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, 2019

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	**Name of each exchange on which registered**
Common Stock, $.01 par value	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 is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

As of June 30, 2019 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $1,078,303,225 computed using the closing price of $29.93 per share of Common Stock on June 30, 2019, 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 14, 2020 the number of outstanding shares of Common Stock of the registrant was 39,081,335.

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, 2019	Part III

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Forward-Looking Statements

This Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act of 1934 (the "Exchange Act"). The words "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future," "assume," and variations of such words and other similar expressions generally 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. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Part I, Item 1A, "Risk Factors" and elsewhere in 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 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 belief regarding the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- Our beliefs about the unavailability of handpieces for cardiac laser therapy, the temporary nature of this unavailability, and a possible resolution of this unavailability during the second half of 2020;
- Our belief that revenue from cardiac laser therapy can vary from quarter to quarter and year to year due to the use of cardiac laser therapy adjunctively with cardiac bypass surgery by a limited number of physicians;
- Our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the agreements with Endospan, and our beliefs about the costs and expected timeline regarding certain clinical trial milestones for the regulatory approval of NEXUS stent graft system in the U.S.;
- Our plans, costs, and expected 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 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 borrowing capacity or financing;
- Our belief that we will incur expenses for clinical research work to gain regulatory approvals for products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and expenses for research and development for new products;
- Our expectations regarding the timing of clinical research work and regulatory approvals for and expected distribution of products or indications, including JOTEC, On-X, PerClot, and BioGlue products;
- Our plans and expectations regarding reinvesting the unremitted earnings of our non-U.S. subsidiaries;
- Our expectations regarding the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation; 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. We assume no obligation 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, JOTEC stent grafts and surgical products, On-X mechanical heart valves and surgical products, and implantable cardiac and vascular human tissues. In addition to these four major product families, we sell or distribute PhotoFix™ bovine surgical patch, PerClot® hemostatic powder, NEXUS™ endovascular stent graft system, and CardioGenesis cardiac laser therapy.

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, JOTEC products, On-X products, CardioGenesis cardiac laser therapy, PerClot, PhotoFix, and NEXUS. The Preservation Services segment includes services revenues from the preservation of cardiac and vascular implantable human tissues. See Part II, Item 8, Note 18 of the "Notes to Consolidated Financial Statements" for further information on our segments and for our geographic information.

Strategy

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 near term. These four growth areas and their key elements are described below:

- *New Products* – Drive growth through product development and commercialization of new and next-generation products and services focused on aortic repair;
- *New Indications* – Drive growth through new regulatory approvals and expanded indications for our existing products and services to increase the size of our addressable U.S. or international markets;
- *Global Expansion* – Drive growth 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* – Drive growth by selectively pursuing 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 and On-X 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.

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, 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 banks. Many of our current and potential competitors have substantially 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 impose 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. Some might be developing additional competitive products that could compete with our products or services in the future. We cannot assure that our current or future competitors will not succeed in developing alternative technologies, products, or services that have significant advantages over those that have been, or are being, developed by us or that would render our products or technologies obsolete and 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") in the European Economic Area ("EEA") 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 sealants from Baxter International Inc, ("Baxter"); Ethicon, Inc. (a Johnson & Johnson Company); Integra LifeSciences Holdings Corporation; and Bard ("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 are approved to sell BioGlue throughout the U.S. and in approximately 85 other countries. Revenues from BioGlue accounted for 25%, 25%, and 35% of total revenues in 2019, 2018, and 2017, 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 relatively inexpensive 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 a degenerating valve must be replaced. Multiple replacements, each requiring open heart surgery, can be a significant concern for 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 merely 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 long term resistance to calcification and the 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.

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. The On-X aortic heart valve is the only mechanical valve FDA approved to be marketed as, and clinically proven to be, safer with lower doses of warfarin than those required for other mechanical heart valves. In a prospective, randomized, controlled clinical trial comparing reduced warfarin to standard warfarin dose in On-X aortic heart valve patients, the reduced warfarin dose group had 60% fewer bleeding events without an increase in stroke risk.

While patients with an On-X aortic heart can be safely maintained on lower doses of warfarin, an unmet clinical need remains for an alternative to warfarin, such as a direct oral anticoagulant ("DOAC"), for anticoagulation in patients with an aortic mechanical prosthetic valve. We believe that if there was an alternative to warfarin, some younger patients would have a strong incentive to choose an On-X Aortic Valve.

To evaluate the potential to address this unmet clinical need, we are initiating 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®), an alternative to warfarin that does not carry the same risks and restrictions as that therapy. In December 2019 we received authorization from the FDA pursuant to an Investigational New Drug application to begin the PROACT Xa clinical trial. We anticipate enrollment to begin the first quarter of 2020.

The On-X heart valve is FDA approved for the replacement of diseased, damaged, or malfunctioning native or prosthetic heart valves in the aortic and mitral positions and is classified as a Class III medical device. On-X distributes the On-X heart valve under CE Mark in the EEA. Additional marketing approvals have been granted in several other countries throughout the world.

The On-X heart valves compete primarily with mechanical valves from Abbott Laboratories, Medtronic, Inc. ("Medtronic"); and LivaNova PLC ("LivaNova"). The On-X heart valves compete with these products based on its features and benefits, such as full, 90-degree leaflet opening, pure pyrolytic carbon, flared inlet, and approved labeling claim for lower warfarin requirements for aortic valves.

We began selling On-X heart valves in January 2016. We are approved to sell On-X heart valves throughout the U.S. and in approximately 95 other countries. Revenues from On-X products accounted for 18%, 17%, and 19% of total revenues in 2019, 2018, and 2017.

Cardiac Preservation Services

Our proprietary preservation process involves our dissection, processing, preservation, and storage of donated human tissues until they are shipped to an implanting physician. The cardiac tissues we currently preserve include aortic and pulmonary heart valves and cardiac patches in three primary anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary 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 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 with our proprietary SynerGraft SGPV valves had a 17% re-operation rate, as compared to a 40% re-operation rate for patients 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.

At least one domestic tissue bank, LifeNet Health, Inc. ("LifeNet"), offers 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.; Admedus, Inc. ("Admedus"); 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%, 14%, and 17% of total revenues in 2019, 2018, and 2017, respectively.

PhotoFix

PhotoFix is a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix has FDA 510(k) clearance and 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 and arteriovenous access revisions).

Our PhotoFix product line competes with bioprosthetic and synthetic cardiac 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.

In 2014 we entered into an exclusive supply and distribution agreement with Genesee Biomedical, Inc. ("GBI") to acquire the distribution rights to PhotoFix. In April 2016 we exercised our right to acquire the PhotoFix technology from GBI and began shipping product manufactured at our headquarters facility in 2018. Revenues from PhotoFix accounted for approximately 1% of our total revenues in each of 2019, 2018, and 2017.

Stent Grafts for Aortic Arch and Thoracic Aortic Repair

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

Many patients with an aortic dissection in the aortic arch also have an aneurysm or an aortic dissection in the descending thoracic aorta. 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 distribute NEXUS to treat these conditions impacting the aortic arch and thoracic aorta.

E-vita OPEN PLUS

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

We sell the E-vita OPEN PLUS under CE Mark in the EEA. 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%, 3%, and less than 1% of total revenues in 2019, 2018, and 2017, respectively.

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 in the aorta above and below the aneurysm. Blood will then flow through the graft. This surgery reinforces the diseased aorta and reduces the chance of vessel rupture.

Endovascular repair is minimally invasive, 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.

Through 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 products are tailor-made for individual patients. There are currently only limited off-the-shelf product offerings 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 products 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 products in the EEA and in a limited number of other countries around the world. E-xtra DESIGN ENGINEERING products compete with customized product offerings from Cook and Terumo.

Revenues from E-xtra DESIGN ENGINEERING accounted for 5%, 5%, and less than 1% of total revenues in 2019, 2018, and 2017, 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 the 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 CE Mark for E-nside in the fourth quarter of 2019 and will begin limited selling of E-nside in the second quarter of 2020 with full product launch in the third quarter of 2020.

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 implant 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 sell the E-vita THORACIC 3G under CE Mark in the EEA. Additional marketing approvals have been granted in several other countries throughout the world. The E-vita THORACIC 3G competes with primarily products from Medtronic, Gore, Terumo, and Cook.

Revenues from the E-vita THORACIC 3G accounted for 2%, 2%, and less than 1% of total revenues in 2019, 2018, and 2017, 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 CE Mark for E-nya in the fourth quarter of 2019 and will begin limited distribution of E-nya in the second quarter of 2020 with full product launch in the third quarter of 2020.

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.

We distribute the E-ventus BX under CE Mark in the EEA and under additional marketing approvals in several other countries throughout the world. The E-ventus BX competes with products from Maquet, Inc. ("Maquet"), Gore, and BD.

Revenues from the E-ventus BX accounted for 3%, 3%, and less than 1% of total revenues in 2019, 2018, and 2017, 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 sell the E-liac under CE Mark in the EEA. 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%, 2%, and less than 1% of total revenues in 2019, 2018, and 2017, respectively.

E-tegra

The E-tegra is an 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 products and the E-liac.

We sell the E-tegra under CE Mark in the EEA. 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 6%, 5%, and less than 1% of total revenues in 2019, 2018, and 2017, respectively.

NEXUS

JOTEC acquired the exclusive distribution rights in certain countries in Europe for NEXUS stent graft system ("NEXUS") in September 2019 from Endospan Ltd., an Israeli corporation ("Endospan"). NEXUS 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"), the Valiant Mona LSA device (Medtronic), 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. Revenues from NEXUS accounted for less than 1% of total revenues in 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 an implanting 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.

Two other domestic tissue banks, LifeNet, and LeMaitre, offer 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, Artegraft, Inc., 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%, 15%, and 20% of total revenues in 2019, 2018, and 2017, 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 our expertise in synthetic graft manufacturing complements our ability to manufacture our own nitinol stents, both of which are used in our stent graft systems.

We distribute our synthetic surgical vascular grafts under CE Mark in the EEA. 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, and Maquet.

Revenues from synthetic surgical vascular grafts accounted for 2%, 2%, and less than 1% of total revenues in 2019, 2018, and 2017, 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. Although the CardioGenesis cardiac laser therapy product line has a CE Mark allowing commercialization into the EEA, we do not actively market the product line internationally.

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. The only directly competitive laser technology for the performance of TMR is the CO_2 Heart Laser System manufactured by Novadaq Technologies, Inc. Novadaq was acquired by Stryker in 2017 and Stryker discontinued the manufacturing and servicing of this product. Currently, Laser Engineering Inc. services the laser system and sells the handpiece kits. Our CardioGenesis cardiac laser therapy product competes 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 sell handpieces and consoles primarily in the U.S. Revenues from CardioGenesis cardiac laser therapy accounted for 2%, 2%, and 4% of total revenues in 2019, 2018, and 2017, 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 allowing commercialization in the EEA and other markets. 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 hemostats including thrombin products from Pfizer, Inc., Baxter, and Ethicon, Inc., and surgical hemostats from Pfizer, Inc., BD, Baxter, Ethicon, Inc., and BioCer Entwicklungs-GmbH. Other competitive products may include argon beam coagulators, which provide an electrical source of hemostasis. 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 second half of 2020. Revenues from PerClot accounted for 1%, 2%, and 2% of total revenues in 2019, 2018, and 2017, respectively.

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 dialysis or transplant. Patients with ESRD often undergo hemodialysis through an access site. We market our CryoVein femoral vein and CryoArtery femoral artery vascular preservation services for vascular access and previously marketed the Hemodialysis Reliable Outflow Graft ("HeRO® Graft") and ProCol® Vascular Bioprosthesis ("ProCol") 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 60-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, we conduct field training for surgeons regarding the surgical applications of our products and tissues.

In the EEA, the Middle East, and Africa ("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 subsidiaries based throughout Asia Pacific as well as through independent distributors.

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. 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 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."

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 is currently unable to supply handpieces until the FDA approves our supplier's change in manufacturing location, pending resolution of several observations the FDA raised during a manufacturing site change inspection. We do not believe these observations relate to quality or safety. We currently anticipate resumption of supply during the second half of 2020. See also Part I, Item 1A, "Risk Factors—Risks Relating To Our Business—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 and place orders for additional product in anticipation of higher sales to ensure a continuous supply. 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 57 OPOs and tissue banks throughout the U.S. We believe these relationships 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.

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.

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.

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 the ISO 13485.

The Medical Device Directive ("MDD") is the governing document for the EEA that details requirements for safety and risk of devices. Effective May 26, 2020 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—Risks Relating To Our Business—Our products and tissues are highly regulated and subject to significant quality and regulatory risks," for a discussion of risks related 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"), and the British Standards Institute ("BSI"). 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, auditing organizations BSI and LRQA perform assessments affirming compliance to the Medical Device Single Audit Program ("MDSAP"), which includes 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. On July 5, 2019 the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA") granted us a one year grace period 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—Risks Relating To Our Business— We are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting them," 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 for marketing 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 has approved the PMA.

