UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2020

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

CRYOLIFE, INC.
(Exact name of registrant as specified in its charter)

Florida	**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	CRY	New York Stock Exchange

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☒ Accelerated filer ☐
Non-accelerated filer ☐ Smaller reporting company ☐
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

As of June 30, 2020 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $694,069,423 computed using the closing price of $19.17 per share of Common Stock on June 30, 2020, 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 12, 2021 the number of outstanding shares of Common Stock of the registrant was 38,956,550.

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, 2020	Part III

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Forward-Looking Statements

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 our business operations, cash flow, business development, employees, and research and development projects, including clinical research projects;
- Our belief that our distributors may delay or reduce purchases of products in U.S. 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, in certain areas can enhance the efficacy 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 OPOs, 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 activities and approvals;
- Potential competition and competitive products, potential adverse regulatory consequences, potential security vulnerabilities, and 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 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 U.S. and the AMDS globally;
- Our plans, costs, and anticipated timeline regarding regulatory approval for PerClot in the U.S. and additional international markets and the distribution of PerClot in those markets after the requisite regulatory approvals are obtained;
- Our beliefs regarding the impact alternative anticoagulation therapy may have on the number of patients choosing On-X mechanical heart valves;
- 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, 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;

- 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, PerClot, 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 expectations regarding the timing of clinical research work and regulatory approvals for and expected distribution of products or indications, including On-X, PerClot, 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 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; 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 statements are based on certain assumptions and analyses 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. Whether actual results and developments will conform with our expectations and predictions, however, is subject to a number of risks and uncertainties that could cause actual results to differ materially 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

CryoLife, Inc. ("CryoLife," 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: BioGlue® Surgical Adhesive ("BioGlue") products, aortic stents and stent grafts, 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, Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, and NEXUS™ endovascular stent graft system ("NEXUS"). In addition to these four major product families, we sell or distribute PhotoFix™ bovine surgical patch, PerClot® hemostatic powder, CardioGenesis cardiac laser therapy, and NeoPatch® chorioamniotic allograft.

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 Holdings, 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 U.K. Additionally, we have entities in 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 BioGlue products, aortic stents and stent grafts, On-X products, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix. The Preservation Services segment includes services revenues from the preservation of cardiac and vascular implantable human tissues. See Part II, Item 8, Note 17 of the "Notes to Consolidated Financial Statements" for further information on our segments and for our geographic information.

Strategy

CryoLife is committed to partnering with surgeons and cardiologists to deliver innovative technologies 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:

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

To the extent that we may own or develop non-core products or applications, we may dispose of those assets or pursue development, licensing, or other commercialization agreements with third-party partners.

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 U.S. 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 cardiac and vascular surgery markets in which we compete and our products, services, and technologies with which we compete in each of these markets below.

Cardiac Surgery Markets

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, cerebrospinal fluid in neurosurgeries, and gastrointestinal contents in abdominal surgeries. Fluid, air, and gastric leakage resulting from surgical procedures can lead to 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, the dural membrane surrounding the brain and spinal cord, and the gastrointestinal tract. 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.

BioGlue

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, pulmonary, and general surgical applications. 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 Conformité Européene Mark product certification ("CE Mark") for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). 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 International Inc, ("Baxter"); Ethicon, Inc., a Johnson & Johnson Company ("Ethicon"); Integra LifeSciences Holdings Corporation; and C.R. Bard Inc. ("Bard"), a subsidiary of Becton, Dickinson, and Company ("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, Europe, the Middle East, and Africa (collectively, "EMEA"), Asia Pacific ("APAC"), and Latin America ("LATAM"). Revenues from BioGlue accounted for 25% of total revenues in each of the years 2020, 2019, and 2018, respectively.

Heart Valves and Cardiac Patches for Cardiac Reconstruction

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.

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 valves are readily available and are a less expensive solution for those requiring a heart valve replacement. These valves contain a synthetic sewing ring to facilitate surgical implantation of the device. 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 valves are readily available and are a relatively inexpensive solution for those requiring a valve replacement. Bioprosthetic tissues 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. Bioprosthetic heart valves usually have a life of 7 to 20 years, after which the valve typically must be replaced. Multiple replacements, each requiring open heart surgery, can be a significant concern for patients, particularly younger patients. 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.

The sewing rings of both mechanical and bioprosthetic heart valves are synthetic materials that may harbor bacteria and lead to infection (endocarditis), which can be difficult to treat with antibiotics. Patients with an infected mechanical or bioprosthetic valve may require valve replacement surgery. The 2013 Society of Thoracic Surgeons Guidelines, (the "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 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 available for use 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 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 valve's long-term resistance to calcification and the patient's relative freedom from re-intervention surgery. In a Ross Procedures, 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 also available for use 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.

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.

On-X Mechanical Heart Valves

The On-X product line includes the On-X prosthetic aortic and mitral heart valve 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 CE Mark for On-X heart valves.

As discussed above, all mechanical 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 is still under clinical investigation. Enrollment in the On-X mitral valve replacement arm is now complete, and we currently intend to submit the results of this trial for FDA approval in mid 2021.

While patients with an On-X aortic heart valve can be safely maintained at a lower INR, patients with mechanical prosthetic 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, CryoLife initiated the PROACT Xa clinical trial to determine if patients with an On-X mechanical aortic valve can be maintained safely and effectively on apixaban (Eliquis®) as an alternative to warfarin, given the drawbacks associated with warfarin. This prospective, randomized, controlled, parallel-arm clinical trial is on-going and the first patient was enrolled in May 2020; enrollment will continue through 2021.

On-X heart valves compete primarily with mechanical valves from Abbott Laboratories, Medtronic, Inc. ("Medtronic"); and LivaNova PLC ("LivaNova") (which business LivaNova recently sold to Gyrus Capital SA). 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 the acquisition of On-X. We sell On-X heart valves throughout the world including North America, EMEA, Asia Pacific, and Latin America. Revenues from On-X products accounted for 19%, 18%, and 17% of total revenues in 2020, 2019, and 2018, respectively.

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, patients implanted with our proprietary SynerGraft SGPV valves had a 17% re-operation rate, as compared to a 40% re-operation rate for patients implanted with non-SynerGraft valves.

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, Inc. ("LifeNet") and LeMaitre Vascular ("LeMaitre"), offer preserved human heart valves and patches in competition with us. We believe that we compete favorably on the basis of surgeon preference, documented clinical data, technology, and customer service, particularly with respect to the capabilities of our field representatives. Alternatives to human heart valves processed by us include valve repair and valve replacement with bioprosthetic valves or mechanical valves. We compete with bioprosthetic or mechanical valves from companies including Medtronic; Edwards Life Sciences, Inc.; LivaNova; 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, Inc.; Anteris Technologies Ltd. ("Anteris"); Abbott Laboratories; and Baxter.

We ship human cardiac tissues to implanting institutions throughout the U.S. 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. Revenues from cardiac tissue preservation services accounted for 15%, 15%, and 14% of total revenues in 2020, 2019, and 2018, respectively.

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. Revenues from PhotoFix accounted for 2%, 1%, and 1% of our total revenues in 2020, 2019, and 2018, respectively.

Stents and Stent Grafts for Aortic Arch and Thoracic Aortic Repair

Hybrid stent grafts, surgical grafts, and endovascular stent grafts can be used in the treatment of complex aortic arch and thoracic aortic disease, such as aortic dissections and thoracic aortic aneurysms.

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. Left untreated, an aortic dissection often results in a ruptured aorta, leading to death.

An aortic aneurysm results from a weakening in the wall of an aorta, which causes the aorta to progressively "balloon" or expand in size. Risk factors for a patient to develop an aortic aneurysm 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 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 and AMDS as well as distribute NEXUS to treat these conditions impacting the aortic arch and thoracic aorta.

E-vita OPEN PLUS and E-vita OPEN NEO

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 U.S. with products from Terumo Medical Corporation ("Terumo") and two smaller competitors. We do not currently sell E-vita OPEN PLUS in the U.S. and we believe there are no competitive products currently being commercialized in the U.S. The E-vita OPEN PLUS competes in the EU primarily on its proven stent graft technology and long-term clinical data.

Through our acquisition of JOTEC, we began selling the E-vita OPEN PLUS in many markets outside of the United States in December 2017. Revenues from the E-vita OPEN PLUS accounted for 2%, 2%, and 3% of total revenues in 2020, 2019, and 2018, respectively.

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

CryoLife acquired Ascyrus Medical LLC ("Ascyrus") in September 2020. Ascyrus has developed the Ascyrus Medical Dissection Stent ("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 the 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. In addition, several manufacturers, including Cook Medical ("Cook"), Gore, Medtronic, and Terumo Aortic are attempting to develop fully endovascular products aimed at treating the ascending aorta. Limited experience exists with these products to date through the custom-made device process in Europe and physician sponsored IDEs within the United States.

Through our acquisition of Ascyrus in September 2020, we began selling AMDS in EMEA and Canada. Revenues from AMDS accounted for less than 1% of total revenues in 2020.

Endovascular and Open Vascular Surgery Markets

Aortic Aneurysm Repair

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 larger 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 death.

There are two types of aortic aneurysm repair: open surgical repair or 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 aortic repair. 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.

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 individual patient's therapeutic requirements. E-xtra DESIGN ENGINEERING 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 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 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.

Revenues from E-xtra DESIGN ENGINEERING accounted for 6%, 5%, and 5% of total revenues in 2020, 2019, and 2018, respectively.

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 the E-nside positions JOTEC 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 JOTEC's existing 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 anticipate full product launch in the first quarter of 2021.

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.

Revenues from the E-vita THORACIC 3G accounted for 2% of total revenues in each of the years 2020, 2019, and 2018, respectively.

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 anticipate full product launch in the second half of 2021.

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 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, Inc. ("Maquet"), Gore, BD and Bentley InnoMed.

Revenues from the distribution of E-ventus BX accounted for 2%, 3%, and 3% of total revenues in 2020, 2019, and 2018, respectively.

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.

Revenues from the E-liac accounted for 2%, of total revenues in each of the years 2020, 2019, and 2018, respectively.

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, Antegraft, Inc, and Cook.

Revenues from the E-tegra accounted for 5%, 6%, and 5% of total revenues for in each of the years 2020, 2019, and 2018, respectively.

NEXUS

JOTEC acquired the exclusive distribution rights in certain countries in Europe for the NEXUS stent graft system ("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 JOTEC's 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 the Zenith arch branched device (Cook), the TAG thoracic branch endoprosthesis (Gore), and the Ascending Thoracic Device based on the Relay NBS Plus (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 chimney or snorkels.

We began limited distribution of NEXUS in the fourth quarter of 2019 in EMEA. Revenues from NEXUS accounted for less than 1% of total revenues in each of 2020 and 2019.

We also entered into a securities purchase option agreement with Endospan in September 2019 which provides CryoLife 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.

Peripheral Vascular 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 artery and vascular repair procedures include procedures related to infected abdominal aortic grafts, vascular access for dialysis patients, carotid endarterectomy, or 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.

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.

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.

We ship human vascular tissues to implanting institutions throughout the U.S. and Canada. Revenues from vascular preservation services accounted for 14%, 14%, and 15% of total revenues in 2020, 2019, and 2018, respectively.

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 in synthetic graft manufacturing. Both of these are used in our stent 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, BD, Gore, LeMaitre, Vascutek Ltd., and Maquet.

Revenues from synthetic surgical vascular grafts accounted for 2%, of total revenues in each of the years 2020, 2019, and 2018, respectively.

Other Technologies

Angina Treatment

Angina consists of pressure, discomfort, or pain in the chest typically due to narrowed or blocked arteries, which may result in 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.

CardioGenesis Cardiac Laser Therapy

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 U.S., 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 PMA-supplement. In January 2021 we received PMA-S approval for this change in manufacturing site and we anticipate resuming limited sales of TMR handpieces in first half of 2021.

We sell handpieces and consoles primarily in the U.S. Revenues from CardioGenesis cardiac laser therapy accounted for less than 1%, 2%, and 2% of total revenues in 2020, 2019, and 2018, respectively.

Hemostats

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. We currently distribute the powdered hemostatic agent PerClot.

PerClot

PerClot is an absorbable powdered hemostat, consisting of plant starch modified into ultra-hydrophilic, adhesive-forming hemostatic polymers. PerClot granules are biocompatible, absorbable polysaccharides containing no animal or human components. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier to any further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) at the site of application. PerClot does not require additional operating room preparation or special storage conditions and is easy to apply. PerClot is readily dissolved by saline irrigation and is totally absorbed by the body within several days. In September 2010, we entered into a distribution agreement and a license and manufacturing agreement with Starch Medical, Inc. ("SMI"), which allows us to distribute PerClot worldwide, except in China, Hong Kong, Macau, Taiwan, North Korea, Iran, and Syria. We are approved to distribute SMI's PerClot in approximately 70 countries.

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, Inc., Baxter, Ethicon, Bard, and BioCer Entwicklungs-GmbH. 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 January 2019 we completed enrolling patients in a clinical trial for the purpose of obtaining FDA Premarket Approval ("PMA") to sell PerClot in the U.S., as discussed further in "Research and Development and Clinical Research" below. We anticipate PMA submission to the FDA during the third quarter of 2021. Revenues from PerClot accounted for 1% of total revenues in each of 2020, 2019, and 2018.

Vascular Access

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.

Marketing and Distribution

In the U.S 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 JOTEC, 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 Germany, the U.K., France, Spain, Italy, Poland, Austria, Switzerland, Netherlands, Belgium, and Ireland in the EMEA region. We provide customer service, logistics, marketing, and clinical support to cardiac, vascular, thoracic, and general surgeons throughout the EMEA region.

In Asia Pacific and Latin America, we commercialize our products through our independent distributors and our subsidiaries through approximately 23 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 2020. We sponsor programs, and work with other companies such as Endospan to sponsor programs, where surgeons train other surgeons in best-demonstrated 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 U.S. 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 small group of suppliers or a single- or sole-source supplier. Certain raw materials and components used in our products and tissue processing have stringent specifications. Supply interruptions or supplier quality, financial, regulatory or operational issues could cause us to have to temporarily reduce, temporarily halt, or permanently halt manufacturing, processing, marketing, selling or distribution activities. Ongoing sustaining efforts are in process to find alternative suppliers for single- or sole-source raw materials and supplies wherever feasible. The process of qualifying alternative suppliers could result in additional costs or lengthy delays or may not be possible. Any of these adverse outcomes could have a material, adverse effect on our revenues or profitability. Supplies of materials are discussed for each of our main products and services below. See also Part I, Item 1A, "Risk Factors – Operational Risks."

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 maintain an inventory of finished delivery devices to help mitigate the effects of a potential supply interruption.

We purchase grafts for our On-X AAP from a single supplier. We also purchase various components for our On-X valves from single suppliers. We maintain inventories of these grafts and components to help mitigate the effects of a potential supply interruption.

We purchase handpieces for our CardioGenesis cardiac laser therapy product line from a separate single-source contract manufacturer. In addition, this manufacturer obtains certain fiber-optic components and subassemblies from single sources. Our manufacturer of handpieces has been unable to supply handpieces until the FDA recently approved our supplier's change in manufacturing location through approval of our PMA supplement. On January 21, 2021 we received notice that the FDA had approved our PMA supplement. We currently anticipate resumption of supply during the first half of 2021. See also Part I, Item 1A, "Risk Factors—Operational Risks—We are dependent on single- and sole-source suppliers and single facilities." In addition, we no longer have a supplier for consoles and do not intend to manufacture consoles in the future, although we will continue to sell consoles in our inventory and provide parts and service for customers with whom we have service contracts for laser consoles.

We purchase PerClot for distribution from SMI pursuant to the above referenced agreements. We maintain an inventory of PerClot purchased from SMI to supply our customer orders and place orders for additional product from SMI to maintain inventory at appropriate levels based on demand. Our business may be subject to interruption if SMI were unable or became unwilling to supply PerClot to us for a sustained period of time.

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 58 OPOs and tissue banks throughout the U.S. 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. All of these factors subject us to risk of supply interruption. 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 in-process quality controls. The contaminated solution is currently estimated to have impacted a small percentage of the tissue processed with this lot of solution, causing us to write-off those contaminated tissues. We are conducting further review to determine if remaining tissue processed with this lot of solution can be released for distribution. See Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Preservation Services,” see also Part I, Item IA, “Risk Factors – Operational Risks – We are dependent on single- and sole-source suppliers and single facilities.”

The 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.

The 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.

The 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.

The NEXUS product is solely manufactured by Endospan in Herzelia, Israel, and our AMDS product is solely manufactured by our supplier in Charlotte, North Carolina.

Operations, Manufacturing, and Tissue Preservation

We maintain a facility, which contains our corporate headquarters and laboratory space, and an additional off-site warehouse in Kennesaw, Georgia. We manufacture BioGlue and PhotoFix and process human tissues at our headquarters 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, and additional office space in Kennesaw, Georgia, both of which we currently sublet to third-parties. Our Atlanta facility was sublet beginning in 2018 and our Kennesaw, Georgia additional space was sublet beginning in 2016.

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 U.K., 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. Currently scheduled to be fully implemented by May 26, 2021 the Medical Device Regulation ("MDR") will replace MDD and will impose 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.

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 U.S., Japan, Australia, Canada, and Brazil.

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, has 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 to a new Notified Body for BioGlue and PhotoFix. 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.

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.

Government Regulation

Medical devices and human tissues are subject to a number of regulations from various government bodies including the U.S., federal, state, and local governments, as well as various international 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.

U.S. 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 U.S. 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 U.S. 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, including our CryoValve SGPV, from unclassified medical devices to a 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 for reclassification of MMM allograft heart valves. 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".

U.S. 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 U.S. 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 CE Mark which allows for distribution of an approved product throughout the EEA without additional general applications in each country. Individual EEA members, however, reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third-parties called "Notified Bodies" award the CE Mark. These Notified Bodies are approved and subject to review by the "Competent Authorities" of their respective countries. Our Notified Bodies perform periodic on-site inspections to independently review our compliance with systems and regulatory requirements. A number of countries outside of the EEA accept the CE Mark in lieu of marketing submissions as an addendum to that country's application process. We have CE Marks for BioGlue, On-X heart valves, On-X AAP, On-X Chord-X sutures, PhotoFix, E-vita OPEN PLUS, E-vita OPEN NEO, E-vita THORACIC 3G, E-tegra, E-liac, E-nya, E-nside, AMDS, and other devices. We are currently addressing the cessation of LRQA as a Notified Body as it pertains to our BioGlue and PhotoFix CE Mark certifications. In addition, PerClot, E-ventus and NEXUS, which we distribute, have CE Marks.

