conditions from the COVID-19 pandemic for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. Revenues for the twelve months ended December 31, 2021 increased primarily in EMEA. The revenue increase in EMEA during the twelve months ended December 31, 2021 is primarily due to an increase in sales of newly launched JOTEC Products. Revenues for the twelve months ended December 31, 2021 were also positively impacted by increased revenues from the AMDS as a result of the Ascyrus acquisition in the third quarter of 2020. Aortic stents and stent grafts OEM sales accounted for less than 1% of product revenues for the three and twelve months ended December 31, 2021 and 2020.

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 14% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. This increase was primarily due to an increase in the volume of milliliters sold, which increased revenues by 13%, and the effect of foreign exchange rates, which increased revenues by 1%.

On a constant currency basis, revenues from the sales of surgical sealants increased 13% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. The increase in revenues for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020 was primarily due to increases in North America, EMEA, and LATAM, partially offset by decreases in APAC. The revenue increase in these markets was primarily due to an increase of surgical procedures due to improved conditions related to the COVID-19 pandemic during the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. Revenue decreases for the twelve months ended December 31, 2021 in APAC was primarily due to changes in distributor buying patterns in this market.

See Part I Item 1A, “Risk Factors—Operational Risks— We may not be successful in obtaining necessary clinical results or regulatory clearances/approvals for new and existing products and services, and our approved products and services may not achieve market acceptance.”

Domestic BioGlue revenues accounted for 51% of total surgical sealant revenues for the twelve months ended December 31, 2021 and 50% of total BioGlue revenues for the twelve months ended December 31, 2020.

On-X

The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis (“AAP”) for heart valve replacement. On-X product revenues also 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 also generates revenue from pyrolytic carbon coating products produced for OEM customers.

On-X product revenues increased 19% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020.

On-X product revenues, excluding OEM, increased 20% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. This increase was primarily due to an increase in volume of units sold, which increased revenues by 23%, and the effect of foreign exchange rates which increased revenues by 1%, partially offset by a decrease in average sales prices, which decreased revenues by 4%.

On a constant currency basis, On-X revenues, excluding OEM, increased 19% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. The increase in revenues for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020 was primarily due to revenue increases in North America, APAC, and EMEA. The revenue increases in these markets were partially due to improved conditions from the COVID-19 pandemic for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. Revenues were also positively impacted in the North American market due to increases in market share, in EMEA due to an increase of shipments in direct and indirect markets, and in APAC due to growth in distributor markets. On-X OEM sales accounted for less than 1% of product revenues for the twelve months ended December 31, 2021 and 2020.

Domestic revenues from On-X accounted for 62% of total On-X revenues for the twelve months ended December 31, 2021, and 65% of On-X revenues for the twelve months ended December 31, 2020.

Other

Other revenues are comprised of PhotoFix, PerClot (prior to the Baxter Transaction), and CardioGenesis cardiac laser therapy product revenues. Other revenues increased 8% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020.

The increase in other revenues for the twelve months ended December 31, 2021 was primarily due to an increase in PhotoFix and, to a lesser extent CardioGenesis cardiac laser therapy product revenues, partially offset by a decrease in PerClot product revenues. The increase in PhotoFix revenues was primarily due to an increase in volume of units sold for the twelve months ended December 31, 2021. The increase in CardioGenesis cardiac therapy product revenues for the twelve months ended December 31, 2021 was primarily due to our ability to restart selling handpieces during the fourth quarter of 2021, as further described below. The decrease in PerClot product revenues for the twelve months ended December 31, 2021 was due to the Baxter Transaction, described above.

Revenues from our CardioGenesis cardiac laser therapy product line historically consisted primarily of sales of handpieces and, in certain periods, the sale of laser consoles. During the nine months ended September 30, 2021 and twelve months ended December 31, 2020 we had minimal revenues from the CardioGenesis cardiac laser therapy product line as we did not have a supply of handpieces due to the FDA's review of our supplier's change in manufacturing location. After obtaining approval, our supplier resumed manufacturing a limited supply of handpieces allowing us to resume limited sales during the fourth quarter of 2021.

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.

In the fourth quarter of 2020 we became aware that a supplier shipped to us a saline solution lot that we use in our tissue processing that contained some contamination in a small number of bottles of the solution lot. The contamination was identified by our in-process quality controls. The contaminated solution was estimated to have impacted a small percentage of tissue processed with this solution lot, causing us to write-off approximately $826,000 of tissue in the fourth quarter of 2020. An additional $5.0 million of tissue was quarantined in process pending further testing. Upon completion, and FDA acceptance of the testing, we began releasing tissue meeting our release criteria late in the second quarter of 2021.We believe that the written-off and quarantined tissue impacted the availability of tissue for distribution, which had a negative impact on revenue in the first quarter of 2021 and, to a lesser extent, the second quarter of 2021. Our ability to continue to release this quarantined and other tissue in the third quarter was negatively impacted by trained staffing availability.

Revenues from tissue processing increased 4% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020.

The increase in revenues for the twelve months ended December 31, 2021 was primarily due to a 5% and 3% increase in cardiac and vascular tissue revenues, respectively. The increase in cardiac tissue revenues was primarily due to an increase in cardiac tissue shipments, which increased revenues by 6%, partially offset by a decrease in average service fees, which decreased revenues by 1%. The increase in vascular tissue revenues was primarily due to an increase in vascular tissue shipments, which increased revenues by 4%, partially offset by a decrease in average service fees, which decreased revenues by 1%.

Cost of Products and Preservation Services

Cost of Products

	Twelve Months Ended December 31,	
	2021	2020
Cost of products	$ 65,196	$ 50,128

Cost of products increased 30% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. Cost of products for the twelve months ended December 31, 2021 and 2020 included costs related to aortic stents and stent grafts, surgical sealants, On-X, and other products.

The increase in cost of products for the twelve months ended December 31, 2021 was primarily due to an increase in shipments due to improved conditions from the COVID-19 pandemic, JOTEC product launches in late 2020, AMDS which was acquired in the third quarter of 2020, and write-downs of certain products, as compared to the twelve months ended December 31, 2020.

Cost of Preservation Services

	Twelve Months Ended December 31,	
	2021	2020
Cost of preservation services	$ 36,126	$ 35,315

Cost of preservation services increased 2% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The increase in cost of preservation services for the twelve months ended December 31, 2021 was primarily due to an increase in shipments due to improved conditions from the COVID-19 pandemic as compared to the twelve months ended December 31, 2020.

Gross Margin

	Twelve Months Ended December 31,	
	2021	2020
Gross margin	$ 197,514	$ 167,784
Gross margin as a percentage of total revenues	66%	66%

Gross margin increased 18% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. The increase for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020 was primarily due to favorable pricing of certain products and an increase in the volume of products sold. Gross margin as a percentage of total revenues remained flat for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020 primarily due to favorable gross margins of newly launched JOTEC Products and AMDS, mix of products sold, offset by write-downs of certain products.

Operating Expenses

General, Administrative, and Marketing Expenses

	Twelve Months Ended December 31,	
	2021	**2020**
General, administrative, and marketing expenses	$ 169,774	$ 141,136
General, administrative, and marketing expenses as a percentage of total revenues	57%	56%

General, administrative, and marketing expenses increased 20% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. The increase in General, administrative, and marketing expenses for the twelve months ended December 31, 2021 was primarily due to an increase in personnel, commission, amortization, and business development expenses.

General, administrative, and marketing expenses included $16.1 million of business development expenses for the twelve months ended December 31, 2021 as compared to $6.2 million for the twelve months ended December 31, 2020.

Business development expenses during the twelve months ended December 31, 2021 included $4.9 million related to the impairment of the Endospan Option and $9.7 million of fair value adjustments for the Ascyrus contingent consideration. Business development expenses during the twelve months ended December 31, 2020 primarily consisted of fair value adjustments for the Ascyrus contingent consideration.

Research and Development Expenses

	Twelve Months Ended December 31,	
	2021	**2020**
Research and development expenses	$ 35,546	$ 24,207
Research and development expenses as a percentage of total revenues	12%	10%

Research and development expenses increased 47% for the twelve months ended December 31, 2021 as compared to the twelve months ended December 31, 2020. Research and development spending for the twelve months ended December 31, 2021 was primarily focused on clinical work to gain regulatory approvals for On-X, JOTEC, and PerClot products. Research and development spending for the twelve months ended December 31, 2020 was primarily focused on clinical work to gain regulatory approval for On-X and JOTEC Products.

Gain from Sale of Non-Financial Assets

Gain from sale of non-financial assets for the twelve months ended December 31, 2021 consisted of the net $15.9 million gain from the sale of PerClot assets as part of the Baxter Transaction on July 28, 2021.

Interest Expense

Interest expense was $16.9 million and $16.7 million for the twelve months ended December 31, 2021 and 2020, respectively. Interest expense for the twelve months ended December 31, 2021 and 2020 relates to interest on debt and uncertain tax positions.

Other Expense (Income), Net

Other expense, net was $6.1 million and $3.1 million for the twelve months ended December 31, 2021 and 2020, respectively. Other expense, net for the twelve months ended December 31, 2021 primarily includes the realized and unrealized effects of foreign currency gains and losses. Other expense, net for the twelve months ended December 31, 2020 primarily includes realized and unrealized effects of foreign currency gains and losses and fair value adjustments of financial instruments.

Earnings

	Twelve Months Ended December 31,	
	2021	**2020**
Loss before income taxes	$ (14,827)	$ (17,174)
Income tax expense (benefit)	7	(492)
Net loss	$ (14,834)	$ (16,682)
Diluted loss per common share	$ (0.38)	$ (0.44)
Diluted weighted-average common shares outstanding	38,983	37,861

We incurred a loss before income taxes for the twelve months ended December 31, 2021 and 2020. The loss before income taxes for the twelve months ended December 31, 2021 was primarily due to business development, expenses primarily related to our financial instruments, investments in the research and development pipeline, and delays and cancellations of some surgical procedures as a result of reduced hospital capacity and hospital restrictions due to the COVID-19 pandemic.

Our effective income tax rate was break-even for the twelve months ended December 31, 2021 as compared to a benefit of 3% for the twelve months ended December 31, 2020. The change in the tax rate for the twelve months ended December 31, 2021 is primarily due to changes in pre-tax book loss, an increase in the excess tax benefit related to stock compensation, the estimated current year valuation allowance, and a reduction in the benefit related to uncertain tax position statute expirations for the twelve months ended December 31, 2021 as compared to twelve months ended December 31, 2020.

Our income tax rate for the twelve months ended December 31, 2021 was primarily impacted by excess tax benefits on stock compensation, the research and development tax credit, non-deductible executive compensation, changes in our valuation allowance against our net deferred tax assets, and changes in our uncertain tax position liabilities.

Our income tax rate for the twelve months ended December 31, 2020 was primarily impacted by changes in our valuation allowance against our net deferred tax assets and changes in our uncertain tax position liabilities.

In response to the COVID-19 pandemic, the US government enacted the Coronavirus Aid, Relief, and Economic Security Act, (“CARES Act”) on March 27, 2020. The CARES Act provided various forms of relief and assistance to U.S. businesses. We recorded a reduction to income taxes payable and deferred tax assets of approximately $1.3 million for the change to the 2019 Section 163(j) interest expense deduction limitation for the three months ended March 31, 2020. See Part II, Item 8, Note 9 of the “Notes to Consolidated Financial Statements” of this Form 10-K for further discussion of our interest expense deduction limitation and carryforward.

We experienced a net loss and diluted loss per common share for the twelve months ended December 31, 2021 and 2020. Net loss and diluted loss per common share for the twelve months ended December 31, 2021 was primarily due to an increase in loss before income taxes, as discussed above.

Seasonality

As a result of the uncertainty and other impacts of the COVID-19 pandemic and the resulting shifts of timing in some revenue, our historically observable seasonality of revenues has been impacted or obscured in 2020 and 2021 and potentially beyond.

Historically, we believe the demand for JOTEC Products is seasonal, with a decline in demand generally occurring in the third quarter due to the summer holiday season in Europe. We are uncertain whether the demand for AMDS and NEXUS products

is seasonal, as these products have not fully penetrated many markets and, therefore, the nature of any seasonal trends may not yet be obvious.

Historically, we believe the demand for BioGlue and On-X products 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 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

Net Working Capital

At December 31, 2021 net working capital (current assets of $247.7 million less current liabilities of $45.0 million) was $202.7 million, with a current ratio (current assets divided by current liabilities) of 6 to 1, compared to net working capital of $174.1 million and a current ratio of 4 to 1 at December 31, 2020.

Overall Liquidity and Capital Resources

Our primary cash requirements for the twelve months ended December 31, 2021 were for general working capital needs, capital expenditures for facilities and equipment, interest and principal payments under our Credit Agreement (defined below), interest payments under our Convertible Senior Notes (defined below), a milestone payment related to the Ascyrus acquisition, and repurchases of stock to cover tax withholdings. We funded our cash requirements through our existing cash reserves, proceeds from stock option exercises, and the Baxter Transaction described above.