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. 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 would, upon approval, be classified as Class III medical devices: BioGlue, On-X heart valve, On-X AAP, PerClot, CardioGenesis cardiac laser therapy, E-vita OPEN PLUS, E-Vita OPEN NEO, E-vita THORACIC 3G, E-xtra, E-tegra, E-liac, E-nya, and E-nside. CryoPatch SG is classified as Class II medical devices. 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 October 2014 the FDA convened an advisory committee meeting to consider the FDA's recommendation to reclassify more than minimally manipulated ("MMM") allograft heart valves from an unclassified medical device to a Class III medical device. The class of allograft heart valves potentially covered by this recommendation includes our CryoValve SGPV. At the meeting, a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves be

reclassified as a Class III product. In December 2019, we learned that the FDA is preparing to issue a proposed rule for reclassification of MMM allograft heart valves as Class III medical devices, which would be subject to a comment period before publication of a final rule. Upon publication of the 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—Risks Relating To Our Business— 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, 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, BioFoam, On-X heart valves, On-X Chord-X sutures, CardioGenesis cardiac laser therapy consoles and handpieces, E-vita OPEN PLUS, E-vita THORACIC 3G, E-tegra, E-liac, E-nya, E-nside, and other devices. We are currently addressing the cessation of LRQA as a Notified Body as it pertains to our BioGlue and PhotoFix certifications. See Part I, Item 1A, "Risk Factors—Risks Relating To Our Business—We are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting them." And we are currently pursuing another pathway to CE Mark for On-X AAP, which was temporarily suspended. See Part I, Item 1A, "Risk Factors—Risks Relating To Our Business—Our revenues for the On-X AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP's CE Mark." In addition, E-ventus and NEXUS, which we distribute, have CE Marks.

Backlog

As of December 31, 2019, 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 will not have a supply of handpieces for cardiac laser therapy until the FDA approves 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. We currently anticipate resumption of supply during the second half of 2020.

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 inform third-parties on the benefits of our products and services and to help direct our continuing improvement efforts.

In 2019, 2018, and 2017 we spent approximately $23.0 million, $23.1 million, and $19.5 million, respectively, on research and development activities on new and existing products. These amounts accounted for approximately 8%, 9%, and 10% of our revenues for each of 2019, 2018, and 2017, 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 2020.

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 2020.

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 2020.

We are initiating 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®) 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. We anticipate enrollment to begin the first quarter of 2020.

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 second half of 2020. See also Part I, Item 1A, "Risk Factors—Risks Relating To Our Business—Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S. either directly or indirectly."

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 have also obtained additional rights through license and distribution agreements for additional products and technologies, including PerClot and NEXUS. We own or have licensed rights to 42 U.S. patents and 157 foreign patents for legacy CryoLife products, JOTEC products, and On-X products, including patents that relate to our technology for BioGlue, JOTEC products, On-X heart valves, CardioGenesis cardiac laser therapy, PerClot, cardiac and vascular tissue preservation, and decellularization of tissue. We have 17 pending U.S. patent applications and 51 pending foreign applications that relate to our legacy CryoLife products and services, On-X products, and JOTEC products. There can be no assurance that any patent applications pending will ultimately be issued as patents.

The remaining duration of our issued patents ranges from 1 year to 16 years. 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 patent for BioGlue has 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 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—Risks Relating To Our Business—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.

Employees

As of December 31, 2019 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.

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. 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 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.

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; and (iii) the charter of each active committee of our Board of Directors. We also intend to disclose any amendments to our Code of Conduct, or waivers of our Code 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

We may not realize all the anticipated benefits of the JOTEC Acquisition.

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 ("JOTEC"), and its subsidiaries (the "JOTEC Acquisition") for $169.1 million in cash and 2,682,754 shares of CryoLife common stock with a value of $53.1 million on the date of closing, for a total purchase price of approximately $222.2 million, including debt and cash acquired on the date of closing. We paid part of the cash portion of the purchase price using available cash on hand and financed the remainder of the cash portion of the purchase price and related expenses and refinanced our then existing approximately $69.0 million term loan, with a new $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility and a $30.0 million undrawn secured revolving credit facility.

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

- The continued growth of the global market for stent grafts used in endovascular and open repair of aortic disease;
- Our ability to leverage our global infrastructure to sell JOTEC products, including in the markets in which JOTEC is already direct;
- Our ability to foster cross-selling opportunities between the CryoLife and JOTEC product portfolios;
- Our ability to bring JOTEC products to the U.S. market;
- Our ability to harness the JOTEC new product pipeline and R&D capabilities to drive long-term growth, including our ability to obtain Conformité Européene Mark product certification ("CE Mark") for pipeline products;
- Our ability to drive gross margin expansion;
- Our ability to compete effectively;
- Our ability to carry, service, and manage significantly more debt and repayment obligations; and
- Our ability to manage the unforeseen risks and uncertainties related to JOTEC's business, including any related to intellectual property rights.

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, which could materially, adversely impact our business, financial condition, profitability, and cash flows. These benefits 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 the acquisition, we could experience an interruption or loss of momentum in our existing business activities, which could adversely affect our revenues, financial condition, profitability, and cash flows.

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

Our current and future levels of indebtedness could:

- Limit our ability to borrow money for our working capital, capital expenditures, development projects, strategic initiatives, or other purposes;
- Require us to dedicate a substantial portion of our cash flow from operations to the repayment of our indebtedness, thereby reducing funds available to us for other purposes;
- Limit our flexibility in planning for, or reacting to, changes in our operations or business;
- Make us more vulnerable to downturns in our business, the economy, or the industry in which we operate;
- Restrict us from making strategic acquisitions, introducing new technologies, or exploiting business opportunities; and
- Expose us to the risk of increased interest rates as most of our borrowings are at a variable rate of interest.

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;
- Pay dividends on or make distributions in respect 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 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;
- Create liens on certain assets;

- Enter into certain transactions with our affiliates;
- 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 organizational documents or the organizational documents of a subsidiary 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;
- Change our, or permit a subsidiary to change its, 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.

As a result of these covenants, we are limited in the manner in which we conduct our business, and we may be unable to engage in favorable business activities or finance future operations or capital needs.

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 contained in our existing Credit Agreement could result in an event of default under such agreements, which, if not cured or waived, could have a material, adverse effect on our business, financial condition, and profitability. In the event of any default under our existing debt agreement, 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 the collateral granted to them to secure that indebtedness. If the indebtedness under our existing debt agreements were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

Our charges to earnings resulting from acquisition, restructuring, and integration costs may materially, adversely affect the market value of our common stock.

We account for the completion of our acquisitions using the purchase method of accounting. We allocate the total estimated purchase prices to net tangible assets, amortizable intangible assets and indefinite-lived intangible assets, and based on their fair values as of the date of completion of the acquisitions, record the excess of the purchase price over those fair values as goodwill. Our financial results, including earnings per share, could be adversely affected by a number of financial adjustments required in purchase accounting including the following:

- We will incur additional amortization expense over the estimated useful lives of some of the intangible assets acquired in connection with acquisitions during such estimated useful lives;
- We will incur additional depreciation expense as a result of recording purchased tangible assets;
- To the extent the value of goodwill or intangible assets becomes impaired, we may be required to incur material charges relating to the impairment of those assets;
- Cost of sales may increase temporarily following an acquisition as a result of acquired inventory being recorded at its fair market value;
- Earnings may be affected by changes in estimates of future contingent consideration to be paid when an earn-out is part of the consideration; or
- Earnings may be affected by transaction and integration costs, which are expensed immediately.

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% for the years ended December 31, 2019 and 2018, and 37% of revenues in the year ended December 31, 2017. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows, if we are unable to:

- Source sufficient quantities of some tissue types from human donors or address potential excess supply of other tissue types. We rely primarily upon the efforts of third-party procurement organizations, tissue banks (most of which are not-for-profit), and others 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 in tissue preservation services, as we may be unable to capitalize on our clinical advantage or our competitors may have advantages over us in terms of cost structure, pricing, back office automation, marketing, and sourcing tissue; or
- Mitigate sufficiently the risk that processed tissue cannot be sterilized and hence carries an inherent risk of infection or disease transmission; there is no assurance that our quality controls will be adequate to mitigate such risk.

In addition, U.S. and foreign governments and regulatory agencies have adopted restrictive laws, regulations, and rules that apply to our tissue preservation services. These include but are not limited to:

- National Organ Transplant Act, which prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation, but allows for the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs; and
- U.S. Department of Labor, Occupational Safety and Health Administration, and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment.

Any of these laws, regulations, and rules or others could change, our interpretation of them could be challenged by U.S., state, or foreign governments and regulatory agencies, or these governments and regulatory agencies could adopt more restrictive laws or regulations in the future regarding tissue preservation services that could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

BioGlue® Surgical Adhesive ("BioGlue") is a significant source of our revenues, accounting for 25% for the years ended December 31, 2019 and 2018, and 35% of revenues in the year ended December 31, 2017. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated BioGlue revenue in the U.S. and in international markets outside the U.S.;
- BioGlue is a mature product, our U.S. Patent for BioGlue expired in mid-2012, and our patents in most of the rest of the world for BioGlue expired in mid-2013. Other companies may use the inventions disclosed in the expired patents to develop and make competing products;
- Some companies have launched competitive products and others may pursue regulatory approval for competitive products in the future. These companies may have greater financial, technical, manufacturing, and marketing resources than we do and may be better established in their markets;
- We may be unable to obtain regulatory approvals to commercialize BioGlue in certain countries other than the U.S. at the same rate as our competitors or at all. We also may not be able to capitalize on new regulatory approvals we obtain for BioGlue in countries other than the U.S., including approvals for new indications;
- BioGlue contains a bovine blood protein. Animal-based products are subject to increased scrutiny from the public and regulators, who may have concerns about the use of animal-based products or concerns about the transmission of disease from animals to humans. These concerns could lead to additional regulations or product bans in certain countries;
- Changes to components in the BioGlue product, including in the delivery system, require regulatory approval, which, if delayed, could cause prolonged disruptions to our ability to supply BioGlue; and

- On June 13, 2019 our European Notified Body for BioGlue, Lloyd's Register Quality Assurance Limited, which is headquartered in the U.K., informed us that it would no longer provide Notified Body services to companies in European Economic Area ("EEA") effective September 2019. On July 5, 2019 the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA") granted us a one year grace period to transfer 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) in the EEA. 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 the situation is resolved.

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

JOTEC is now a significant source of our revenues, accounting for 24% for the years ended December 31, 2019 and 2018, and 2% of revenues in the year ended December 31, 2017. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated JOTEC revenue in international markets outside the U.S.;
- Our ability to meet demand for JOTEC products as we seek to expand our business globally;
- 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;
- Our ability to develop innovative and in-demand products in the aortic surgery space;
- Our ability to contend with enhanced regulatory requirements and enforcement activities; and
- Our ability to 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 risks affecting them.

On-X is a significant source of our revenues, accounting for 18%, 17%, and 19% of revenues in the years ended December 31, 2019, 2018, and 2017, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated On-X revenue in the U.S. and in international markets outside the U.S.;
- Our ability to capitalize on the FDA's approved reduced International Normalized Ratio ("INR") indication;
- 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;
- Our ability to manage the risks associated with less favorable contract terms for On-X products on consignment at hospitals with more bargaining power;
- Clinical trial data or changes in technology that may impact the market for mechanical heart valves, such as transcatheter aortic valve replacement, or "TAVR" devices;
- Enhanced regulatory enforcement activities or failure to receive renewed certifications that could cause interruption in our ability to sell On-X products in certain markets; and
- Our ability to execute and complete the FDA mandated post-approval study to assess the occurrence of adverse events with the On-X Aortic Prosthetic Heart Valve when targeted at an INR level of 1.8 (1.5-2.0 range) during a 5-year follow-up.

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

The manufacture and sale of medical devices and processing, preservation, and distribution of human tissues are highly complex and subject to significant quality and regulatory risks in the U.S. and internationally. Any of the following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our products and tissues may be recalled or placed on hold by us, the FDA, or other regulatory bodies;
- Our products and tissues allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose, us to product and tissue processing liability claims, and such claims could lead to additional regulatory scrutiny and inspections;

- Our manufacturing and tissue processing operations are subject to regulatory scrutiny and inspections, including by the FDA and foreign regulatory agencies, and these agencies could require us to change or modify our manufacturing operations, processes, and procedures or take other adverse action. For example, in January 2013 we received a warning letter from the FDA related to the manufacture of our products and our processing, preservation, and distribution of human tissue, as well as a subsequent 2014 Form 483, after a FDA re-inspection related to the warning letter that included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training. After an FDA re-inspection in the first quarter of 2015, the FDA closed out the warning letter issued in 2013;
- Regulatory agencies could reclassify, reevaluate, or suspend our clearances and approvals, or fail, or decline to timely issue, or reissue, our clearances and approvals, that are necessary to sell our products and distribute tissues;
- Local and international regulatory and quality laws and standards are subject to change, which could adversely affect our clearances and approvals to sell our products and distribute tissues; and
- Adverse publicity associated with our products or processed tissues or our industry could lead to a decreased use of our products or tissues, additional regulatory scrutiny, and/or product or tissue processing liability lawsuits.