As a result of the United Kingdom's exit from the European Union, or "Brexit," the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA") has announced that CE Marking will continue to be recognized in the U.K. and certificates issued by EU-recognized Notified bodies will continue to be valid in the U.K. market until June 30, 2023. Going forward, all devices marketed in the U.K. will require U.K. Conformity Assessed ("UKCA") Marks certified by a U.K. Approved Body (the re-designation of the U.K. Notified Body). See Part I, Item 1A, "Risk Factors—Industry Risks— Our products and tissues are highly regulated and subject to significant quality and regulatory risks."

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 regarding 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.

Backlog

As of December 31, 2020, we did not have a firm backlog of orders related to BioGlue, On-X heart valves, PerClot, or PhotoFix. 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 varies based on 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 have not had 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 PMA-supplement. On January 21, 2021 we received notice that the FDA had approved our PMA supplement. We currently anticipate resumption of supply during the first half of 2021.

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 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 2020, 2019, and 2018 we spent approximately $24.2 million, $23.0 million, and $23.1 million, respectively, on research and development activities on new and existing products. These amounts accounted for approximately 10%, 8%, and 9% of our revenues for each of 2020, 2019, and 2018, 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.

We are currently conducting clinical trials on the safety and efficacy of an additional size of the On-X aortic heart valve. This study is ongoing, and enrollment will continue through 2021.

We are currently conducting a clinical trial to assess reduced levels of required anticoagulation or warfarin for the On-X mitral heart valve. This study is ongoing, and enrollment was completed in 2019. Follow-up data collection on these patients will continue through 2021. We anticipate PMA submission to the FDA mid 2021.

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 into the fourth quarter of 2021.

We have initiated the PROACT Xa clinical trial to determine if patients with an On-X aortic heart valve can be maintained safely and effectively on apixaban (Eliquis®) rather than on warfarin. In December 2019 we received authorization from the FDA pursuant to an Investigational New Drug application to begin the PROACT Xa clinical trial. This study is ongoing with the first patient enrolled in May 2020 and enrollment will continue through 2021.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate PMA submission 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 U.S. either directly or indirectly."

We will be conducting a pivotal clinical trial to gain approval to commercialize the AMDS hybrid prosthesis in the U.S. for treatment of acute Type A aortic dissections. We anticipate IDE approval in the fourth quarter of 2021 followed by study initiation and first patient enrollment.

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 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 expect to submit an IDE application for E-vita OPEN NEO to initiate an Early Feasibility clinical trial in the US in late 2021.

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 U.S. 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 PerClot and 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 U.S. 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

As of December 31, 2020 we had approximately 1,200 employees. Most of our employees are located in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany, where our employees have a Works Council. 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. We believe our relations with our employees worldwide and with the Works Council in Germany are good.

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. We have programs and processes in place to help ensure that our compensation and benefits programs, and our work environment, attract and retain such personnel. See also Part II, Item 7, “Effects of COVID-19” for discussion about COVID-19’s impact on our employees.

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.cryolife.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 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 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 uncertainty 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.

In 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 waves of COVID-19 and longer than anticipated timelines for widespread therapeutic and vaccine availability remain. These conditions have impacted and could continue to impact our business activities, including the following activities:

- Our product sales. We have experienced an impact on revenues in the twelve months ending December 31, 2020, due principally to the COVID-19 pandemic. The extent to which our financial performance will be impacted by the pandemic in 2021 and beyond will depend largely on future developments, including the availability of the vaccine.
- 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. The COVID-19 virus is contagious and our efforts to reduce the spread of COVID-19 among our employees, including our key personnel, and to protect our supply chain may not succeed.
- Our management of our indebtedness. Partly as a precautionary measure to increase cash and maintain maximum financial flexibility during the COVID-19 pandemic, we issued $100.0 million aggregate principal amount of 4.25% convertible senior notes with a maturity date of July 1, 2025 ("Convertible Senior Notes"), using portions of those proceeds to repay our Revolving Credit Facility and retaining the remainder for general

corporate purposes which may limit our operational flexibility and adversely affect our ability to raise additional capital.

- Our research and development projects. We have reduced spending on research and development projects, including clinical research projects. These reductions could adversely impact future revenue, and additional reductions in spending might be required, 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 and limit access to healthcare facilities or as patients decline to participate or are hesitant to voluntarily visit healthcare facilities. In addition, 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 continues to spread, if efforts to contain COVID-19 continue or are unsuccessful, if we experience new infections of COVID-19 in areas previously successful in containing its spread, or if COVID-19 spreads among our employees or impacts our supply chain, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows. 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 U.S. operations, including:

- 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 U.K. Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, and the European Union's General Data Protection Regulation;
- 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 U.S. Dollar;
- Potential adverse tax consequences of overlapping tax structures; and
- Potential adverse financial and regulatory consequences resulting from the exit of the U.K. from the European Union, or "Brexit."

Our key growth areas may not generate anticipated benefits.

Our strategic plan is focused on four areas – new products, new indications, global expansion and business development – to drive growth and/or increase the size of our total addressable markets, primarily in the cardiac and vascular surgery segment, but we cannot be certain that these strategies will ultimately drive business expansion and enhance shareholder value.

We operate in highly competitive market segments, face competition from large, well-established medical device companies and tissue service providers with greater resources and 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.; Bard, a subsidiary of Becton, Dickinson and Company; Integra Life Sciences Holdings; LifeNet; 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;
- 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, accounting for 29% of revenues in the years ended December 31, 2020, 2019, and 2018 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.

In addition, U.S. 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, accounting for 25% of revenues in the years ended December 31, 2020, 2019, and 2018 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 U.S. 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 U.S. 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 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 U.K. 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 is a significant source of our revenues, accounting for 24% of revenues in the years ended December 31, 2020, 2019, and 2018 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 and in-demand aortic repair products;

- Respond adequately to enhanced regulatory requirements and enforcement activities;
- 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 and are subject to a variety of related risks.

On-X is a significant source of our revenues, accounting for 19%, 18%, and 17% of revenues in the years ended December 31, 2020, 2019, and 2018, respectively 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 OUS regulatory requirements or enforcement activities; and
- Receive timely renewal certifications in certain markets.

Continued fluctuation of foreign currencies relative to the U.S. 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 U.S. 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 U.S. 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.

Our existing insurance coverage may be insufficient, and we may be unable to obtain insurance in the future.

We maintain claims-made insurance policies to mitigate our financial exposure to securities, as well as product and tissue processing liability, claims 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.

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. The contaminated solution is currently estimated to have impacted a small percentage of the tissue processed with this lot of solution, causing us to write-off those contaminated tissues. We are conducting further review to determine if the remaining tissue processed with this lot of solution can be released for distribution.

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.

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

Some of the materials, supplies, and services in our product manufacturing or 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, 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 PMA supplement and FDA approval before handpiece manufacturing and distribution could resume. We anticipate resumption of limited supply during the first half of 2021.

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. 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, our business could be substantially disrupted.

We are dependent on our key personnel.

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, some of whom would be difficult to replace. Our business and future operating results, including production at our manufacturing and tissue processing facilities, also depend in significant part on our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel. Our facilities are in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany, where the supply of qualified medical device and tissue processing 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.

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, 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 CryoLife to Endospan; and a security purchase option agreement for CryoLife to purchase all the then outstanding Endospan securities from Endospan's existing securityholders upon FDA approval of NEXUS; and
- 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").

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 U.S. 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 obtain Conformité Européene Mark product certification ("CE Mark") for pipeline products and obtain or maintain certification for pipeline and current products at all;

- Execute on development and clinical trial timelines for acquired 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 in markets 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; and (f) obtain FDA approval of NEXUS.

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 acquisition, and negatively impact the price of our common stock. In addition, if we fail to realize the anticipated benefits of an acquisition, we could experience an interruption or loss of momentum in our existing business activities.

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 U.S. either directly or indirectly.

In 2010 and 2011, we entered into various agreements with SMI pursuant to which, among other things, we (i) may distribute PerClot in certain international markets.; (ii) acquired technology to assist in the production of a key component in PerClot; and (iii) obtained the exclusive right to pursue, obtain, and maintain FDA Pre-Market Approval ("PMA") for PerClot. We are currently conducting our pivotal trial to gain PMA for PerClot for surgical indications, and we completed enrollment in January 2019. We anticipate being in a position to submit to the FDA during the third quarter of 2021. There is no guarantee, however, that we will obtain FDA approval when anticipated or at all including based on factors such as, unforeseen scheduling difficulties and unfavorable results at stages in the PMA process. We may also decide to delay or terminate our pursuit of PMA at any time due to changing conditions at CryoLife, in the marketplace, or in the economy in general. Even if we receive PMA for PerClot, we may be unsuccessful in selling PerClot in the U.S. By the time we secure approvals, competitors may have substantial market share or significant market protections. We may also be unsuccessful in selling outside the U.S. due, in part, to a proliferation of generic competitors, any breach by SMI of its contractual obligations, or the lack of adequate intellectual property protection or enforcement.

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, personal information, 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, or data loss 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 U.S. 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, there can be no assurance that our efforts will prevent 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, reevaluate, 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 is currently scheduled to be fully implemented by May 26, 2021. Upon implementation, among other changes, MDR will place 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 EEA.

At the same time, European Notified Bodies have begun engaging in more rigorous regulatory enforcement and may continue to do so. For example, in anticipation of MDR, Notified Bodies have declined to review many routine submissions unless they are in accordance with MDR, and Notified Bodies may continue to do so despite the postponement of MDR implementation. Our inability to timely adapt to these new requirements of our Notified Bodies could adversely impact our clearances or approvals.

Finally, we anticipate additional regulatory impact as a result of the United Kingdom’s exit from the European Union (“Brexit”). The U.K. Medicines and Healthcare Products Regulatory Agency (“MHRA”) has announced that CE Marking will continue to be recognized in the U.K. and certificates issued by EU-recognized Notified bodies will continue to be valid in the U.K. market until June 30, 2023. Going forward, all devices marketed in the U.K. will require U.K. Conformity Assessed (“UKCA”) Marks certified by a U.K. Approved Body (the re-designation of the U.K. Notified Body). In 2019 we were informed of the cancellation of notified body services by our former Notified Body for BioGlue and PhotoFix, Lloyd’s Register Quality Assurance Limited. The German competent authority, Regierungspraesidium-Tubingen, granted us an extended grace period until December 31, 2021, to complete the transfer of our registration to a new notified body, provided that we meet certain conditions, including the demonstration of adequate progress in the CE Mark certification process with our new Notified Body. If we are delayed or unsuccessful in transferring to a new Notified Body for BioGlue and PhotoFix in the EEA, or if we are otherwise unable to timely meet applicable regulatory requirements, we may be unable to place BioGlue or PhotoFix on the market in the EEA until we resolve the situation.

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, which could include our CryoValve SGPV, from unclassified medical devices to a Class III medical device. 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 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 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 necessary clinical results or regulatory clearances/approvals for products and services in development, and our new 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, requiring that we invest significant time and resources to obtain required regulatory clearances/approvals, including investment into pre and post-market clinical studies. Although we believe certain products and services under development may be effective in a particular application, we cannot be certain until we successfully execute on a clinical trial, 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 engaged in several pre and post-market clinical studies, including PROACT Xa which will determine if patients with an On-X mechanical aortic valve can be maintained safely and effectively on apixaban (Eliquis®) rather than on warfarin, and a U.S. IDE for PerClot. We also have begun to initiate U.S. clinical trials for certain JOTEC products, initiate U.S. and international clinical trials for the AMDS, and we support Endospan's U.S. clinical trial efforts for NEXUS. Each of these trials or studies 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 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 U.S. 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 control these costs and, more generally, to reform the healthcare systems. Additional uncertainty is anticipated particularly in light of the recent presidential election in the United States and the impact the results of the presidential and congressional elections may have on U.S. law relating to the healthcare industry. Many U.S. 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. 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 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, however, could adversely affect our business and profitability.

Legal, Quality, and Regulatory Risks

We are subject to various U.S. 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 U.S. 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 or healthcare organizations, including some who may order our products or make decisions to use them. We have also adopted the AdvaMed Code of Conduct and the MedTech Europe Code of Ethical Business Practice, which govern our relationships with healthcare professionals to bolster our compliance with healthcare compliance law. While our relationships with healthcare professional 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 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 implementation of new data privacy laws, including the General Data Protection Regulation in the European Union in May 2018, 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.

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. We have had investors who we believe to be activist investors with respect to some of their positions recently invest in our stock.

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, 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 patent that we 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 an intellectual property dispute, 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;
- Deviate from 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;
- 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;
- Comply with certain financial ratios set forth in the agreement;

- 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 expose us to increased interest rate fluctuation risk as most of our borrowings are at a variable rate of interest.

We have pledged substantially all of our U.S. 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;
- 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; or
- Could require us to apply all of our available cash to repay such indebtedness.

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against their secured collateral. 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

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 Florida 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.

We are subject to the Florida affiliated transactions statute, which generally requires approval by the disinterested directors or supermajority approval by shareholders for "affiliated transactions" between a corporation and an "interested stockholder." Additionally, our organizational documents 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 Florida 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.

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. We are in the process of constructing a 76,000 square feet facility that we anticipate leasing in 2021 for future growth.

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, and a facility, which consists of approximately 25,000 square feet of additional office space in Kennesaw, Georgia, both of which we sublet to a third party. Our Atlanta 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 "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.

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

2019	High	Low
First quarter	$ 30.86	$ 23.99
Second quarter	32.59	26.78
Third quarter	33.00	25.53
Fourth quarter	27.45	20.76

As of February 12, 2021 we had 232 shareholders of record.

Dividends

No dividends were paid in 2020, 2019, or 2018.

On December 1, 2017 we entered into a Credit and Guaranty Agreement (the "Credit Agreement"), among CryoLife, as borrower, CryoLife International, Inc., On-X Life Technologies Holdings, Inc. ("On-X Holdings"), 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 10 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, 2020 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
10/01/20 - 10/31/20	--	--	--	--
11/01/20 - 11/30/20	4,898	$ 19.19	--	--
12/01/20 - 12/31/20	8,992	20.93	--	--
Total	13,890	20.31	--	--

The common shares purchased during the quarter ended December 31, 2020 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. Companies can elect to comply with certain or all amendments on or after February 10, 2021, with compliance becoming mandatory on August 9, 2021. 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.

Overview

CryoLife, Inc. ("CryoLife," 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: BioGlue Surgical Adhesive ("BioGlue") products, aortic stents and stent grafts, 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, Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, and NEXUS endovascular stent graft system ("NEXUS"). In addition to these four major product families, we sell or distribute PhotoFix bovine surgical patch, PerClot hemostatic powder, CardioGenesis cardiac laser therapy, and NeoPatch chorioamniotic allograft.

For the year ended December 31, 2020 we reported annual revenues of $253.2 million, decreasing 8% over the prior year, largely due to decreases in revenues from BioGlue, CardioGenesis cardiac laser therapy, cardiac preservation service revenues, Aortic stents and stent grafts, On-X and PerClot product revenues, partially offset by an increase in PhotoFix product revenues. For the year ended December 31, 2020 we generated $12.4 million in cash flows from operations and reported a net loss of $16.7 million. See the "Results of Operations" section below for additional analysis of the fourth quarter and full year 2020 results. See Part I, Item 1, "Business," for further discussion of our business and activities during 2020.

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 "global pandemic."

Starting 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 have included but were not limited to, implementing specific protocols to minimize workplace exposures to COVID-19 by our employees, implementing remote work arrangements for employees we deem able to do so, restricting business travel, issuing $100.0 million in aggregate principal amount convertible senior notes ("Convertible Senior Notes"), using portions of those proceeds to repay our Revolving Credit Facility and the remainder for general corporate purposes, see the "Liquidity and Capital Resources" identified in Part II, Item 7 of this form 10-K for further detail of this transaction, 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 CryoLife stock instead of cash compensation for a six month period through October 2020; and deferring management merit increases.

Our efforts to reduce the spread of COVID-19 among our employees, including our key personnel and to protect our supply chain were largely successful in 2020 as we continued to operate all manufacturing sites at near full production and our work-from-home arrangements 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 will continue to be successful in the future. Further, our

reductions and delays 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 effects of the pandemic.

We continue to monitor the impact of the COVID-19 pandemic on our business and recognize that it could continue to negatively impact our business and results of operations in 2021. The extent to which our operations and financial performance will be impacted by the pandemic in 2021 will depend largely on future developments, including the vaccine rollout. If COVID-19 becomes more contagious, continues to spread, if efforts to contain COVID-19 are unsuccessful, if we experience new infections of COVID-19 in areas previously successful in containing its spread, or if COVID-19 spreads among our employees or impacts our supply chain, or if we experience a prolonged period of uncertainty 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.

Transaction with Ascyrus

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 has 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 may 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 CryoLife common stock, in each case, delivered at the closing of the acquisition, (ii) if the U.S. Food and Drug Administration (the "FDA") approves an Investigational Device Exemption ("IDE") application for the AMDS, a cash payment of $10.0 million and the issuance of $10.0 million in shares of CryoLife common stock, (iii) if the FDA approves a Premarket Approval ("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 up to $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 Premarket Approval application submitted for the AMDS.

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 U.S., 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.

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 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 consign 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 $1.7 million, $787,000, and $437,000 for the years ended December 31, 2020, 2019, and 2018, 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.

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.

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.