We believe 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 future cash requirements are expected to include interest and principal payments under our Credit Agreement and Convertible Senior Notes (described in “Significant Sources and Uses of Liquidity” section below), expenditures for clinical trials, research and development expenditures, general working capital needs, capital expenditures, and other corporate purposes and may include cash to fund business development activities including obligations in the Endospan and Ascyrus agreements. These items may have a significant effect on our future cash flows during the next twelve months. Subject to the terms of our Credit Agreement, 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

On December 1, 2017 we entered into a credit and guaranty agreement for a $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility (the “Term Loan Facility”) and a $30.0 million secured revolving credit facility (“the Revolving Credit Facility” and, together with the Term Loan Facility, the “Credit Agreement”). We and each of our existing domestic subsidiaries (subject to certain exceptions and exclusions) guarantee the obligations under the Credit Agreement (the “Guarantors”). The Credit Agreement is 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.

In March 2020 partly as a precautionary measure to increase cash and maintain maximum financial flexibility during the uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million Revolving Credit Facility at an aggregate interest rate of 5.20%. On June 29, 2020 we used a portion of the net proceeds from the issuance of Convertible Senior Notes, as discussed below, to repay the $30.0 million outstanding under our Revolving Credit Facility.

On June 2, 2021 we entered into an amendment to our Credit Agreement to extend the maturity dates of both the Company's Term Loan and its Revolving Credit Facility. As part of the amendment, the maturity dates of both the Company's Term Loan and its 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 if our 4.25% Convertible Senior Notes, described below, remain outstanding on April 1, 2025 and December 31, 2024, respectively. With respect to the Term Loan, if the Convertible Senior Notes remain outstanding on April 1, 2025, the Term Loan's maturity date will be April 1, 2025, or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 91 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2027. In the case of the Revolving Credit Facility, if the Convertible Senior Notes are still outstanding on December 31, 2024, the Revolving Credit Facility's maturity date will be either December 31, 2024 or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 182 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2025. Under the amendment, the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.50%, or LIBOR, plus a margin of 3.50%. Prior to the amendment, the optional floating annual rate was equal to either the base rate plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%.

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 balance was $100.0 million recorded in Long-term debt on the Consolidated Balance Sheets as of December 31, 2021. 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. The fair value and the effective interest rate of the Convertible Senior Notes as of December 31, 2021 was approximately $116.0 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.

The interest expense recognized on the Convertible Senior Notes includes approximately $4.9 million for the aggregate of the contractual coupon interest, and the amortization of the debt issuance during the twelve months ended December 31, 2021. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually.

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 cannot redeem the Convertible Senior Notes before July 5, 2023. We can redeem them on or after July 5, 2023, 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 its other securities.

We have benefited from various aspects of the CARES Act including a decrease in the amount of interest expense limitation in 2020 and the deferment of a portion of the 2020 employer's portion of social security tax into 2021 and 2022.

As of December 31, 2021 approximately 36% of our cash and cash equivalents were held in foreign jurisdictions.

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

	Year Ended December 31,	
	2021	2020
Cash flows provided by (used in):		
Operating activities	$ (2,585)	$ 12,369
Investing activities	5,660	(73,128)
Financing activities	(12,223)	93,608
Effect of exchange rate changes on cash, cash equivalents, and restricted securities	2,200	(5,185)
(Decrease) increase in cash, cash equivalents, and restricted securities	$ (6,948)	$ 27,664

Net Cash Flows from Operating Activities

Net cash used in operating activities was $2.6 million for the twelve months ended December 31, 2021 as compared to net cash provided by operating activities of $12.4 million for the twelve months ended December 31, 2020.

We use the indirect method to prepare our cash flow statement, and accordingly, the operating cash flows are based on our net (loss) income, which is then adjusted to remove non-cash items, items classified as investing and financing cash flows, and for changes in operating assets and liabilities from the prior year end. For the twelve months ended December 31, 2021 these non-cash items included $24.0 million in depreciation and amortization expenses, $15.9 million of gain from the sale of non-financial assets, $10.7 million in non-cash compensation, $8.9 million in fair value adjustments of financial instruments, and $7.5 million in non-cash lease expense.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the twelve months ended December 31, 2021 these changes included unfavorable adjustments of $18.4 million due to an increase in inventory balances and deferred preservation costs, $11.6 million due to the timing differences between recording receivables and the receipt of cash, unfavorable effect of $1.9 million due to timing differences between the recording of accounts payable and other current liabilities, and $1.4 million due to an increase in prepaid expenses and other assets.

Net Cash Flows from Investing Activities

Net cash provided by investing activities was $5.7 million for the twelve months ended December 31, 2021 as compared to cash used in investing activities of $73.1 million for the twelve months ended December 31, 2020. During the twelve months ended December 31, 2021 cash flows provided by investing activities included $19.0 million of net proceeds from the sale of non-financial assets, partially offset by $13.1 million of cash used for capital expenditures. During the twelve months ended December 31, 2020 cash flows used in investing activities included $59.1 million of payments related to the Ascyrus Acquisition, net of cash acquired, $7.3 million in capital expenditures, and $5.0 million in cash payments related to the Endospan agreements.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $12.2 million for the twelve months ended December 31, 2021 as compared to net cash provided by financing activities of $93.6 million for the twelve months ended December 31, 2020. The current year cash used in financing activities was primarily due to $8.2 million related to the Ascyrus milestone payment, $3.1 million repayment of debt, $2.2 million payment of debt issuance costs, and $1.9 million for repurchases of common stock to cover tax withholdings, partially offset by $3.8 million of proceeds from exercise of stock options and issuances of common stock.

Net cash provided by financing activities was $93.6 million for the twelve months ended December 31, 2020. Cash provided by financing activities was primarily due to the $100.0 million cash proceeds from the issuance of the Convertible Senior Notes partially offset by $3.6 million of debt issuance costs associated with these Convertible Senior Notes. During the twelve months ended December 31, 2020, we borrowed and subsequently repaid $30.0 million from the Revolving Credit Facility.

Scheduled Contractual Obligations and Future Payments

Our long-term debt obligations and interest payments include $317.6 million of scheduled principal payments and $66.1 million in anticipated interest payments related to our Credit Agreement, Convertible Senior Notes, and JOTEC governmental loans.

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. We are obliged to make a $5.0 million third tranche payment under our loan agreement with Endospan upon receipt of certification that certain clinical trial milestones have been achieved. See “Overview” identified in Part II, Item 8, Note 3 of the “Notes to Consolidated Financial Statements” of this Form 10-K.

As part of the Baxter Transaction, we may be required to pay up to $9.0 million to SMI if certain milestones are met. See “Overview” identified in Part II, Item 8, Note 2 of the “Notes to Consolidated Financial Statements” of this Form 10-K.

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 equipment and other equipment.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2021 and 2020 were $13.1 million and $7.3 million, respectively. Capital expenditures in the twelve months ended December 31, 2021 were primarily related to leasehold improvements needed to support our business, routine purchases of manufacturing and tissue processing equipment, and computer software and equipment.

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

Interest Rate Risk

Our interest income and interest expense are sensitive to changes in the general level of US interest rates. In this regard, changes in US interest rates affect the interest earned on our cash and cash equivalents of $55.0 million as of December 31, 2021, and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility, Term Loan Facility, and Convertible Senior Notes. A 10% adverse change in interest rates as compared to the rates experienced by us in the twelve months ended December 31, 2021 affecting our cash and cash equivalents, Term Loan Facility, Revolving Credit Facility, and Convertible Senior Notes would not have had a material impact on our financial position, profitability, or cash flows.

Foreign Currency Exchange Rate Risk

We have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency denominated balances are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the US Dollar equivalent of cash or funds that we will receive in payment for assets or that we would have to pay to settle liabilities. As a result, we could be required to record these changes as gains or losses on foreign currency translation. Realized and unrealized gains and losses were a loss of $5.5 million, gain of $1.9 million, and a loss of $1.2 million, for the years ended December 31, 2021, 2020, and 2019, respectively. Losses incurred during 2021 were primarily related to cross currency intercompany receivables and payables resulting from large inventory transfers during 2021, impacted by fluctuations in the US dollar relative to other currencies.

We have revenues and expenses that are denominated in foreign currencies. Specifically, a portion of our international aortic stent and stent grafts, surgical sealants, On-X, and other product revenues are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, and Brazilian Reals and a portion of our General, administrative, and marketing expenses are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, Brazilian Reals, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the US Dollar equivalent of net income from transactions conducted in other currencies. As a result, we could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on December 31, 2021 affecting our balances denominated in foreign currencies could impact our financial position or cash flows by approximately $8.0 million. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by us for the twelve months ended December 31, 2021 affecting our revenue and expense transactions denominated in foreign currencies, would not have had a material impact on our financial position, profitability, or cash flows.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Management's Report on Internal Control over Financial Reporting

The management of Artivion, Inc. and subsidiaries ("Artivion" or "we") is responsible for establishing and maintaining adequate internal control 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 control over financial reporting as of December 31, 2021. 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, 2021, our internal control 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 control over financial reporting as of December 31, 2021.

Artivion, Inc.
February 22, 2022

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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with 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, 2021, 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 22, 2022 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, 2021, the Company's deferred preservation costs balance was $42.9 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 actual 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 methodology 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 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 capitalized 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 capitalized. 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 22, 2022

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, 2021, 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, 2021, 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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 22, 2022 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 Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP
Atlanta, Georgia
February 22, 2022

Artivion, Inc. and Subsidiaries
Consolidated Balance Sheets
In Thousands, Except Per Share Data

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,010	$ 61,412
Restricted securities	--	546
Trade receivables, net	53,019	45,964
Other receivables	5,086	2,788
Inventories, net	76,971	73,038
Deferred preservation costs, net	42,863	36,546
Prepaid expenses and other	14,748	14,295
Total current assets	**247,697**	**234,589**
Goodwill	250,000	260,061
Acquired technology, net	166,994	186,091
Operating lease right-of-use assets, net	45,714	18,571
Property and equipment, net	37,521	33,077
Other intangibles, net	34,502	40,966
Deferred income taxes	2,357	1,446
Other long-term assets	8,267	14,603
Total assets	**$ 793,052**	**$ 789,404**

Artivion, Inc. and Subsidiaries
Consolidated Balance Sheets
In Thousands, Except Per Share Data

	December 31, 2021	December 31, 2020
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,395	$ 9,623
Accrued expenses	7,687	7,472
Accrued compensation	13,163	10,192
Taxes payable	3,634	2,808
Accrued procurement fees	3,689	3,619
Current portion of finance lease obligation	528	614
Current maturities of operating leases	3,149	5,763
Current portion of long-term debt	1,630	1,195
Current portion of contingent consideration	--	16,430
Other	1,078	2,752
Total current liabilities	**44,953**	**60,468**
Long-term debt	307,493	290,468
Contingent consideration	49,400	43,500
Non-current maturities of operating leases	44,869	14,034
Non-current finance lease obligations	4,374	5,300
Deferred income taxes	28,799	34,713
Deferred compensation liability	5,952	5,518
Other	6,484	6,690
Total liabilities	**492,324**	**460,691**
Commitments and contingencies		
Shareholders' equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued	--	--
Common stock $0.01 par value per share, 75,000 shares authorized, 41,397 and 40,394 shares issued as of December 31, 2021 and 2020, respectively	414	404
Additional paid-in capital	322,874	316,192
Retained earnings	1,975	20,022
Accumulated other comprehensive (loss) income	(9,887)	6,743
Treasury stock at cost, 1,487 shares as of December 31, 2021 and 2020	(14,648)	(14,648)
Total shareholders' equity	**300,728**	**328,713**
Total liabilities and shareholders' equity	**$ 793,052**	**$ 789,404**

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,		
	2021	**2020**	**2019**
Revenues:			
Products	$ 221,597	$ 179,299	$ 197,246
Preservation services	77,239	73,928	78,976
Total revenues	**298,836**	**253,227**	**276,222**
Cost of products and preservation services:			
Products	65,196	50,128	55,022
Preservation services	36,126	35,315	38,187
Total cost of products and preservation services	**101,322**	**85,443**	**93,209**
Gross margin	**197,514**	**167,784**	**183,013**
Operating expenses:			
General, administrative, and marketing	169,774	141,136	143,011
Research and development	35,546	24,207	22,960
Total operating expenses	**205,320**	**165,343**	**165,971**
Gain from sale of non-financial assets	(15,923)	--	--
Operating income	**8,117**	**2,441**	**17,042**
Interest expense	16,887	16,698	14,886
Interest income	(79)	(217)	(738)
Other expense, net	6,136	3,134	1,250
(Loss) income before income taxes	**(14,827)**	**(17,174)**	**1,644**
Income tax expense (benefit)	7	(492)	(76)
Net (loss) income	$ **(14,834)**	$ **(16,682)**	$ **1,720**
(Loss) income per share:			
Basic	$ **(0.38)**	$ **(0.44)**	$ **0.05**
Diluted	$ **(0.38)**	$ **(0.44)**	$ **0.05**
Weighted-average common shares outstanding:			
Basic	38,983	37,861	37,118
Diluted	38,983	37,861	37,860
Net (loss) income	$ **(14,834)**	$ **(16,682)**	$ **1,720**
Other Comprehensive loss:			
Foreign currency translation adjustments	(16,630)	15,332	(2,517)
Comprehensive loss	$ **(31,464)**	$ **(1,350)**	$ **(797)**

See accompanying Notes to Consolidated Financial Statements.