Further, on May 25, 2017, the European Union adopted a new Medical Device Regulation (MDR 2017/745) ("MDR"), which takes effect on May 26, 2020. Among other changes, MDR places more stringent requirements on manufacturers and European Notified Bodies regarding product classifications, pre- and post-market clinical studies, and other regulatory requirements for product clearances and approvals. These changes could result in product reclassifications and the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the EEA. In addition, we or our Notified Bodies (or both) might be unable to timely meet the requirements of MDR. If either of the foregoing were to occur, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

At the same time, European Notified Bodies have begun engaging in more rigorous regulatory enforcement activities and may continue to do so. For example, our Notified Body for the On-X product line temporarily suspended the CE Mark for the On-X ascending aortic prosthesis ("AAP") in the EEA. See the risk factor below entitled "Our revenues for the On-X AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP's CE Mark" for further discussion. Further, in anticipation of MDR, Notified Bodies will generally no longer review routine submissions unless they are submitted in accordance with MDR. Our inability to timely adapt to these new requirements of our Notified Bodies could adversely impact our clearances and approvals, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

We may not realize all the anticipated benefits of our agreements with Endospan.

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 NEXUS stent graft system ("NEXUS") in certain countries in Europe for a fixed distribution fee of $9.0 million; a loan agreement ("Endospan Loan") for a secured loan from CryoLife to Endospan in an amount up to $15.0 million, funded over three tranches of $5.0 million each upon the completion of certain milestones (the first tranche of which was paid in September 2019); and a security purchase option agreement providing CryoLife the option to purchase all the then outstanding securities of Endospan from Endospan's existing securityholders for a price between $350.0 million and $450.0 million before or upon FDA approval of NEXUS, for which option CryoLife paid to Endospan $1.0 million.

Our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the Endospan Transaction depends on a number of factors including:

- The continued growth of the global market for stent grafts used in endovascular repair of aortic disease;
- Our ability to introduce and drive adoption of NEXUS in the European market;
- Our ability to foster cross-selling opportunities between JOTEC product portfolio and NEXUS;
- Our ability to leverage our global infrastructure to sell NEXUS, including in the markets in which JOTEC is already direct;
- Our ability to address unforeseen risks, uncertainties and opportunities given our obligations to Endospan;
- Endospan's ability to comply with the Endospan Loan, as well as other debt obligations, and avoid an event of default;
- Endospan's ability to successfully commercialize NEXUS in markets outside of Europe;
- Endospan's ability to meet demand for NEXUS;

- Endospan's ability to meet quality and regulatory requirements;
- Endospan's ability to manage any intellectual property risks and uncertainties associated with NEXUS;
- Endospan's ability to obtain FDA approval of NEXUS; and
- Our ability to manage the unforeseen risks and uncertainties related to 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, which could materially, adversely impact our business, financial condition, profitability, and cash flows. These benefits may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share and negatively impact the price of our common stock.

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

We own patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that we believe provide us with important competitive advantages. We cannot be certain 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. Furthermore, competitors may independently develop similar technologies either before or after our patents expire, or duplicate our technologies, or design around the patented aspects of such technologies.

Our technologies, products, or services could infringe patents or other rights owned by others, or others could infringe our patents. If we become involved in a patent dispute, the costs of the dispute could be expensive, and if we were to lose or decide to settle the dispute, the amounts or effects of the settlement or award by a tribunal could be costly.

We also have obtained licenses from third parties for certain patents and patent application rights. These licenses allow us to use intellectual property rights owned by or licensed to these third parties. We do not control the maintenance, prosecution, enforcement, or strategy for many of these patents or patent application rights and as such are dependent in part on the owners of the intellectual property rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit those technologies.

Our revenues for the On-X AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP's CE Mark.

On November 22, 2016, we received a letter from G-Med, which acts as our Notified Body for the On-X product line, indicating that it was temporarily suspending the CE Mark for the On-X AAP in the EEA, due to an allegedly untimely and allegedly deficient plan by us to address certain technical documentation issues found by G-Med during a review and renewal of the design examination certificate for the On-X AAP. On July 26, 2017, we received a letter from G-Med indicating that it was continuing the suspension of the CE Mark for the AAP product for a period of up to 18 months pending further assessment. We have since withdrawn our application from G-Med for certification of the AAP product and are currently pursuing another pathway to CE Mark for the AAP. Failure to obtain CE Mark for the On-X AAP in the EEA could have a material, adverse effect on EEA revenues for 2020.

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 and are licensed to manufacture PerClot in the U.S.; (ii) acquired some technology to assist in the production of a potentially 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 clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S., and we completed enrollment in January 2019. We anticipate submission to the FDA during the second half of 2020. There is no guarantee, however, that we will obtain FDA approval when anticipated or at all. The estimated timing of regulatory approval for PerClot is based on factors beyond our control, including but not limited to, unforeseen scheduling difficulties and unfavorable results at various stages in the PMA application process. We may also decide to delay or terminate our pursuit of U.S. regulatory approval for PerClot at any time due to changing conditions at CryoLife, in the marketplace, or in the economy in general.

Further, even if we receive FDA 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 due to contracts, among other things. We may also be unsuccessful in selling in countries other than the U.S. due, in part, to a proliferation in other countries of multiple generic competitors, any breach by SMI of its contractual obligations, or the lack of adequate intellectual property protection or enforcement. Any of these occurrences could materially, adversely affect our future revenues, financial condition, profitability, and cash flows.

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

In October 2014 the FDA convened an advisory committee meeting to consider the FDA's recommendation to re-classify more than minimally manipulated ("MMM") allograft heart valves from an unclassified medical device to a Class III medical device. The class of allograft heart valves potentially covered by this recommendation includes our CryoValve SGPV. At the meeting, a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves be re-classified as a Class III product. In December 2019, we learned that the FDA is preparing to issue a proposed rule for reclassification of MMM allograft heart valves as Class III medical devices, which would be subject to a comment period before publication of a final rule. Upon 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.

We have continued to process and ship our CryoValve SGPV tissues. 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, this could materially, adversely affect our revenues, financial condition, profitability, and/or cash flows in future periods. In addition, we could decide that the requirements for obtaining a PMA make continued processing of the CryoValve SGPV too onerous, leading us to discontinue distribution of these tissues.

Our key growth areas may not generate anticipated benefits.

Our strategic plan is focused on four growth areas, primarily in the cardiac and vascular surgery segment, which are expected to drive our business in the near term. These growth areas and their key elements are described below:

- *New Products* – Drive growth through product development and commercialization of new and next-generation products and services focused on aortic repair;
- *New Indications* – Drive growth through new regulatory approvals and expanded indications for our existing products and services to increase the size of our addressable U.S. or international markets;
- *Global Expansion* – Drive growth 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* – Drive growth by selectively pursuing 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 and On-X 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.

Although we continue to implement these strategies, we cannot be certain that they will ultimately drive business expansion and enhance shareholder value.

We may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and our new products and services may not achieve market acceptance.

Our growth and profitability will depend, in part, upon our ability to complete development of, and successfully introduce, new products and services, or expand upon existing indications, which requires that we invest significant time and resources to obtain required regulatory approvals, including significant investment of time and resources into clinical trials. Although we have conducted clinical studies on certain products and services under development, which indicate that such products and services may be effective in a particular application, we cannot be certain that we will be able to successfully

execute on these clinical trials or that the results we obtain from clinical studies will be sufficient for us to obtain any required regulatory approvals or clearances. In addition, we must complete various post-market clinical studies to satisfy various regulatory and reimbursement requirements. These post-market clinical studies also require significant time and resources, and we cannot be certain that we will be able to successfully execute them or that the results we obtain will satisfy post-market regulatory and reimbursement requirements.

We are currently engaged in several clinical trials and post-market clinical studies for our products, including our PROACT Xa clinical trial to determine if patients with an On-X mechanical aortic valve can be maintained safely and effectively on apixaban (Eliquis®) rather than on warfarin, and we also have begun efforts to initiate future U.S. clinical trials for certain JOTEC products. Each of these trials or studies is subject to the risks outlined herein.

We cannot give assurance that the relevant 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 applicable market or achieve market acceptance. We may encounter delays or rejections during any stage of the regulatory approval process if clinical or other data fails to demonstrate satisfactorily compliance with, or if the service or product fails to meet, the regulatory agency's requirements for safety, efficacy, and quality, or the regulatory agency otherwise has concerns about our quality or regulatory compliance. Regulatory requirements for safety, efficacy, quality, and the conduct of clinical trials and post-market clinical studies may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials and post-market clinical studies may also be delayed or halted due to the following, among other factors:

- Unanticipated side effects;
- Lack of funding;
- Inability to locate or recruit clinical investigators;
- Inability to locate, recruit, and qualify sufficient numbers of patients;
- Redesign of clinical trial or post-market clinical study programs;
- Inability to manufacture or acquire sufficient quantities of the products, tissues, or any other components required for clinical trials or post-market clinical study programs;
- Changes in development focus; or
- Disclosure of trial results by competitors.

Our ability to complete the development of any of our products and services is subject to all of the risks associated with the commercialization of new products and services based on innovative technologies. Such risks include unanticipated technical or other problems, manufacturing, or processing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Consequently, we may not be able to successfully introduce and market our products or services, or we may not be able to do so on a timely basis. These products and services may not meet price or performance objectives and may not prove to be as effective as competing products and services.

If we are unable to successfully complete the development of a product, service, or application, or if we determine for financial, technical, competitive, or other reasons 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 revenues, financial condition, profitability, and cash flows. 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. The introduction of new products or services may require significant physician training and years of clinical evidence derived from follow-up studies on human patients in order to gain acceptance in the medical community.

All of these could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

We are subject to a variety of risks as we seek to expand our business globally.

The expansion of our international operations is subject 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, including foreign distributor relationships, and developing direct sales operations in key foreign countries;
- Expanded compliance obligations, including obligations associated with 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;
- Broader exposure to corruption;
- Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement policies and programs;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;
- Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the U.S. Dollar;
- Differing local product preferences and product requirements;
- Differing local labor and employment laws, including those related to terminations, unionization, and the formation of works councils or other similar employee organizations;
- Adverse economic or political changes or political instability;
- Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs;
- Potential adverse tax consequences of overlapping tax structures; and
- Potential adverse financial consequences resulting from the exit of the U.K. from the European Union, or "Brexit," including a potential disruption of sales into the U.K.

Our failure to adequately address these risks could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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 selectively pursue the potential acquisition, licensing, or distribution rights of companies or technologies that complement our existing products, services, and infrastructure. In connection with one or more of the acquisition transactions, we may:

- Issue additional equity securities that would dilute our stockholders' ownership interest in us;
- Use cash that we may need in the future to operate our business;
- Incur debt, including on terms that could be unfavorable to us or debt that we might be unable to repay;
- Structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;
- Be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales;
- Be unable to integrate, upgrade, or replace the purchasing, accounting, financial, sales, billing, employee benefits, payroll, and regulatory compliance functions of an acquisition target;
- Be unable to secure or retain the services of key employees related to the acquisition;
- Be unable to succeed in the marketplace with the acquisition; or
- Assume material unknown liabilities associated with the acquired business.

As an example of these risks, in December 2017 we acquired JOTEC, which we financed by incurring further debt, using cash on hand, and issuing additional equity securities. This acquisition posed many of the same risks as set forth above.

Any of the above risks, should they occur, could materially, adversely affect our revenues, financial condition, profitability, and cash flows, including the inability to recover our investment or cause a write-down or write-off of such investment, associated goodwill, or assets.

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

The materials and supplies used in our product manufacturing and our tissue processing are subject to stringent quality standards and requirements, and many of these materials and supplies are subject to significant regulatory oversight and action. If materials or supplies used in our processes fail to meet these standards and requirements or are subject to recall or other quality action, an outcome could be the rejection or recall of our products or tissues and/or the immediate expense of the costs of the manufacturing or preservation. In addition, if these materials and 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, whether by government order, natural disaster, or other reason, or if the related suppliers are otherwise unable or unwilling to supply us, there may not be sufficient materials or supplies available for purchase to allow us 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 other products. If these contract manufacturers fail to meet our quality standards and requirements or if they are unable or unwilling to supply the products, we may not be able to meet demand for these products. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

Some of the materials, supplies, and services that are key components of our product manufacturing or our 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, we will not have a supply of handpieces for cardiac laser therapy until the FDA approves 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. We currently anticipate resumption of supply during the second half of 2020.

We also conduct nearly all our operations at three facilities: Austin, Texas for our On-X product line, Hechingen, Germany for our JOTEC product line, and Kennesaw, Georgia for all our other products. If one of these facilities ceases operations temporarily or permanently, due to natural disaster or other reason, our business could be substantially disrupted.

Regulatory enforcement activities regarding Etheylene 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 in the U.S., 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. For example, in February 2019, the Illinois Environmental Protection Agency issued an order to stop Sterigenics from using EtO at its Willowbrook, Illinois facility; Sterigenics subsequently announced that the facility would not reopen. Also, in October 2019, the Georgia State Attorney General took action to request the potential closure of a Becton Dickinson and Company EtO facility in Covington, Georgia. 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, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows. In addition, any regulatory enforcement activities against us for our use of EtO could result in financial, legal, business, and reputational harm to us.

The Coronavirus, and similar outbreaks, could have a material, adverse impact on us.