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

(In thousands)

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

Revenues

	Revenues for the Three Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2020	2019	Percent Change	2020	2019
Products:					
BioGlue	$ 17,083	$ 17,777	-4%	25%	26%
Aortic stents and stent grafts	17,731	16,038	11%	26%	23%
On-X	13,668	13,345	2%	20%	19%
PhotoFix	1,113	1,002	11%	2%	1%
PerClot	801	981	-18%	1%	1%
CardioGenesis cardiac laser therapy	106	1,050	-90%	0%	2%
Total products	50,502	50,193	1%	74%	72%
Preservation services:					
Cardiac tissue	9,135	10,145	-10%	14%	15%
Vascular tissue	8,195	9,359	-12%	12%	13%
NeoPatch	64	--	100%	0%	0%
Total preservation services	17,394	19,504	-11%	26%	28%
Total	$ 67,896	$ 69,697	-3%	100%	100%

	Revenues for the Twelve Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2020	2019	Percent Change	2020	2019
Products:					
BioGlue	$ 62,068	$ 68,611	-10%	25%	25%
Aortic stents and stent grafts	61,663	64,974	-5%	24%	24%
On-X	48,053	50,096	-4%	19%	18%
PhotoFix	4,169	3,754	11%	2%	1%
PerClot	2,882	3,795	-24%	1%	1%
CardioGenesis cardiac laser therapy	464	6,016	-92%	0%	2%
Total products	179,299	197,246	-9%	71%	71%
Preservation services:					
Cardiac tissue	37,893	40,879	-7%	15%	15%
Vascular tissue	35,852	38,097	-6%	14%	14%
NeoPatch	183	--	100%	0%	0%
Total preservation services	73,928	78,976	-6%	29%	29%
Total	$ 253,227	$ 276,222	-8%	100%	100%

Revenues decreased 3% and 8% for the three and twelve months ended December 31, 2020, respectively, as compared to the three and twelve months ended December 31, 2019. The decrease in revenues for the three months ended December 31, 2020 was primarily due to decrease in revenues from vascular and cardiac preservation services, CardioGenesis cardiac laser therapy revenues, BioGlue and PerClot product revenues, partially offset by increases in aortic stents and stent grafts, On-X, and PhotoFix product revenues. The decrease in revenues for the twelve months ended December 31, 2020 was primarily due to decreases in revenues from all products, except PhotoFix. Excluding the effects for foreign exchange, revenues decreased 4% and 8% for the three and twelve months ended December 31, 2020, respectively, as compared to the three and twelve months ended December 31, 2019. Revenues for the three and twelve months ended December 31, 2020 were negatively impacted by delays or cancellations of some surgical procedures as a result of reduced hospital capacity and hospital restrictions due to the COVID-19 pandemic, as well as patient reluctance to undergo procedures once the adverse impacts to capacity and restrictions decreased. Revenue decreases during 2020 as compared to 2019 were larger during the second quarter with smaller sequential decreases during the third and fourth quarters as procedure volumes increased throughout second half of 2020.

A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2020 is presented below.

Products

Revenues from products increased 1% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. Revenues from products decreased 9% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. The increase in revenues for the three months ended December 31, 2020 was primarily due to increases in aortic stents and stent grafts, On-X and PhotoFix product revenues, partially offset by decreases in revenues from CardioGenesis cardiac laser therapy, BioGlue and PerClot products. The decrease for the twelve months ended December 31, 2020 was due to decreases in revenues from all products except for PhotoFix. A detailed discussion of the changes in product revenues for BioGlue, aortic stents and stent grafts, On-X, PhotoFix, PerClot, and CardioGenesis cardiac laser therapy 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 three and twelve months ended December 31, 2020 as compared to the three and twelve months ended December 31, 2019, the U.S. Dollar weakened in comparison to major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into U.S. 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 U.S. 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 U.S. Dollars depending on the relative price of these goods in their local currencies.

BioGlue

The BioGlue product line is 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 sale of BioGlue decreased 4% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. This decrease was primarily due to a 5% decrease in volume of milliliters sold, which decreased revenues by 4%. Excluding the effects for foreign exchange, revenues decreased 5% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019.

Revenues from the sale of BioGlue decreased 10% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. This decrease was primarily due to a 9% decrease in the volume of milliliters sold, which decreased revenues by 10%. Excluding the effects for foreign exchange, revenues decreased 9% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019.

On a constant currency basis, revenues from sales of BioGlue decreased in the three and twelve months ended December 31, 2020 compared to the three and twelve months ended December 31, 2019 primarily in North America, Europe, the Middle East, and Africa (collectively, “EMEA”) and to a lesser extent in Asia Pacific, partially offset by an increase in the Latin America market. These markets were impacted by a decrease in volume of milliliters sold in the three and twelve months ended December 31, 2020 as compared to the three and twelve months ended December 31, 2019 primarily due to delays and cancellations of surgical procedures due to the COVID-19 pandemic. The increase in Latin America was primarily due to continued expansion in Brazil and enhanced distributor performance in other Latin American countries.

We are currently seeking regulatory approval for BioGlue in China, and if this effort is successful, management believes this will provide an additional international growth opportunity for BioGlue in future years.

Domestic BioGlue revenues accounted for 49% and 50% of total BioGlue revenues for the three and twelve months ended December 31, 2020, respectively, and 49% and 51% of total BioGlue revenues for the three and twelve months ended December 31, 2019, respectively.

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.

On September 11, 2019 CryoLife 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 stent graft system (“NEXUS”) and accessories in certain countries in Europe. NEXUS revenues are included as a component of aortic stents and stent grafts revenues from the date of the agreement.

On September 2, 2020 CryoLife entered into an agreement to acquire all of the equity interests of Ascyrus Medical LLC (“Ascyrus”). Ascyrus has developed the Ascyrus Medical Dissection Stent, an aortic arch remodeling device used for the treatment of acute Type A aortic dissections (“AMDS”). AMDS is currently distributed in EMEA and Canada 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 11% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. Aortic stents and stent grafts revenues decreased 5% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019.

Aortic stents and stent grafts revenues, excluding original equipment manufacturing (“OEM”), increased 8% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. The factors affecting revenue during this period include a change in mix of volume sold which increased revenues by 10%, the effect of foreign exchange rates, which increased revenues by 4%, offset by a change in average sales prices which decreased revenues 6%.

Aortic stents and stent grafts revenues, excluding OEM, decreased 5% for the twelve months ended December 31, 2020 as compared to the twelve months ended December 31, 2019. This decrease was primarily due to a change in average sales prices, which decreased revenues by 3% and a change in mix of volume sold, which decreased revenues by 2%.

On a constant currency basis, revenues for aortic stents and stent grafts, excluding OEM, increased 3% in the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. Revenues for the three months ended December 31, 2020 increased primarily in Asia Pacific, North America, and EMEA markets, partially offset by a decrease in the Latin American market. The increase in Asia Pacific was primarily due to growth in distributor markets. The increase in North America markets was primarily due to sales of AMDS to Canada as a result of the Ascyrus acquisition in September 2020. The increase in EMEA markets was primary due to sales of AMDS as a result of the Ascyrus acquisition and an increase in NEXUS sales as these products continue to penetrate the EMEA markets, partially offset by a decrease in JOTEC products due to the delay in surgical procedures due to the COVID-19 pandemic. The decrease in Latin America was primarily in direct markets due to the delay in surgical procedures due to the COVID-19 pandemic.

On a constant currency basis, revenues for aortic stents and stent grafts, excluding OEM, decreased 5% in the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. Revenues for the twelve months ended December 31, 2020 decreased in EMEA and Latin America primarily in direct markets due to the delay in surgical procedures due to the COVID-19 pandemic, offset by an increase in Asia Pacific due to growth in distributor markets. Aortic stents and stent grafts OEM sales accounted for less than 1% of product revenues for both the three and twelve months ended December 31, 2020 and 2019.

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 2% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. On-X product revenues decreased 4% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019.

On-X product revenues, excluding OEM, increased 2% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. This increase was primarily due to a mix in volume of units sold, which increased revenues by 2%.

On-X product revenues, excluding OEM, decreased 4% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. This decrease was primarily due to a 16% decrease in volume of units sold, which decreased revenues by 4%.

On a constant currency basis, On-X revenues, excluding OEM, increased 1% in the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. This increase in the three months ended December 31, 2020 as compared to the three months ended December 31, 2019 was primarily in North America, partially offset by decreases in EMEA, Asia Pacific, and Latin America. The increase in revenues in North America was due to an increase in market share. The decrease in revenues in all other regions was due to delays and cancellations of surgical procedures due to the COVID-19 pandemic.

On a constant currency basis, On-X revenues, excluding OEM, decreased 4% in the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. The decrease in the twelve months ended December 31, 2020 as compared to the twelve months ended December 31, 2019 was primarily in EMEA and, to a lesser extent, in Asia Pacific due to delays and cancellations of surgical procedures due to the COVID-19 pandemic, partially offset by an increase in North America due to an increase in market share. On-X OEM sales accounted for less than 1% of product revenues for both the three and twelve months ended December 31, 2020 and 2019.

PhotoFix

PhotoFix revenues increased 11% for both the three and twelve months ended December 31, 2020, as compared to the three and twelve months ended December 31, 2019. The increase for the three months ended December 31, 2020 was primarily due to an increase in average sales prices, which increased revenues by 5%, a mix of units sold which increased revenues 5%, and the effect of foreign exchange rates which increased revenues by 1%. The increase for the twelve months ended December 31, 2020 was primarily due to a 3% increase in units sold, which increased revenues by 6%, and an increase in average sales prices, which increased revenues 5%.

The increase in units sold for the twelve months ended December 31, 2020 was primarily due to an increase in the number of physicians who implant PhotoFix compared to the twelve months ended December 31, 2019 as PhotoFix continues to increase penetration in domestic and European markets.

PerClot

Revenues from the sale of PerClot decreased 18% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. This decrease was primarily due to a 24% decrease in the volume of grams sold, which decreased revenues by 20%, and a change in the mix of average sales prices, which decreased revenues 1%, partially offset by the effect of foreign exchange rates, which increased revenues by 3%.

Revenues from the sale of PerClot decreased 24% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. This decrease was primarily due to a 25% decrease in volume of grams sold, which decreased revenues by 20%, and a change in the mix of average sales prices, which decreased revenues by 5%, partially offset by the effect of foreign exchange rates, which increased revenues by 1%.

The decrease in volume for both the three and twelve months ended December 31, 2020 was primarily due to a decrease in sales of PerClot in Asia Pacific and EMEA due to delays and cancellations of surgical procedures due to the COVID-19 pandemic and competitive pressures in certain regions.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019, and we anticipate being in a position to submit the PMA to the FDA in the third quarter of 2021.

CardioGenesis Cardiac Laser Therapy

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 three and twelve months ended December 31, 2020, we did not have a supply of handpieces as our contract manufacturer of handpieces was unable to supply them until the FDA approved our supplier's change in manufacturing location, pending our supplier's resolution of several observations the FDA raised during a manufacturing site change inspection. We do not believe these observations relate to quality or safety. In January 2021 we received PMA-S approval for a change in manufacturing site for our contract manufacturer and we anticipate resuming limited sales of TMR handpieces in the first half of 2021.

Revenues from cardiac laser therapy decreased 90% and 92% for the three and twelve months ended December 31, 2020, respectively, as compared to the three and twelve months ended December 31, 2019 as a result of this handpiece supply issue.

Preservation Services

Preservation services primarily include services revenues from the preservation of cardiac and vascular tissues. Revenues from preservation services decreased 11% and 6% for the three and twelve months ended December 31, 2020, respectively, as compared to the three and twelve months ended December 31, 2019. Revenues decreased for the three and twelve months ended December 31, 2020 from a decrease in cardiac and vascular preservation service revenues as compared to the three and twelve months ended December 31, 2019. The detailed discussion of the changes in cardiac and vascular preservation services revenues is presented below.

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 lot of saline solution 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 is currently 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. We are conducting further review to determine if the remaining $5.0 million in quarantined tissue processed with this lot of saline can be released for distribution. We believe the amount of tissue written-off and held in quarantine that was not available for distribution had an impact on tissue revenues in the fourth quarter of 2020, and we anticipate an additional impact on revenues in 2021 primarily in the first quarter. Although we believe it is probable that the tissues held in quarantine will be released, if they are not released, there could be an additional write-off of up to $5.0 million.

See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and twelve months ended December 31, 2020.

Cardiac Preservation Services

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.

Revenues from cardiac preservation services, consisting of revenues from the distribution of human heart valves and cardiac patch tissues, decreased 10% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. This decrease was primarily due to a 10% decrease in unit shipments of cardiac tissues, which decreased revenues by 8%, and a change in average service fees, which decreased revenues by 2%.

Revenues from cardiac preservation services decreased 7% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. This decrease was primarily due to a 7% decrease in unit shipments of cardiac tissues, which decreased revenues by 7%.

The decrease in unit shipments for the three months ended December 31, 2020, was primarily due to a decrease in aortic and pulmonary valve shipments as well as cardiac patch shipments due to delays and cancellations of surgical procedures and a slowdown of procurement due to the COVID-19 pandemic. The decrease in unit shipments for the twelve months ended December 31, 2020, was primarily due to a decrease in pulmonary and aortic valve shipments due to delays and cancellations of surgical procedures and a slowdown of procurement due to the COVID-19 pandemic as well as the tissues being held in quarantine as a result of the saline solution lot that contained some contamination as described above, partially offset by an increase in cardiac patch shipments.

Vascular Preservation Services

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.

Revenues from vascular preservation services decreased 12% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. This decrease was primarily due to a 5% decrease in vascular unit shipments, which decreased revenues by 10%, and a decrease in average service fees, which decreased revenues by 2%.

Revenues from vascular preservation services decreased 6% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. This decrease was primarily due to a 4% decrease in vascular tissue shipments, which decreased revenues by 4%, and a decrease in average service fees, which decreased revenues by 2%.

The decrease in shipments of vascular tissues for the three months ended December 31, 2020 was primarily due to a decrease in saphenous vein shipments, partially offset by an increase in femoral artery shipments. The decrease in shipments of vascular tissue for the twelve months ended December 31, 2020, was primarily due to a decrease in femoral vein and

artery shipments, as well as saphenous vein shipments. The decrease in shipments for the three and twelve months ended December 31, 2020 are due to delays and cancellations of surgical procedures and a slowdown in procurement due to the COVID-19 pandemic as well as the tissues being held in quarantine as a result of the saline solution lot that contained some contamination as described above.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Cost of products	$ 14,050	$ 14,001	$ 50,128	$ 55,022

Cost of products remained flat for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. Cost of products decreased 9% for the twelve months ended December 31, 2020, as compared to the twelve months ended December 31, 2019. Cost of products for the three and twelve months ended December 31, 2020 and 2019 included costs related to aortic stents and stent grafts, On-X, BioGlue, PhotoFix, PerClot, and CardioGenesis cardiac laser therapy products.

The decrease in cost of products for the twelve months ended December 31, 2020 was primarily due to a decrease in unit shipments.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Cost of preservation services	$ 9,255	$ 9,144	$ 35,315	$ 38,187

Cost of preservation services increased 1% for the three months ended December 31, 2020, as compared to the three months ended December 31, 2019. Cost of preservation services decreased 8% for December 31, 2020, as compared to the twelve months ended December 31, 2019. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three months ended December 31, 2020 primarily due to a $1.1 million write-off of tissues not expected to be shipped, partially offset by a decrease in tissues shipped and a decrease in tissue unit costs. Cost of preservation services decreased in the twelve months ended December 31, 2020 primarily due to a decrease of tissue unit costs, and a decrease in tissues shipped, partially offset by a $1.7 million write-off of tissues not expected to be shipped.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Gross margin	$ 44,591	$ 46,552	$ 167,784	$ 183,013
Gross margin as a percentage of total revenues	66%	67%	66%	66%

Gross margin decreased 4% and 8% for the three and twelve months ended December 31, 2020, respectively as compared to the three and twelve months ended December 31, 2019. The gross margin decrease for the three months ended December 31, 2020 was due to an overall decrease in total revenues. Gross margin as a percentage of total revenues decreased in the three months ended December 31, 2020 as compared to the three months ended December 30, 2019, primarily due to tissue and product write-offs, partially offset by a change in the mix of products sold during the three months ended December 31, 2020.

The gross margin decrease for the twelve months ended December 31, 2020 as compared to twelve months ended December 31, 2019 was due to an overall decrease in revenues from products and preservation services and a corresponding overall decrease in costs of products and preservation services. Gross margin as a percentage of total revenues remained flat in the twelve months ended December 31, 2020 as compared to December 31, 2019.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
General, administrative, and marketing expenses	$ 36,103	$ 37,609	$ 141,136	$ 143,011
General, administrative, and marketing expenses as a percentage of total revenues	53%	54%	56%	52%

General, administrative, and marketing expenses decreased 4% and 1% for the three and twelve months ended December 31, 2020, respectively, as compared to the three and twelve months ended December 31, 2019. The decreases in general, administrative, and marketing expenses for the three and twelve months ended December 31, 2020 were primarily due to a reduction of stock compensation expense resulting from stock award performances that were not achieved and a reduction in the vacation accrual that in aggregate was $4.2 million combined with decreases in travel and marketing expenses from reduced and cancelled travel and events as well as reduced commissions due to the COVID-19 pandemic, partially offset by a $4.5 million fair value adjustment related to the Ascyrus Agreement. General, administrative, and marketing expenses included $4.8 million and $6.2 million of business development expenses for the three and twelve months ended December 31, 2020 as compared to approximately $500,000 and $3.1 million as of the three and twelve months ended December 31, 2019. Business development expenses for three and twelve months ended December 31, 2020 were primarily comprised of expenses related to the Ascyrus Acquisition. Business development expenses during the twelve months ended December 31, 2019 primarily consisted of expenses related to the Endospan agreements.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Research and development expenses	$ 6,574	$ 5,312	$ 24,207	$ 22,960
Research and development expenses as a percentage of total revenues	10%	8%	10%	8%

Research and development expenses increased 24% and 5% for the three and twelve months ended December 31, 2020, respectively as compared to the three and twelve months ended December 31, 2019. Research and development spending in the three and twelve months ended December 31, 2020 was primarily focused on clinical work to gain regulatory approvals for On-X and JOTEC products. Research and development spending in the three and twelve months ended December 31, 2019 was primarily focused on clinical work for JOTEC products and to gain regulatory approval for On-X products as well as approval to commercialize PerClot for surgical indications in the U.S.