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Net cash flows from operating activities:			
Net (loss) income	$ (14,834)	$ (16,682)	$ 1,720
Adjustments to reconcile net (loss) income to net cash from operating activities:			
Depreciation and amortization	23,977	20,712	18,317
Non-cash compensation	10,711	6,912	8,799
Change in fair value of contingent consideration	8,870	4,523	--
Non-cash lease expense	7,521	7,145	5,009
Write-down of inventories and deferred preservation costs	5,377	3,443	1,488
Write-off of Endospan Option	4,944	--	--
Non-cash interest expense	2,005	3,656	1,631
Change in fair value of long-term loan receivable	409	4,949	--
Deferred income taxes	(4,470)	4,283	(2,305)
Gain on sale of non-financial assets	(15,923)	--	--
Other	2,060	124	551
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(1,404)	(2,720)	(6,177)
Accounts payable, accrued expenses, and other liabilities	(1,893)	(9,157)	251
Receivables	(11,560)	9,938	(5,332)
Inventories and deferred preservation costs	(18,375)	(24,757)	(8,125)
Net cash flows (used in) provided by operating activities	**(2,585)**	**12,369**	**15,827**
Net cash flows from investing activities:			
Proceeds from sale of non-financial assets, net	19,000	--	--
Ascyrus Acquisition, net of cash acquired	--	(59,119)	--
Payments for Endospan agreement	--	(5,000)	(15,000)
Capital expenditures	(13,091)	(7,328)	(8,072)
Other	(249)	(1,681)	(871)
Net cash flows provided by (used in) investing activities	**5,660**	**(73,128)**	**(23,943)**
Net cash flows from financing activities:			
Proceeds from exercise of stock options and issuance of common stock	3,756	2,432	4,758
Proceeds from issuance of convertible debt	--	100,000	--
Proceeds from revolving line of credit	--	30,000	--
Proceeds from financing insurance premiums	--	2,815	--
Repayment of revolving line of credit	--	(30,000)	--
Redemption and repurchase of stock to cover tax withholdings	(1,914)	(1,995)	(2,743)
Payment of debt issuance costs	(2,219)	(3,647)	--
Repayment of debt	(3,085)	(5,346)	(2,780)
Payment of contingent consideration	(8,200)	--	--
Other	(561)	(651)	(728)
Net cash flows (used in) provided by financing activities	**(12,223)**	**93,608**	**(1,493)**
Effect of exchange rate changes on cash, cash equivalents, and restricted securities	2,200	(5,185)	1,667
(Decrease) increase in cash, cash equivalents, and restricted securities	**(6,948)**	**27,664**	**(7,942)**
Cash, cash equivalents, and restricted securities, beginning of year	61,958	34,294	42,236
Cash, cash equivalents, and restricted securities, end of year	**$ 55,010**	**$ 61,958**	**$ 34,294**

See accompanying Notes to Consolidated Financial Statements.

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

	Common Stock		Additional Paid In Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2018	**38,463**	**$ 385**	**$ 260,361**	**$ 34,984**	**$ (6,072)**	**(1,484)**	**$ (14,591)**	**$ 275,067**
Net income	--	--	--	1,720	--	--	--	1,720
Other comprehensive loss	--	--	--	--	(2,517)	--	--	(2,517)
Equity compensation	254	2	9,409	--	--	--	--	9,411
Exercise of options	334	3	3,292	--	--	--	--	3,295
Employee stock purchase plan	61	1	1,462	--	--	--	--	1,463
Redemption and repurchase of stock to cover tax withholdings	(94)	(1)	(2,742)	--	--	--	--	(2,743)
Balance at December 31, 2019	**39,018**	**$ 390**	**$ 271,782**	**$ 36,704**	**$ (8,589)**	**(1,484)**	**$ (14,591)**	**$ 285,696**
Net loss	--	--	--	(16,682)	--	--	--	(16,682)
Other comprehensive income	--	--	--	--	15,332	--	--	15,332
Stock issued for the Ascyrus Acquisition	992	10	19,990	--	--	--	--	20,000
Equity component of the convertible note issuance	--	--	16,426	--	--	--	--	16,426
Equity compensation	296	3	7,501	--	--	--	--	7,504
Exercise of options	89	1	927	--	--	(3)	(57)	871
Employee stock purchase plan	83	1	1,560	--	--	--	--	1,561
Redemption and repurchase of stock to cover tax withholdings	(84)	(1)	(1,994)	--	--	--	--	(1,995)
Balance at December 31, 2020	**40,394**	**$ 404**	**$ 316,192**	**$ 20,022**	**$ 6,743**	**(1,487)**	**$ (14,648)**	**$ 328,713**
Net loss	--	--	--	(14,834)	--	--	--	(14,834)
Other comprehensive loss	--	--	--	--	(16,630)	--	--	(16,630)
Stock issued for contingent consideration	553	6	9,994	--	--	--	--	10,000
Adoption of ASU 2020-06	--	--	(16,426)	(3,213)	--	--	--	(19,639)
Equity compensation	260	3	11,274	--	--	--	--	11,277
Exercise of options	179	1	2,145	--	--	--	--	2,146
Employee stock purchase plan	87	1	1,608	--	--	--	--	1,609
Redemption and repurchase of stock to cover tax withholdings	(76)	(1)	(1,913)	--	--	--	--	(1,914)
Balance at December 31, 2021	**41,397**	**$ 414**	**$ 322,874**	**$ 1,975**	**$ (9,887)**	**(1,487)**	**$ (14,648)**	**$ 300,728**

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 stents and stent grafts, surgical sealants, On-X® mechanical heart valves and related surgical products, and implantable cardiac and vascular human tissues. Aortic stents and stent grafts include JOTEC® stent grafts and surgical products (collectively, "JOTEC Products"), the Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, and the NEXUS® endovascular stent graft system ("NEXUS"). Surgical sealants include BioGlue® Surgical Adhesive ("BioGlue") products. In addition to these four major product families, we sell or distribute PhotoFix® bovine surgical patches, CardioGenesis® cardiac laser therapy, Therion® chorioamniotic allografts (previously marketed as NeoPatch®), and PerClot® hemostatic powder (prior to the sale to a subsidiary of Baxter International, Inc ("Baxter")).

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 Currencies

Our revenues and expenses transacted in foreign currencies are remeasured as they occur at exchange rates in effect at the time of each transaction. Realized and unrealized gains and losses on foreign currency transactions are recorded as a component of Other expense, net on our Consolidated Statements of Operations and Comprehensive Loss. Realized and unrealized gains and losses were a loss of $5.5 million, a gain of $1.8 million, and a loss of $1.2 million for the years ended December 31, 2021, 2020, and 2019, respectively. Our assets and liabilities denominated in foreign currencies are recognized at the exchange rate in effect at the time of each transaction. At period end, the assets and liabilities are translated at the exchange rate in effect as of the balance sheet date and are recorded as a separate component of accumulated other comprehensive loss in the shareholders' equity section of our Consolidated Balance Sheets.

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 allowance for doubtful accounts, inventory, deferred preservation costs, acquired assets or businesses, intangible assets, deferred income taxes, commitments and contingencies (including product and tissue processing liability claims, claims incurred but not reported, and amounts recoverable from insurance companies), stock based compensation, certain accrued liabilities (including accrued procurement fees, income taxes, and financial instruments), 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, except in rare credit related circumstances. We do not have any material performance obligations where we are acting as an agent for another entity.

Revenues for products, including: aortic stents and 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 the medical device is implanted. We recognize revenues for preservation services when tissue is shipped to the customer.

Warranty

Our general product warranties do not extend beyond an assurance that the products or services delivered will be consistent with stated specifications and do not include separate performance obligations. Warranties included with our CardioGenesis cardiac laser products provide for annual maintenance services, which are priced separately and are recognized as revenues at the stand-alone price over the service period, whether invoiced separately or recognized based on our allocation of the transaction price.

Significant Judgments in the Application of the Guidance in ASC 606

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, other than as identified for E-xtra Design Engineering products, therefore, the value of unsatisfied performance obligations at the end of any reporting period is immaterial.

For performance obligations provided through our E-xtra Design Engineering product line, we determine the value of our enforceable right to payment based on the time required and costs incurred for design services and manufacture of the in-process device in relation to the total inputs required to complete the device.

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 from the sale of products and services 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 product and service revenues and cost of sales and are accrued in current liabilities until remitted to governmental authorities.

Advertising Costs

The costs to develop, produce, and communicate our advertising are expensed as incurred and are classified as General, administrative, and marketing expenses. The total amount of advertising expense included in our Consolidated Statements of Operations and Comprehensive Loss was $1.0 million, $1.1 million, and $1.7 million for the years ended December 31, 2021, 2020, and 2019, 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 shareholder 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 granted by us typically vest over a one to three-year period. The stock options granted by us 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 forfeited.

Income Per Common Share

Income 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, restricted securities, accounts receivable, notes receivable, accounts payable, and debt obligations. The financial assets' and liabilities' such as receivables, and accounts payable carrying values approximate their fair value due to their short-term duration, and the carrying value of their debt obligations approximate 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 at fair value on a recurring basis, including cash equivalents and certain restricted securities. 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 non-amortizing 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 labilities 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 on 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 net realizable value or reflective of future fair values.

Cash and Cash Equivalents

Cash and cash equivalents consist primarily of highly liquid investments with maturity dates of three months or less 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.

Cash Flow Supplemental Disclosures

Supplemental disclosures of cash flow information for the years ended December 31 (in thousands):

	2021	2020	2019
Cash paid during the year for:			
Interest	$ 14,407	$ 13,049	$ 13,297
Income taxes	5,483	4,122	1,944
Non-cash investing and financing activities:			
Issuance of common stock for Ascyrus Acquisition	$ --	$ 20,000	$ --
Issuance of common stock for contingent consideration	10,000	--	--
Operating lease right of use assets	31,726	1,864	2,604

Accounts Receivable and Allowance for Doubtful Accounts

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 doubtful accounts based upon specific reserves for known collection issues, as well as a non-specific reserve based upon aging buckets. 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 allowance for doubtful accounts of $1.1 million and $973,000 as of December 31, 2021 and 2020, respectively.

Inventories, net

Inventories, net are comprised of finished goods for our product lines including: aortic stents and stent grafts; surgical sealants; On-X products; CardioGenesis laser consoles, handpieces, and accessories; PerClot before the Baxter Transaction defined below; PhotoFix; other medical devices; work-in-process; and raw materials. Inventories for finished goods are valued at the lower of cost or market on a first-in, first-out basis and raw materials are valued on a moving average cost basis. Typically, upon shipment or upon 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 market 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 market 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 market value write-downs are recorded if the book value exceeds the estimated net realizable value of the inventory, 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 inventory 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.

We recorded write-downs to our inventory totaling $4.8 million, $1.7 million, and $601,000 for the years ended December 31, 2021, 2020, and 2019, respectively. The 2021 write-down was primarily related to JOTEC inventory and On-X ascending aortic prosthesis ("AAP") inventory. The 2020 write-down was primarily related to JOTEC inventory, On-X AAP inventory, and BioGlue inventory not expected to ship prior to the expiration date. The 2019 write-down was primarily related to PerClot inventory not expected to ship prior to the expiration date.

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 market 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 market 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 experience and reevaluate 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 market 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 market 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.

We recorded write-downs to our deferred preservation costs totaling $575,000, $1.7 million, and $787,000 for the years ended December 31, 2021, 2020, and 2019, respectively, due primarily to tissues not expected to ship prior to the expiration date of the packaging. In addition, write-offs during the year ended December 31, 2020 included $826,000 of non-conforming tissues resulting from contaminated saline solution.

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 amortized 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 balance for the years ended December 31 is as follows (in thousands):

	2021	2020
Equipment and software	$ 73,820	$ 66,141
Furniture and fixtures	6,668	6,186
Leasehold improvements	39,175	38,256
Total property and equipment	119,663	110,583
Less accumulated depreciation and amortization	82,142	77,506
Property and equipment, net	$ 37,521	$ 33,077

Depreciation expense for the years ended December 31 is as follows (in thousands):

	2021	2020	2019
Depreciation expense	$ 7,157	$ 6,948	$ 7,467

Goodwill and Other Intangible Assets

Our intangible assets consist of goodwill, acquired technology, customer lists and relationships, patents, trademarks, and other intangible assets, as discussed in Note 8. 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. Upon divestiture of a component of our business, the goodwill related to the reporting unit is allocated to the divested business using the relative fair value allocation method.

We evaluate our goodwill and other non-amortizing 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, 2021 and 2020, our non-amortizing intangible assets consisted of goodwill, in-process research and development, acquired procurement contracts and agreements, and trademarks. We performed a qualitative analysis of our non-amortizing intangible assets as of October 31, 2021 and 2020 and determined that the fair value of the assets and the fair value of the reporting unit more likely than not exceeded their associated carrying values and were, therefore, not impaired.

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 in "Impairments of Long-Lived Assets and Non-Amortizing Intangible Assets" below.

Impairments of Long-Lived Assets and Non-Amortizing Intangible Assets

Long-Lived 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. For the years ended December 31, 2021, 2020, and 2019 we did not record an impairment of our long-lived assets as there were no indicators of impairment or the sum of the undiscounted future cash flows exceeded the carrying value of the long-lived asset (asset group).