An outbreak of respiratory illness caused by a new coronavirus named "2019-nCoV" (the "Coronavirus"), which was first detected in Wuhan City, Hubei Province, China, has resulted in tens of thousands of infections in China and continues to spread, including to the United States. On January 30, 2020, the World Health Organization declared the Coronavirus

outbreak a “public health emergency of international concern.” If the Coronavirus worsens in China or if the Chinese government’s efforts to contain the Coronavirus continue to restrict the movement of goods and people in China, our business activities in and originating from China, including our activities related to product sales, our supply chain, and regulatory approval for BioGlue in China, could be adversely affected. In addition, if the Coronavirus continues to spread outside of China, our activities worldwide could be adversely affected. If either of the foregoing were to occur, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

The market for our products and services is intensely competitive and significantly affected by new product introductions and activities of other industry participants. We face intense competition from other companies engaged in the following lines of business:

- The sale of endovascular and surgical stents;
- The sale of mechanical, synthetic, and animal-based tissue valves for implantation;
- The sale of synthetic and animal-based patches for implantation;
- The sale of surgical adhesives, surgical sealants, and hemostatic agents; and
- The processing and preservation of human tissue.

A significant percentage of market revenues from these products was generated by Baxter International, Inc.; Ethicon (a Johnson & Johnson Company); Medtronic, Inc.; Abbott Laboratories; LivaNova PLC; Edwards Lifesciences Corp.; Bard, a subsidiary of Becton, Dickinson, and Company; Integra Life Sciences Holdings; LifeNet; Admedus, Inc.; Aziyo Biologics; Cook Medical; Gore & Associates; Terumo Corp.; Endologix; Antegraft, Inc.; LeMaitre Vascular, Inc.; Maquet, Inc.; Vascutek; Novadaq Technologies, Inc.; Pfizer, Inc.; and BioCer Entwicklungs-GmbH.

Several of our competitors enjoy competitive advantages over us, including:

- Greater financial and other resources for product research and development, sales and marketing, acquisitions, and patent litigation;
- Enhanced experience in, and resources for, launching, marketing, distributing, and selling products;
- Greater name recognition as well as more recognizable trademarks for products similar to the products that we sell;
- More established record of obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements;
- More established relationships with healthcare providers and payors;
- Lower cost of goods sold or preservation costs;
- Advanced systems for back office automation, product development, and manufacturing, which may provide certain cost advantages; and
- Larger direct sales forces and more established distribution networks.

Our competitors may develop services, products, or processes with significant advantages over the products, services and processes that we offer or are seeking to develop, and our products and tissues may not be able to compete successfully. If we are unable to successfully market and sell innovative and in-demand products and services, our competitors may gain competitive advantages that may be difficult to overcome. In addition, consolidation among our competitors may make it more difficult for us to compete effectively. If we fail to compete effectively, this could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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, 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. Competition for such personnel is intense, and we cannot ensure that we will be successful in attracting and retaining such personnel. If we lose any key employees, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees as needed, this could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Future tax reform regulations could have a material, adverse impact on us.

The December 2017 tax reform legislation known as H.R. 1, commonly referred to as the "Tax Cuts and Jobs Act" ("the Tax Act"), made significant changes to U.S. federal income tax law. In response, the U.S. Treasury Department issued multiple significant proposed regulation packages to further interpret certain provisions of the Tax Act. As of December 31, 2019, certain significant proposed regulation packages have not yet been finalized. It is possible that when released in final form, these regulation packages could have a material tax impact on us. In addition, we continue to await responses from various state taxing jurisdictions on the impact of the Tax Act on their local taxing regimes. We will continue to monitor and account for the future impacts of federal regulatory and state guidance in the interim period in which such guidance is issued.

Our operating results may fluctuate significantly on a quarterly or annual basis as a result of a variety of factors, many of which are outside our control.

Fluctuations in our quarterly and annual financial results have resulted, and will continue to result, from numerous factors, including:

- Changes in demand for the products we sell;
- Increased product and price competition, due to the announcement or introduction of new products by our competitors, market conditions, the regulatory landscape, or other factors;
- Changes in the mix of products we sell;
- Availability of products, materials, and supplies, including donated tissue used in preservation services;
- Our pricing strategy with respect to different product lines;
- Strategic actions by us, such as acquisitions of businesses, products, or technologies;
- Unanticipated costs and expenses;
- Effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- The divestiture or discontinuation of a product line or other revenue generating activity;
- The relocation and integration of manufacturing operations and other strategic restructuring;
- Regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
- Failure of government and private health plans to adequately and timely reimburse the users of our products or changes in reimbursement policies;
- Costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;
- Our ability to collect outstanding accounts receivable in selected countries outside of the U.S.;
- The expiration or utilization of deferred tax assets such as net operating loss carryforwards;
- Market reception of our new or improved product offerings; and
- The loss of any significant customer, especially in regard to any product that has a limited customer base.

We have based our current and future expense levels largely on our investment plans and estimates of future events, although some of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenue relative to our planned expenditures would have an immediate, adverse effect on our business, results of operations, and financial condition. Further, as a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service, or marketing decisions that could have a material, adverse effect on our business, results of operations, and financial condition. Due to the foregoing factors, some of which are not within our control, the price of our common stock may fluctuate substantially. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe the quarterly comparisons of our financial results are not always meaningful and should not be relied upon as an indication of our future performance.

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 and traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including, but not limited to, personal information, intellectual property, and, in some instances, patient data). We have also outsourced elements of our operations to third parties, including elements of our information technology systems and, as a result, we manage a number of independent vendor relationships with third parties who may or could have access to our confidential information. 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 or vendors. Our information technology and information security systems and records are also potentially vulnerable to malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of expertise and motives (including, but not limited to, financial crime, industrial espionage, and market manipulation).

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, 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. The impersonator had taken a number of steps to deceive our employees and reduce the likelihood of detection. We expect our cyber-insurance to cover all but a de minimis amount of the unrecovered losses from this compromise.

While we have invested, and continue to invest, significantly in our information technology and information security systems, there can be no assurance that our efforts will prevent further security breaches, service interruptions, or data losses. We have only limited cyber-insurance coverage that does not cover all possible events, and this insurance is subject to deductibles and coverage limitations. In addition, we may not be able to maintain this insurance. We thus do not have insurance coverage for all possible claims that could be raised and, for those where we do have coverage, those claims could exceed the limits of our coverage. Any security breaches, service interruptions, or data losses could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result 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.

The implementation of the General Data Protection Regulation in the European Union in May 2018 could adversely affect our business.

The European Union's General Data Protection Regulation ("GDPR") took effect in May 2018. GDPR includes significant new requirements for companies that receive or process the personal data of residents of the European Union (including company employees), which increase our operating costs and require significant management time and energy. GDPR also includes significant penalties for noncompliance. Although our personal data practices, policies, and procedures are intended to comply with GDPR, there can be no assurance that regulatory or enforcement authorities will view these 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 GDPR related government enforcement activities may be costly to comply with, result in negative publicity, and subject us to significant penalties, any of which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Consolidation in the healthcare industry could have an adverse effect on our revenues and results of operations.

Many healthcare industry companies, including health care systems, are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions. If we are forced to reduce our prices because of consolidation in the healthcare industry, our revenues would decrease and our financial condition, profitability, and/or cash flows would suffer.

The success of some of our products and preservation services depends upon relationships with healthcare professionals.

If we fail to maintain our working relationships with healthcare professionals, many of our products and preservation services may not be developed and marketed to appropriately meet the needs and expectations of the professionals who use and support our products and preservation services or the patients who receive them.

The research, development, marketing, and sales of many of our new and improved products and preservation services are dependent upon us maintaining working relationships with healthcare professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding our products and preservation services. Healthcare professionals assist us as researchers, marketing and training consultants, product consultants, and speakers. If we are unable to maintain our relationships with these professionals and do not continue to receive their advice and input, the development and commercialization of our products and preservation services could suffer, which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

We may be subject to fines, penalties, injunctions, 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 specific approved uses. Generally, unless the products are approved or cleared by the FDA for the alternative uses, the FDA contends that 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 the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing, and/or support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the Federal Food, Drug, and Cosmetic Act. We also face the risk that the FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs, and other activities. 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. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. In addition, as a result of an enforcement action against us or our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

Our acquired federal tax net operating loss and general business credit carryforwards will be limited or may expire, which could result in greater future income tax expense and adversely impact future cash flows.

Our federal tax net operating loss and general business credit carryforwards include acquired net operating loss carryforwards. Such acquired net operating loss carryforwards will be limited in future periods due to a change in control of our former subsidiaries Hemosphere and Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended (“Section 382”). We believe that our acquisitions of these companies each constituted a change in control, and that prior to our acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. We also acquired net operating loss carryforwards in certain foreign jurisdictions with the JOTEC Acquisition, but we do not believe these carryforwards will be limited in any material way due to a change of control provision. The deferred tax assets recorded on our Consolidated Balance Sheets exclude amounts that we expect will not be realizable due to these 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 these deferred tax assets will not be realized. Therefore, we recorded a valuation allowance against these state net operating loss carryforwards. Limitations on our federal tax net operating loss and general business credit carryforwards could result in greater future income tax expense and adversely impact future cash flows.

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 changing interpretations. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal penalties, exclusion from government healthcare programs, and forfeiture of amounts collected in violation of such prohibitions. Any government investigation or a finding of a violation of these laws, despite our compliance efforts, could result in a material, adverse effect on our business, financial condition, and profitability.

We have entered into consulting agreements, speaker agreements, research agreements, and product development agreements with healthcare professionals or healthcare organizations, including some who may order our products or make decisions to use them. While these transactions were structured with the intention of complying with all applicable compliance laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties.

We have also adopted the AdvaMed Code of Conduct and the MedTech Europe Code of Ethical Business Practice into our Code of Business Conduct, which governs our relationships with healthcare professionals, including our payment of travel and lodging expenses, research and educational grant procedures, and sponsorship of third-party conferences. In addition, we conduct training sessions on these principles. There can be no assurance, however, that regulatory or enforcement authorities will view these 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. Because our strategy relies on the involvement of healthcare professionals or healthcare organizations who consult with us on the design of our products, perform clinical research on our behalf, or educate the market about the efficacy and uses of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with healthcare professionals or healthcare organizations, who refer or order our products, to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the healthcare professionals or healthcare organizations we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from government funded healthcare programs, including Medicare and Medicaid, for noncompliance.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the scarcity of applicable precedent and regulations. There can be no assurance that regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material, adverse effect on our business, financial condition, and profitability. Any regulatory or enforcement review of us, regardless of the outcome, would 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.

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 federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Some of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material, adverse effect on our financial condition and profitability. Candidates for the 2020 presidential election have put forward numerous healthcare reform proposals, including "Medicare for All." These proposals may affect aspects of our business. We cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us. Any changes that lower reimbursement for our products or reduce medical procedure volumes, however, could adversely affect our business and profitability.

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 product sales are made to customers in other countries who must convert local currencies into U.S. Dollars 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 existing insurance coverage may be insufficient, and we may be unable to obtain insurance in the future.

Our products and tissues allegedly have caused, and may in the future cause, injury to patients using our products or tissues, and we have been, and may be, exposed to product and tissue processing liability claims. 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. In addition, our product and tissue processing liability insurance policies do not include coverage for any punitive damages. Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, it is possible that:

- We could be exposed to product and tissue processing liability claims and security claims greater than the amount that we have insured;
- We may be unable to obtain future insurance policies in an amount sufficient to cover our anticipated claims at a reasonable cost or at all; or
- Because we are not insured against all potential losses, uninsured losses due to natural disasters or other catastrophes could adversely impact our business.

Any product liability claim, with or without merit, could result in an increase in our product insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future due to market, industry, or other factors. Any product liability claim, even a meritless or unsuccessful one, would be time-consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, withdrawal of clinical trial participants, injury to our reputation, and loss of revenue.

If we are unsuccessful in arranging acceptable settlements of future product or tissue processing liability claims or future securities class action or derivative claims, we may not have sufficient insurance coverage and liquid assets to meet these obligations. If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from product or tissue processing liability or securities claims. Additionally, if one or more claims with respect to which we may become, in the future, a defendant should result in a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve any outstanding or any future claims, this will materially, adversely affect our financial condition, profitability, and cash flows. Further, although we have an estimated reserve for our unreported product and tissue processing liability claims for which we do expect that we will obtain recovery under our insurance policies, these costs could exceed our current estimates. Finally, our facilities could be materially damaged by tornadoes, flooding, other natural disasters, or catastrophic circumstances, for which we are not fully covered by business interruption and disaster insurance, and, even with such coverage, we could suffer substantial losses in our inventory and operational capacity, along with a potential adverse impact on our customers and opportunity costs for which our insurance would not compensate us.

Any of these events could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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 frequently propose to involve themselves in the governance, strategic direction, and operations of a company. We may in the future become subject to such shareholder activism and demands. Such demands may disrupt our business and divert the attention of our management and employees, and any perceived uncertainties as to our future direction resulting from such a situation could result in the loss of potential business opportunities, be exploited by our competitors, cause concern to our current or potential customers, and make it more difficult to attract and retain qualified personnel and business partners, all of which could adversely affect our business. In addition, actions of activist shareholders may cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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 if the market price of our common stock has increased when they sell shares of our common stock that they own. Future dividends, if any, will be authorized by our Board of Directors and declared by us based upon a variety of factors deemed relevant by our directors, including, among other things, our financial condition, liquidity, earnings projections, and business prospects. In addition, restrictions in our credit facility limit our ability to pay future dividends. We can provide no assurance of our ability to pay cash dividends in the future.