Interest Expense

Interest expense was $4.7 million and $16.7 million for the three and twelve months ended December 31, 2020, respectively, and interest expense was $3.6 million and $14.9 million for the three and twelve months ended December 31, 2019, respectively. Interest expense for the three and twelve months ended December 31, 2020 and 2019 relates to interest on debt and uncertain tax positions. Interest on debt includes $1.4 million and $3.7 million of non-cash interest related to the convertible and term loan debt for the three and twelve months ended December 31, 2020, respectively. Interest on debt includes $406,000 and $1.6 million of non-cash interest related to the term loan debt for the three and twelve months ended December 31, 2019, respectively.

Other Expense (Income), Net

Other income, net was $2.7 million and $1.4 million for the three months ended December 31, 2020, as compared to three months ended December 31, 2019, respectively. Other expense was $3.1 million and $1.3 million for the twelve months ended December 31, 2020 as compared to the twelve months ended December 31, 2019, respectively. Other income, net includes $2.7 million and $1.6 million in realized and unrealized gains due of foreign currency fluctuations for the three months ended December 31, 2020, and 2019, respectively. Other expense, net includes $4.9 million in fair value adjustments of financial instruments for the twelve months ended December 31, 2020. Additionally, other expense, net included $1.8 million in realized and unrealized gains and $1.2 million in realized and unrealized losses due to foreign currency fluctuations during the twelve months ended December 31, 2020, and 2019, respectively.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
(Loss) income before income taxes	$ (92)	$ 1,547	$ (17,174)	$ 1,644
Income tax expense (benefit)	3,366	2,228	(492)	(76)
Net (loss) income	$ (3,458)	$ (681)	$ (16,682)	$ 1,720
Diluted (loss) income per common share	$ (0.09)	$ (0.02)	$ (0.44)	$ 0.05
Diluted weighted-average common shares outstanding	38,613	37,274	37,861	37,860

We experienced a loss before income taxes for the three months ended December 31, 2020 as compared to income before income taxes for the three months ended December 31, 2019. We experienced a loss before income taxes for the twelve months ended December 31, 2020 as compared to income before income taxes for the twelve months ended December 31, 2019. The loss before income taxes for the three and twelve months ended December 31, 2020 was primarily due to decreases in revenues impacted by delays and cancellations of some surgical procedures as a result of reduced hospital capacity and hospital restrictions due to the COVID-19 pandemic as well as the fixed nature of certain operating expenses.

Our effective income tax rate was an expense of 3,654% and a benefit of 3% for the three and twelve months ended December 31, 2020, respectively, as compared to an expense of 144% and a benefit of 5% for the three and twelve months ended December 31, 2019, respectively. The change in the tax rate for the three and twelve months ended December 31, 2020 is primarily due to a change in pre-tax book loss, a reduction in the excess tax benefit related to stock compensation, the recording of a valuation allowance against deferred tax assets, as well as adjustments for prior year items for the three and twelve months ended December 31, 2020, as compared to the three and twelve months ended December 31, 2019.

The income tax rate for the three and twelve months ended December 31, 2020 and 2019 was favorably impacted by excess tax benefit deductions related to stock compensation, the research and development tax credit, adjustments for prior year tax items, and releases of uncertain tax position liabilities. These factors were partially offset by the unfavorable impacts of nondeductible executive compensation, intercompany interest expense disallowance, changes in valuation allowances on future tax assets, and nondeductible operating expenses.

In response to the COVID-19 pandemic, the U.S. government enacted the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) on March 27, 2020. The CARES Act provides various forms of relief and assistance to U.S. businesses. We were able to utilize $2.9 million and $3.3 million of our previously disallowed interest expense in 2020 and 2019, respectively, as a result of the CARES Act changes to the interest expense deductibility guidance. See Note 8 for further discussion of our interest expense deduction limitation and carryforward.

We experienced a net loss and diluted loss per common share for the three months ended December 31, 2020 and 2019. We experienced net loss and diluted loss per common share for the twelve months ended December 31, 2020 as compared to a net income and diluted income per common share for twelve months ended December 31, 2019. Net loss and diluted loss per common share for the three and twelve months ended December 31, 2020 was primarily due to an increase in loss before income taxes, as discussed above.

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Revenues

	Revenues for the Three Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2019	2018	Percent Change	2019	2018
Products:					
BioGlue	$ 17,777	$ 17,975	-1%	26%	27%
Aortic stents and stent grafts	16,038	16,672	-4%	23%	25%
On-X	13,345	11,337	18%	19%	17%
CardioGenesis cardiac laser therapy	1,050	1,703	-38%	2%	2%
PerClot	981	945	4%	1%	1%
PhotoFix	1,002	699	43%	1%	1%
Total products	50,193	49,331	2%	72%	73%
Preservation services:					
Cardiac tissue	10,145	9,023	12%	15%	13%
Vascular tissue	9,359	9,445	-1%	13%	14%
Total preservation services	19,504	18,468	6%	28%	27%
Total	$ 69,697	$ 67,799	3%	100%	100%

	Revenues for the Twelve Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2019	2018	Percent Change	2019	2018
Products:					
BioGlue	$ 68,611	$ 66,660	3%	25%	25%
Aortic stents and stent grafts	64,974	63,341	3%	24%	24%
On-X	50,096	44,832	12%	18%	17%
CardioGenesis cardiac laser therapy	6,016	6,217	-3%	2%	2%
PerClot	3,795	3,767	1%	1%	2%
PhotoFix	3,754	2,577	46%	1%	1%
Total products	197,246	187,394	5%	71%	71%
Preservation services:					
Cardiac tissue	40,879	35,683	15%	15%	14%
Vascular tissue	38,097	39,764	-4%	14%	15%
Total preservation services	78,976	75,447	5%	29%	29%
Total	$ 276,222	$ 262,841	5%	100%	100%

Revenues increased 3% and 5% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018. The increase in revenues for the three months ended December 31, 2019 was primarily due to increases in On-X product revenues and cardiac preservation services revenues. The increase in revenues for the twelve months ended December 31, 2019 was primarily due to increases in On-X product revenues and cardiac preservation services revenues, as well as BioGlue and aortic stents and stent grafts. Excluding the effects for foreign exchange, revenues increased 4% and 7% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2019 is presented below.

Products

Revenues from products increased 2% and 5% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018. The increase in revenues for the three months ended December 31, 2019 was primarily due to increases in On-X product revenues. The increase in revenues in the twelve months ended December 31, 2019 was primarily due to increases in On-X, BioGlue, and aortic stents and stent grafts. A detailed discussion of the changes in product revenues for BioGlue, JOTEC, On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix 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, with a concentration denominated in Euros in addition to British Pounds, Polish Zlotys, Swiss Francs, Brazilian Reals, and Canadian Dollars which are subject to exchange rate fluctuations. For the three and twelve months ended December 31, 2019 compared to the three and twelve months ended December 31, 2018 the U.S. Dollar strengthened in comparison to major currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into U.S. 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 U.S. 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 U.S. Dollars depending on the relative price of these goods in their local currencies.

BioGlue

The BioGlue product line is 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 sale of BioGlue decreased 1% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. This decrease was primarily due to an impact of foreign exchange rates and a change in average sales prices, each of which decreased revenues by 1%, partially offset by a change in the mix of milliliters sold, which increased revenues by 1%. Excluding the effects for foreign exchange, revenues were flat for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018.

Revenues from the sale of BioGlue increased 3% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. This increase was primarily due to a 5% increase in the volume of milliliters sold, which increased revenues by 5%, partially offset by the effect of foreign exchange rates, which decreased revenues by 1%, and a decrease in average sales prices, which decreased revenues by 1%. Excluding the effects for foreign exchange, revenues increased 5% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018.

Excluding the effects for foreign exchange, revenues for BioGlue increased in the three and twelve months ended December 31, 2019 as compared to the three and twelve months ended December 31, 2018 in all international markets, with the largest growth in Asia Pacific for the three months ended December 31, 2019 and EEA, the Middle East, and Africa ("EMEA") and Asia Pacific for the twelve months ended December 31, 2019. The increase in revenue in Asia Pacific is due to distributor buying patterns for the three and twelve months ended December 31, 2019. The increase in revenue in EMEA is due to an increase in direct sales during the twelve months ended December 31, 2019. The increases in all international markets were partially offset by decreases in domestic markets during the three and twelve months ended December 31, 2019 as compared to the three and twelve months ended December 31, 2018.

We are currently seeking regulatory approval for BioGlue in China, and if this effort is successful, management believes this will provide an additional international growth opportunity for BioGlue in future years.

Domestic BioGlue revenues accounted for 49% and 51% of total BioGlue revenues for the three and twelve months ended December 31, 2019, respectively, and 50% and 53% of total BioGlue revenues for the three and twelve months ended December 31, 2018, respectively.

Aortic Stents and Stent Grafts

On December 1, 2017 CryoLife acquired JOTEC AG and its subsidiaries (the "JOTEC Acquisition"), a Germany-based, developer of technologically differentiated endovascular stent grafts, and cardiac and vascular surgical grafts, focused on aortic repair. The JOTEC product line is used in endovascular and open vascular surgery, as well as for the treatment of complex aortic arch and thoracic aortic diseases.

Aortic stents and stent grafts revenues decreased 4% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. JOTEC revenues increased 3% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018.

Aortic stents and stent grafts revenues, excluding original equipment manufacturing ("OEM"), were flat for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. The factors affecting revenue during this period include a change in mix of volume sold which increased revenues by 5%, offset by the effect of foreign exchange rates, which decreased revenues by 4%, and a change in average sales prices which decreased revenues 1%.

Aortic stents and stent grafts revenues, excluding OEM, increased 3% for the twelve months ended December 31, 2019 as compared to the twelve months ended December 31, 2018. This increase in revenues was primarily due to an 8% increase in volume of units sold, which increased revenues by 11%, partially offset by the effect of foreign exchange rates, which decreased revenues by 6%, and a decrease in average sales price, which decreased revenues by 2%.

Excluding the effects for foreign exchange, aortic stents and stent grafts revenues, excluding OEM, increased 4% and 10% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018.

Revenues for aortic stents and stent grafts, excluding OEM, increased in the three months ended December 31, 2019, as compared to the three months ended December 31, 2018 in EMEA and Latin America, on a constant currency basis, due to growth in distributor markets.

Revenues for aortic stents and stent grafts, excluding OEM, increased in the twelve months ended December 31, 2019 as compared to the twelve months ended December 31, 2018 in EMEA, Latin America, and Asia Pacific with the largest growth in EMEA, on a constant currency basis, due to growth in distributor markets.

On-X

The On-X product line 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.

On-X product revenues increased 18% and 12% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018.

On-X product revenues, excluding OEM, increased 19% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. This increase was primarily due to a 28% increase in volume of units sold, which increased revenues by 20%, and a change in average sales prices, which increased revenues by 1%, partially offset by the effect of foreign exchange rates, which decreased revenues by 2%.

On-X product revenues, excluding OEM, increased 12% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. This increase was primarily due to an 11% increase in volume of units sold, which increased revenues by 14%, partially offset by a change in average sales prices, which decreased revenues by 1%, and by the effect of foreign exchange rates, which decreased revenues by 1%.

Excluding the effects for foreign exchange, On-X revenues, excluding OEM, increased 20% and 12% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018.

On-X revenues, excluding OEM, increased worldwide in the three and twelve months ended December 31, 2019 compared to the three and twelve months ended December 31, 2018 with the largest growth in EMEA in the fourth quarter of 2019 and in North America for the twelve months ended December 31, 2019 as a result of increases in market share. On-X OEM sales accounted for less than 1% of product revenues for both the three and twelve months ended December 31, 2019 and 2018.

CardioGenesis Cardiac Laser Therapy

Revenues from our CardioGenesis cardiac laser therapy product line historically consist primarily of sales of handpieces and, in certain periods, the sale of laser consoles. However, during the three months ended December 31, 2019, we did not have a supply of handpieces as our contract manufacturer of handpieces was unable to supply them until the FDA approved our supplier's change in manufacturing location, pending resolution of several observations the FDA raised during a manufacturing site change reinspection. In January 2021 we received PMA-S approval for the change in manufacturing site for our contract manufacturer and we currently anticipate resumption of limited supply during the first half of 2021.

Revenues from cardiac laser therapy decreased 38% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. This decrease was primarily due to a 93% decrease in unit shipments of handpieces, which decreased revenues by 93%, partially offset by the effect of higher average laser console selling prices for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018.

Revenues from cardiac laser therapy decreased 3% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. This decrease was primarily due to an 18% decrease in unit shipments of handpieces, which decreased revenues by 18%, partially offset by the effect of higher average laser console selling prices and an increase in service fees for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018.

Cardiac laser therapy is generally used adjunctively with cardiac bypass surgery by a limited number of physicians who perform these procedures, which usage patterns can cause period over period revenue fluctuations.

PerClot

Revenues from the sale of PerClot increased 4% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. This increase was primarily due to a 2% increase in the volume of grams sold, which increased revenues by 19%, partially offset by a decrease in average sales price, which decreased revenues by 12% and the effect of foreign exchange rates, which decreased revenues by 3%.

Revenues from the sale of PerClot increased 1% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. This increase was primarily due to a 3% increase in volume of grams sold, which increased revenues by 15%, partially offset by a decrease in average sales price which decreased revenues by 11%, and the effect of foreign exchange rates, which decreased revenues by 3%.

The decrease in average selling prices for the three and twelve months ended December 31, 2019 was in both indirect and direct markets due to price reductions to certain customers in Europe as a result of pricing pressures from competitive products. The increase in volume for the three and twelve months ended December 31, 2019 was primarily due to an increase in sales of PerClot in EMEA in the direct markets.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate PMA submission to the FDA during the third quarter of 2021.

PhotoFix

PhotoFix revenues increased 43% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. This increase was primarily due to a 44% increase in units sold, which increased revenues by 44%, partially offset by a decrease in average sales prices per unit, which decreased revenues by 1%.

PhotoFix revenues increased 46% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. This increase was primarily due to a 74% increase in units sold, which increased revenues by 46%.

The increase in units sold for the three and twelve months ended December 31, 2019 was primarily due to an increase in the number of implanting physicians when compared to the prior year period, as this product continues to penetrate domestic markets. Additional increases in unit shipments for the three and twelve months ended December 31, 2019 were from sales in EMEA, which is a new market in 2019, as well as from the introduction of smaller sized PhotoFix patches in 2018 and a larger sized PhotoFix patch in the second quarter of 2019.

Preservation Services

Preservation services include services revenues from the preservation of cardiac and vascular tissues. Revenues from preservation services increased 6% and 5% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018. A detailed discussion of the changes in cardiac and vascular preservation services revenues is presented below.

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. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and twelve months ended December 31, 2019.

Cardiac Preservation Services

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.

Revenues from cardiac preservation services, consisting of revenues from the distribution of human heart valves and cardiac patch tissues, increased 12% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. This increase was primarily due to a 10% increase in unit shipments of cardiac tissues, which increased revenues by 12%.

Revenues from cardiac preservation services increased 15% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. This increase was primarily due to a 14% increase in unit shipments of cardiac tissues, which increased revenues by 15%.

The increase in cardiac volume for the three and twelve months ended December 31, 2019 was primarily due to an increase in the volume of cardiac valve shipments and, to a lesser extent, cardiac patch shipments.

Vascular Preservation Services

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.

Revenues from vascular preservation services decreased 1% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. This decrease was primarily due to a 2% decrease in vascular unit shipments, which decreased revenues by 2%, partially offset by an increase in average service fees, which increased revenues by 1%.

Revenues from vascular preservation services decreased 4% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. This decrease was primarily due to a 3% decrease in vascular tissue shipments, which decreased revenues by 3%, and a decrease in average service fees, which decreased revenues by 1%.

The decrease in shipments of vascular tissues for the three months ended December 31, 2019 was primarily due to decreases in femoral artery and aortoiliac shipments, partially offset by increases in saphenous vein shipments. The decrease in shipments of vascular tissue for the twelve months ended December 31, 2019, was primarily due to decreases in saphenous shipments.

The change in average service fees for the three and twelve months ended December 31, 2019 was primarily driven by fee differences due to physical characteristics of vascular tissues, the routine negotiation of pricing contracts with certain customers, as well as competitive pricing pressures.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Cost of products	$ 14,001	$ 13,606	$ 55,022	$ 53,772

Cost of products increased 3% and 2% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018. Cost of products for the three and twelve months ended December 31, 2019 and 2018 included costs related to aortic stents and stent grafts, On-X, BioGlue, PhotoFix, PerClot, and CardioGenesis cardiac laser therapy.

Cost of products for the twelve months ended December 31, 2018 includes $2.8 million in inventory basis step-up expense, primarily related to the aortic stents and stent grafts inventory fair value adjustment recorded in purchase accounting, all included prior to the three months ended December 31, 2018.

The increase in cost of products for the three and twelve months ended December 31, 2019 was primarily due to increases in unit shipments.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Cost of preservation services	$ 9,144	$ 9,002	$ 38,187	$ 36,085

Cost of preservation services increased 2% and 6% for three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three and twelve months ended December 31, 2019 primarily due to an increase in the unit shipment of tissues.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Gross margin	$ 46,552	$ 45,191	$ 183,013	$ 172,984
Gross margin as a percentage of total revenues	67%	67%	66%	66%

Gross margin increased 3% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018, primarily due to increases in On-X, PhotoFix, and tissue revenues. Gross margin as a percentage of total revenues remained flat in the three months ended December 31, 2019, as compared to the three months ended December 31, 2018, primarily due to a decrease in aortic stents and stent grafts margins driven by a decrease in revenue, offset by an increase in On-X and BioGlue margins driven by an increase in revenue.