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 Company vehicles; and leases on a variety of office and other equipment, as discussed in Note 10. 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 Issuance Costs

Debt issuance costs related to our term loan and line of credit are capitalized and reported net of the current and long-term debt or as a prepaid asset when there are no outstanding borrowings. If there are unamortized debt issuance costs related to our line of credit but only borrowings on the term loan, these debt issuance costs will be combined with the debt issuance costs related to the term loan and reported net of the current and long-term debt for the term loan. We amortize debt issuance costs to interest expense on our term loan using the effective interest method over the life of the debt agreement. We amortize debt issuance costs to interest expense on our line of credit on a straight-line basis over the life of the debt agreement. Debt issuance costs related to our convertible debt agreement are amortized using the effective interest rate method as a direct deduction from the recorded debt issuance costs allocated to debt.

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 engage external advisors to assist us in estimating our liability and any related amount recoverable under our insurance policies as of each balance sheet date. We use a frequency-severity approach to estimate our unreported product and tissue processing liability claims, whereby projected losses are calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims are determined based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of our historical claim experience and industry data. The estimated cost per claim is calculated using a lognormal claims model blending our historical average cost per claim with industry claims data. We use a number of assumptions in order to estimate the unreported loss liability including: the future claim reporting time lag, the frequency of reported claims, the average cost per claim, and the maximum liability per claim. We believe that the assumptions we use provide a reasonable basis for our calculation. However, the accuracy of the estimates is limited by various factors, including, but not limited to, our specific conditions, uncertainties surrounding the assumptions used, and the scarcity of industry data directly relevant to our business activities. Due to these factors, actual results may differ significantly from our assumptions and from the amounts accrued.

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 on 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 on our Consolidated Statements of Operations and Comprehensive Loss. See Note 9 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.

Valuation of Acquired Assets or Businesses

As part of our corporate strategy, we are seeking to identify and capitalize upon acquisition opportunities of complementary product lines and companies. We evaluate and account for acquired patents, licenses, distribution rights, and other tangible or intangible assets as the purchase of an asset or asset group, or as a business combination, as appropriate. The determination of whether the purchase of a group of assets should be accounted for as an asset group or as a business combination requires judgment based on the weight of available evidence.

For the purchase of an asset group, we allocate the cost of the asset group, including transaction costs, to the individual assets purchased based on their relative estimated fair values. In-process research and development acquired as part of an asset group is expensed upon acquisition.

We account for business combinations using the acquisition method. Under this method, the allocation of the purchase price is based on the fair value of the tangible and identifiable intangible assets acquired and the liabilities assumed as of the date of the acquisition. The excess of the purchase price over the estimated fair value of the tangible net assets and identifiable intangible assets is recorded as goodwill. The identifiable intangible assets typically consist of developed technology, trade names, customer relationships, and in-process research and development costs. Transaction costs related to business combinations are expensed as incurred. In-process research and development acquired as part of a business combination is accounted for as an indefinite-lived intangible asset until the related research and development project gains regulatory approval or is discontinued.

We typically engage external advisors to assist us in determining the fair value of acquired asset groups or business combinations, using valuation methodologies such as: the excess earnings, the discounted cash flow, Monte Carlo, or the relief from royalty methods. The determination of fair value in accordance with the fair value measurement framework requires significant judgments and estimates, including, but not limited to: timing of product life cycles, estimates of future revenues, estimates of profitability for new or acquired products, cost estimates for new or changed manufacturing processes, estimates of the cost or timing of obtaining regulatory approvals, estimates of the success of competitive products, and discount rates and represent Level 3 measurements. We, in consultation with our advisors, make these estimates based on our prior experiences and industry knowledge. We believe that our estimates are reasonable, but actual results could differ significantly from our estimates. A significant change in our estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by us and, therefore, could materially impact our financial position and profitability. If the value of the liabilities assumed by us, including contingent liabilities, is determined to be significantly different from the amounts previously recorded in purchase accounting, we may need to record additional expenses or write-downs in future periods, which could materially impact our financial position and profitability.

New Accounting Pronouncements

Recently Adopted

In August 2020 the Financial Accounting Standards Board (the "FASB") issued Accounting Standard Update ("ASU") Update No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). The update simplifies the accounting for convertible instruments by eliminating two accounting models (i.e., the cash conversion model and beneficial conversion feature model) and reducing the number of embedded conversion features that could be recognized separately from the host contract. ASU 2020-06 also enhances transparency and improves disclosures for convertible instruments and earnings per share guidance. On January 1, 2021 we adopted ASU 2020-06 using the modified retrospective approach and recorded $20.4 million to increase long-term debt, $3.2 million to reduce retained earnings, and $16.4 million to reduce additional paid-in capital included on the Consolidated Balance Sheets. See Note 11 for further discussion of convertible debt.

In December 2019 the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). The amendments in this ASU simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify accounting principles generally accepted in the United States of America ("GAAP") for other areas of Topic 740 by clarifying and amending existing guidance. The amendments are effective for public entities in fiscal years beginning after December 15, 2020 including interim periods within those fiscal years. We adopted ASU 2019-12 on January 1, 2021 and the adoption did not have a material impact on our financial condition or results of operations.

As of January 1, 2020 we adopted the Accounting Standards Codification ("ASC") No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The purpose of Update No. 2016-13 is to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. Update No. 2016-13 is effective for annual periods beginning after December 15, 2019. The adoption of ASU 2016-13 did not result in a material effect on the Company's financial condition, results of operations, or cash flows.

As of January 1, 2019 we adopted the ASC Topic 842, *Leases* ("ASC 842"). The final guidance requires lessees to recognize a right-of-use asset and a lease liability for all leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to former Topic 840, *Leases*. We used the modified retrospective approach, which allows application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented. The adoption of this standard resulted in the recognition of operating lease agreements with a net present value of $22.7 million and corresponding right-of-use assets obtained in the same amount at January 1, 2019. See Note 9 for further discussion of leases.

Not Yet Effective

In March 2020 the FASB issued ASU 2020-04, *Reference Rate Reform Topic 848* ("ASC 848"). The amendments in this ASU were put forth in response to the market transition from the LIBOR and other interbank offered rates to alternative reference rates. GAAP requires entities to evaluate whether a contract modification, such as the replacement or change of a reference rate, results in the establishment of a new contract or continuation of an existing contract. ASC 848 allows an entity to elect not to apply certain modification accounting requirements to contracts affected by reference rate reform. The standard provides this temporary election through December 31, 2022 and cannot be applied to contract modifications that occur after December 31, 2022. In January 2021 the FASB issued ASU 2021-01, *Reference Rate Reform (Topic 848)*. The objective of the new reference rate reform standard is to clarify the scope of Topic 848 and provide explicit guidance to help companies applying optional expedients and exceptions. This ASU is effective immediately for all entities that have applied optional expedients and exceptions. We are in the process of evaluating the effect that the adoption of this standard will have on our financial position and results of operations.

2. Sale of PerClot

Overview

On July 28, 2021 we entered into an asset purchase agreement and other ancillary agreements related to the sale of PerClot to 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 $60.8 million in consideration (we will receive up to $45.8 million and SMI will receive up to $15.0 million), consisting of (i) $25.0 million at closing, of which $6.0 million was paid to SMI; (ii) up to $25.0 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 up to $6.0 million is payable to SMI, subject to certain reductions for delay in PMA approval; 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 is payable to SMI. In addition, at the conclusion of our manufacturing and supply services for Baxter, Baxter will pay $780,000 upon transfer of our PerClot manufacturing equipment. Under the terms of the Baxter Transaction, we will continue to provide to Baxter certain transition and manufacturing and supply services relating to the sale of SMI PerClot outside of the US and manufacture and supply of PerClot to Baxter post PMA approval.

Accounting for the Transaction

Upon closing of the Baxter Transaction, we received $25.0 million from Baxter and paid $6.0 million to SMI. We derecognized intangible assets with a carrying value of $1.6 million and wrote-off $1.5 million of prepaid royalties previously recorded on our Consolidated Balance Sheets related to PerClot. Under the terms of the agreement, Baxter acquired intellectual property related to our development efforts for PerClot. We recorded a pre-tax gain of $15.9 million, included as Gain from sale of non-financial assets within the Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2021. The PerClot product line was included as part of our Medical Devices segment.

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

Upon closing of the acquisition on September 2, 2020 we paid $82.4 million consisting of $62.4 million in cash consideration and $20.0 million in shares of Artivion common stock. The number of shares issued was based on a 10-day moving volume weighted average closing price of a share of Artivion common stock as of the date immediately prior to closing, resulting in an issuance of 991,800 shares of Artivion common stock.

As part of the acquisition, we may be required to pay additional consideration in cash and equity up to $120.0 million to the former shareholders of Ascyrus upon the achievement of certain milestones and the sales-based additional earnout described above. As of September 2, 2020 the fair value of the total potential purchase consideration of $200.0 million was calculated to be $137.8 million, which includes 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 9% and estimated future achievement of milestone dates between 2025 and 2026 to calculate the fair value of contingent consideration as of December 31, 2021. We will remeasure this liability at each reporting date and will record changes in the fair value of the contingent consideration in General, administrative, and marketing expenses on 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 passage of time, discount rates, the timing and amount of our revenue estimates, and the timing and expectation of regulatory approvals.

We performed an assessment of the fair value of the contingent consideration and recorded $9.5 million and $4.5 million in fair value adjustments for the year ended December 31, 2021 and 2020, respectively, in General, administrative, and marketing expenses on the Consolidated Statements of Operations and Comprehensive Loss, as a result of this assessment.

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. We recorded the contingent consideration liability of $49.4 million in Other long-term liabilities as of December 31, 2021 and $16.4 million and $43.5 million in Current liabilities and Other long-term liabilities, respectively, as of December 31, 2020 in the Consolidated Balance Sheets.

We recorded $62.4 million of goodwill, all of which was deductible for tax purposes, based on the amount by which the total purchase consideration price exceeded the fair value of the net assets acquired and liabilities assumed. Goodwill from this transaction primarily relates to synergies expected from the acquisition and has been allocated to our Medical devices reporting unit. The allocation of assets acquired and liabilities assumed is based on the information available that would have been known as of the acquisition date.

The September 2, 2020 final allocation of purchase price consideration consisted of the following (in thousands):

Consideration		
Cash paid for acquisition	$	62,359
Common stock issued		20,000
Contingent consideration		55,407
Fair value of total consideration	**$**	**137,766**
Purchase Price Allocation		
Cash and cash equivalents	$	4,017
Intangible assets		72,600
Net other assets/liabilities acquired		(1,267)
Goodwill		62,416
Net assets acquired	**$**	**137,766**

Pro forma financial information related to the Ascyrus Agreement has not been provided as it is not material to our consolidated results of operations. The results of operations of the Ascyrus acquisition are included in results of operations from the date of acquisition and were not significant for the years ended December 31, 2021 and 2020. The results of operations of the Ascyrus acquisition are included in our Medical devices reportable segment.

4. Agreements with Endospan

Exclusive Distribution Agreement and Securities Purchase Option Agreement

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 and accessories in certain countries in Europe in exchange for a fixed distribution fee of $9.0 million paid in September 2019.

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 provides 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 or 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.

Loan Agreement

Artivion and Endospan also entered into a loan agreement (“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.

The first tranche of the Endospan Loan was funded upon execution of the agreement in September 2019. In September 2020 we funded the second tranche payment of $5.0 million upon the certification of the NEXUS IDE from the FDA. The third tranche is required to be funded upon certification of enrollment of at least 50% of the required number of patients in the primary arm of the FDA approved clinical trial for NEXUS, in each case subject to Endospan’s continued compliance with the Endospan Loan and certain other conditions. If a termination fee becomes payable by Endospan under the Endospan Distribution Agreement, it will be added to the amount payable to Artivion under the Endospan Loan.

Variable Interest Entity

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. Our payments to Endospan in September 2019 totaled $15.0 million which included a $9.0 million distribution fee, a $1.0 million securities purchase option, and $5.0 million for the first tranche of the Endospan Loan. An additional $5.0 million was funded as part of the second tranche payment described above. We evaluated Endospan for VIE classification as of December 31, 2021 and determined that Endospan meets the criteria of a non-consolidating VIE. Our payments to date, including any loans, guarantees, and other subordinated financial support related to this VIE, totaled $20.0 million as of December 31, 2021, representing our maximum exposure to loss, and were not individually significant to our consolidated financial statements.

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 the Monte Carlo simulation. 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. Based on the initial fair value of the Endospan Loan and the relative fair values of the Endospan Distribution Agreement and Endospan Option Agreement, we recorded the Endospan Loan value of $358,000 in Other long-term assets in the Consolidated Balance Sheets as of December 31, 2019. The Endospan Distribution Agreement was recorded at $5.5 million and $8.0 million in Other Intangibles, net in the Consolidated Balance Sheets as of December 31, 2021, and 2020, respectively.

In the fourth quarter of 2021 we fully impaired the value of the Endospan Option primarily driven by a decrease in forecasted operating results. We recorded $4.9 million impairment expense included in General, administrative, and marketing expense on the Consolidated Statements of Operations and Comprehensive Loss. The value of the Endospan Option was $4.9 million as of December 31, 2020.