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 restricting persons who may call shareholder meetings and allowing 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. A nearby building contains approximately 53,000 square feet of additional empty space that could be leased 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 of 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 or 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.

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

2018	High	Low
First quarter	$ 22.70	$ 16.80
Second quarter	29.55	19.05
Third quarter	36.05	27.50
Fourth quarter	35.44	25.58

As of February 14, 2020 we had 218 shareholders of record.

Dividends

No dividends were paid in 2019, 2018, or 2017.

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, 2019 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
10/01/19 - 10/31/19	--	--	--	--
11/01/19 - 11/30/19	404	$ 24.21	--	--
12/01/19 - 12/31/19	--	--	--	--
Total	404	24.21	--	--

The common shares purchased during the quarter ended December 31, 2019 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.

The following Selected Financial Data should be read in conjunction with our consolidated financial statements and notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and other financial information included elsewhere in this report.

Selected Financial Data
(in thousands, except percentages, current ratio, and per share data)

	December 31,				
	2019	**2018**	**2017 [1]**	**2016 [2]**	**2015**
Operations					
Revenues	$ 276,222	$ 262,841	$ 189,702	$ 180,380	$ 145,898
Operating income	17,042	9,312	7,970	21,820	5,354
Net income (loss)	1,720	(2,840)	3,704	10,778	4,005
Net income (loss) applicable to common shareholders	1,708	(2,813)	3,643	10,576	3,918
Research and development expense as a percentage of revenues	8%	9%	10%	7%	7%
Income (loss) Per Common Share					
Basic	$ 0.05	$ (0.08)	$ 0.11	$ 0.33	$ 0.14
Diluted	$ 0.05	$ (0.08)	$ 0.11	$ 0.32	$ 0.14
Dividend Declared Per Common Share	$ --	$ --	$ --	$ --	$ 0.12
Year-End Financial Position					
Total assets	$ 605,654	$ 571,091	$ 589,693	$ 316,140	$ 181,179
Working capital	142,195	144,645	136,340	117,131	90,058
Long-term liabilities	274,763	261,501	269,695	77,055	6,323
Shareholders' equity	285,696	275,067	277,058	208,983	155,251
Current ratio[3]	4:1	5:1	4:1	5:1	6:1

[1] In December 2017 we completed our acquisition of JOTEC AG ("JOTEC Acquisition"), which we converted to JOTEC GmbH and is being operated as a wholly-owned subsidiary of CryoLife.

[2] In January 2016 we completed our acquisition of On-X Holdings, which is being operated as a wholly-owned subsidiary of CryoLife. In 2016 we also sold our HeRO Graft product line and our ProCol product line and ceased sales of these products during 2016.

[3] Current assets divided by current liabilities.

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, JOTEC stent grafts and surgical products, On-X mechanical heart valves and surgical products, and implantable cardiac and vascular human tissues. In addition to these four major product families, we sell or distribute PhotoFix™ bovine surgical patch, PerClot® hemostatic powder, NEXUS™ endovascular stent graft system, and CardioGenesis cardiac laser therapy.

For the year ended December 31, 2019 we reported record annual revenues of $276.2 million, increasing 5% over the prior year, largely due to an increase in revenues from On-X and preservation services. For the year ended December 31, 2019 we generated $15.8 million in cash flows from operations and reported a net income of $1.7 million. See the "Results of Operations" section below for additional analysis of the fourth quarter and full year 2019 results. See Part I, Item 1, "Business," for further discussion of our business and activities during 2019.

Agreements with Endospan

On September 11, 2019 CryoLife or its wholly-owned subsidiary, JOTEC, entered into exclusive distribution and loan agreements with Endospan Ltd. ("Endospan"), an Israeli corporation, as well as a securities purchase option agreement to purchase Endospan. We paid Endospan $15.0 million in September 2019 related to these agreements.

JOTEC entered into an exclusive distribution agreement ("Endospan Distribution Agreement") with Endospan, pursuant to which JOTEC obtained exclusive distribution rights for Endospan's NEXUS stent graft system ("NEXUS") and accessories in certain countries in Europe. In addition, CryoLife entered into a securities purchase option agreement ("Endospan Option Agreement") with Endospan which provides CryoLife the option to purchase all of the outstanding securities of Endospan from Endospan's securityholders at the time of the acquisition, or the option to acquire all of Endospan's assets, in each case, for a price between $350.0 and $450.0 million before, or within, a certain period of time after U.S. Food and Drug Administration ("FDA") approval of NEXUS, with such option expiring 90 days after receiving notice that Endospan has received approval from the FDA for NEXUS. Lastly, CryoLife and Endospan entered into a loan agreement ("Endospan Loan Agreement"), in which CryoLife agreed to provide Endospan a secured loan to be funded in three tranches of $5.0 million each, of which the first tranche was funded in September of 2019.

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 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. We use the fair value measurement framework to value these assets 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 $787,000, $437,000, and $922,000 for the years ended December 31, 2019, 2018, and 2017, respectively, due primarily to tissues not expected to ship prior to the expiration date of the packaging.

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 periodically assess the recoverability of our deferred tax assets, as necessary, when we experience changes that could materially affect our determination of the recoverability of our deferred tax assets. We 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 in conjunction with 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:

- Projected future operating results;
- Anticipated future state tax apportionment;
- Timing and amounts of anticipated future taxable income;
- Timing of the anticipated reversal of book/tax temporary differences;
- 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. We also acquired net operating loss carryforwards in certain foreign jurisdictions in our recent acquisition of JOTEC. We believe these loss carryforwards will be fully realizable. 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.

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, 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%
JOTEC	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%
JOTEC	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 JOTEC product revenues. 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 JOTEC product revenues. 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, 2019.

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.

JOTEC

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.

JOTEC 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.

JOTEC 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%.

JOTEC 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, JOTEC 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 JOTEC, 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 JOTEC, 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 manufacturer of handpieces needs the FDA to approve its change in manufacturing location, pending resolution of several observations the FDA raised during a manufacturing site change reinspection. We do not believe these observations relate to quality or safety. We will not have any handpieces available to ship until our supplier resolves these issues with the FDA. We currently anticipate resumption of supply during the second half of 2020.

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 second half of 2020.

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 JOTEC, 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 JOTEC 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 JOTEC 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, JOTEC, 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 expense (benefit)	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 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.

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Revenues

	Revenues for the Three Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2018	2017	Percent Change	2018	2017
Products:					
BioGlue and BioFoam	$ 17,975	$ 17,845	1%	27%	34%
JOTEC	16,672	4,136	303%	25%	8%
On-X	11,337	9,993	13%	17%	19%
CardioGenesis cardiac laser therapy	1,703	1,736	-2%	2%	3%
PerClot	945	892	6%	1%	2%
PhotoFix	699	510	37%	1%	1%
Total products	49,331	35,112	40%	73%	67%
Preservation services:					
Cardiac tissue	9,023	8,599	5%	13%	16%
Vascular tissue	9,445	9,115	4%	14%	17%
Total preservation services	18,468	17,714	4%	27%	33%
Total	$ 67,799	$ 52,826	28%	100%	100%

	Revenues for the Twelve Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2018	2017	Percent Change	2018	2017
Products:					
BioGlue and BioFoam	$ 66,660	$ 65,939	1%	25%	35%
JOTEC	63,341	4,136	1431%	24%	2%
On-X	44,832	37,041	21%	17%	19%
CardioGenesis cardiac laser therapy	6,217	6,866	-9%	2%	4%
PerClot	3,767	3,533	7%	2%	2%
PhotoFix	2,577	2,116	22%	1%	1%
Total products	187,394	119,631	57%	71%	63%
Preservation services:					
Cardiac tissue	35,683	32,510	10%	14%	17%
Vascular tissue	39,764	37,561	6%	15%	20%
Total preservation services	75,447	70,071	8%	29%	37%
Total	$ 262,841	$ 189,702	39%	100%	100%

Revenues increased 28% and 39% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2018 is presented below.

Products

Revenues from products increased 40% and 57% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017, respectively. These increases were primarily due to the acquisition of JOTEC in December 2017 as well as increased revenues from the sale of On-X products. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; 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 Zloty, Swiss Francs, Brazilian Real, and Canadian Dollars which are subject to exchange rate fluctuations. For the three months ended December 31, 2018, compared to the three months ended December 31, 2017, the U.S. Dollar strengthened in comparison to these currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into U.S. Dollars. For the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017, the U.S. Dollar weakened in comparison to the major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into U.S. Dollars. The year-over-year average change in these currencies and the net impact on the results of operations from translations to reporting currency was not material in either period. The impact of currency translation adjustments are substantially mitigated by natural hedges which reduce our revenue and expense net exposure by currency. 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 and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 1% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This increase was primarily due to a 4% increase in the volume of milliliters sold, which increased revenues by 4%, partially offset by the impact of foreign exchange rates, which decreased revenues by 1%, and a decrease in average sales prices, which decreased revenues by 2%.

Revenues from the sale of surgical sealants increased 1% for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017. This increase was primarily due to a favorable mix in packaging sizes that vary in price per milliliter, which increased revenues by 1%, and the impact of foreign exchange rates, which increased revenues by 1%, partially offset by a decrease in average sales prices, which decreased revenues by 1%.

The increase in revenues for the three months ended December 31, 2018 was in the European Economic Area (“EEA”), Middle East, and Africa (“EMEA”), partially offset by slight decreases in other regions. The increase in revenues for the twelve months ended December 31, 2018 was in the U.S., Canada, and EMEA markets, partially offset by a reduction in revenues from certain Asia Pacific and Latin American distributors due to changes in their buying patterns.

Domestic BioGlue revenues accounted for 50% and 53% of total BioGlue revenues for the three and twelve months ended December 31, 2018, respectively, and 51% and 53% of total BioGlue revenues for the three and twelve months ended December 31, 2017, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2018 and 2017. BioFoam is currently approved for sale in certain international markets.

JOTEC

On December 1, 2017 CryoLife acquired JOTEC AG and its subsidiaries (the “JOTEC Acquisition”), a Germany-based, privately held developer of technologically differentiated endovascular stent grafts, and cardiac and vascular surgical grafts, focused on aortic repair. JOTEC products are distributed in a variety of international markets.

JOTEC post-acquisition revenues for the three and twelve months ended December 31, 2018 increased 17% and 25%, respectively, when compared to JOTEC combined pre-acquisition and post-acquisition revenues for the three and twelve months ended December 31, 2017. Excluding the effects for foreign exchange, revenues for the three and twelve months ended December 31, 2018 increased 19% and 20%, respectively, as compared to the JOTEC combined pre-acquisition and post-acquisition revenues for the three and twelve months ended December 31, 2017, primarily due to an increase in unit shipments.

On-X

On-X product revenues, excluding Original Equipment Manufacturer ("OEM"), increased 13% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This increase was primarily due to a 15% increase in volume of units sold, which increased revenues by 14%, partially offset by a decrease in average sales prices, which decreased revenues by 1%.

On-X product revenues, excluding OEM, increased 21% for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017. This increase was primarily due to a 26% increase in volume of units sold, which increased revenues by 30%, partially offset by a decrease in average sales prices, which decreased revenues by 9%, primarily due to geographic revenue mix.

The volume increase of On-X products, excluding OEM, for the three and twelve months ended December 31, 2018 was primarily due to an increase in volume in the U.S., EMEA, and Canada, after establishing a direct market in Canada in July 2017. On-X OEM sales accounted for less than 1% of product revenues for the three and twelve months ended December 31, 2018 and 2017.

CardioGenesis Cardiac Laser Therapy

Revenues from our CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, the sale of laser consoles. Revenues from cardiac laser therapy decreased 2% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This decrease was primarily due to a 27% decrease in unit shipments of handpieces, which decreased revenues by 27%, offset by the effect of the sale of one additional laser console for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017.

Revenues from cardiac laser therapy decreased 9% for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017. This decrease was primarily due to a 12% decrease in unit shipments of handpieces, which decreased revenues by 12%, partially offset by the effect of higher average laser console selling prices for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017.

The major contributing factors to the decrease in handpiece revenues included the de-emphasis on this product line since 2016, when the On-X product line was acquired and the corresponding realignment of our sales force. Cardiac laser therapy is generally used adjunctively with cardiac bypass surgery by a limited number of physicians who perform these procedures, although there has been a slight growth in the number of performing physicians in recent months. Revenues from laser console sales are difficult to predict and can vary significantly from quarter to quarter.

PerClot

Revenues from the sale of PerClot increased 6% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This increase was primarily due to a 16% increase in the volume of grams sold, which increased revenues by 3%, and an increase in average selling prices, which increased revenues by 3%. The volume increase included a larger proportion of products that have lower prices and, therefore, did not have as large of an effect on total PerClot revenues.

Revenues from the sale of PerClot increased 7% for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017. This increase was primarily due to a 12% increase in sales volume, which increased revenues by 8%, and the favorable effect of foreign currency exchange, which increased revenues by 3%, partially offset by a decrease in average selling prices, which decreased revenues by 4%.

The sales volume increase for the three months ended December 31, 2018 was primarily due to higher sales of PerClot in the EMEA. The decrease in average selling prices for the twelve months ended December 31, 2018 was primarily due to price reductions to certain customers in Europe as a result of pricing pressures from competitive products.