Gross margin increased 6% for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018, primarily due to increases in On-X, BioGlue, aortic stents and stent grafts, and tissue revenues. Gross margin as a percentage of total revenues remained flat in the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018, primarily due to additional costs in 2018 for the inventory fair value adjustment recorded in purchase accounting for the JOTEC Acquisition, offset by an increase in revenues in certain international regions that have lower margins during the twelve months ended December 31, 2019.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
General, administrative, and marketing expenses	$ 37,609	$ 35,628	$ 143,011	$ 140,574
General, administrative, and marketing expenses as a percentage of total revenues	54%	53%	52%	53%

General, administrative, and marketing expenses increased 6% and 2% for the three and twelve months ended December 31, 2019, respectively, as compared to the three and twelve months ended December 31, 2018. The increases in general, administrative, and marketing expenses for the three and twelve months ended December 31, 2019 were primarily due to higher expenses to support our increased revenue base and employee headcount, offset by decreased business development and integration expenses primarily related to the JOTEC Acquisition. General, administrative, and marketing expenses for the three and twelve months ended December 31, 2019 included approximately $500,000 and $3.1 million, respectively, in business development and integration expenses, as compared to $1.4 million and $8.4 million for the three and twelve months ended December 31, 2018, respectively, primarily related to the JOTEC Acquisition and the transaction with Endospan.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Research and development expenses	$ 5,312	$ 6,784	$ 22,960	$ 23,098
Research and development expenses as a percentage of total revenues	8%	10%	8%	9%

Research and development expenses decreased 22% for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018, and remained flat for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018. Research and development spending in the three and twelve months ended December 31, 2019 was primarily focused on clinical work for JOTEC products and to gain regulatory approval for On-X products as well as approval to commercialize PerClot for surgical indications in the U.S. Research and development spending in the twelve months ended December 31, 2018 was primarily on clinical trials for PerClot in the U.S., JOTEC products, On-X products, and BioGlue in China.

Interest Expense

Interest expense was $3.6 million and $14.9 million for the three and twelve months ended December 31, 2019, respectively, and interest expense was $3.9 million and $15.8 million for the three and twelve months ended December 31, 2018, respectively. Interest expense in the 2019 and 2018 periods included interest on debt and uncertain tax positions.

Other Expense (Income), Net

Other income was $1.4 million for the three months ended December 31, 2019 as compared to other expense of $398,000 for the three months ended December 31, 2018. Other expense was $1.3 million and $141,000 for the twelve months ended December 31, 2019, and 2018, respectively. Other income and other expense primarily include the realized and unrealized effects of foreign currency gains and losses.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Income (loss) before income taxes	$ 1,547	$ (1,459)	$ 1,644	$ (6,391)
Income tax (benefit) expense	2,228	(683)	(76)	(3,551)
Net (loss) income	$ (681)	$ (776)	$ 1,720	$ (2,840)
Diluted (loss) income per common share	$ (0.02)	$ (0.02)	$ 0.05	$ (0.08)
Diluted weighted-average common shares outstanding	37,274	36,652	37,860	36,412

We experienced income before income taxes for the three and twelve months ended December 31, 2019 and a loss before income taxes for the three and twelve months ended December 31, 2018. Income before income taxes for the three months ended December 31, 2019, as compared to a loss for the three months ended December 31, 2018, was primarily due to the effect of foreign currency gains and losses. Income before income taxes for the twelve months ended December 31, 2019, as compared to a loss for the twelve months ended December 31, 2018, was primarily due to a decrease in integration and business development expenses and inventory basis step-up expense related to the JOTEC Acquisition.

Our effective income tax rate was an expense of 144% and a benefit of 5% for the three and twelve months ended December 31, 2019, respectively, as compared to a benefit of 47% and 56% for the three and twelve months ended December 31, 2018, respectively. Our income tax rate for the three months ended December 31, 2019 was primarily affected by the recording of uncertain tax positions and prior year provision to return true-ups. Our income tax rate for the three months ended December 31, 2018 was primarily affected by excess tax benefits related to stock compensation.

Our income tax rate for the year ended December 31, 2019 was primarily affected by excess tax benefits on stock compensation, the research and development tax credit, releases of uncertain tax position liabilities, offset by nondeductible executive compensation, intercompany interest expense disallowance, and nondeductible meals and entertainment expenses. Our income tax rate for the year ended December 31, 2018 was primarily affected by excess tax benefits on stock compensation, the research and development tax credit and non-includable income related to the On-X settlement which increased our benefit.

On December 22, 2017 the United States enacted tax reform legislation known as the H.R. 1, commonly referred to as the “Tax Cuts and Jobs Act” (the “Tax Act”), resulting in significant modifications to existing law. As of December 31, 2017 we remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future (which was generally from 35% to 21%), which resulted in a nominal provisional amount for 2017. Upon further analysis of certain aspects of the Tax Act and refinement of our calculations during the year ended December 31, 2018, we made immaterial adjustments to our provisional estimate in accordance with SEC Staff Accounting Bullet 118, which are included as a component of income tax expense from continuing operations.

We elected to account for the global intangible low-taxed income (“GILTI”) tax in the period in which it is incurred, and therefore, have not provided any deferred tax impacts of GILTI in our consolidated financial statements for the years ended December 31, 2019 and 2018. For the years ending December 31, 2019 and 2018 our GILTI inclusion was nominal.

The Tax Act also created a new provision, foreign derived intangible income (“FDII”), whereby certain sales made from the U.S. to overseas markets are taxed at a lower U.S. rate. We are favorably impacted by the new FDII provision and as of December 31, 2019 and 2018 our FDII deduction was $737,000 and $525,000, respectively.

We are also affected by the new interest deductibility rule under the Tax Act. This rule disallows interest expense to the extent it exceeds 30% of adjusted taxable income. For the year ending December 31, 2019 and 2018 our interest deduction was limited to $10.5 million and $6.6 million, respectively. The excess interest not deducted in 2019 and 2018 of $2.4 million and $17.7 million, respectively, can be carried forward indefinitely for use in future years.

Net loss decreased and diluted income per common share was flat for the three months ended December 31, 2019, as compared to the three months ended December 31, 2018. The decrease for the three months ended December 31, 2019 was primarily due to an increase in income before income taxes, offset by higher income tax expense as discussed above. Net income and diluted income per common share increased for the twelve months ended December 31, 2019, as compared to the twelve months ended December 31, 2018, primarily due to the increase in income before income taxes, partially offset by a lower income tax benefit in the twelve months ended December 31, 2019 as compared to the twelve months ended December 31, 2018.

Diluted income per common share could be affected in future periods by changes in our common stock outstanding.

Seasonality

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 U.S.

We believe the demand for aortic stents and stent grafts is seasonal, with a decline in demand generally occurring in the third quarter due to the summer holiday season in Europe. However, the nature of any seasonal trends may be obscured due to integration activities in 2018 and 2019 subsequent to the JOTEC Acquisition including the implementation of our distributor-to-direct strategy and our European sales force realignment as well as the recent market introduction of AMDS and NEXUS products.

We do not believe the demand for CardioGenesis cardiac laser therapy or PerClot is seasonal.

We are uncertain whether the demand for PhotoFix, Endospan, and Ascyrus 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.

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 is 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.

As a result of the uncertain impact of the COVID-19 pandemic and the resulting shifts of timing in some revenue, our historically observable seasonality of revenues has been obscured in 2020 and may be obscured for the first half of 2021 and potentially beyond.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2020 net working capital (current assets of $234.6 million less current liabilities of $60.5 million) was $174.1 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of $142.2 million and a current ratio of 4 to 1 at December 31, 2019.

Overall Liquidity and Capital Resources

Our primary cash requirements for the twelve months ended December 31, 2020 were for the acquisition of Ascyrus as further described below, general working capital needs, capital expenditures for facilities and equipment, interest and principal payments under our Credit Agreement, defined below, debt issuance costs under our Convertible Senior Notes (described in “Significant Sources and Uses of Liquidity” section below), funding of the second tranche payment related to the Endospan Loan, and repurchases of stock to cover tax withholdings. We funded our cash requirements through the issuance of our Convertible Senior Notes, our existing cash reserves, and proceeds from stock option exercises.

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, 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 and equity financing. 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.

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 CryoLife 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. As of December 31, 2020 the aggregate interest rate was 4.25% per annum. 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 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 18, 2020 we issued $100.0 million aggregate principal amount of 4.25% convertible senior notes with a maturity date of July 1, 2025 (“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. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. Our current intent is to settle in cash the principal amount outstanding and any note conversion value over the principal amount with shares of our Common Stock. 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 treasury stock method for assumed conversion of the Convertible Senior Notes to compute the weighted average shares of common stock outstanding for diluted earnings per share.

The conversion feature of the Convertible Senior Notes required bifurcation from the notes and was initially accounted for as an equity instrument classified to stockholders’ equity, which resulted in recognizing $16.4 million in additional paid-in-capital, net of tax of $4.7 million, during the twelve months ended December 31, 2020. 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 for the twelve months ended December 31, 2020. 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. As of December 31, 2020, we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes. We have used a portion of the proceeds to pay off the $30.0 million outstanding under our Revolving Credit Facility and finance the Ascyrus transaction and anticipate using the remaining funds for general corporate purposes.

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

Under the terms of the Ascyrus Agreement, we may 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 CryoLife common stock, in each case, delivered at the closing of the acquisition, (ii) if the FDA approves an IDE application for the AMDS, a cash payment of $10.0 million and the issuance of $10.0 million in shares of CryoLife common stock, (iii) if the FDA approves a 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 up to $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 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 Premarket Approval application submitted for the AMDS. Upon closing of the acquisition on September 2, 2020, we paid $83.7 million consisting of $63.7 million in cash consideration, and $20.0 million in shares of CryoLife common stock. The number of shares issued was based on a 10-day moving volume weighted average closing price of a share of CryoLife common stock as of the date immediately prior to closing, resulting in an issuance of 991,800 shares of CryoLife common stock.

We have benefited from various aspects of the CARES Act including a decrease in the amount of interest expense limitation in 2019 and 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, 2020 approximately 34% of our cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $12.4 million for the twelve months ended December 31, 2020, as compared to $15.8 million for the twelve months ended December 31, 2019.

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, 2020 these non-cash items included $20.7 million in depreciation and amortization expenses, $7.1 million in non-cash lease expense, and $6.9 million in non-cash compensation.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the twelve months ended December 31, 2020 these changes included unfavorable adjustments of $24.8 million due to an increase in inventory balances and deferred preservation costs, unfavorable effect of $9.2 million due to timing differences between the recording of accounts payable and other current liabilities, and $2.7 million due to an increase in prepaid expenses and other assets, partially offset by $9.9 million due to the timing differences between recording receivables and the receipt of cash.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $73.1 million for the twelve months ended December 31, 2020, as compared to $23.9 million for the twelve months ended December 31, 2019. 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 further described below, and $5.0 million in cash payments related to the Endospan agreements.

Net Cash Flows from Financing Activities

Net cash provided by financing activities was $93.6 million for the twelve months ended December 31, 2020, as compared to net cash used in financing activities of $1.5 million for the twelve months ended December 31, 2019. The current year 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 as described in the "Significant Sources and Uses of Liquidity" section above. During the twelve months ended December 31, 2020, we borrowed and subsequently repaid $30.0 million from the Revolving Credit Facility, as described in the "Significant Sources and Uses of Liquidity" section above.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Our long-term debt obligations and interest payments include $320.6 million of scheduled principal payments and anticipated interest payments related to our Credit Agreement, Convertible Senior Notes, and JOTEC governmental loans.

We have contingent payment obligations that include up to $120.0 million to be paid to the former shareholders of Ascyrus, of which $10.0 million is expected to be paid in CryoLife common stock, upon the achievement of certain milestones described in the "Significant Sources of and Uses of Liquidity" section above. We anticipate making a $5.0 million third tranche payment under the Endospan Loan upon receipt of certification that certain approvals and clinical trial milestones have been achieved. We have other contingent payment obligations if certain U.S. regulatory approvals and certain commercial milestones are achieved related to our transaction with Starch Medical, Inc. ("SMI") for PerClot and other licensed technologies.

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.

We have purchase commitments that include obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under a distribution agreement with SMI. Pursuant to the terms of the distribution agreement, we may terminate that agreement, including the minimum purchase requirements set forth in the agreement for various reasons, one of which is if we obtain FDA approval for PerClot.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2020 and 2019 were $7.3 million and $8.1 million, respectively. Capital expenditures in the twelve months ended December 31, 2020 were primarily related to leasehold improvements needed to support our business, computer software, and routine purchases of manufacturing and tissues processing 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 U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on our cash and cash equivalents of $61.4 million as of

December 31, 2020, 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, 2020, affecting our cash and cash equivalents, restricted cash and securities, 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 U.S. 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 gain of $1.9 million, a loss of $1.2 million, and a loss of $2.6 million for the years ended December 31, 2020, 2019, and 2018, respectively. Gains incurred during 2020 were primarily related to cross currency intercompany receivables and payables resulting from large inventory transfers during 2020, impacted by fluctuations in the U.S. dollar relative to other currencies.

We have revenues and expenses that are denominated in foreign currencies. Specifically, a portion of our international BioGlue, On-X, PerClot, and aortic stents and stent grafts 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 U.S. 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, 2020 affecting our balances denominated in foreign currencies could impact on our financial position or cash flows by approximately $12 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, 2020 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 CryoLife, Inc. and subsidiaries ("CryoLife" 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. CryoLife's internal control system was designed to provide reasonable assurance to CryoLife's management and Board of Directors regarding the preparation and fair presentation of published financial statements.

On September 2, 2020 we completed the acquisition of 100% of the outstanding equity of Ascyrus Medical LLC, ("Ascyrus"), a privately held company. As permitted by SEC guidance, we excluded Ascyrus from management's assessment of internal control over financial reporting as of December 31, 2020. Ascyrus, which is included in the 2020 consolidated financial statements of CryoLife, constituted $138.7 million and $136.1 million of total assets and net assets, respectively, as of December 31, 2020 and $1.2 million and $1.0 million of revenues and gross margin, respectively, for the year then ended. Ascyrus will be included in management's assessment of the internal control over financial reporting as of December 31, 2021.

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.

CryoLife management assessed the effectiveness of CryoLife's internal control over financial reporting as of December 31, 2020. 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, 2020, our internal control over financial reporting was effective based on those criteria.

CryoLife's independent registered public accounting firm, Ernst & Young, LLP, has issued an audit report on the effectiveness of CryoLife's internal control over financial reporting as of December 31, 2020.

CryoLife, Inc.
February 22, 2021

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CryoLife, Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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, 2021 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 Matters

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

Deferred Preservation Costs

Description of the Matter

At December 31, 2020, the Company's deferred preservation costs balance was $36.5 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 yield estimates to all tissues in process 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 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 evaluated the Company's assessment that deferred preservation costs are recorded at the lower of cost or market value by comparing the costs of the Company's tissue types to average selling prices as of the balance sheet date. 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.

Valuation of contingent consideration liability and acquired developed technology intangible asset - Ascyrus acquisition

Description of the Matter

During 2020, the Company completed its acquisition of Ascyrus Medical for total purchase consideration of $138.5 million, including $63.1 million paid in cash, $20.0 million of common stock issued and $55.4 million representing the estimated fair value of the contingent consideration liability, as disclosed in Note 2 to the consolidated financial statements. The transaction was accounted for as a business combination.

Auditing the Company's accounting for its acquisition of Ascyrus Medical was complex due to the significant estimation required by management to determine the fair value of the contingent consideration liability of $55.4 million and the developed technology intangible asset acquired of $72.6 million. The significant estimation was primarily due to the assumptions required in the valuation models used by management to measure the fair value of the contingent consideration and the developed technology intangible asset, and the sensitivity of the respective fair values to the significant underlying assumptions. The Company used a probability weighted discounted cash flow approach to calculate the fair value of the contingent consideration liability. The significant assumptions used in this approach included the discount rate and the probability and timing of expected payments. The Company used a discounted cash flow model to measure the fair value of the developed technology intangible asset. The significant assumptions in this approach included the discount rate and forecasted revenues. These significant assumptions are forward looking, inherently uncertain, and could be affected by future industry, economic and market conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company’s controls over the Company’s accounting for the acquisition. Our testing of controls included controls over the recognition and measurement of the contingent consideration liability and the valuation of the developed technology intangible asset. For example, we tested the Company’s controls over the forecasted financial information, the review of the valuation models, and the underlying assumptions used to develop such estimates.

To test the estimated fair value of the contingent consideration liability and the developed technology intangible, we performed audit procedures that included, among others, evaluating the Company's use of the income approach (the multi-period excess earnings method and probability weighted discounted cash flow method), testing the significant assumptions used in the model, as described above, and assessing the completeness and accuracy of the underlying data. We compared the significant assumptions to current industry and market data, to assumptions used to value similar assets in other acquisitions, and to other guideline companies within the same industry. We involved our valuation professionals to assist with our evaluation of the methodology used by the Company and significant assumptions included in the fair value estimates.

/s/ Ernst & Young LLP
We have served as the Company‘s auditor since 2013.
Atlanta, Georgia
February 22, 2021

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited CryoLife, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2020, 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, CryoLife, Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Ascyrus Medical LLC ("Ascyrus"), which is included in the 2020 consolidated financial statements of the Company and constituted $138.7 million and $136.1 million of total and net assets, respectively, as of December 31, 2020 and $1.2 million and $1.0 million of revenues and gross margin, respectively, for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Ascyrus.