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 loan fair value decreased and had no value as of December 31, 2021. As a result of the fair value adjustment, we recorded an expense of $409,000 in Other Expense on the Consolidated Statements of Operations and Comprehensive Loss as of December 31, 2021. The value of the Endospan Loan was $409,000 as of December 31, 2020.

5. Financial Instruments

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

December 31, 2021	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 10,015	--	--	$ 10,015
Total assets	$ 10,015	$ --	$ --	$ 10,015
Long-term liabilities:				
Contingent consideration	--	--	(49,400)	(49,400)
Total liabilities	$ --	$ --	$ (49,400)	$ (49,400)

December 31, 2020	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 11,484	--	--	$ 11,484
Restricted securities:				
Money market funds	546	--	--	546
Endospan loan	--	--	409	409
Total assets	$ 12,030	$ --	$ 409	$ 12,439
Current liabilities:				
Contingent consideration	--	--	(16,430)	(16,430)
Long-term liabilities:				
Contingent consideration	--	--	(43,500)	(43,500)
Total liabilities	$ --	$ --	$ **(59,930)**	$ **(59,930)**

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds. We recorded the Endospan Loan, classified as Level 3, as a result of an agreement with Endospan in September 2019. The contingent consideration component of the Ascyrus acquisition was updated using Level 3 inputs. See Note 3 and Note 4 for further discussion of the Ascyrus acquisition, and the Endospan Loan, respectively. Changes in fair value of Level 3 assets and liabilities are listed in the tables below (in thousands):

	Endospan Loan	**Contingent Consideration**
Balance as of December 31, 2020	$ 409	$ (59,930)
Payments	--	20,000
Change in valuation	(409)	(9,470)
Balance as of December 31, 2021	$ --	$ (49,400)

6. Cash Equivalents and Restricted Cash and Securities

The following is a summary of cash equivalents and marketable securities (in thousands):

December 31, 2021	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 10,015	--	$ 10,015
Total assets	$ 10,015	$ --	$ 10,015

December 31, 2020	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 11,484	--	$ 11,484
Restricted securities:			
Money market funds	546	--	546
Total assets	$ 12,030	$ --	$ 12,030

As of December 31, 2020 $546,000 of our money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations.

There were no gross realized gains or losses on cash equivalents or restricted securities for the years ended December 31, 2021, 2020, and 2019. As of December 31, 2020 $546,000 of our restricted securities had a maturity date within three months.

7. Inventories, net and Deferred Preservation Costs

Inventories, net at December 31, 2021 and 2020 are comprised of the following (in thousands):

	2021	2020
Raw materials and supplies	$ 35,780	$ 33,625
Work-in-process	9,712	6,318
Finished goods	31,479	33,095
Total inventories, net	$ 76,971	$ 73,038

Deferred preservation costs, net at December 31, 2021 and 2020 are comprised of the following (in thousands):

	2021	2020
Cardiac tissues	$ 20,591	$ 17,374
Vascular tissues	22,272	19,172
Total deferred preservation costs, net	$ 42,863	$ 36,546

To facilitate product usage, we maintain consignment inventory of our On-X heart valves at domestic hospital locations and On-X heart valves, JOTEC Products, and AMDS products at international hospital locations. We retain title and control over this consignment inventory until the device is implanted, at which time we invoice the hospital and recognize revenue. As of December 31, 2021 we had $12.9 million in consignment inventory, with approximately 43% in domestic locations and 57% in foreign locations. As of December 31, 2020 we had $11.9 million in consignment inventory, with approximately 47% in domestic locations and 53% in foreign locations.

Inventory and deferred preservation costs obsolescence reserves were $3.2 million and $3.5 million as of December 31, 2021 and 2020, respectively.

8. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of December 31, 2021 and 2020 the carrying values of our indefinite lived intangible assets are as follows (in thousands):

	2021	2020
Goodwill	$ 250,000	$ 260,061
In-process R&D	2,208	2,392
Procurement contracts and agreements	2,013	2,013
Trademarks	66	765

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. The company did not record any impairment of indefinite lived intangible assets during the twelve months ended December 31, 2021 and 2020. In-process research and development, procurement contracts and agreements and trademarks are included in Other intangibles, net on the consolidated balance sheets as of December 31, 2021 and 2020.

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. We believe that our trademarks have indefinite useful lives as we currently anticipate that these trademarks will contribute to our cash flows indefinitely.

As of December 31, 2021 and 2020 the value of our goodwill, all of which is related to our Medical Devices reporting unit, is as follows (in thousands):

	2021	2020
Balance as of January 1,	$ 260,061	$ 186,697
Ascyrus acquisition	(942)	63,357
Revaluation of goodwill denominated in foreign currency	(9,119)	10,007
Balance as of December 31,	$ 250,000	$ 260,061

Definite Lived Intangible Assets

As of December 31, 2021 and 2020 gross carrying values, accumulated amortization, and approximate amortization periods of our definite lived intangible assets are as follows (dollars in thousands):

December 31, 2021	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 213,626	$ 46,632	$ 166,994	17.7
Other intangibles:				
Customer lists and relationships	31,148	9,618	21,530	20.5
Distribution and manufacturing rights and know-how	9,847	4,308	5,539	5.0
Patents	4,083	3,144	939	17.0
Other	3,969	1,762	2,207	4.4
Total other intangibles	$ 49,047	$ 18,832	$ 30,215	10.6

December 31, 2020	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 222,182	$ 36,091	$ 186,091	17.6
Other intangibles:				
Customer lists and relationships	31,316	8,132	23,184	20.5
Distribution and manufacturing rights and know-how	14,728	5,349	9,379	6.1
Patents	3,966	3,113	853	17.0
Other	3,453	1,073	2,380	4.4
Total other intangibles	$ 53,463	$ 17,667	$ 35,796	10.8

Amortization Expense

Amortization expense recorded in General, administrative, and marketing expenses on our Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31 is as follows (in thousands):

	2021	2020	2019
Amortization expense	$ 16,820	$ 13,764	$ 10,850

As of December 31, 2021 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2022	2023	2024	2025	2026	Total
Amortization expense	$ 15,765	$ 15,261	$ 14,885	$ 12,878	$ 12,650	$ 71,439

9. Income Taxes

Income Tax Expense

(Loss) income before income taxes consists of the following (in thousands):

	2021	2020	2019
Domestic	$ (10,263)	$ (11,443)	$ 6,369
Foreign	(4,564)	(5,731)	(4,725)
(Loss) income before income taxes	$ (14,827)	$ (17,174)	$ 1,644

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

	2021	2020	2019
Current:			
Federal	$ 1,896	$ (2,460)	$ 48
State	551	445	80
Foreign	3,391	707	2,041
	5,838	(1,308)	2,169
Deferred:			
Federal	(2,801)	1,721	(850)
State	(307)	384	(131)
Foreign	(2,723)	(1,289)	(1,264)
	(5,831)	816	(2,245)
Income tax expense (benefit)	$ 7	$ (492)	$ (76)

Our income tax expense (benefit) in 2021, 2020 and 2019 included our federal, state, and foreign tax obligations. Our effective income tax rate was break-even for the year ended December 31, 2021. Our effective income tax was a tax benefit of 3% and 5% for the years ended December 31, 2020 and 2019, respectively. Our income tax rate for the year ended December 31, 2021 was primarily impacted by excess tax benefits on stock compensation, the research and development tax credit, non-deductible executive compensation, changes in our valuation allowance against our net deferred tax assets, and changes in our uncertain tax position liabilities. Our income tax rate

for the year ended December 31, 2020 was primarily impacted by changes in our valuation allowance against our net deferred tax assets and changes in our uncertain tax position liabilities. Our income tax rate for the year ended December 31, 2019 was primarily impacted by excess tax benefits on stock compensation, the research and development tax credit, and changes in our uncertain tax position liabilities.

The income tax benefit amounts differ from the amounts computed by applying the US federal statutory income tax rate of 21% for the years ended December 31, 2021, 2020, and 2019 to pretax income as a result of the following (in thousands):

	2021	2020	2019
Tax expense (benefit) at statutory rate	$ (3,114)	$ (3,606)	$ 345
Increase (reduction) in income taxes resulting from:			
Valuation allowance change	1,566	3,952	153
Foreign income taxes	1,138	378	425
Nondeductible executive compensation	1,075	580	778
Net change in uncertain tax positions	762	(1,115)	(360)
Foreign interest disallowance	307	298	292
State income taxes, net of federal benefit	73	(455)	(108)
Nondeductible entertainment expenses	65	94	201
Foreign deferred items	53	(63)	365
Equity compensation	(477)	(204)	(1,921)
Research and development credit	(959)	(457)	(400)
Other	(482)	106	154
Total income tax expense (benefit)	$ 7	$ (492)	$ (76)

Deferred Taxes

We generate deferred tax assets primarily as a result of net operating losses, excess interest carryforward, accrued compensation, stock compensation, and capital leases. Our deferred tax liabilities are primarily made up of intangible assets acquired in previous years, unrealized gains and losses, and capital leases.

The tax effects of temporary differences which give rise to deferred tax assets and liabilities at December 31 are as follows (in thousands):

	2021	2020
Deferred tax assets:		
Finance and operating leases	$ 13,762	$ 6,880
Loss carryforwards	6,649	7,911
Excess interest carryforward	3,547	2,660
Accrued expenses	2,088	2,002
Stock compensation	2,007	2,034
Deferred compensation	1,535	1,326
Property	1,356	1,397
Credit carryforwards	601	1,214
Inventory and deferred preservation costs write-downs	397	308
Other	3,770	2,798
Less valuation allowance	(13,282)	(7,170)
Total deferred tax assets, net	22,430	21,360

	2021	2020
Deferred tax liabilities:		
Intangible assets	(29,086)	(35,770)
Finance and operating leases	(13,404)	(6,617)
Unrealized gains and losses	(4,088)	(4,929)
Debt costs	(1,024)	(1,528)
Prepaid items	(395)	(417)
Inventory and deferred preservation costs write-downs	(105)	--
Financing arrangements	--	(4,700)

Other	(770)	(665)
Total deferred tax liabilities	(48,872)	(54,626)
Total deferred tax liabilities, net	$ (26,442)	$ (33,266)

As of December 31, 2021 and 2020 we maintained a net deferred tax liability of $26.4 million and $33.3 million, respectively. As of December 31, 2021 and 2020 we maintained valuation allowances against our deferred tax assets of $13.3 million and $7.2 million, respectively, primarily related to net operating loss carryforwards and disallowed excess interest carryforwards.

As of December 31, 2021 we had approximately $2.0 million of federal net operating loss carryforwards related to the acquisitions of Cardiogenesis and Hemosphere that we anticipate partially utilizing before expiration, approximately $3.0 million of state net operating loss carryforwards, that will begin to expire in 2022, approximately $1.8 million of foreign net operating loss carryforwards that will begin to expire in 2025, and approximately $500,000 in research and development tax credit carryforwards that begin to expire in 2030, and $110,000 in credits from other jurisdictions that mostly expire in 2027.

As of December 31, 2021 we had a deferred tax asset of $3.5 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, modified to be 50% in 2020 and 2019 by the CARES Act. For the years ended December 31, 2021 and 2020 our interest deduction was limited to $11.7 million and $15.8 million, respectively.

During the twelve months ended December 31, 2021 we corrected certain immaterial prior year errors primarily related to the release of a valuation allowance, reduction of income taxes payable, and an increase in the tax reserve. On correcting the errors, we recorded an income tax benefit of $2.1 million.

We believe that the realizability of our acquired net operating loss carryforwards will be limited in future periods due to a change in control of our former subsidiaries Hemosphere, Inc. (“Hemosphere”) and Cardiogenesis Corporation (“Cardiogenesis”), as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. We believe that our acquisitions of these companies each constituted a change in control as defined in Section 382 and that, prior to our acquisition, Hemosphere had experienced other equity ownership changes that should be considered such a change in control. The deferred tax assets recorded on our Consolidated Balance Sheets exclude amounts that we expect will not be realizable due to changes in control. A portion of the acquired net operating loss carryforwards is related to state income taxes for which we believe it is more likely than not, that some will not be realized. Therefore, we recorded a valuation allowance against these state net operating loss carryforwards. In addition, during the year, the realizability of a portion of our net operating loss carryforwards and other deferred tax assets was limited. We recorded a valuation allowance against these deferred tax assets.

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 non-US subsidiaries with the exception of one of its German subsidiaries. As of December 31, 2021 we had a deferred tax liability of $175,000 for the tax effects of this outside basis difference in its Consolidated Statements of Operations and Comprehensive Loss.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of our uncertain tax position liability, excluding interest and penalties, is as follows (in thousands):

	2021	2020	2019
Beginning balance	$ 2,574	$ 3,523	$ 3,889
Increases related to current year tax positions	1,661	473	691
Decreases due to the lapsing of statutes of limitations	(241)	(1,703)	(880)
Decreases related to prior year tax positions	(170)	(238)	(154)
(Decreases) increases for foreign exchange differences	(121)	99	(22)
Increases (decreases) related to prior year tax positions	386	420	(1)
Ending balance	$ 4,089	$ 2,574	$ 3,523

We recorded non-current liabilities of $220,000 and $261,000 related to interest and penalties on uncertain tax positions on our Consolidated Balance Sheets as of December 31, 2021 and 2020, respectively. We included income of $35,000 and $180,000 for December 31, 2021 and 2020, respectively, and expense of $27,000 for December 31, 2019 for interest and penalties related to unrecognized tax benefits in our Consolidated Statements of Operations and Comprehensive Loss.