PhotoFix

PhotoFix revenues increased 37% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This increase was primarily due to a 189% increase in units sold, which increased revenues by 38%, partially offset by a decrease in average sales prices per unit which decreased revenues by 1%.

PhotoFix revenues increased 22% for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017. This increase was primarily due to a 109% increase in units sold, which increased revenues by 22%.

PhotoFix is sold in a variety of unit sizes to accommodate surgical needs. We introduced smaller PhotoFix sizes in 2018 which have lower prices and, therefore, did not have as large of an effect on total revenues in both the three and twelve months ended December 31, 2018. The increase in volume for both the three and twelve months ended December 31, 2018 is primarily due to an increase in the number of implanting physicians when compared to the prior year period.

Preservation Services

Revenues from preservation services increased 4% and 8% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017, respectively. A detailed discussion of the changes in cardiac and vascular preservation services revenues is presented below.

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 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. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and twelve months ended December 31, 2018.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of human heart valves and cardiac patch tissues increased 5% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This increase was primarily due to a 12% increase in unit shipments of cardiac tissues, which increased revenues by 6%, partially offset by a decrease in average service fees, which decreased revenues by 1%.

Revenues from cardiac preservation services increased 10% for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017. This increase was primarily due to a 16% increase in unit shipments of cardiac tissues, which increased revenues by 11%, partially offset by a decrease in average service fees, which decreased revenues by 1%.

The increase in volume for the three months ended December 31, 2018 was due to an increase in the volume of patch and cardiac valve shipments. The increase in volume for the twelve months ended December 31, 2018 was primarily due to an increase in the volume of cardiac valve and, to a lesser extent, patch shipments. The decrease in average service fees for the three and twelve months ended December 31, 2018 was primarily due to fee differences related to physical characteristics of these tissues and the routine negotiation of pricing contracts with certain customers.

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.

Vascular Preservation Services

Revenues from vascular preservation services increased 4% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This increase was primarily due to a 10% increase in unit shipments of vascular tissues, which increased revenues by 8%, partially offset by a decrease in average service fees, which decreased revenues by 4%, primarily due to a change in product mix.

Revenues from vascular preservation services increased 6% for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017. This increase was primarily due to an 11% increase in unit shipments of vascular tissues, which increased revenues by 10%, partially offset by a decrease in average service fees, which decreased revenues by 4%, primarily due to a change in product mix.

The increase in shipments of vascular tissues for the three months ended December 31, 2018 was due to an increase in all vascular tissue types, but primarily due to increases in femoral artery and aortoiliac shipments. The increase in shipments of

vascular tissues for the twelve months ended December 31, 2018 was primarily due to increases in saphenous vein and femoral artery shipments.

The decrease in average service fees for the three and twelve months ended December 31, 2018 was primarily due to fee differences related to physical characteristics of vascular tissues and the routine negotiation of pricing contracts with certain customers.

The majority of our vascular preservation services revenues were generated by shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. These tissues are primarily distributed in domestic markets.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Cost of products	$ 13,606	$ 8,601	$ 53,772	$ 29,798

Cost of products increased 58% and 80% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017. Cost of products for the three and twelve months ended December 31, 2018 and 2017 included costs related to BioGlue, BioFoam, JOTEC, On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix.

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 JOTEC inventory fair value adjustment recorded in purchase accounting, all included prior to the three months ended December 31, 2018. Cost of products for the three and twelve months ended December 31, 2017 included $584,000 and $2.7 million, respectively, in inventory basis step-up expense related to costs for On-X products repurchased from previous international and domestic distributors in excess of the unit cost to manufacture the inventory, in addition to fair value adjustments recorded in purchase accounting for JOTEC products.

The increase in cost of products for the three and twelve months ended December 31, 2018 was primarily due to having a full year of revenues related to JOTEC, which we acquired in December 2017, partially offset by a decrease in acquisition inventory basis step-up expense for the three months ended December 31, 2018, as compared to the prior year period as discussed above.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Cost of preservation services	$ 9,002	$ 7,862	$ 36,085	$ 31,262

Cost of preservation services increased 15% for both three and twelve months ended December 31, 2018, as compared to the three and twelve months ended December 31, 2017. 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, 2018 primarily due to an increase in the unit shipment of tissues and a small increase in the unit cost of tissues. The unit cost of preservation services increased during 2018 when compared to 2017, primarily resulting from the impact of lower volume on the unit cost of tissues processed during 2017, which were an increasing portion of units shipped each quarter during 2018.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Gross margin	$ 45,191	$ 36,363	$ 172,984	$ 128,642
Gross margin as a percentage of total revenues	67%	69%	66%	68%

Gross margin increased 24% and 34% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017, respectively. These increases were primarily due to the addition of margins related to the JOTEC product line and by increases in On-X product margins due to an increase in revenues.

Gross margin as a percentage of total revenues decreased in the three and twelve months ended December 31, 2018, as compared to the three and twelve months ended December 31, 2017, respectively. These decreases were primarily due to the decrease in tissue margins and a decrease in the average selling price per tissue, partially offset by JOTEC and On-X product revenue growth as a percentage of total revenues in comparison to the prior year periods.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
General, administrative, and marketing expenses	$ 35,628	$ 30,195	$ 140,574	$ 101,211
General, administrative, and marketing expenses as a percentage of total revenues	53%	57%	53%	53%

General, administrative, and marketing expenses increased 18% and 39% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017, respectively. The increase in general, administrative, and marketing expenses for the three and twelve months ended December 31, 2018 was primarily due to the addition of JOTEC's general, administrative, and marketing expenses as well as higher expense to support our increased revenue base and employee headcount. General, administrative, and marketing expenses for the three and twelve months ended December 31, 2018 included $1.4 million and $8.4 million, respectively, in business development costs primarily related to the acquisition of JOTEC in December 2017, which include, among other costs, expenses related to the termination of international distribution agreements. General, administrative, and marketing expenses for the three and twelve months ended December 31, 2017 included $6.6 million and $10.9 million, respectively, in business development costs primarily related to the acquisition of JOTEC in December 2017, which include, among other costs, expenses related to the termination of international distribution agreements.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Research and development expenses	$ 6,784	$ 6,363	$ 23,098	$ 19,461
Research and development expenses as a percentage of total revenues	10%	12%	9%	10%

Research and development expenses increased 7% and 19% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017. 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. Research and development spending in the twelve months ended December 31, 2017 was primarily for clinical trials for PerClot in the U.S., our tissue processing, On-X products, and BioGlue in China, and the purchase of commercial rights to an early stage technology.

Interest Expense

Interest expense was $3.9 million and $15.8 million for the three and twelve months ended December 31, 2018, respectively, and interest expense was $2.4 million and $4.9 million for the three and twelve months ended December 31, 2017, respectively. Interest expense in the 2018 and 2017 periods included interest on debt and uncertain tax positions. Interest expense in the three and twelve months ended December 31, 2018 includes interest on borrowings under the $225.0 million secured term loan we entered into in December 2017 to finance, in part, the acquisition of JOTEC. Interest expense in the three and twelve months ended December 31, 2017 included interest on borrowings under the $225.0 million secured term loan and interest on the previous $75.0 million term loan.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
(Loss) income before income taxes	$ (1,459)	$ (2,348)	$ (6,391)	$ 3,561
Income tax (benefit) expense	(683)	659	(3,551)	(143)
Net (loss) income	$ (776)	$ (3,007)	$ (2,840)	$ 3,704
Diluted (loss) income per common share	$ (0.02)	$ (0.09)	$ (0.08)	$ 0.11
Diluted weighted-average common shares outstanding	36,652	34,025	36,412	34,163

Loss before income taxes decreased 38% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. There was a loss before income taxes for the twelve months ended December 31, 2018, as compared to income before income taxes for the twelve months ended December 31, 2017. The decrease in loss before income taxes for the three months ended December 31, 2018 was due to an increase in gross margins, partially offset by an increase in operating expenses and interest expense, as discussed above. The loss before income taxes for the twelve months ended December 31, 2018 was due to an increase in operating expenses and interest expense, partially offset by an increase in gross margins, as discussed above.

Our effective income tax rate was a benefit of 47% and 56% for the three and twelve months ended December 31, 2018, respectively, as compared to an expense of 28% and a benefit of 4% for the three and twelve months ended December 31, 2017, respectively. 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 three months ended December 31, 2017 was unfavorably affected by nondeductible transaction costs related to the acquisition of JOTEC, partially offset by additional excess tax benefit deductions related to stock compensation.

Our income tax rate for the year ended December 31, 2018 was 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. Our income tax rate for the twelve months ended December 31, 2017 was favorably affected by excess tax benefits on stock compensation and the Research and Development Tax Credit, partially offset by nondeductible transaction costs related to the JOTEC Acquisition and nondeductible meals and entertainment expenses.

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. For 2017, we elected to follow the guidance in SEC Staff Accounting Bulletin 118 (“SAB 118”), which provides additional clarification regarding the application of Accounting Standards Codification Topic 740 in situations where we do not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act for the reporting period in which the Tax Act was enacted. We estimated the accounting for the effects of the Tax Act to be included in our 2017 Consolidated Balance Sheets and Statements of Operations and Comprehensive Income, and, as a result, our financial statements for the year ended December 31, 2017 reflect these effects of the Tax Act as provisional based on a reasonable estimate of the income tax effects and recorded a one-time estimated deemed repatriation transition tax resulting in a nominal tax impact to us, based on the interplay of the transition tax and the foreign tax credit. At December 31, 2018 after further analyses of the Tax Act, notices, and regulations issued and proposed by the U.S. Department of the Treasury and the Internal Revenue Service, we completed our accounting for all of the enactment-date

income tax effects of the Tax Act. As further discussed below, during 2018, certain immaterial adjustments to the provisional amounts recorded at December 31, 2017 are included as a component of income tax expense.

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, 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 its consolidated financial statements for the years ended December 31, 2018 and 2017. For the year ending December 31, 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 is taxed at a lower U.S. rate. We are favorably impacted by the new FDII provision and as of December 31, 2018 our FDII deduction was $1.1 million.

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, 2018 our interest deduction was limited to $4.9 million. The excess interest not deducted in 2018 of $21.1 million can be carried forward indefinitely for use in future years.

Net loss decreased for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017, primarily due to a decrease in loss before income taxes and by a decrease in income tax expense, as discussed above. We incurred a net loss for the twelve months ended December 31, 2018, as compared to a net gain for the twelve months ended December 31, 2017, primarily due to a decrease in income before income taxes, partially offset by an increase in income tax benefit, as discussed above.

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 seasonality for On-X products may be obscured as the On-X products have not fully penetrated many markets.

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

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

We are uncertain whether the demand for PhotoFix 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.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2019 net working capital (current assets of $187.4 million less current liabilities of $45.2 million) was $142.2 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of $144.7 million and a current ratio of 5 to 1 at December 31, 2018.

Overall Liquidity and Capital Resources

Our primary cash requirements for the twelve months ended December 31, 2019 were for general working capital needs, funding of the Endospan agreements, interest and principal payments under our debt agreement, capital expenditures for facilities and equipment, repurchases of stock to cover tax withholdings, and business development and integration expenses. We funded our cash requirements through 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 debt agreement, expenditures for clinical trials, additional 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 as defined in the Endospan 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 facility, considering our revolving credit availability and other obligations, 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 drawing down monies under our credit agreement, discussed below, obtaining additional debt financing, or using a registration statement to sell equities. 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

In connection with the closing of the JOTEC Acquisition, we entered into a credit and guaranty agreement for a new $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 CryoLife 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 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.

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 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, 2019 the remaining availability on our revolving credit facility was $30.0 million.

We intend to incur expenses for clinical research work to gain regulatory approvals for new products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and to incur expenses for research and development for new products.

We also intend to fund two additional $5.0 million tranches upon completion of certain clinical trial milestones in connection with the Endospan Loan.

As of December 31, 2019 approximately 29% of our cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $15.8 million for the twelve months ended December 31, 2019, as compared to $9.9 million for the twelve months ended December 31, 2018. The prior year cash provided by operating activities was reduced as a result of increased integration and business development costs resulting in a higher net loss, primarily related to the JOTEC Acquisition. These expenses made up a large portion of the $8.9 million unfavorable adjustment due to the timing differences between recording accounts payable, accrued expenses, and other liabilities and the payment of cash.