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, 2020 and 2019, the related consolidated statements of operations and comprehensive (loss) income, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 22, 2021 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, 2021

CRYOLIFE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,412	$ 33,766
Restricted securities	546	528
Receivables:		
Trade accounts, net	45,964	52,940
Other	2,788	2,921
Total receivables	**48,752**	**55,861**
Inventories	73,038	53,071
Deferred preservation costs	36,546	32,551
Prepaid expenses and other	14,295	11,613
Total current assets	**234,589**	**187,390**
Property and equipment:		
Equipment and software	66,141	61,271
Furniture and fixtures	6,186	5,650
Leasehold improvements	38,256	36,173
Total property and equipment	110,583	103,094
Less accumulated depreciation and amortization	77,506	70,944
Net property and equipment	**33,077**	**32,150**
Other assets:		
Operating lease right-of-use assets, net	18,571	21,994
Goodwill	260,061	186,697
Acquired technology, less accumulated amortization of $36,091 as of December 31, 2020 and $24,778 as of December 31, 2019	186,091	115,415
Other Intangibles, less accumulated amortization of $17,667 as of December 31, 2020 and $13,460 as of December 31, 2019	40,966	42,319
Deferred income taxes	1,446	5,481
Other	14,603	14,208
Total assets	**$ 789,404**	**$ 605,654**

CRYOLIFE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2020	December 31, 2019
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accrued expenses	$ 7,472	$ 6,733
Accrued compensation	10,192	12,260
Accounts payable	9,623	9,796
Taxes payable	2,808	2,984
Accrued procurement fees	3,619	4,362
Current portion of finance lease obligation	614	597
Current maturities of operating leases	5,763	5,487
Current portion of long-term debt	1,195	1,164
Current portion of contingent consideration	16,430	--
Other	2,752	1,812
Total current liabilities	**60,468**	**45,195**
Long-term debt	290,468	214,571
Deferred income taxes	34,713	25,844
Non-current maturities of operating leases	14,034	17,918
Non-current finance lease obligations	5,300	5,415
Contingent consideration	43,500	--
Deferred compensation liability	5,518	4,434
Other	6,690	6,581
Total liabilities	**460,691**	**319,958**
Commitments and contingencies		
Shareholders' equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued	--	--
Common stock $0.01 par value per share, 75,000 shares authorized, 40,394 and 39,018 shares issued as of December 31, 2020 and 2019, respectively	404	390
Additional paid-in capital	316,192	271,782
Retained earnings	20,022	36,704
Accumulated other comprehensive income (loss)	6,743	(8,589)
Treasury stock at cost, 1,487 and 1,484 shares as of December 31, 2020 and 2019, respectively	(14,648)	(14,591)
Total shareholders' equity	**328,713**	**285,696**
Total liabilities and shareholders' equity	**$ 789,404**	**$ 605,654**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Year Ended December 31,		
	2020	**2019**	**2018**
Revenues:			
Products	$ 179,299	$ 197,246	$ 187,394
Preservation services	73,928	78,976	75,447
Total revenues	**253,227**	**276,222**	**262,841**
Cost of products and preservation services:			
Products	50,128	55,022	53,772
Preservation services	35,315	38,187	36,085
Total cost of products and preservation services	**85,443**	**93,209**	**89,857**
Gross margin	**167,784**	**183,013**	**172,984**
Operating expenses:			
General, administrative, and marketing	141,136	143,011	140,574
Research and development	24,207	22,960	23,098
Total operating expenses	**165,343**	**165,971**	**163,672**
Operating income	**2,441**	**17,042**	**9,312**
Interest expense	16,698	14,886	15,788
Interest income	(217)	(738)	(226)
Other expense, net	3,134	1,250	141
(Loss) income before income taxes	**(17,174)**	**1,644**	**(6,391)**
Income tax benefit	(492)	(76)	(3,551)
Net (loss) income	$ **(16,682)**	$ **1,720**	$ **(2,840)**
(Loss) income per common share:			
Basic	$ **(0.44)**	$ **0.05**	$ **(0.08)**
Diluted	$ **(0.44)**	$ **0.05**	$ **(0.08)**
Weighted-average common shares outstanding:			
Basic	37,861	37,118	36,412
Diluted	37,861	37,860	36,412
Net (loss) income	$ **(16,682)**	$ **1,720**	$ **(2,840)**
Other comprehensive income (loss)	15,332	(2,517)	(7,929)
Comprehensive loss	$ **(1,350)**	$ **(797)**	$ **(10,769)**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Net cash flows from operating activities:			
Net (loss) income	$ (16,682)	$ 1,720	$ (2,840)
Adjustments to reconcile net (loss) income to net cash from operating activities:			
Depreciation and amortization	20,712	18,317	18,095
Non-cash lease expense	7,145	5,009	--
Non-cash compensation	6,912	8,799	6,325
Change in fair value of long-term loan receivable	4,949	--	--
Change in fair value of contingent consideration	4,523	--	--
Deferred income taxes	4,283	(2,305)	(4,485)
Write-down of inventories and deferred preservation costs	3,443	1,488	649
Other	3,780	2,182	2,149
Changes in operating assets and liabilities:			
Receivables	9,938	(5,332)	(1,119)
Prepaid expenses and other assets	(2,720)	(6,177)	(2,407)
Accounts payable, accrued expenses, and other liabilities	(9,157)	251	(8,870)
Inventories and deferred preservation costs	(24,757)	(8,125)	2,384
Net cash flows provided by operating activities	**12,369**	**15,827**	**9,881**
Net cash flows used in investing activities:			
Ascyrus Acquisition, net of cash acquired	(59,119)	--	--
Capital expenditures	(7,328)	(8,072)	(5,786)
Payments for Endospan Agreements	(5,000)	(15,000)	--
Other	(1,681)	(871)	(929)
Net cash flows used in investing activities	**(73,128)**	**(23,943)**	**(6,715)**
Net cash flows from financing activities:			
Proceeds from issuance of convertible debt	100,000	--	--
Proceeds from revolving line of credit	30,000	--	--
Proceeds from financing insurance premiums	2,815	--	--
Proceeds from exercise of stock options and issuance of common stock	2,432	4,758	3,854
Repayment of revolving line of credit	(30,000)	--	--
Repayment of debt	(5,346)	(2,780)	(2,790)
Payment of debt issuance costs	(3,647)	--	(624)
Redemption and repurchase of stock to cover tax withholdings	(1,995)	(2,743)	(2,100)
Other	(651)	(728)	(902)
Net cash flows provided by (used in) financing activities	**93,608**	**(1,493)**	**(2,562)**
Effect of exchange rate changes on cash	(5,185)	1,667	879
Increase (decrease) in cash, cash equivalents, and restricted securities	**27,664**	**(7,942)**	**1,483**
Cash, cash equivalents, and restricted securities, beginning of year	34,294	42,236	40,753
Cash, cash equivalents, and restricted securities, end of year	**$ 61,958**	**$ 34,294**	**$ 42,236**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2017	**37,618**	**$ 376**	**$ 249,935**	**$ 37,609**	**$ 1,857**	**(1,386)**	**$ (12,719)**	**$ 277,058**
Cumulative effect of ASU 606 Adjustment	--	--	--	215	--	--	--	215
Net loss	--	--	--	(2,840)	--	--	--	(2,840)
Other comprehensive loss:								
Foreign currency translation loss, net of tax	--	--	--	--	(7,929)	--	--	(7,929)
Comprehensive loss								(10,769)
Equity compensation	287	3	6,806	--	--	--	--	6,809
Exercise of options	578	5	4,382	--	--	(98)	(1,872)	2,515
Employee stock purchase plan	83	1	1,338	--	--	--	--	1,339
Redemption and repurchase of stock to cover tax withholdings	(103)	--	(2,100)	--	--	--	--	(2,100)
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:								
Foreign currency translation loss, net of tax	--	--	--	--	(2,517)	--	--	(2,517)
Comprehensive loss								(797)
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:								
Foreign currency translation gain, net of tax	--	--	--	--	15,332	--	--	15,332
Comprehensive loss								(1,350)
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**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Nature of Business

CryoLife, Inc. ("CryoLife," 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: BioGlue Surgical Adhesive ("BioGlue") products, aortic stents and stent grafts, 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, Ascyrus Medical Dissection Stent ("AMDS") hybrid prosthesis, and NEXUS endovascular stent graft system ("NEXUS"). In addition to these four major product families, we sell or distribute PhotoFix bovine surgical patch, PerClot hemostatic powder, CardioGenesis cardiac laser therapy, and NeoPatch chorioamniotic allograft.

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 ("U.S. 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.

Translation of Foreign Currencies

Our revenues and expenses transacted in foreign currencies are translated 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 (income), net on our Consolidated Statements of Operations and Comprehensive Loss. Realized and unrealized gains and losses were a gain of $1.8 million, a loss of $1.2 million, and a loss of $2.6 million for the years ended December 31, 2020, 2019, and 2018, respectively. Our assets and liabilities denominated in foreign currencies 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 accounting principles generally accepted in the U.S. 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 adopted Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* effective January 1, 2018 using the modified retrospective method applied to those contracts which were not substantially completed as of January 1, 2018. These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. The standard requires that an entity recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

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: BioGlue, On-X products, aortic stents and stent grafts, PerClot, PhotoFix 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.

Our E-xtra DESIGN ENGINEERING products are specifically designed to meet specifications of a particular patient, and therefore, do not create an asset with an alternative use. We evaluate open orders for these products each reporting period, and when material, we recognize the revenue and related contract asset based on the amount of payment we believe we are entitled to at that time.

In certain limited circumstances, CardioGenesis cardiac laser consoles are provided to a customer for their use without transfer of title for evaluation purposes. We have determined that a portion of the revenue for the handpieces purchased during these evaluations constitutes revenues associated with the use of the laser console, however, these are immaterial to reported revenues.

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 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 the E-xtra DESIGN ENGINEERING product, 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. We record the cost to print or copy certain sales materials as a prepaid expense and amortize these costs as an advertising expense over the period they are expected to be used, typically six months to one year. The total amount of advertising expense included in our Consolidated Statements of Operations and Comprehensive Loss was $1.1 million, $1.7 million, and $732,000 for the years ended December 31, 2020, 2019, and 2018, 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), performance stock awards ("PSA"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, PSAs, 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, PSAs, RSUs, and PSUs based on the stock price on the date of grant. We expense the related compensation cost of RSAs, PSAs, 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 was updated to include a zero-dividend yield assumption when our quarterly dividends were discontinued after the fourth quarter of 2015, and we do not anticipate paying dividends in the future. The risk-free interest rate is based on recent U.S. 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 and PSAs 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. We typically value financial assets and liabilities at their carrying values, such as receivables, and accounts payable due to their short-term duration, and debt obligations 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 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 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 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 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 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):

	2020	2019	2018
Cash paid during the year for:			
Interest	$ 13,049	$ 13,297	$ 15,005
Income taxes	4,122	1,944	1,699
Non-cash investing and financing activities:			
Issuance of common stock for Ascyrus Acquisition	$ 20,000	$ --	$ --
Assets acquired in exchange for operating leases	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 uncollectable 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 $973,000 and $966,000 as of December 31, 2020 and 2019, respectively.

Inventories

Inventories are comprised of finished goods for our major product lines including: BioGlue; aortic stents and stent grafts; On-X products; CardioGenesis cardiac laser therapy laser consoles, handpieces, and accessories; PerClot; 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 $1.7 million, $601,000, and $212,000 for the years ended December 31, 2020, 2019, and 2018, respectively. The 2020 write-down is primarily related to JOTEC inventory, On-X ascending aortic prosthesis ("AAP") inventory and BioGlue inventory not expected to ship prior to the expiration date. The 2019 write-down is primarily related to PerClot inventory not expected to ship prior to the expiration date. The 2018 write-down is primarily related to On-X AAP inventory not expected to ship prior to the expiration date and the disposal of obsolete surgical sealant product packaging materials.

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 consign 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 $1.7 million, $787,000, and $437,000 for the years ended December 31, 2020, 2019, and 2018, respectively, due primarily to tissues not expected to ship prior to the expiration date of the packaging. In addition, write-offs during for the year ended December 31, 2020 included $826,000 of non-conforming tissues resulting from contaminated saline solution.

Property and Equipment

Property and equipment is stated at cost. Depreciation is provided 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.

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

	2020	2019	2018
Depreciation expense	$ 6,948	$ 7,467	$ 7,303

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 7. Our goodwill is attributable to a segment or segments of our business, as appropriate, as the related acquired business that generated the goodwill is integrated into our operations. Upon divestiture of a component of our business, the goodwill related to the operating segment is allocated to the divested business using the relative fair value allocation method.

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

We assess the potential impairment of our property and equipment and amortizing intangible long-lived assets to be held and used 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. For the years ended December 31, 2020, 2019, and 2018 we did not experience any factors that indicated that an impairment review of our long-lived assets was warranted.

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, 2020 and 2019, our non-amortizing intangible assets consisted of goodwill, in-process research and development, acquired procurement contracts and agreements, and trademarks. We performed an analysis of our non-amortizing intangible assets as of October 31, 2020 and 2019 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. We will continue to evaluate the recoverability of these non-amortizing intangible assets.

Accrued Procurement Fees

Donated tissue is procured from deceased human donors by OPOs and tissue banks, which consign 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 9. Certain of our leases contain escalation clauses, rent concessions, and renewal options for additional periods.

In February 2016 the FASB amended its ASC and created a new Topic 842, Leases. The final guidance requires lessees to recognize a right-of-use asset and a lease liability for all long-term leases at the commencement date and recognize expenses on their statements of income similar to the former Topic 840, Leases. We adopted ASC 842, Leases effective January 1, 2019 using 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. Therefore, no changes were made to the 2018 financial statements.

The adoption of this standard resulted in the recognition of operating lease liability with a net present value of $22.7 million, and corresponding right-of-use assets obtained in the same amount, at January 1, 2019. The leases recognized were calculated using a weighted average discount rate of 5.5% and a weighted average remaining lease term of six years. In addition, deferred rent obligations of approximately $2.4 million recognized under prior lease rules were offset against the corresponding right-of-use asset and will be reflected in amortization over the remaining life of the lease. Our leases had remaining lease terms of one year up to 11 years, some of which had options to extend the leases for up to 29 years and one lease contained a termination option with a two year notice requirement. The adoption of the new leasing standard had no significant impact on covenants or other provisions of our current term and revolver loan facility agreements.

We exercised judgment in the adoption of the new leasing standard, including 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 used the implicit discount rate in the lease contract to discount lease payments to present value. If an implicit discount rate was not available in the lease contract, we used our incremental borrowing rate. We elected the package of practical expedients permitted under the transition guidance of the new leasing standard which includes a provision that allows us to carry forward the historical lease classification of identified leasing arrangements and not reassess (i) classification for any existing leases, (ii) whether any expired or existing agreements are or contain a lease, or (iii) whether any initial direct costs qualified for capitalization. We have also elected the 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 operating and finance lease liabilities result from the lease of land and buildings that comprise our corporate headquarters, various manufacturing facilities and related space, leases on company vehicles, and leases on a variety of office and other equipment. 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 were allocated between the debt and equity component of the agreement. Debt issuance costs allocated to the debt component are amortized using the effective interest rate method as a direct deduction from the recorded debt issuance costs allocated to debt. The portion of debt issuance costs allocated to equity are recorded in Additional paid-in-capital on our Consolidated Balance Sheets.

Liability Claims

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

We 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. Gains from legal contingencies are recorded when the contingency is resolved.

Legal Fees

We expense the costs of legal services, including legal services related to product and tissue processing liability claims and legal contingencies, as they are incurred. Reimbursement of legal fees by an insurance company or other third party is recorded as a reduction to legal expense.

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 other expense (income), net on our Consolidated Statements of Operations and Comprehensive Loss. See Note 8 for further discussion of our liabilities for uncertain tax positions.

Deferred Income Taxes

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

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

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

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

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.

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

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.

As of January 1, 2018 we adopted ASU No. 2014-09, *Revenue from Contracts with Customers* and the additional related ASUs ("ASC 606"). These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. ASC 606 provides that we recognize revenue to depict the transfer of control of promised goods or services to our customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. We used the modified retrospective method applied to those contracts that were not substantially completed as of January 1, 2018. As a result of the adoption, we recorded an immaterial adjustment to increase retained earnings to recognize the impact of contract assets under the new revenue recognition guidance.

Adoption of ASC 606 did not have a material impact on our consolidated financial statements. See Note 13 for further discussion of revenue recognition.

Not Yet Effective

In August 2020 the FASB issued ASC 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 mode) 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. ASU 2020-06 is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. This update permits the use of either the modified retrospective or fully retrospective method of transition. We anticipate early adopting this guidance as of January 1, 2021 and are in the process of evaluating the effect this adoption on our financial position and results of operations.

2. 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 has developed the Ascyrus Medical Dissection Stent ("AMDS") hybrid prothesis, 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 CryoLife common stock, in each case, were delivered at the closing of the acquisition, (ii) if the U.S. Food and Drug Administration (the "FDA") approves an Investigational Device Exemption ("IDE") application for the AMDS, a cash payment of $10.0 million and the issuance of $10.0 million in shares of CryoLife common stock, (iii) if the FDA approves a Premarket Approval ("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 up to $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 Premarket Approval application submitted for the AMDS.

Accounting for the Transaction

Upon closing of the acquisition on September 2, 2020, we paid $83.1 million consisting of $63.1 million in cash consideration, and $20.0 million in shares of CryoLife common stock. The number of shares issued was based on a 10-day moving volume weighted average closing price of a share of CryoLife common stock as of the date immediately prior to closing, resulting in an issuance of 991,800 shares of CryoLife 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. The fair value of the total potential purchase consideration of $200.0 million was calculated to be $138.5 million, which includes total purchase consideration, as well as the contingent consideration liability discussed below. Our preliminary 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.

We recorded the contingent consideration liability of $16.4 million and $43.5 million in Current liabilities and Other long-term liabilities as of December 31, 2020, respectively, in the Consolidated Balance Sheets, representing 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 4. 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, change in discount rates, changes in the timing and amount of our revenue estimates, and changes in the timing and expectation of regulatory approvals.

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

We recorded $63.4 million of preliminary goodwill, of which $62.1 million 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 segment. The estimated allocation of assets acquired and liabilities assumed is based on the information available to us as of December 31, 2020. We are completing our procedures related to the purchase price allocation and if information regarding these values is received that would result in a material adjustment to the values recorded, we will recognize the adjustment, which may include the recognition of additional expenses or other allocation adjustments, in the period this determination is made.

The preliminary purchase consideration allocated as of September 2, 2020 consisted of the following (in thousands):

Consideration		
Cash paid for acquisition	$	63,136
Common stock issued		20,000
Contingent consideration		55,407
Fair value of total consideration	**$**	**138,543**
Purchase Price Allocation		
Cash and cash equivalents	$	4,017
Intangible assets		72,600
Net other assets/liabilities acquired		(1,431)
Goodwill		63,357
Net assets acquired	**$**	**138,543**

We incurred transaction costs of $888,000 for the twelve months ended December 31, 2020, respectively, primarily related to the acquisition, which included, among other costs, expenses related to legal and professional fees. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on our Consolidated Statements of Operations and Comprehensive Loss.

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 our results of operations from the date of acquisition and were not significant for the year ended December 31, 2020.

3. Agreements with Endospan

Exclusive Distribution Agreement and Securities Purchase Option Agreement

On September 11, 2019 CryoLife, Inc.'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 Endospan's Nexus™ stent graft system ("NEXUS") and accessories in certain countries in Europe in exchange for a fixed distribution fee of $9.0 million paid in September 2019.