As of December 31, 2021 our uncertain tax liability of $4.3 million, including interest and penalties, was recorded as a reduction to deferred tax assets of $300,000, and a non-current liability of $4.0 million on our Consolidated Balance Sheets. The amount of uncertain tax liabilities that are expected to affect our tax rate if recognized were $3.2 million, $2.6 million, and $3.5 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2020 our total uncertain tax liability, including interest and penalties of $2.8 million, was recorded as a reduction to deferred tax assets of $300,000 and as a non-current liability of $2.5 million on our Consolidated Balance Sheets.

We believe it is reasonably possible that approximately $185,000 of our uncertain tax liability will be recognized in 2022 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 2018 and forward generally remain open to examination by the major taxing jurisdictions to which we are subject. However, certain returns from years prior to 2018, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

10. 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.

On January 6, 2021 we executed a modification to extend the lease of our headquarters located in Kennesaw, Georgia. This modification resulted in an increase in the present value of future lease obligations and corresponding right-of-use asset of $23.3 million, using a discount rate of 6.41%.

On June 1, 2021 we began occupancy of the newly constructed addition to our leased JOTEC headquarters located in Hechingen, Germany. This lease resulted in an increase in the present value of future lease obligations and corresponding right-of-use asset of $9.8 million, using a discount rate of 5.46%.

Supplemental consolidated balance sheet information related to leases was as follows (in thousands, except lease term and discount rate):

Operating leases:	December 31, 2021	December 31, 2020
Operating lease right-of-use assets	$ 58,097	$ 28,242
Accumulated amortization	(12,383)	(9,671)
Operating lease right-of-use assets, net	**$ 45,714**	**$ 18,571**
Current maturities of operating leases	$ 3,149	$ 5,763
Non-current maturities of operating leases	44,869	14,034
Total operating lease liabilities	**$ 48,018**	**$ 19,797**
Finance leases:		
Property and equipment, at cost	$ 6,759	$ 7,620
Accumulated amortization	(2,105)	(1,905)
Property and equipment, net	**$ 4,654**	**$ 5,715**
Current maturities of finance leases	$ 528	$ 614
Non-current maturities of finance leases	4,374	5,300
Total finance lease liabilities	**$ 4,902**	**$ 5,914**
Weighted average remaining lease term (in years):		
Operating leases	12.5	5.1
Finance leases	8.8	9.8
Weighted average discount rate:		
Operating leases	5.8%	5.2%
Finance leases	2.0%	2.0%

Current maturities of finance leases are included as a component of Other current liabilities and non-current maturities of finance leases are included as a component of Other long-term liabilities on our Consolidated Balance Sheets. A summary of lease expenses for our finance and operating leases included in General, administrative, and marketing expenses on our Consolidated Statements of Operations and Comprehensive Loss are as follows (in thousands):

	December 31, 2021	December 31, 2020
Amortization of property and equipment	$ 596	$ 643
Interest expense on finance leases	110	118
Total finance lease expense	706	761
Operating lease expense[a]	7,521	7,145
Sublease income	(399)	(905)
Total lease expense	**$ 7,828**	**$ 7,001**

[a] Total rental expense for operating leases was $6.6 million in 2019.

A summary of our supplemental cash flow information is as follows (in thousands):

Cash paid for amounts included in the measurement of lease liabilities:	2021	2020
Operating cash flows for operating leases	$ 6,061	$ 7,407
Financing cash flows for finance leases	557	653
Operating cash flows for finance leases	105	126

Future minimum lease payments and sublease rental income are as follows (in thousands):

	Finance Leases	Operating Leases	Sublease Income
2022	$ 600	$ 5,928	$ 306
2023	629	5,619	--
2024	623	6,174	--
2025	599	5,188	--
2026	579	4,797	--
Thereafter	2,318	42,210	--
Total minimum lease payments	$ 5,348	$ 69,916	$ 306
Less amount representing interest	446	21,898	
Present value of net minimum lease payments	4,902	48,018	
Less current maturities	528	3,149	
Lease obligations, less current maturities	$ 4,374	$ 44,869	

11. Debt

Credit Agreement

On December 1, 2017 we entered into a credit and guaranty agreement for a $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility (the "Term Loan Facility") and a $30.0 million secured revolving credit facility ("the Revolving Credit Facility" and, together with the Term Loan Facility, the "Credit Agreement"). We and each of our existing domestic subsidiaries (subject to certain exceptions and exclusions) guarantee the obligations under the Credit Agreement (the "Guarantors"). The Credit Agreement is 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.

On December 1, 2017 we borrowed the entire $225.0 million Term Loan Facility. The proceeds of the Term Loan Facility were used along with cash on hand and shares of Artivion common stock to (i) fund the acquisition of JOTEC and its subsidiaries (the "JOTEC Acquisition"), (ii) pay certain fees and expenses related to the JOTEC Acquisition and the Credit Agreement, and (iii) pay the outstanding balance of our prior credit facility. The Revolving Credit Facility may be used for working capital, capital expenditures, acquisitions permitted under the Credit Agreement, and other general corporate purposes pursuant to the terms of the Credit Agreement.

The loan under the Term Loan Facility is repayable on a quarterly basis according to the amortization provisions set forth in the Credit Agreement. We have the right to repay the loan under the Credit Agreement in whole or in part at any time. Amounts repaid in respect of the loan under the Term Loan Facility may not be reborrowed. Amounts repaid in respect of the loan under the Revolving Credit Facility may be reborrowed. All outstanding principal and interest in respect of (i) the Term Loan Facility must be repaid on or before December 1, 2024 and (ii) the Revolving Credit Facility must be repaid on or before December 1, 2022.

In October 2018 we finalized an amendment to the Credit Agreement to reprice interest rates, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loan under the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. Prior to the repricing, the optional floating annual rate was equal to either the base rate plus a margin of 3.00%, or LIBOR, plus a margin of 4.00%. The loan under the Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of between 3.00% and 3.25%, depending on our consolidated leverage ratio, or LIBOR, plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. While a payment event of default or bankruptcy event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% in excess of the interest rate otherwise payable with respect to the overdue principal amount of any loans outstanding and overdue interest payments and other overdue fees and amounts. We are obligated to pay an unused commitment fee equal to 0.50% of the unutilized portion of the revolving loans. In addition, we are also obligated to pay other customary fees for a credit facility of this size and type.

The Credit Agreement contains 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. In addition, with respect to the Revolving Credit Facility, when the principal amount of loans outstanding thereunder is in excess of 25% of the Revolving Credit Facility, the Credit Agreement requires us to comply with a specified maximum first lien net leverage ratio.

The Credit Agreement includes certain customary events of default that include, among other things, non-payment of principal, interest, or fees; inaccuracy of representations and warranties; breach of covenants; cross-default to certain material indebtedness; bankruptcy and insolvency; and change of control. Upon the occurrence and during the continuance of an event of default, the lenders may declare all outstanding principal and accrued but unpaid interest under the Credit Agreement immediately due and payable and may exercise the other rights and remedies provided under the Credit Agreement and related loan documents.

In March 2020 partly as a precautionary measure to increase cash and maintain maximum financial flexibility during the current uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million Revolving Credit Facility at an aggregate interest rate of 5.20%. On June 29, 2020 we used a portion of the net proceeds from the issuance of Convertible Senior Notes, as discussed below, to repay the $30.0 million outstanding under our Revolving Credit Facility.

On April 29, 2020 we entered into an amendment to our Credit Agreement. As part of the amendment, we obtained a waiver of our maximum first lien net leverage ratio covenant through the end of 2020. In addition, the amendment to our Credit Agreement provides that EBITDA, for covenant testing purposes, in each quarter of 2020 will be deemed equal to a fixed value equal to our bank covenant EBITDA in the fourth quarter of 2019, when our first lien net leverage was 3.4x. As a result of these changes, we are subject to a new minimum liquidity covenant. We are also subject to restrictions on certain payments, including cash dividends. We are required to maintain a minimum liquidity of at least $12.0 million as of the last day of any month in 2020, and as of the last day of any quarter through the third quarter of 2021 when our Revolving Credit Facility is drawn in excess of 25% (or $7.5 million) of the amount available as of the last day of any fiscal quarter during that period. Beginning in 2021, if we repay borrowings under our Revolving Credit Facility to 25% or less, no financial maintenance covenants, including the minimum liquidity covenant and the maximum first lien net leverage ratio covenant, are applicable.

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 its 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 if our 4.25%. Convertible Senior Notes, described below, remain outstanding on April 1, 2025 and December 31, 2024, respectively. With respect to the Term Loan, if the Convertible Senior Notes remain outstanding on April 1, 2025, the Term Loan's maturity date will be April 1, 2025, or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 91 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2027. In the case of the Revolving Credit Facility, if the Convertible Senior Notes are still outstanding on December 31, 2024, the Revolving Credit Facility's maturity date will be either December 31, 2024 or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 182 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2025. Under the amendment, the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.50%, or LIBOR, plus a margin of 3.50%. Prior to the amendment, the optional floating annual rate was equal to either the base rate plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. We paid debt issuance costs of $2.1 million, of which $1.8 million will be amortized over the life of the term loan facility and included in current and long-term debt on the Consolidated Balance Sheets. The remaining $361,000 of debt issuance costs and $474,000 of non-cash debt extinguishment costs were recorded in Interest expense on the Consolidated Statements of Operations and Comprehensive Loss. As of December 31, 2021 the aggregate interest rate of the Credit Agreement was 4.50% per annum.

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 balance was $100.0 million recorded in Long-term debt on the Consolidated Balance Sheets as of December 31, 2021. 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. The fair value and the effective interest rate of the Convertible Senior Notes as of December 31, 2021 was approximately $116.0 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.

The interest expense recognized on the Convertible Senior Notes includes approximately $4.9 million for the aggregate of the contractual coupon interest, and the amortization of the debt issuance during the twelve months ended December 31, 2021. The interest expense recognized on the Convertible Senior Notes includes approximately $4.2 million for the aggregate of the contractual coupon interest, the accretion of the debt discount, and the amortization of the debt issuance costs during the twelve months ended December 31, 2020. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. As of December 31, 2021 there were $2.5 million of unamortized debt issuance costs related to convertible senior notes.

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 cannot redeem the Convertible Senior Notes before July 5, 2023. We can redeem them on or after July 5, 2023, 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, 2021 we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes. During the twelve months ended December 31, 2020 we used a portion of the proceeds to pay off the $30.0 million outstanding under our Revolving Credit Facility and to finance the Ascyrus transaction and used the remaining funds for general corporate purposes.

Government Supported Bank Debt

In June 2015 JOTEC obtained two loans from Sparkasse Zollernalb, which are government sponsored by the Kreditanstalt für Wiederaufbau Bank (KFW). Both KFW loans have a term of nine years and the interest rates are 2.45% and 1.40%.

The short-term and long-term balances of our term loans are as follows (in thousands):

	As of December 31,	
	2021	**2020**
Term loan balance	$ 216,000	$ 218,250
Convertible senior notes	100,000	79,555
2.45% Sparkasse Zollernalb (KFW Loan 1)	566	886
1.40% Sparkasse Zollernalb (KFW Loan 2)	1,061	1,457
Total loan balance	317,627	300,148
Less unamortized loan origination costs	(8,504)	(8,485)
Net borrowings	309,123	291,663
Less short-term loan balance, net	(1,630)	(1,195)
Long-term loan balance, net	$ 307,493	$ 290,468

At December 31, 2021 the aggregate maturities of long-term debt for the next five years is as follows (in thousands):

	2022	**2023**	**2024**	**2025**	**2026**	**Thereafter**	**Total**
Maturities	$ 2,785	$ 2,785	$ 2,596	$ 102,462	$ 2,250	$ 204,749	$ 317,627

Our aggregate maturity schedule is subject to change due to a provision within the Credit Agreement that requires us to make annual prepayments based on an excess cash flow calculation.

Interest Expense

Total interest expense was $16.9 million, $16.7 million, and $14.9 million in 2021, 2020, and 2019, respectively. Interest expense includes interest on debt and uncertain tax positions in all periods.

12. 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, 2021 and 2020 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.

Employment Agreements

The employment agreement of our Chairman, President, and Chief Executive Officer (“CEO”), Mr. J. Patrick Mackin, provides for a severance payment, which would become payable upon the occurrence of certain employment termination events, including termination by us without cause.

13. 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 2021 and 2020 and 3.5% in 2019. Our contributions approximated $2.1 million, $1.9 million, and $1.6 million for the years ended 2021, 2020, and 2019, 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.