We use the indirect method to prepare our cash flow statement, and accordingly, the operating cash flows are based on our net income (loss), 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, 2019 these non-cash items included $18.3 million in depreciation and amortization expenses, $8.8 million in non-cash compensation and $5.0 million in non-cash lease expense.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the twelve months ended December 31, 2019 these changes included unfavorable adjustments of $8.1 million due to an increase in inventory balances offset by lower deferred preservation costs, $6.2 million due to an increase in prepaid expenses and other assets, and $5.3 million due to the timing difference between recording receivables and the receipt of cash.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $23.9 million for the twelve months ended December 31, 2019, as compared to $6.7 million for the twelve months ended December 31, 2018. The increase is primarily due to cash payments totaling $15.0 million in connection with the agreements with Endospan and $8.1 million in capital expenditures. See Part II, Item 8, Note 2 of the “Notes to Consolidated Financial Statements” for further information on agreements with Endospan.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $1.5 million for the twelve months ended December 31, 2019, as compared to $2.6 million for the twelve months ended December 31, 2018. The current year cash used was primarily due to $2.8 million in principal payments on borrowings and $2.7 million related to the redemption and repurchase of stock to cover tax withholdings, partially offset by $4.8 million in proceeds from the exercise of stock options and issuance of common stock under our employee stock purchase plan. The prior year cash used was primarily due to $2.8 million in principal payments on borrowings and $2.1 million related to the redemption and repurchase of stock to cover tax withholdings, partially offset by $3.9 million in proceeds from the exercise of stock options and issuance of common stock under our employee stock purchase plan.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of December 31, 2019 are as follows (in thousands):

	Total	2020	2021	2022	2023	2024	Thereafter
Long-term debt obligations	$ 223,176	$ 2,780	$ 2,780	$ 2,780	$ 2,780	$ 211,843	$ 213
Interest payments	55,055	11,445	11,318	11,192	11,065	10,033	2
Research obligations	27,948	7,404	8,536	7,360	4,195	453	--
Operating leases	26,855	6,585	6,280	3,809	2,584	2,570	5,027
Contingent payments	14,000	5,500	6,500	2,000	--	--	--
Purchase obligations	9,332	6,301	2,833	140	19	15	24
Finance leases	6,672	712	658	613	612	610	3,467
Total contractual obligations	$ 363,038	$ 40,727	$ 38,905	$ 27,894	$ 21,255	$ 225,524	$ 8,733

Our long-term debt obligations and interest payments above result from scheduled principal payments and anticipated interest payments related to our Credit Agreement and the JOTEC governmental loans.

Our research obligations represent commitments for ongoing studies and payments to support research and development activities.

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. The operating and finance lease obligations in this schedule are based on actual payments which includes both interest and lease liability.

The contingent payments obligation includes two additional $5.0 million tranches under the Endospan Loan that we are required, subject to certain conditions, to advance to Endospan upon receipt of certification that certain approvals and clinical trial milestones have been achieved. The contingent payments obligation also includes payments that we may make 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 purchase commitments 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. These minimum purchases are included in the table above through 2021, based on the assumption that we will not terminate the distribution agreement before receiving FDA approval for PerClot. However, if we do not obtain FDA approval for PerClot and/or we choose not to terminate the distribution agreement, we may have minimum purchase obligations of up to $1.75 million per year through the end of the contract term in 2025.

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, as no assessments have been made for specific litigation, and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $4.0 million, as no specific assessments have been made by any taxing authorities.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2019 and 2018 were $8.1 million and $5.8 million, respectively. Capital expenditures in the twelve months ended December 31, 2019 were primarily related to manufacturing and tissue processing equipment, leasehold improvements needed to support our business and the routine purchases of computer software.

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 $33.8 million as of December 31, 2019, and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility and our $225.0 million secured Term Loan Facility. A 10% adverse change in interest rates as compared to the rates experienced by us in the twelve months ended December 31, 2019, affecting our cash and cash equivalents, restricted securities, $225.0 million secured Term Loan Facility, and Revolving Credit Facility 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 loss of $1.2 million, loss of $2.6 million and a gain of $257,000 for the years ended December 31, 2019, 2018, and 2017, respectively. Losses incurred during 2019 were primarily related to cross currency intercompany receivables and payables resulting from large inventory transfers during 2019, impacted by fluctuations in the Euro 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 JOTEC 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, 2019 affecting our balances denominated in foreign currencies would not have had a material impact on our financial position or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by us for the twelve months ended December 31, 2019 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.

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, 2019. 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, 2019, 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, 2019.

CryoLife, Inc.
February 19, 2020

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 19, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Deferred Preservation Costs

Description of the Matter	At December 31, 2019, the Company's deferred preservation costs balance was $32.6 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.

/s/ Ernst & Young LLP
We have served as the Company‘s auditor since 2013.
Atlanta, Georgia
February 19, 2020

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, 2019, 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, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, 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, 2019, and the related notes and our report dated February 19, 2020 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 19, 2020

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,766	$ 41,489
Restricted securities	528	747
Receivables:		
Trade accounts, net	52,940	47,108
Other	2,921	4,324
Total receivables	**55,861**	**51,432**
Inventories	53,071	45,478
Deferred preservation costs	32,551	33,174
Prepaid expenses and other	11,613	6,848
Total current assets	**187,390**	**179,168**
Property and equipment:		
Equipment and software	61,271	48,323
Furniture and fixtures	5,650	5,369
Leasehold improvements	36,173	41,906
Total property and equipment	103,094	95,598
Less accumulated depreciation and amortization	70,944	64,570
Net property and equipment	**32,150**	**31,028**
Other assets:		
Operating lease right-of-use assets, net	21,994	--
Goodwill	186,697	188,781
Acquired technology, less accumulated amortization of $24,778 as of December 31, 2019 and $16,815 as of December 31, 2018	115,415	118,184
Other Intangibles, less accumulated amortization of $13,460 as of December 31, 2019 and $10,572 as of December 31, 2018	42,319	41,897
Deferred income taxes	5,481	4,111
Other	14,208	7,922
Total assets	**$ 605,654**	**$ 571,091**

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

	December 31,	
	2019	**2018**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accrued expenses	$ 6,733	$ 7,193
Accrued compensation	12,260	10,733
Accounts payable	9,796	7,547
Taxes payable	2,984	2,250
Accrued procurement fees	4,362	3,308
Current portion of finance lease obligation	597	729
Current maturities of operating leases	5,487	--
Current portion of long-term debt	1,164	1,160
Other	1,812	1,603
Total current liabilities	**45,195**	**34,523**
Long-term debt	214,571	215,721
Deferred income taxes	25,844	27,267
Non-current maturities of operating leases	17,918	--
Non-current finance lease obligations	5,415	5,937
Deferred compensation liability	4,434	3,250
Deferred rent obligations	--	2,457
Other	6,581	6,869
Total liabilities	**319,958**	**296,024**
Commitments and contingencies		
Shareholders' equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued	--	--
Common stock $0.01 par value per share, 75,000 shares authorized, 39,018 and 38,463 shares issued as of December 31, 2019 and 2018, respectively	390	385
Additional paid-in capital	271,782	260,361
Retained earnings	36,704	34,984
Accumulated other comprehensive loss	(8,589)	(6,072)
Treasury stock at cost, 1,484 shares as of December 31, 2019 and 2018, respectively	(14,591)	(14,591)
Total shareholders' equity	**285,696**	**275,067**
Total liabilities and shareholders' equity	**$ 605,654**	**$ 571,091**

See accompanying Notes to Consolidated Financial Statements.

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Revenues:			
Products	$ 197,246	$ 187,394	$ 119,631
Preservation services	78,976	75,447	70,071
Total revenues	**276,222**	**262,841**	**189,702**
Cost of products and preservation services:			
Products	55,022	53,772	29,798
Preservation services	38,187	36,085	31,262
Total cost of products and preservation services	**93,209**	**89,857**	**61,060**
Gross margin	**183,013**	**172,984**	**128,642**
Operating expenses:			
General, administrative, and marketing	143,011	140,574	101,211
Research and development	22,960	23,098	19,461
Total operating expenses	**165,971**	**163,672**	**120,672**
Operating income	**17,042**	**9,312**	**7,970**
Interest expense	14,886	15,788	4,881
Interest income	(738)	(226)	(212)
Other expense (income), net	1,250	141	(260)
Income (loss) before income taxes	**1,644**	**(6,391)**	**3,561**
Income tax benefit	(76)	(3,551)	(143)
Net income (loss)	$ **1,720**	$ **(2,840)**	$ **3,704**
Income (loss) per common share:			
Basic	$ **0.05**	$ **(0.08)**	$ **0.11**
Diluted	$ **0.05**	$ **(0.08)**	$ **0.11**
Weighted-average common shares outstanding:			
Basic	37,118	36,412	33,008
Diluted	37,860	36,412	34,163
Net income (loss)	$ **1,720**	$ **(2,840)**	$ **3,704**
Other comprehensive (loss) income	(2,517)	(7,929)	2,286
Comprehensive (loss) income	$ **(797)**	$ **(10,769)**	$ **5,990**

See accompanying Notes to Consolidated Financial Statements.

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Net cash flows from operating activities:			
Net income (loss)	$ 1,720	$ (2,840)	$ 3,704
Adjustments to reconcile net income to net cash from operating activities:			
Depreciation and amortization	18,317	18,095	9,745
Non-cash compensation	8,799	6,325	6,919
Non-cash lease expense	5,009	--	--
Write-down of inventories and deferred preservation costs	1,488	649	2,110
Deferred income taxes	(2,305)	(4,485)	(1,483)
Other	2,182	2,149	676
Changes in operating assets and liabilities:			
Receivables	(5,332)	(1,119)	(7,258)
Inventories and deferred preservation costs	(8,125)	2,384	(9,369)
Prepaid expenses and other assets	(6,177)	(2,407)	(2,968)
Accounts payable, accrued expenses, and other liabilities	251	(8,870)	8,727
Net cash flows provided by operating activities	**15,827**	**9,881**	**10,803**
Net cash flows used in investing activities:			
Payments for Endospan Agreements	(15,000)	--	--
Capital expenditures	(8,072)	(5,786)	(6,632)
Acquisition of JOTEC, net of cash acquired	--	--	(164,661)
Acquisition of PhotoFix technology	--	--	(409)
Proceeds from sale of business components	--	--	740
Other	(871)	(929)	(86)
Net cash flows used in investing activities	**(23,943)**	**(6,715)**	**(171,048)**
Net cash flows from financing activities:			
Repayment of term loan	(2,780)	(2,790)	(4,994)
Payment of debt issuance costs	--	(624)	(10,144)
Proceeds from issuance of term loan	--	--	225,000
Payoff of debt agreement	--	--	(67,219)
Proceeds from exercise of stock options and issuance of common stock	4,758	3,854	3,126
Redemption and repurchase of stock to cover tax withholdings	(2,743)	(2,100)	(1,614)
Other	(728)	(902)	(910)
Net cash flows (used in) provided by financing activities	**(1,493)**	**(2,562)**	**143,245**
Effect of exchange rate changes on cash	1,667	879	412
(Decrease) increase in cash, cash equivalents, and restricted securities	**(7,942)**	**1,483**	**(16,588)**
Cash, cash equivalents, and restricted securities, beginning of year	42,236	40,753	57,341
Cash, cash equivalents, and restricted securities, end of year	**$ 34,294**	**$ 42,236**	**$ 40,753**

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 (Loss) Income	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2016	**34,230**	**$ 342**	**$ 187,061**	**$ 34,143**	**$ (429)**	**(1,356)**	**$ (12,134)**	**$ 208,983**
Cumulative effect of ASU 2016-09 Adjustment	--	--	379	(238)	--	--	--	141
Net income	--	--	--	3,704	--	--	--	3,704
Other comprehensive income:								
Foreign currency translation gain	--	--	--	--	2,286	--	--	2,286
Comprehensive income								5,990
Stock issued for JOTEC transaction	2,683	27	53,092	--	--	--	--	53,119
Equity compensation	311	3	7,310	--	--	--	--	7,313
Exercise of options	393	4	2,476	--	--	(30)	(585)	1,895
Employee stock purchase plan	93	1	1,230	--	--	--	--	1,231
Redemption and repurchase of stock to cover tax withholdings	(92)	(1)	(1,613)	--	--	--	--	(1,614)
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	--	--	--	--	(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	--	--	--	--	(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**

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, JOTEC GmbH ("JOTEC") stent grafts and surgical products, On-X mechanical heart valves and surgical products, and implantable cardiac and vascular human tissues. In addition to these four major product families, we sell or distribute PhotoFix™ bovine surgical patch, PerClot® hemostatic powder, NEXUS™ endovascular stent graft system, and CardioGenesis cardiac laser therapy.

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) Income. Realized and unrealized gains and losses were a loss of $1.2 million, a loss of $2.6 million, and a gain of $257,000 for the years ended December 31, 2019, 2018, and 2017, respectively. Losses incurred during 2019 were primarily related to cross currency intercompany receivables and payables resulting from large inventory transfers during 2019, impacted by fluctuations in the Euro relative to other currencies. 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) income 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. Revenues for 2019 and 2018 are reported under ASC 606, while 2017 amounts are not adjusted and continue to be reported under ASC 605, *Revenue Recognition*.

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, JOTEC products, 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) Income. 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) Income was $1.7 million, $732,000, and $606,000 for the years ended December 31, 2019, 2018, and 2017, 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.

Change in Accounting for Employee Share-Based Payments

As of January 1, 2017 we made an entity-wide accounting policy election in accordance with Accounting Standards Update ("ASU") No. 2016-09, *Improvements to Employee Share-Based Payment Accounting,* ("ASU 2016-09") to change our accounting policy to account for stock compensation forfeitures in the period awards are forfeited rather than estimating the effect of forfeitures. We elected to make this accounting policy change to simplify the accounting for share-based compensation and believe this method provides a more accurate reflection of periodic share-based compensation cost from the grant date forward. We used the modified retrospective transition method to record a net $238,000 cumulative-effect adjustment decrease to retained earnings for the accounting policy change, which included a $379,000 increase to additional paid-in capital and a $141,000 increase in deferred tax assets.