CryoLife also entered into a securities purchase option agreement (“Endospan Option Agreement”) with Endospan for $1.0 million paid in September 2019. The Endospan Option Agreement provides CryoLife 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

CryoLife and Endospan also entered into a loan agreement (“Endospan Loan”), dated September 11, 2019, in which CryoLife 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. During September 2020, we funded the second tranche payment of $5.0 million upon the certification of the NEXUS Investigational Device Exemption (“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 CryoLife 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, 2020 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, 2020, 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 Agreement 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 Summary Consolidated Balance Sheets as of December 31, 2019. The Endospan Option Agreement was valued at $4.8 million in Other long-term assets in the Consolidated Balance Sheets as of December 31, 2020, and 2019. The Endospan Distribution Agreement was recorded at $8.0 million and $9.8 million in Other Intangibles, net in the Consolidated Balance Sheets as of December 31, 2020, and 2019, respectively.

We elected the fair value option for recording the Endospan Loan. We assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics, and adjust the amount recorded to its current fair market value at each reporting period. We performed an assessment of the fair value of the Endospan Loan after funding the second tranche payment and adjusted the fair value of the Endospan Loan to $409,000 as of December 31, 2020. As a result of the fair value adjustment, we recorded an expense of $4.9 million in Other Expense on the Consolidated Statements of Operations and Comprehensive Loss during the twelve months ended December 31, 2020.

4. Financial Instruments

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

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)

December 31, 2019	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 1,472	--	--	$ 1,472
Restricted securities:				
Money market funds	528	--	--	528
Endospan Loan	--	--	358	358
Total assets	$ 2,000	$ --	$ 358	$ 2,358

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 classified as a Level 3 financial instrument. See Note 2 and Note 3 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, 2019	$ 358	Balance as of December 31, 2019	$ --
Additional investment in Endospan	5,000	Fair value at acquisition	(55,407)
Change in valuation	(4,949)	Change in valuation	(4,523)
Balance as of December 31, 2020	$ **409**	Balance as of December 31, 2020	$ **(59,930)**

5. Cash Equivalents and Restricted Cash and Securities

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

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

December 31, 2019	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 1,472	--	$ 1,472
Restricted securities:			
Money market funds	528	--	528
Total assets	$ 2,000	$ --	$ 2,000

As of December 31, 2020 and 2019 $546,000 and $528,000, respectively, 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, 2020, 2019, and 2018. As of December 31, 2020 $546,000 of our restricted securities had a maturity date within three months. As of December 31, 2019 $528,000 of our restricted securities had a maturity date within three months.

6. Inventories and Deferred Preservation Costs

Inventories at December 31, 2020 and 2019 are comprised of the following (in thousands):

	2020	2019
Raw materials and supplies	$ 33,625	$ 21,180
Work-in-process	6,318	5,127
Finished goods	33,095	26,764
Total inventories	$ 73,038	$ 53,071

Deferred preservation costs at December 31, 2020 and 2019 are comprised of the following (in thousands):

	2020	2019
Cardiac tissues	$ 17,374	$ 15,365
Vascular tissues	19,172	17,186
Total deferred preservation costs	$ 36,546	$ 32,551

To facilitate product usage, we maintain consignment inventory of our On-X heart valves at domestic hospital locations and both On-X heart valves and JOTEC 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, 2020 we had $11.9 million in consignment inventory, with approximately 47% in domestic locations and 53% in foreign locations. As of December 31, 2019 we had $12.0 million in consignment inventory, with approximately 51% in domestic locations and 49% in foreign locations.

7. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of December 31, 2020 and 2019 the carrying values of our indefinite lived intangible assets are as follows (in thousands):

	2020	2019
Goodwill	$ 260,061	$ 186,697
In-process R&D	2,392	2,190
Procurement contracts and agreements	2,013	2,013
Trademarks	765	844

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, 2020 and 2019.

During the twelve months ended December 31, 2019, the Company received CE Mark for the E-nside multibranch stent graft system for the endovascular treatment of thoraco-abdominal aneurysms. The company reclassed $7.4 million related to the E-nside European business from in-process research and development and into defined lived intangible assets with a useful life of 20 years.

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, 2020 and 2019 the value of our goodwill, all of which is related to our Medical Devices segment, is as follows (in thousands):

	2020	2019
Balance as of January 1,	$ 186,697	$ 188,781
Ascyrus acquisition	63,357	--
Revaluation of goodwill denominated in foreign currency	10,007	(2,084)
Balance as of December 31,	$ 260,061	$ 186,697

Definite Lived Intangible Assets

As of December 31, 2020 and 2019 gross carrying values, accumulated amortization, and approximate amortization periods of our definite lived intangible assets are as follows (dollars in thousands):

December 31, 2020	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 222,182	36,091	11 – 22 Years
Customer lists and relationships	31,316	8,132	13 – 22 Years
Distribution and manufacturing rights and know-how	14,728	5,349	5 – 15 Years
Patents	3,966	3,113	17 Years
Other	3,453	1,073	4 – 5 Years

December 31, 2019	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 140,193	24,778	11 – 22 Years
Customer lists and relationships	31,131	6,581	13 – 22 Years
Distribution and manufacturing rights and know-how	13,826	3,005	5 – 15 Years
Patents	3,664	3,074	17 Years
Other	1,919	608	3 – 5 Years

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):

	2020	2019	2018
Amortization expense	$ 13,764	$ 10,850	$ 10,792

As of December 31, 2020 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2021	2022	2023	2024	2025	Total
Amortization expense	$ 17,095	$ 16,512	$ 16,059	$ 15,707	$ 13,481	$ 78,854

8. Income Taxes

Income Tax Expense

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

	2020	2019	2018
Domestic	$ (11,443)	$ 6,369	$ 4,560
Foreign	(5,731)	(4,725)	(10,951)
(Loss) income before income taxes	$ (17,174)	$ 1,644	$ (6,391)

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

	2020	2019	2018
Current:			
Federal	$ (2,460)	$ 48	$ 402
State	445	80	246
Foreign	707	2,041	2,009
	(1,308)	2,169	2,657
Deferred:			
Federal	1,721	(850)	(2,188)
State	384	(131)	(154)
Foreign	(1,289)	(1,264)	(3,866)
	816	(2,245)	(6,208)
Income tax benefit	$ (492)	$ (76)	$ (3,551)

Our income tax benefit in 2020, 2019, and 2018 included our federal, state, and foreign tax obligations. Our effective income tax rate was a tax benefit of 3%, 5%, and 56% for the years ended December 31, 2020, 2019, and 2018, respectively. Our income tax rate for the year ended December 31, 2020 was primary affected by excess tax benefits on stock compensation, the research and development tax credit, adjustments for prior year tax items, and releases of uncertain tax position liabilities. These tax benefits were partially offset by nondeductible executive compensation, intercompany interest expense disallowance, changes in valuation allowances on future tax assets, and nondeductible meals and entertainment expenses. Our income tax rate for the year ended December 31, 2019 was primarily affected by excess tax benefits on stock compensation, the research and development tax credit and releases of uncertain tax position liabilities. These tax benefits were partially offset by nondeductible executive compensation, intercompany interest expense disallowance, and nondeductible meals and entertainment expenses. Our income tax rate for the year ended December 31, 2018 was primarily affected by excess tax benefits on stock compensation, the research and development tax credit, and non-includable income related to the On-X settlement which increased our benefit. These tax benefits were offset by changes in valuation allowances on future tax benefits and nondeductible meals and entertainment expenses.

The income tax benefit amounts differ from the amounts computed by applying the U.S. federal statutory income tax rate of 21% for the years ended December 31, 2020, 2019, and 2018 to pretax income as a result of the following (in thousands):

	2020	2019	2018
Tax expense (benefit) at statutory rate	$ (3,606)	$ 345	$ (1,340)
Increase (reduction) in income taxes resulting from:			
Valuation allowance change	3,952	153	719
Nondeductible executive compensation	580	778	320
Foreign income taxes	378	425	(250)
Foreign interest disallowance	298	292	--
Nondeductible entertainment expenses	94	201	206
Foreign deferred items	(63)	365	--
Equity compensation	(204)	(1,921)	(2,081)
State income taxes, net of federal benefit	(455)	(108)	(8)
Research and development credit	(457)	(400)	(557)
Net change in uncertain tax positions	(1,115)	(360)	(154)
Other	106	154	(406)
Total income tax benefit	$ (492)	$ (76)	$ (3,551)

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):

	2020	2019
Deferred tax assets:		
Loss carryforwards	$ 7,911	$ 7,030
Finance and operating leases	6,880	7,497
Excess interest carryforward	2,660	4,544
Stock compensation	2,034	2,153
Accrued expenses	2,002	1,890
Property	1,397	1,147
Deferred compensation	1,326	1,107
Credit carryforwards	1,214	710
Inventory and deferred preservation costs write-downs	308	299
UNICAP	97	425
Tax benefit of tax reserves	54	52
Other	2,647	1,659
Less valuation allowance	(7,170)	(3,218)
Total deferred tax assets, net	21,360	25,295

	2020	2019
Deferred tax liabilities:		
Intangible assets	(35,770)	(35,555)
Finance and operating leases	(6,617)	(7,048)
Unrealized gains and losses	(4,929)	--
Financing arrangements	(4,700)	--
Debt costs	(1,528)	(1,917)
Prepaid items	(417)	(494)
Property	--	(28)
Other	(665)	(616)
Total deferred tax liabilities	(54,626)	(45,658)
Total net deferred tax liabilities	$ (33,266)	$ (20,363)

As of December 31, 2020 we maintained a total of $7.2 million in valuation allowances against deferred tax assets, including state and federal net operating loss carryforwards, and a net deferred tax liability of $33.3 million. As of December 31, 2019 we maintained a total of $3.2 million in valuation allowances against deferred tax assets, related primarily to state and foreign net operating loss carryforwards, and a net deferred tax liability of $20.4 million.

As of December 31, 2020 we had approximately $2.4 million of federal net operating loss carryforwards related to the acquisitions of Cardiogenesis and Hemosphere that we anticipate partially utilizing before expiration, $3.4 million of state net operating loss carryforwards, that will begin to expire in 2021, approximately $2.3 million of foreign net operating loss carryforwards that will begin to expire in 2025, $1.2 million in research and development tax credit carryforwards that begin to expire in 2030, and $138,000 in credits from other jurisdictions that mostly expire in 2027.

As of December 31, 2020 we had a deferred tax asset of $2.7 million of disallowed interest expense deduction carryforwards as a result of the new interest deductibility rule imposed by the "Tax Cuts and Jobs Act" of 2017 ("Tax Act"), and modified by the CARES Act. This rule disallows interest expense to the extent it exceeds 30% of adjusted taxable income, modified to be 50% in 2019 and 2020 by the CARES Act. For the years ending December 31, 2020 and 2019 our interest deduction was limited to $15.8 million and $16.3 million, respectively. The temporary increase in the limit as a result of the CARES Act allowed us to utilize previously disallowed interest in the amounts of $2.9 million and $3.3 million in 2020 and 2019 respectively. The remaining unutilized interest deduction deferred tax asset of $2.7 million can be carried forward indefinitely.

Reinvestment of Unremitted Earnings

We intend to reinvest substantially all of the unremitted earnings of our non-U.S. 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-U.S. subsidiaries with the exception of one of its German subsidiaries. As of December 31, 2020 we had a deferred tax liability of $141,000 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):

	2020	2019	2018
Beginning balance	$ 3,523	$ 3,889	$ 4,328
Increases related to current year tax positions	473	691	368
Decreases due to the lapsing of statutes of limitations	(1,703)	(880)	(467)
Decreases related to prior year tax positions	(238)	(154)	--
Increases (decreases) for foreign exchange differences	99	(22)	16
Increases (decreases) related to prior year tax positions	420	(1)	249
Decreases related to settlements	--	--	(605)
Ending balance	$ 2,574	$ 3,523	$ 3,889

A reconciliation of the beginning and ending balances of our liability for interest and penalties on uncertain tax positions is as follows (in thousands):

	2020	2019	2018
Beginning balance	$ 434	$ 402	$ 315
Accrual of interest and penalties	81	227	161
Decreases related to prior year tax positions	(254)	(195)	(74)
Ending balance	$ 261	$ 434	$ 402

As of December 31, 2020 our uncertain tax liability of $2.8 million, including interest and penalties, was recorded as a reduction to deferred tax assets of $300,000, and a non-current liability of $2.5 million on our Consolidated Balance Sheets, all of which, except for the portion related to interest and penalties, is expected to impact our tax rate when recognized. The uncertain tax position decrease related to prior year tax positions is primarily due to the lapse of the statute of limitations in various jurisdictions. As of December 31, 2019 our total uncertain tax liability, including interest and penalties of $4.0 million, was recorded as a reduction to deferred tax assets of $300,000 and as a non-current liability of $3.7 million on our Consolidated Balance Sheets.

We believe it is reasonably possible that approximately $210,000 of our uncertain tax liability will be recognized in 2020 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 2017 and forward generally remain open to examination by the major taxing jurisdictions to which we are subject. However, certain returns from years prior to 2017, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

9. Leases

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

We sublease, on an operating lease basis, two unused office space facilities near our corporate office. Total annual rental income for these facilities is approximately $905,000.

On March 8, 2019 we executed a modification to extend the lease of our On-X manufacturing facilities. This modification resulted in an increase in the net present value and corresponding right-of-use asset of $3.7 million, using a discount rate of 5.83%. We have not executed any material lease arrangements which have not commenced. We do not have any related party leasing arrangements.

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

Operating leases:	**December 31, 2020**	**December 31, 2019**
Operating lease right-of-use assets	$ 28,242	$ 27,007
Accumulated amortization	(9,671)	(5,013)
Operating lease right-of-use assets, net	**$ 18,571**	**$ 21,994**
Current maturities of operating leases	$ 5,763	$ 5,487
Non-current maturities of operating leases	14,034	17,918
Total operating lease liabilities	**$ 19,797**	**$ 23,405**
Finance leases:		
Property and equipment, at cost	$ 7,620	$ 7,161
Accumulated amortization	(1,905)	(1,279)
Property and equipment, net	**$ 5,715**	**$ 5,882**
Current maturities of finance leases	$ 614	$ 597
Non-current maturities of finance leases	5,300	5,415
Total finance lease liabilities	**$ 5,914**	**$ 6,012**
Weighted average remaining lease term (in years):		
Operating leases	5.1	5.5
Finance leases	9.8	10.6
Weighted average discount rate:		
Operating leases	5.2%	5.4%
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, 2020	December 31, 2019
Amortization of property and equipment	$ 643	$ 771
Interest expense on finance leases	118	124
Total finance lease expense	761	895
Operating lease expense[a]	7,145	6,624
Sublease income	(905)	(905)
Total lease expense	**$ 7,001**	**$ 6,614**

[a] Total rental expense for operating leases was $6.4 million in 2018.

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

Cash paid for amounts included in the measurement of lease liabilities:	2020	2019
Operating cash flows for operating leases	$ 7,407	$ 6,827
Financing cash flows for finance leases	653	728
Operating cash flows for finance leases	126	124

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

	Finance Leases	Operating Leases	Sublease Income
2021	$ 719	$ 6,616	$ 905
2022	670	4,511	305
2023	669	3,007	--
2024	666	2,758	--
2025	647	1,909	--
Thereafter	3,138	3,569	--
Total minimum lease payments	$ 6,509	$ 22,370	$ 1,210
Less amount representing interest	595	2,573	
Present value of net minimum lease payments	5,914	19,797	
Less current maturities	614	5,763	
Finance lease obligations, less current maturities	$ 5,300	$ 14,034	

10. 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 CryoLife 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. As of December 31, 2020 the aggregate interest rate was 4.25% per annum. 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.

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. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. Our current intent is to settle in cash the principal amount outstanding and any note conversion value over the principal amount with shares of our common stock. 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 treasury stock method for assumed conversion of the Convertible Senior Notes to compute the weighted average shares of common stock outstanding for diluted earnings per share.

The conversion feature of the Convertible Senior Notes required bifurcation from the notes and was initially accounted for as an equity instrument classified to stockholders' equity, which resulted in recognizing $16.4 million in additional paid-in-capital, net of tax of $4.7 million, during the twelve months ended December 31, 2020. 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 as of twelve months ended December 31, 2020. 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. As of December 31, 2020, we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes. We have used a portion of the proceeds to pay off the $30.0 million outstanding under our Revolving Credit Facility and finance the Ascyrus transaction and anticipate using 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,	
	2020	**2019**
Term loan balance	$ 218,250	$ 220,500
Convertible senior notes	79,555	--
2.45% Sparkasse Zollernalb (KFW Loan 1)	886	1,061
1.40% Sparkasse Zollernalb (KFW Loan 2)	1,457	1,615
Total loan balance	300,148	223,176
Less unamortized loan origination costs	(8,485)	(7,441)
Net borrowings	291,663	215,735
Less short-term loan balance	(1,195)	(1,164)
Long-term loan balance	$ 290,468	$ 214,571

At December 31, 2020 the aggregate maturities of long-term debt for the next five years is as follows (in thousands):

	2021	**2022**	**2023**	**2024**	**2025**	**Thereafter**	**Total**
Maturities	$ 2,829	$ 2,829	$ 2,829	$ 211,875	$ 100,231	$ -	$ 320,593

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 $16.7 million, $14.9 million, and $15.8 million in 2020, 2019, and 2018, respectively. Interest expense includes interest on debt and uncertain tax positions in all periods.

11. Commitments and Contingencies

Liability Claims

At December 31, 2020 and 2019 our unreported loss liability was $1.9 million. As of December 31, 2020 and 2019, the related insurance recoverable amounts were $974,000 and $935,000, respectively. We accrue our estimate of unreported product and tissue processing liability claims as other long-term liabilities and record the related recoverable insurance amounts as other long-term assets. Further analysis indicated that the liability as of December 31, 2020 could be estimated to be as high as $4.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

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.

PerClot Technology

On September 28, 2010 we entered into a worldwide distribution agreement (the “Distribution Agreement”) and a license and manufacturing agreement (the “License Agreement”) with Starch Medical, Inc. (“SMI”), for PerClot, a polysaccharide hemostatic agent used in surgery. The Distribution Agreement has a term of 15 years, but we can terminate it for any reason before the expiration date by providing 180 days’ notice. The Distribution Agreement also contains minimum purchase requirements that expire upon the termination of the Distribution Agreement or following U.S. regulatory approval for PerClot. Separate and apart from the terms of the Distribution Agreement, pursuant to the License Agreement, as amended by a September 2, 2011 technology transfer agreement, we can manufacture and sell PerClot, assuming appropriate regulatory approvals, in the U.S. and certain other jurisdictions and may be required to pay royalties to SMI at certain rates on net revenues of products.