Our deferred compensation liabilities are recorded as a component of Other current liabilities and long-term Deferred compensation liabilities, as appropriate, on the Consolidated Balance Sheets based on the anticipated distribution dates. The cash surrender value of COLI is recorded in Other long-term assets on the Consolidated Balance Sheets was $6.6 million and $6.4 million as of December 31, 2021 and 2020, 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. We recorded deferred compensation liability of $378,000 and $68,000 in Other current liabilities and $6.0 million and $5.5 million in Long-term liabilities as of December 31, 2021 and 2020, respectively, in the Consolidated Balance Sheets.

14. Revenue Recognition

Sources of Revenue

Revenues are disaggregated by following sources:

- Domestic Hospitals – direct sales of products and preservation services.
- International Hospitals – direct sales of products and preservation services.
- International Distributors – generally these contracts specify a geographic area that the distributor will service, terms and conditions of the relationship, and purchase targets for the next calendar year.
- CardioGenesis Cardiac Laser Console Trials and Sales – CardioGenesis cardiac trialed laser consoles are delivered under separate agreements.

For the years ended December 31, 2021, 2020, and 2019 the sources of revenue were as follows (in thousands):

	2021	2020	2019
Domestic hospitals	$ 150,301	$ 137,810	$ 144,538
International hospitals	106,639	80,524	85,241
International distributors	41,046	34,429	40,427
CardioGenesis cardiac laser therapy	850	464	6,016
Total sources of revenue	**$ 298,836**	**$ 253,227**	**$ 276,222**

Also see segment and geographic disclosure in Note 18 below.

15. 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, 2021 and 2020:

Plan	Authorized Shares	Available for Grant 2021	Available for Grant 2020
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	63,000	150,000
2009 Equity and Cash Incentive Plan	7,570,000	--	52,000
2020 Equity and Cash Incentive Plan	4,105,000	3,310,000	4,094,000
Total	13,575,000	3,373,000	4,296,000

During 2020 the Shareholders 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.

During 2019 the Company amended the 2009 Equity and Cash Incentive Plan to increase the authorized shares under the plan by 1.9 million shares. Upon the exercise of stock options or grants of RSAs, RSUs, or PSUs, we may issue the required shares out of authorized but unissued common stock or out of treasury stock, at our discretion.

Stock Awards

In 2021 the Compensation Committee of our Board of Directors (the “Committee”) authorized awards from approved stock incentive plans of RSUs to certain employees, RSAs to non-employee Directors, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 500,000 shares and had an aggregate grant date market value of $12.6 million. Two types of PSUs were granted in 2021, an annual grant with a one year performance period (“Annual PSU”) and a special PSU award (“special PSU”) with a one year performance period. If the highest performance threshold is met, the Annual PSU granted in 2021 represented the right to receive up to 150% of the target number of shares of common stock. The performance component of the Annual PSU awards granted in 2021 is based on attaining specified levels of revenue growth and certain non-financial metrics, as defined in the PSU grant documents, for the 2021 calendar year. The Annual PSUs granted in 2021 earned approximately 102% of the target number of shares. If the highest performance threshold is met, the Special PSUs granted in 2021 represent a right to receive up to 200% of the target number of shares of common stock. The special PSUs granted in 2021 earned approximately 118% of target number of shares.

In 2020 the Committee authorized awards from approved stock incentive plans of RSUs to certain employees, RSAs to non-employee Directors, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 335,000 shares and had an aggregate grant date market value of $8.3 million. If the highest performance threshold is met, the PSU granted in 2020 represented the right to receive up to 150% of the target number of shares of common stock. The performance component of the PSU awards granted in 2020 was based on attaining specified levels of EBITDA, as defined in the PSU grant documents, for the 2020 calendar year. Our actual 2020 EBITDA performance was below the threshold required for any payouts under the 2020 PSU plan which resulted in a $1.1 million reversal of expense in the fourth quarter of 2020. In February 2021 the Committee used structured discretion to determine that the 2020 PSUs were earned and should be paid out at 100% of target resulting in a modification of the award which resulted in $1.3 million of compensation expense during the twelve months ended December 31, 2021 related to these performance awards. This modification resulted in a forfeiture and a subsequent grant of 70,000 PSU shares during the twelve months ended December 31, 2021.

In 2019 the Committee authorized awards from approved stock incentive plans of RSAs to non-employee Directors, RSUs to certain employees, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 507,000 shares and had an aggregate grant date market value of $15.0 million. Two types of PSUs were granted in 2019, Annual PSUs and a special LTIP PSU grant, which has multiple performance periods over a five-year period. If the highest performance threshold is met, the Annual PSU granted in 2019 represents the right to receive up to 150% of the target number of shares of common stock. The performance component of the Annual PSU awards granted in 2019 was based on attaining specified levels of EBITDA, as defined in the Annual PSU grant documents, for the 2019 calendar year. The Annual PSU granted in 2019 earned approximately 83% of the target number of shares. If the highest performance thresholds are met, the PSUs granted in 2019 under the LTIP represent the right to receive up to 288%, and up to 192% for a certain key executive, of the target number of shares of common stock. The performance component of the LTIP awards granted in 2019 was based on attaining specified levels of adjusted revenue growth and gross margin, as defined in the LTIP grant document, for the years 2019 through 2023. During 2020 we determined that the threshold performance under the first performance period (2019 through 2021) of the LTIP was unlikely to be achieved which resulted in a reversal of $1.9 million in expense in the fourth quarter of 2020.

A summary of stock grant activity for the years ended December 31, 2021, 2020, and 2019 for RSAs, RSUs, and PSUs, based on the target number of shares, is as follows:

RSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	326,000	$ 17.19
Granted	93,000	29.77
Vested	(149,000)	14.45
Forfeited	(27,000)	20.53
Unvested at December 31, 2019	243,000	23.30
Granted	123,000	24.70
Vested	(108,000)	20.66
Unvested at December 31, 2020	258,000	25.08
Granted	140,000	25.68
Vested	(130,000)	22.40
Forfeited	(33,000)	27.39
Unvested at December 31, 2021	235,000	26.59

RSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2018	251,000	1.05	$ 7,123,000
Granted	103,000		
Vested	(101,000)		
Forfeited	(27,000)		
Unvested at December 31, 2019	226,000	0.93	6,131,000
Granted	141,000		
Vested	(118,000)		
Forfeited	(37,000)		
Unvested at December 31, 2020	212,000	1.02	5,015,000
Granted	144,000		
Vested	(93,000)		
Forfeited	(39,000)		
Unvested at December 31, 2021	224,000	0.94	4,558,000
Vested and expected to vest	224,000	0.94	$ 4,558,000

PSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2018	147,000	0.72	$ 4,179,000
Granted	322,000		
Vested	(87,000)		
Forfeited	(35,000)		
Unvested at December 31, 2019	347,000	2.33	9,400,000
Granted	70,000		
Vested	(55,000)		
Forfeited	(31,000)		
Unvested at December 31, 2020	331,000	1.64	7,805,000
Granted	215,000		
Vested	(60,000)		
Forfeited	(114,000)		
Unvested at December 31, 2021	372,000	0.90	7,579,000
Vested and expected to vest	372,000	0.90	$ 7,579,000

During the years ended December 31, 2021, 2020, and 2019 the total fair value of $7.3 million, $6.7 million, and $9.8 million, respectively, in combined RSAs, RSUs, and PSUs vested.

Stock Options

The Compensation Committee of our Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers and employees totaling 226,000, 212,000, and 169,000 shares in 2021, 2020, and 2019, respectively, with exercise prices equal to the stock prices on the respective grant dates.

A summary of our stock option activity for the years ended December 31, 2021, 2020, and 2019 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2018	1,333,000	$ 13.04	3.93	$ 20,439,000
Granted	169,000	29.62		
Exercised	(334,000)	9.87		
Forfeited	(39,000)	22.64		
Outstanding at December 31, 2019	1,129,000	16.14	3.67	12,763,000
Granted	212,000	26.24		
Exercised	(88,000)	10.49		
Forfeited	(12,000)	27.36		
Outstanding at December 31, 2020	1,241,000	18.16	3.38	8,215,000
Granted	226,000	24.90		
Exercised	(179,000)	12.02		
Forfeited	(42,000)	26.00		
Outstanding at December 31, 2021	1,246,000	20.00	3.20	4,038,931
Vested and expected to vest	1,246,000	$ 20.00	3.20	$ 4,038,931
Exercisable at December 31, 2021	873,000	$ 17.48	2.19	$ 4,038,931

Other information concerning stock options for the years ended December 31 is as follows:

	2021	2020	2019
Weighted-average fair value of options granted	$ 8.82	$ 8.64	$ 11.47
Intrinsic value of options exercised	2,716,000	1,267,000	6,519,000

Employees purchased common stock totaling 87,000, 83,000, and 61,000 shares in 2021, 2020, and 2019, respectively, through our ESPP.

Stock Compensation Expense

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

	2021		2020		2019	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	5.00 Years	0.50 Years	5.00 Years	0.50 Years	5.00 Years	0.50 Years
Expected stock price volatility	0.40	0.45	0.35	0.52	0.40	0.39
Risk-free interest rate	0.57%	0.07%	1.41%	1.00%	2.54%	2.35%

The following table summarizes stock compensation expense (in thousands):

	2021	2020	2019
RSA, RSU, and PSU expense	$ 9,023	$ 5,288	$ 7,451
Stock option and ESPP option expense	2,254	2,216	1,960
Total stock compensation expense	$ 11,277	$ 7,504	$ 9,411

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 $566,000, $592,000, and $612,000 in the years ended December 31, 2021, 2020, and 2019, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of December 31, 2021 we had total unrecognized compensation expense of $9.1 million related to RSAs, RSUs, and PSUs and $2.0 million related to unvested stock options. As of December 31, 2021 this expense is expected to be recognized over a weighted-average period of 1.64 years for RSUs, 1.57 years for stock options, 1.23 years for RSAs, and 0.90 years for PSUs.

16. (Loss) Income Per Common Share

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

Basic (loss) income per common share	**2021**	**2020**	**2019**
Net (loss) income	$ (14,834)	$ (16,682)	$ 1,720
Net loss (income) allocated to participating securities	94	111	(12)
Net (loss) income allocated to common shareholders	$ (14,740)	$ (16,571)	$ 1,708
Basic weighted-average common shares outstanding	38,983	37,861	37,118
Basic (loss) income per common share	$ (0.38)	$ (0.44)	$ 0.05

Diluted (loss) income per common share	**2021**	**2020**	**2019**
Net (loss) income	$ (14,834)	$ (16,682)	$ 1,720
Net loss (income) allocated to participating securities	94	111	(12)
Net (loss) income allocated to common shareholders	$ (14,740)	$ (16,571)	$ 1,708
Basic weighted-average common shares outstanding	38,983	37,861	37,118
Effect of dilutive options and awards[a]	-	-	742
Diluted weighted-average common shares outstanding	38,983	37,861	37,860
Diluted (loss) income per common share	$ (0.38)	$ (0.44)	$ 0.05

[a] 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) income per common share. For the year ended December 31, 2021 and 2020 all stock options and awards were excluded from the calculation of weighted-average common shares outstanding as these would be antidilutive to the net loss. For the year ended December 31, 2019 stock options to purchase 131,000 shares were excluded from the calculation of diluted weighted-average common shares outstanding.

17. Transactions with Related Parties

A member of our Board of Directors and a shareholder of the Company, who joined our Board of Directors during 2018, is the CEO of a hospital that generated product and preservation services revenues of $222,000, $378,000, and $341,000 in 2021, 2020, and 2019, respectively.

18. 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 stents and stent grafts, surgical sealants, On-X, and other product revenues. Aortic stents and stent grafts include JOTEC, AMDS, and NEXUS product revenues. Surgical sealants include BioGlue Surgical Adhesive product revenues. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

The primary measure of segment performance, as viewed by our management, is segment gross margin, or net external revenues less cost of products and preservation services. 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):

	2021	2020	2019
Revenues:			
Medical devices	$ 221,597	$ 179,299	$ 197,246
Preservation services	77,239	73,928	78,976
Total revenues	298,836	253,227	276,222
Cost of products and preservation services:			
Medical devices	65,196	50,128	55,022
Preservation services	36,126	35,315	38,187
Total cost of products and preservation services	101,322	85,443	93,209
Gross margin:			
Medical devices	156,401	129,171	142,224
Preservation services	41,113	38,613	40,789
Total gross margin	$ 197,514	$ 167,784	$ 183,013

Net revenues by product for the years ended December 31, 2021, 2020, and 2019 were as follows (in thousands):

	2021	2020	2019
Products:			
Aortic stents and stent grafts	$ 85,387	$ 61,663	$ 64,974
Surgical sealants	70,714	62,068	68,611
On-X	57,363	48,053	50,096
Other	8,133	7,515	13,565
Total products	221,597	179,299	197,246
Preservation services:	77,239	73,928	78,976
Total revenues	$ 298,836	$ 253,227	$ 276,222

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2021, 2020, and 2019 were as follows (in thousands):

	2021	2020	2019
US	$ 151,151	$ 138,274	$ 150,553
International	147,685	114,953	125,669
Total revenues	$ 298,836	$ 253,227	$ 276,222

For the years ended December 31, 2021, 2020 and 2019, revenues attributed to customers in Germany accounted for 10% of total revenues.