We may make additional contingent payments to SMI of up to $1.0 million if certain U.S. regulatory and certain commercial milestones are achieved.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate Premarket Approval (“PMA”) submission to the U.S. Food and Drug Administration (“FDA”) during the third quarter of 2021.

As of December 31, 2020 we had $1.5 million in prepaid royalties, $1.8 million in net intangible assets, and $1.2 million in property and equipment, net on our Consolidated Balance Sheets related to the PerClot product line. If we do not ultimately pursue or receive FDA approval to commercialize PerClot in the U.S., these assets could be materially impaired in future periods.

12. Employee Benefit Plans

401(k) Plan

We have a 401(k) savings plan (“401(k) Plan”) providing retirement benefits to all employees who have completed at least three months of service. We made matching contributions of 100% of each participant's contribution for up to 3.5% of each participant’s salary in 2020 and 2019 and 3.0% in 2018. Our contributions approximated $1.9 million, $1.6 million, and $1.4 million for the years ended 2020, 2019, and 2018, 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 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 or long-term deferred compensation liabilities, as appropriate, based on anticipated distribution dates. The cash surrender value of COLI is recorded in Other long-term assets. Changes in the value of participant accounts and changes in the cash surrender value of COLI are recorded as part of our operating expenses and are subject to our normal allocation of expenses to inventory and deferred preservation costs.

13. Revenue Recognition

Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

- 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, 2020, 2019, and 2018 the sources of revenue were as follows (in thousands):

	2020	2019	2018
Domestic hospitals	$ 137,810	144,538	$ 138,432
International hospitals	80,524	85,241	81,203
International distributors	34,429	40,427	36,989
CardioGenesis cardiac laser therapy	464	6,016	6,217
Total sources of revenue	**$ 253,227**	**$ 276,222**	**$ 262,841**

Also see segment and geographic disclosure in Note 17 below.

Contract Balances

We may generate contract assets during the pre-delivery design and manufacturing stage of E-xtra DESIGN ENGINEERING product order fulfillment. We assess the balance related to any arrangements in process and determine if the enforceable right to payment creates a material contract asset requiring disclosure. No material arrangements in process existed as of December 31, 2020 and 2019.

We also incur contract obligations on general customer purchase orders that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product or service, we have determined that the balance related to these contract obligations is generally immaterial at any point in time. We monitor the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate. The value of orders accepted but unfulfilled as of December 31, 2020 and 2019 was not material.

14. Stock Compensation

Overview

We are currently authorized to grant and have available for grant the following number of shares under our stock plans as of December 31, 2020 and 2019:

Plan	Authorized Shares	Available for Grant 2020	Available for Grant 2019
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	150,000	234,000
2009 Equity and Cash Incentive Plan	7,570,000	52,000	2,100,000
2020 Equity and Cash Incentive Plan	4,105,000	4,094,000	--
Total	13,575,000	4,296,000	2,334,000

During 2020 the Shareholders approved a new 2020 Equity and Cash Incentive Plan 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, PSAs, 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 2020 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 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 is based on attaining specified levels of adjusted earnings before interest, taxes, depreciation, and amortization, ("EBITDA"), as defined in the PSU grant documents, for the 2020 calendar year. Our actual 2020 EBIDTA 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 will result in additional stock compensation expense beginning in 2021 related to these performance awards.

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, an annual grant with a one-year performance period ("Annual PSU") and a special Long-Term Incentive Program PSU grant ("LTIP"), 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 is 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 is 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.

In 2018 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 328,000 shares of common stock and had an aggregate grant date market value of $7.5 million. The performance component of PSU awards granted in 2018 was based on attaining specified levels of adjusted EBITDA, as defined in the PSU grant documents, for the 2018 calendar year. The PSUs granted in 2018 earned approximately 80% of the target number of shares.

A summary of stock grant activity for the years ended December 31, 2020, 2019, and 2018 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, 2017	383,000	$ 12.81
Granted	128,000	23.83
Vested	(136,000)	12.96
Forfeited	(49,000)	12.07
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
Forfeited	--	-
Unvested at December 31, 2020	258,000	25.08

RSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2017	286,000	1.26	$ 5,477,000
Granted	115,000		
Vested	(99,000)		
Forfeited	(51,000)		
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
Vested and expected to vest	212,000	1.02	$ 5,015,000

PSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2017	169,000	0.71	$ 3,236,000
Granted	104,000		
Vested	(109,000)		
Forfeited	(17,000)		
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
Vested and expected to vest	331,000	1.64	$ 7,805,000

During the years ended December 31, 2020, 2019, and 2018 the total fair value of $6.7 million, $9.8 million, and $7.3 million, respectively, in combined RSAs, PSAs, 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 212,000, 169,000, and 219,000 shares in 2020, 2019, and 2018, 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, 2020, 2019, and 2018 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2017	1,741,000	10.19	3.64	15,598,000
Granted	219,000	21.55		
Exercised	(578,000)	7.59		
Forfeited	(49,000)	14.10		
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
Vested and expected to vest	1,241,000	$ 18.16	3.38	$ 8,215,000
Exercisable at December 31, 2020	874,000	$ 14.71	2.45	$ 8,094,000

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

	2020	2019	2018
Weighted-average fair value of options granted	$ 8.64	$ 11.47	$ 8.38
Intrinsic value of options exercised	1,267,000	6,519,000	9,961,000

Employees purchased common stock totaling 83,000, 61,000, and 83,000 shares in 2020, 2019, and 2018, respectively, through our ESPP.

Stock Compensation Expense

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

	2020		2019		2018	
	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	0.35	0.52	0.40	0.39	0.40	0.34
Risk-free interest rate	1.41%	1.00%	2.54%	2.35%	2.64%	1.73%

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

	2020	2019	2018
RSA, PSA, RSU, and PSU expense	$ 5,288	$ 7,451	$ 5,076
Stock option and ESPP option expense	2,216	1,960	1,732
Total stock compensation expense	$ 7,504	$ 9,411	$ 6,808

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, PSAs, 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 or normal allocation of expenses to inventory costs and deferred preservation costs. We capitalized $592,000, $612,000, and $484,000 in the years ended December 31, 2020, 2019, and 2018, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of December 31, 2020 we had total unrecognized compensation costs of $7.8 million related to RSAs, RSUs, and PSUs and $2.1 million related to unvested stock options. As of December 31, 2020 this expense is expected to be recognized over a weighted-average period of 1.75 years for RSUs, 1.58 years for stock options, 0.98 years for RSAs, and 1.64 years for PSUs.

15. (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	**2020**	**2019**	**2018**
Net (loss) income	$ (16,682)	$ 1,720	$ (2,840)
Net loss (income) allocated to participating securities	111	(12)	27
Net (loss) income allocated to common shareholders	$ (16,571)	$ 1,708	$ (2,813)
Basic weighted-average common shares outstanding	37,861	37,118	36,412
Basic (loss) income per common share	$ (0.44)	$ 0.05	$ (0.08)

Diluted (loss) income per common share	**2020**	**2019**	**2018**
Net (loss) income	$ (16,682)	$ 1,720	$ (2,840)
Net loss (income) allocated to participating securities	111	(12)	27
Net (loss) income allocated to common shareholders	$ (16,571)	$ 1,708	$ (2,813)
Basic weighted-average common shares outstanding	37,861	37,118	36,412
Effect of dilutive options and awards[a]	-	742	-
Diluted weighted-average common shares outstanding	37,861	37,860	36,412
Diluted (loss) income per common share	$ (0.44)	$ 0.05	$ (0.08)

[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, 2020 and 2018 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 years ended December 31, 2019 stock options to purchase 131,000 shares were excluded from the calculation of diluted weighted-average common shares outstanding.

16. 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 $378,000, $341,000, and $296,000 in 2020, 2019, and 2018, respectively.

17. 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 BioGlue, aortic stents and stent grafts, On-X products, CardioGenesis cardiac laser therapy, PerClot and PhotoFix. 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 operating segments (in thousands):

	2020	2019	2018
Revenues:			
Medical devices	$ 179,299	$ 197,246	$ 187,394
Preservation services	73,928	78,976	75,447
Total revenues	253,227	276,222	262,841
Cost of products and preservation services:			
Medical devices	50,128	55,022	53,772
Preservation services	35,315	38,187	36,085
Total cost of products and preservation services	85,443	93,209	89,857
Gross margin:			
Medical devices	129,171	142,224	133,622
Preservation services	38,613	40,789	39,362
Total gross margin	$ 167,784	$ 183,013	$ 172,984

Net revenues by product for the years ended December 31, 2020, 2019, and 2018 were as follows (in thousands):

	2020	2019	2018
Products:			
BioGlue	$ 62,068	$ 68,611	$ 66,660
Aortic stents and stent grafts	61,663	64,974	63,341
On-X	48,053	50,096	44,832
PhotoFix	4,169	3,754	2,577
PerClot	2,882	3,795	3,767
CardioGenesis cardiac laser therapy	464	6,016	6,217
Total products	179,299	197,246	187,394
Preservation services:			
Cardiac tissue	37,893	40,879	35,683
Vascular tissue	35,852	38,097	39,764
NeoPatch	183	--	--
Total preservation services	73,928	78,976	75,447
Total revenues	$ 253,227	$ 276,222	$ 262,841

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2020, 2019, and 2018 were as follows (in thousands):

	2020	2019	2018
U.S.	$ 138,274	$ 150,553	$ 144,651
International	114,953	125,669	118,190
Total revenues	$ 253,227	$ 276,222	$ 262,841

For the years ended December 31, 2020, 2019 and 2018, revenues attributed to customers in Germany accounted for 10% of total revenues.

At December 31, 2020 and 2019 54% and 57% of our long-lived assets were held in the U.S., where the corporate headquarters and a portion of our manufacturing facilities are located. Our long-lived international assets were $15.1 million and $14.1 million as of December 31, 2020, and 2019, respectively of which 97% were located in Hechingen, Germany. At December 31, 2020 and 2019 $260.1 million and $186.7 million, respectively, of our goodwill was allocated entirely to our Medical Devices segment.

18. Subsequent Events

On January 6, 2021 we entered into an agreement to extend the lease of our headquarters facility located in Kennesaw, Georgia. We are in the process of evaluating the impact of this transaction, but we believe that it will result in the recording of a material right-of-use asset and lease liability on the Consolidated Balance Sheets.

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, 2020, 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 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 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. As previously noted in this Form 10-K, we completed the acquisition of Ascyrus on September 2, 2020. Management's assessment and conclusion on the effectiveness of our disclosure controls and procedures as of December 31, 2020 excludes an assessment of the internal control over financial reporting of Ascyrus. See Part II, Item 8, Note 2, "Notes to Consolidated Financial Statements" contained in this Form 10-K for a description of the significance of the acquired business to us.

As disclosed above, on September 2, 2020 we entered into the Ascyrus Agreement to acquire 100% of the outstanding equity interests of Ascyrus. We are currently in the process of implementing CryoLife's internal control structure over these operations.

During the quarter ended December 31, 2020 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.

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, 2020, with the exception of information concerning executive officers listed below.

The following table lists the executive officers of CryoLife as of December 31, 2020 and their ages, positions with CryoLife, and the dates from which they have continually served as executive officers with CryoLife. Each of the executive officers of CryoLife 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	54	Chairman, President, and Chief Executive Officer
F. Peter Barthold	Since 2020	56	Vice President, Research and Development
Scott B. Capps	Since 2007	54	Vice President, Clinical Research
John E. Davis	Since 2015	56	Senior Vice President, Global Sales and Marketing
Matthew A. Getz	Since 2019	52	Vice President, Human Resources
Jean F. Holloway, Esq.	Since 2015	63	Senior Vice President, General Counsel, Chief Compliance Officer, and Secretary
Amy D. Horton, CPA	Since 2006	50	Vice President and Chief Accounting Officer
D. Ashley Lee, CPA	Since 2000	56	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Dennis B. Maier	Since 2017	47	Vice President, Operations
Michael S. Simpson	Since 2018	53	Senior Vice President, Regulatory Affairs and Quality Assurance

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 CryoLife, 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 U.S. Army. Mr. Mackin received an MBA from Northwestern University's Kellogg Graduate School of Management and is a graduate of the U.S. 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.

Scott B. Capps was appointed to the position of Vice President of Clinical Research in November 2007. Prior to this position, Mr. Capps served as Vice President, General Manager of CryoLife Europa, Ltd. in the U.K. from February 2005 to November 2007 and Director, European Clinical Affairs from April 2003 to January 2005. Mr. Capps joined CryoLife in 1995 as Project Engineer for the allograft heart valve program and was promoted to Director, Clinical Research in 1999. Mr. Capps is responsible for overseeing and implementing clinical trials to achieve FDA and International approval of CryoLife's medical products in cardiac, vascular, and orthopaedic clinical areas. Before joining CryoLife, Mr. Capps was a Research Assistant in the Department of Bioengineering at Clemson University working to develop a computerized database and radiographic image analysis system for total knee replacement. Mr. Capps received his Bachelor of Industrial Engineering from the Georgia Institute of Technology and his M.S. in Bioengineering from Clemson University.

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 CryoLife, 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 CryoLife, 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.

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 CryoLife, 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 J.D./M.B.A. 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 CryoLife 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 B.S. 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 CryoLife 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 CryoLife 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 B.S. 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 CryoLife, 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 U.S. Military Academy at West Point.

Michael S. Simpson was appointed to the position of Senior Vice President, Regulatory Affairs and Quality Assurance in December 2018. Prior to joining CryoLife, Mr. Simpson served as Vice President, Regulatory and Clinical Affairs for Becton Dickinson Urology and Critical Care (legacy Bard). Other prior significant roles included Vice President, Quality and Regulatory Affairs for Beckman Coulter Life Sciences, operating company of Danaher Corporation, Vice President, Quality, Regulatory, Clinical Affairs, and Compliance Officer for Exactech, Inc., and multiple leadership roles in product development and quality engineering at Novoste Corporation. Mr. Simpson received Bachelor and Master of Science degrees in Mechanical Engineering from the Georgia Institute of Technology in Atlanta.

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, 2020.

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, 2020.

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, 2020.

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, 2020.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The following are consolidated financial statements of CryoLife, 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 .

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.

CRYOLIFE, INC.

February 22, 2021 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, 2021
/s/ D. ASHLEY LEE **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 22, 2021
/s/ AMY D. HORTON **Amy D. Horton**	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 22, 2021
/s/ THOMAS F. ACKERMAN **Thomas F. Ackerman**	Director	February 22, 2021
/s/ DANIEL J. BEVEVINO **Daniel J. Bevevino**	Director	February 22, 2021
/s/ MARNA P. BORGSTROM **Marna P. Borgstrom**	Director	February 22, 2021
/s/ JAMES W. BULLOCK **James W. Bullock**	Director	February 22, 2021
/s/ JEFFREY H. BURBANK **Jeffrey H. Burbank**	Director	February 22, 2021
/s/ RONALD D. MCCALL **Ronald D. McCall**	Director	February 22, 2021
/s/ HARVEY MORGAN **Harvey Morgan**	Director	February 22, 2021
/s/ JON W. SALVESON **Jon W. Salveson**	Director	February 22, 2021

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of December 22, 2015, by and among CryoLife, Inc., On-X Life Technologies Holdings, Inc., Cast Acquisition Corporation, Fortis Advisors LLC and each of the security holders who becomes a party thereto. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed January 25, 2016.)
2.2	Securities Purchase Agreement, dated as of October 10, 2017, by and among CryoLife, Inc., CryoLife Germany HoldCo GmbH, Jolly Buyer Acquisition GmbH, JOTEC AG, each of the security holders identified therein, and Lars Sunnanväder as the representative of such security holders. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed October 11, 2017.)
2.3	Securities Purchase Agreement, dated September 2, 2020, by and among CryoLife, 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.)
3.1	Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020)
3.2	Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 22, 2018.)
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 CryoLife, 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 CryoLife, Inc. and U.S. 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 CryoLife, Inc. and U.S. 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†	CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife 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 CryoLife, 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†	CryoLife, 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)†	CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife, 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	CryoLife, 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 CryoLife, 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	CryoLife, 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 CryoLife, Inc. Employee Stock Purchase Plan. (Incorporated herein by reference to the Registrant's Definitive Proxy Statement filed May 20, 2010.)
10.5†	CryoLife, 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 2020 Compensation Arrangements with Non-Employee Directors.
10.7†	Employment Agreement between CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife, 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 CryoLife, 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 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 CryoLife, 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 by reference to Exhibit 10.3 of Registrant's Quarterly Report on Form 10-Q filed July 31, 2020).
10.15	Lease Agreement between CryoLife, 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 CryoLife, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to Amli Land Development—I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999.)
10.15(b)	Restatement and Amendment to Funding Agreement between CryoLife, 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.)

Exhibit Number	Description
10.15(c)	Second Amendment to Lease Agreement between CryoLife, 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 CryoLife, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to P&L Barrett, L.P., dated May 10, 2020.
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 Repo 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 o 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.
10.20	Loan Agreement, dated September 11, 2019, by and between CryoLife, Inc., as lender, and Endospan Ltd., as borrower. (Incorporated 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 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.
10.22	Purchase Agreement, dated as of June 18, 2020, by and between CryoLife, Inc. and Morgan Stanley & Co. LLC, as the initial purchaser. (Incorporated 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 CryoLife, 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 CryoLife, Inc. and Duke University.
21.1*	Subsidiaries of CryoLife, Inc.
23.1*	Consent of Ernst & Young LLP
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification Pursuant To 18 U.S.C. 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

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*Filed herewith.

**Furnished herewith.

† Indicates management contract or compensatory plan or arrangement.
∞ Indicates that the 2018 form was used in 2019, and 2020, except otherwise indicated.
+ The Registrant has redacted exhibit provisions or terms that are both not material and would likely cause competitive harm to the Registrant if publicly disclosed.

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