At December 31, 2021 and 2020 45% and 54% of our long-lived assets were held in the US, where the corporate headquarters and a portion of our manufacturing facilities are located. Our long-lived international assets were $20.6 million and $15.1 million as of December 31, 2021 and 2020, respectively, of which 97% were located in Hechingen, Germany. At December 31, 2021 and 2020, $250.0 million and $260.1 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 Executive Vice President of Finance, Chief Operating Officer, and CFO, 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, 2021, 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 Report on Internal Control over Financial Reporting under Sarbanes-Oxley Section 404" on page 59 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 60 of this report.

The Securities and Exchange Commission's general guidance permits the exclusion of an assessment of the effectiveness of a registrant's disclosure controls and procedures as they relate to its internal control over financial reporting for an acquired business during the first year following such acquisition if, among other circumstances and factors, there is not adequate time between the acquisition date and the date of assessment.

During the quarter ended December 31, 2021 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.

None.

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, 2021, with the exception of information concerning executive officers listed below.

The following table lists the executive officers of Artivion as of December 31, 2021 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 shareholders 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	55	Chairman, President, and Chief Executive Officer
F. Peter Barthold	Since 2020	57	Vice President, Research and Development
John E. Davis	Since 2015	57	Senior Vice President, Global Sales and Marketing
Matthew A. Getz	Since 2019	53	Vice President, Human Resources
Andrew M. Green	Since 2021	53	Vice President, Regulatory Affairs
Jean F. Holloway, Esq.	Since 2015	64	Senior Vice President, General Counsel, Chief Compliance Officer, and Secretary
Amy D. Horton, CPA	Since 2006	51	Vice President and Chief Accounting Officer
D. Ashley Lee, CPA	Since 2000	57	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Dennis B. Maier	Since 2017	48	Vice President, Operations
Rochelle L. Maney	Since 2021	46	Vice President, Global Quality Assurance
Marshall S. Stanton, M.D.	Since 2021	65	Senior Vice President, Clinical Research and Chief Medical Officer

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 20 years of experience in the medical device industry. Prior to joining Artivion, Mr. Mackin served as President of Cardiac Rhythm Disease Management, the 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.

F. Peter Barthold was appointed to the position of Vice President of Research and Development in July 2020. Mr. Barthold has more than 20 years of experience in development, manufacturing, and commercialization of vascular implants. Prior to this position, he served as a Director of Research and Development from January 2018. Over his 20 years of experience with JOTEC GmbH in Hechingen, Germany, Mr. Barthold served as a Director of Research and Development from 2007 to 2017, as well as a number of other leadership positions. Prior to joining JOTEC, he worked as a project manager at MAFO AG and was a research associate at the Institute for Applied Research in Reutlingen, Germany. Mr. Barthold holds a graduate engineering degree in Chemistry of Synthetic Materials from the Reutlingen University, Reutlingen, Germany in 1993.

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 of 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 for four years as a Vice President of Sales in the Cardiac Rhythm Management Devices business at St. Jude Medical, now part of Abbott Laboratories. Before St. Jude Medical, he served for 14 years with Medtronic in the Cardiac Rhythm Disease Management division in senior sales leadership roles. In his early career he served 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 28 years of regulatory, clinical, quality, and business experience in the medical device and biologics industry. More specifically, he spent two 2.5 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 Masters 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 BS and Master's degrees in Accounting from Brigham Young University in Provo, Utah.

D. Ashley Lee, CPA has served as Executive Vice President, Chief Operating Officer, and Chief Financial Officer since November 2004. Mr. Lee has been with Artivion since December 1994 serving as Vice President of Finance, Chief Financial Officer, and Treasurer from December 2002 to November 2004; as Vice President, Finance and Chief Financial Officer from April 2000 to December 2002; and as Controller Artivion from December 1994 until April 2000. From 1993 to 1994, Mr. Lee served as the Assistant Director of Finance for Compass Retail, Inc., a wholly-owned subsidiary of Equitable Real Estate. From 1987 to 1993, Mr. Lee was employed as a Certified Public Accountant with Ernst & Young, LLP. Mr. Lee received his BS in Accounting from the University of Mississippi.

Dennis B. Maier was appointed to the position of Vice President, Operations in July 2017. Mr. Maier has more than 15 years in the medical device industry. Prior to joining Artivion, he served as the Senior Director of Baxter Healthcare's direct material global purchasing and supplier management team. He also served as Vice President of Global Sourcing for Hill-Rom. Prior to that, he spent five years with Medtronic leading several Cardiac Rhythm Disease Management (CRDM) manufacturing operations, as well as serving as Director of CRDM Global Commodity management. Mr. Maier also spent eight years with Abbott Vascular and Boston Scientific (both former Guidant Corporation businesses) in a variety of leadership roles. Prior to entering the medical device industry, Mr. Maier worked briefly for Ford Motor Company and served six years as an officer in the U.S Army. He received an MBA from the Krannert Graduate School of Management at Purdue University and a B.S. in Mechanical Engineering from the US Military Academy at West Point.

Rochelle L. Maney was appointed to the position of Vice President, Global Quality in March of 2021. She has over 20 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 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 BA from the University of Pennsylvania.

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, 2021.

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, 2021.

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, 2021.

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, 2021.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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:

(a) 1. Financial Statements.

Consolidated Financial Statements begin on page 63.

2. 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.

3. 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.

February 22, 2022 By /s/ J. Patrick Mackin
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 22, 2022
/s/ D. Ashley Lee **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 22, 2022
/s/ Amy D. Horton **Amy D. Horton**	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 22, 2022
/s/ Thomas F. Ackerman **Thomas F. Ackerman**	Director	February 22, 2022
/s/ Daniel J. Bevevino **Daniel J. Bevevino**	Director	February 22, 2022
/s/ Marna P. Borgstrom **Marna P. Borgstrom**	Director	February 22, 2022
/s/ James W. Bullock **James W. Bullock**	Director	February 22, 2022
/s/ Jeffrey H. Burbank **Jeffrey H. Burbank**	Director	February 22, 2022
/s/ Harvey Morgan **Harvey Morgan**	Director	February 22, 2022
/s/ Jon W. Salveson **Jon W. Salveson**	Director	February 22, 2022
/s/ Anthony B. Semedo **Anthony B. Semedo**	Director	February 22, 2022

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 Certificate of Incorporation, effective January 1, 2022. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed January 4, 2022).
3.2	Delaware Certificate of Amendment of Certificate of Incorporation, effective January 18, 202. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 20, 2022).
3.3	Amended and Restated Bylaws of Artivion, Inc., a Delaware Corporation (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed January 20, 2022).
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. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019).
4.3	Indenture, dated as of 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 as of 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.)
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.)
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.)

Exhibit Number	Description
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 2020 Grant of 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 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020.)
10.4	Artivion, Inc. Employee Stock Purchase Plan. (Incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement filed April 10, 1996.)
10.4(a)	First Amendment to the Artivion, Inc. Employee Stock Purchase Plan. (Incorporated herein by reference to the Registrant's Definitive Proxy Statement filed May 20, 2010.)
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 2021 Compensation Arrangements with Non-Employee Directors.
10.7†	Employment Agreement between Artivion, Inc. and J. Patrick Mackin, dated as of 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 Certain Officers. (Incorporated herein by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed March 23, 2017.)
10.10†	Change of Control Severance Agreement between Artivion, Inc. and John E. Davis, dated November 21, 2016. (Incorporated herein by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.11†	Change of Control Severance Agreement between Artivion, Inc. and D. Ashley Lee, dated November 21, 2016 (Incorporated herein by reference to Exhibit 10.4 to Registrant's Current Report on Form 8-K filed November 22, 2016.)
10.12†	Change of Control Severance Agreement between Artivion, Inc. and Jean F. Holloway, dated November 21, 2016 (Incorporated herein by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed November 22, 2016.)
10.13	Form Salary Reduction Letter. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020).
10.14	Credit and Guaranty Agreement, dated as of 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.)
10.14(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 as of October 26, 2018. (Incorporated herein by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed October 31, 2018.)
10.14(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 as of April 29, 2020. (Incorporated herein by reference to Exhibit 10.3 of Registrant's Quarterly Report on Form 10-Q filed July 31, 2020).
10.14(c)	Third Amendment to Credit and Guarantee Agreement between CryoLife, 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).
10.15	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.)
10.15(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.)

Exhibit Number	Description
10.15(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.)
10.15(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.)
10.15(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).
10.16++	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.)
10.16(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.)
10.16(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.)
10.16(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.)
10.17	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.)
10.17(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.)
10.18++	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.)
10.18(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.)
10.19++	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).
10.20	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.)
10.21+	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.)
10.21(a)+	First Amendment to Exclusive Distribution Agreement, by and between JOTEC GmbH, as distributor, and Endospan Ltd., as manufacturer, dated as of August 31, 2020. (Incorporated herein by reference to Exhibit 10.21(a) to the Annual Report on Form 10-K filed February 23, 2021).
10.22	Purchase Agreement, dated as of 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).
10.23+	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).
10.23(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).
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

Exhibit Number	Description
31.2*	Certification by D. Ashley Lee 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
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
104	Cover Page Interactive Data File – formatted as Inline XBRL and contained in Exhibit 101

*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 10.6

SUMMARY OF 2021 COMPENSATION ARRANGEMENTS WITH NON-EMPLOYEE DIRECTORS
(Effective as of December 31, 2021)

The following summarizes the compensation and benefits received by the non-employee Directors of Artivion as of December 31, 2021. It is intended to be a summary of compensation arrangements, and in no way is intended to provide any additional rights to any non-employee Director.

Annual Retainer and Committee Chair Fees

Each of the non-employee Directors of the Board of Directors of Artivion (the "Board") receives an annual cash retainer of $50,000. Each committee chair also receives a fee in addition to the annual cash retainer in the amounts shown in the following table.

Annual Fees for Committee Chairs	
Audit Committee	$ 20,000
Compensation Committee	$ 20,000
Corporate Governance Committee	$ 10,000
Compliance Committee	$ 10,000

The Lead Director also receives a $40,000 retainer paid in cash. Currently, the Lead Director is also the Chair of the Corporate Governance Committee, and he is compensated for his position as Chair of that committee. Artivion pays all cash retainers on a monthly basis.

Each committee member also receives a fee, in addition to the annual cash retainer, in the amounts shown in the following table.

Annual Fees for Committee Members	
Audit Committee	$ 10,000
Compensation Committee	$ 7,500
Corporate Governance Committee	$ 5,000
Compliance Committee	$ 5,000

Restricted Stock Grants

Non-employee Directors of Artivion are eligible for equity grants, which are generally made in June of each year. The annual equity portion of non-employee Director compensation for fiscal 2021 was paid in the form of a grant of 4,423 shares of restricted stock. These shares were issued following the annual meeting of stockholders and vest on the first anniversary of issuance. The size and terms of the annual equity grant are subject to annual reevaluation by the Compensation Committee. If a Director ceases to serve as a Director as a result of death or disability or chooses not to stand for reelection following the completion of a full term of service, the equity grant will become fully vested on the date the Director ceases to be a member of the Board. If the Director ceases to be a member of the Board for any other reason, and their equity grant has not fully vested as of the date of termination of Board service, the equity grant shall automatically be forfeited and cancelled as of the date of such termination of Board service. The Compensation Committee, however, has discretion under Artivion's Equity and Cash Incentive Plan to cause the equity grant to fully vest for certain conditions.

Exhibit 21.1

SUBSIDIARIES OF ARTIVION, INC.

Subsidiary	Jurisdiction
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 Europa, Ltd.	England and Wales
CryoLife France, SAS.	France
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 Polska Sp. z.o.o	Poland
JOTEC s.r.l.	Italy
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. 333-258716 on Form S-3 filed on August 11, 2021.
(2) Registration Statement No. 333-244319 on Form S-8 pertaining to the CryoLife, Inc. 2020 Equity and Cash Incentive Plan,
(3) Registration Statement No. 333-229881 on Form S-8 pertaining to the CryoLife, Inc. Equity and Cash Incentive Plan,
(4) Registration Statement No. 333-227473 on Form S-3 filed on September 21, 2018,
(5) Registration Statement No. 333-197545 on Form S-8 pertaining to the CryoLife, Inc. Second Amended and Restated 2009 Stock Incentive Plan,
(6) Registration Statement No. 333-182296 on Form S-8 pertaining to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan,
(7) Registration Statement No. 333-182297 on Form S-4 filed on June 22, 2012,
(8) Registration Statement No. 333-167065 on Form S-8 pertaining to the CryoLife, Inc. Employee Stock Purchase Plan,
(9) Registration Statement No. 333-159608 on Form S-8 pertaining to the CryoLife, Inc. 2009 Employee Stock Incentive Plan,
(10) Registration Statement No. 333-119137 on Form S-8 pertaining to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, and
(11) Registration Statement No. 333-104637 on Form S-8 pertaining to the CryoLife, Inc. 2002 Stock Incentive Plan;

of our reports dated February 22, 2022, 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, 2021.

/s/ Ernst & Young LLP

Atlanta, Georgia
February 22, 2022

Exhibit 31.1

I, James 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 22, 2022

s/ J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer

Exhibit 31.2

I, David Ashley Lee, 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 22, 2022

/s/ D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and
Chief Financial Officer

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, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of James Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer 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
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
February 22, 2022

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and Chief Financial Officer
February 22, 2022