Additionally, as of January 1, 2017 and in accordance with the guidance in ASU 2016-09, we made a change to account for excess tax benefits and deficiencies resulting from the settlement or vesting of share-based awards in income tax expense in our Consolidated Statement of Operations and Comprehensive (Loss) Income instead of accounting for these effects through additional paid in-capital on our Consolidated Balance Sheets. We applied this amendment prospectively and prior periods have not been adjusted.

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.

Dividends

Payment of dividends was discontinued in the fourth quarter of 2015. We did not pay dividends in 2019, 2018 or 2017 and do not currently anticipate paying out dividends in the next year.

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 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. We use the fair value measurement framework to value these assets 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):

	2019	2018	2017
Cash paid during the year for:			
Interest	$ 13,297	$ 15,005	$ 2,561
Income taxes	1,944	1,699	3,358
Non-cash investing and financing activities:			
Issuance of common stock for acquisition of JOTEC intangible assets	$ --	$ --	$ 53,119

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 $966,000 and $533,000 as of December 31, 2019 and 2018, respectively.

Inventories

Inventories are comprised of finished goods for our major product lines including: BioGlue; JOTEC products; 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 $601,000, $212,000, and $1.2 million for the years ended December 31, 2019, 2018, and 2017, respectively. 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 ascending aortic prosthesis ("AAP") inventory not expected to ship prior to the expiration date and the disposal of obsolete surgical sealant product packaging materials. The 2017 write-down is primarily related to AAP inventory not expected to ship prior to the expiration date.

Deferred Preservation Costs

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

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations ("OPOs") and tissue banks, that 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 $787,000, $437,000, and $922,000 for the years ended December 31, 2019, 2018, and 2017, respectively, due primarily to tissues not expected to ship prior to the expiration date of the packaging.

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):

	2019	2018	2017
Depreciation expense	$ 7,467	$ 7,303	$ 4,648

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, 2019, 2018, and 2017 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 as of October 31 and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of October 31, 2019 and 2018, 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, 2019 and 2018 and determined that the fair value of the assets and the fair value of the reporting unit 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 have been made to the 2018 or 2017 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.

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.

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 is 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.

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) Income. 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 periodically assess the recoverability of our deferred tax assets, as necessary, when we experience changes that could materially affect our determination of the recoverability of our deferred tax assets. We 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 in conjunction with 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:

- Projected future operating results;
- Anticipated future state tax apportionment;
- Timing and amounts of anticipated future taxable income;
- Timing of the anticipated reversal of book/tax temporary differences;
- 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. We also acquired net operating loss carryforwards in certain foreign jurisdictions in our recent acquisition of JOTEC. We believe these loss carryforwards will be fully realizable. 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.

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, 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, 2019 we adopted the Accounting Standards Codification ("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 and is not expected to have a material impact in future periods. During our evaluation of the impact of adopting the new revenue standard, which included a detailed review of performance obligations for all material revenue streams, we identified two noteworthy items:

- Certain distributor agreements have historically included inventory buyback provisions under defined change of business conditions. Transactions under these terms would not qualify as a completed revenue transaction until sale through to the end customer, resulting in a revenue deferral until the proper criteria were satisfied. These agreements were modified or replaced to remove the buyback provisions effective on or before January 1, 2018 which eliminated any retrospective adjustment requirements.

- Certain JOTEC products discussed above are manufactured to order, have no alternative use, and contain an enforceable right to receive payment for the performance completed. These factors qualify the transactions for revenue recognition over time. Upon adoption of the new standard, we evaluated all appropriate contracts in progress to determine the value of unbilled revenues representing outstanding contract assets. We recorded an immaterial cumulative effect adjustment to recognize the impact of contract assets.

See Note 14 for further discussion of revenue recognition.

In August 2016 the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"). ASU 2016-18 is intended to address diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The guidance requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We adopted ASU 2016-18 as of January 1, 2018 and disclosure revisions have been made for the periods presented on the Consolidated Statement of Cash Flows.

Not Yet Effective

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASC Update No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* 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. We are currently evaluating the impact related to the adoption of ASU 2016-13 on its financial condition, profitability, and cash flows.

2. 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. Under the terms of the Endospan Distribution Agreement, JOTEC agreed to use its best efforts to market, promote, distribute, sell, and support NEXUS for approved uses in the countries included within JOTEC's exclusive distribution rights. JOTEC is obligated to satisfy a minimum purchase amount beginning in 2020.

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 of 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 million and $450.0 million before or within a certain period of time or after U.S. Food and Drug Administration ("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.

The term of JOTEC's Endospan Distribution Agreement expires upon the earliest to occur of (i) the date on which the acquisition contemplated by the Endospan Option Agreement can no longer be consummated under its terms, or (ii) the date on which the Endospan Option Agreement is terminated pursuant to its terms, or by either party under certain circumstances. JOTEC would be entitled to a termination fee in the event the Endospan Distribution Agreement is terminated by JOTEC due to a suspension of approvals related to NEXUS lasting more than six months or the withdrawal of such approvals, an injunction on NEXUS lasting more

than six months or a permanent injunction on NEXUS (unless such injunction resulted solely from an act or omission of JOTEC, its affiliates, or their sub-distributors), and other significant breaches.

We incurred transaction and integration costs of $1.0 million for the year ended December 31, 2019, related to the execution of the Endospan agreements, which included, among other costs, expenses related to legal, professional, and consulting costs. 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) Income.

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. The second tranche is required to be funded generally under the same terms as the first tranche, upon certification of Investigational Device Exemption ("IDE") approval from the FDA of NEXUS, and 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.

The Endospan Loan is secured by substantially all of Endospan's assets. Such security interest is a first priority security interest, except as to a pre-existing security interest granted to a third party over certain of these assets. The Endospan Loan bears interest at a rate of 5% per annum and is subject to acceleration upon an event of default. Interest on the Endospan Loan is payable upon the closing of the acquisition contemplated in the Endospan Option Agreement, and the principal amount and any additional interest or other obligations are payable upon the first anniversary of the closing of such acquisition. The amounts advanced under the Endospan Loan could be forgiven if Endospan is not in default of the Endospan Loan and certain events as defined in the Endospan agreements have occurred.

Variable Interest Entity

We consolidate the results of a variable interest entity ("VIE") when it is determined that we are the primary beneficiary. 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. Based on our evaluation of Endospan and the related agreements with Endospan, we determined that Endospan is a VIE. We evaluated whether we are the primary beneficiary of the Endospan VIE by considering whether we have (1) the power to direct those activities of the VIE that most significantly impact the entity's economic performance and (2) the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE.

In evaluating whether we have the power to direct those activities of a VIE that most significantly impact its economic performance, we considered the purpose for which the VIE was created, the importance of each of the activities in which the VIE is engaged, and our decision-making role, if any, in those activities that significantly determine the VIE's economic performance, as compared to the role of other economic interest holders. In determining whether we have the right to receive benefits or the obligation to absorb losses that could potentially be significant to the VIE, we considered our economic interests in Endospan, regardless of form. This evaluation considered the relevant factors of Endospan's design, including: Endospan's capital structure, contractual rights to earnings (losses), and subordination of our interests relative to those of other investors, contingent payments, as well as other contractual arrangements that have the potential to be economically significant.

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 date, including any loans and guarantees and other subordinated financial support related to this VIE, totaled $15.0 million as of December 31, 2019, representing our maximum exposure to loss and was 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 that certain approvals and milestones in obtaining FDA approval. Based on the 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 and the Endospan Option Agreement of $4.8 million in "Other long-term assets" and the Endospan Distribution Agreement of $9.8 million in "Other intangibles, net" in the Consolidated Balance Sheets as of December 31, 2019.

We have 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 each period, and we 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 as of December 31, 2019 and concluded that an adjustment to the fair value is not material. As of the transaction date, the initial relative fair value calculations to determine the amounts to be recorded for the Endospan Distribution Agreement and the Endospan Option Agreement represent non-recurring Level 3 fair value calculations. The Endospan Distribution Agreement will be amortized over five years, which is the expected timeframe to achieve FDA approval. The Endospan Option Agreement will remain at the recorded value and will be periodically assessed for impairment based on qualitative and quantitative factors.

3. Acquisition of JOTEC

Overview

On December 1, 2017 we acquired JOTEC (the "JOTEC Acquisition") for a contract value of approximately $225.0 million, subject to certain adjustments. JOTEC is being operated as a wholly-owned subsidiary of CryoLife. In connection with the closing of the JOTEC Acquisition, CryoLife entered into a senior secured credit facility in an aggregate principal amount of $255.0 million, which includes a $225.0 million term loan and a $30.0 million revolving credit facility. See Note 10 for further discussion of the senior secured credit facility.

Accounting for the Transaction

The purchase price of the JOTEC Acquisition totaled approximately $222.2 million, including debt and cash acquired as determined on the date of closing, consisting of $169.1 million in cash and 2,682,754 shares of CryoLife common stock, with a value of $53.1 million on the date of the closing.

We incurred transaction and integration costs of $1.0 million, $7.4 million, and $7.7 million for the years ended December 31, 2019, 2018 and 2017, respectively, primarily related to the acquisition, which included, among other costs, expenses related to the termination of international agreements, severance costs, and legal, professional, and consulting costs. 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) Income.

4. Financial Instruments

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

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

December 31, 2018	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	1,445	--	--	1,445
Restricted securities:				
Money market funds	747	--	--	747
Total assets	$ 2,192	$ --	$ --	$ 2,192

We used prices quoted from our investment management companies 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. See Note 2 for further discussion of the Endospan Loan. Changes in fair value of Level 3 assets are listed in the table below (in thousands):

	Endospan Loan
Balance as of December 31, 2018	$ --
Initial value of Endospan Loan	358
Change in valuation of Endospan Loan	--
Balance as of December 31, 2019	$ 358

During the year ended December 31, 2017 we initially recorded certain non-financial assets at fair value related to the acquisition JOTEC. Disclosure of this initial fair value determination is included in Note 3 above.

5. Cash Equivalents and Restricted Cash and Securities

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

December 31, 2019	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value
Cash equivalents:			
Money market funds	$ 1,472	--	$ 1,472
Restricted securities:			
Money market funds	528	--	528

December 31, 2018	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value
Cash equivalents:			
Money market funds	$ 1,445	--	$ 1,445
Restricted securities:			
Money market funds	747	--	747

As of December 31, 2019 and 2018 $528,000 and $747,000, 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, 2019, 2018, and 2017. As of December 31, 2019, $528,000 of our restricted securities had a maturity date within three months. As of December 31, 2018, $512,000 of our restricted securities had a maturity date within three months and $235,000 of our restricted securities had a maturity date between three months and one year.

6. Inventories and Deferred Preservation Costs

Inventories at December 31, 2019 and 2018 are comprised of the following (in thousands):

	2019	2018
Raw materials and supplies	$ 21,180	$ 17,381
Work-in-process	5,127	3,858
Finished goods	26,764	24,239
Total inventories	$ 53,071	$ 45,478

Deferred preservation costs at December 31, 2019 and 2018 are comprised of the following (in thousands):

	2019	2018
Cardiac tissues	$ 15,365	$ 15,972
Vascular tissues	17,186	17,202
Total deferred preservation costs	$ 32,551	$ 33,174

We maintain consignment inventory of our On-X heart valves at domestic hospital locations and On-X heart valves and JOTEC products at international hospital locations to facilitate usage. We retain title to 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, 2019 we had $12.0 million in consignment inventory, with approximately 51% in domestic locations and 49% in foreign locations. As of December 31, 2018 we had $11.2 million in consignment inventory, with approximately 55% in domestic locations and 45% in foreign locations.

7. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of December 31, 2019 and 2018, the carrying values of our indefinite lived intangible assets are as follows (in thousands):

	2019	2018
Goodwill	$ 186,697	$ 188,781
In-process R&D	2,190	9,382
Procurement contracts and agreements	2,013	2,013
Trademarks	844	844

We monitor the phases of development of our acquired in-process R&D 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 R&D 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, 2019 and 2018.

During the three 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 R&D 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, 2019 and 2018, the value of our goodwill, all of which is related to our Medical Devices segment, is as follows (in thousands):

	2019	2018
Balance as of January 1,	$ 188,781	$ 188,305
Goodwill from JOTEC Acquisition	--	5,100
Revaluation of goodwill denominated in foreign currency	(2,084)	(4,624)
Balance as of December 31,	$ 186,697	$ 188,781

Definite Lived Intangible Assets

As of December 31, 2019 and 2018, gross carrying values, accumulated amortization, and approximate amortization periods of our definite lived intangible assets are as follows (dollars in thousands):

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

December 31, 2018	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 134,999	16,815	11 – 22 Years
Customer lists and relationships	31,169	5,068	13 – 22 Years
Distribution and manufacturing rights and know-how	4,059	2,107	11 – 15 Years
Patents	3,656	2,970	17 Years
Other	1,154	235	3 – 5 Years

Amortization Expense

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

	2019	2018	2017
Amortization expense	$ 10,850	$ 10,792	$ 5,085

As of December 31, 2019 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2020	2021	2022	2023	2024	Total
Amortization expense	$ 12,406	$ 12,383	$ 11,838	$ 11,499	$ 11,279	$ 59,405

8. Income Taxes

Income Tax Expense

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

	2019	2018	2017
Domestic	$ 6,369	$ 4,560	$ 5,086
Foreign	(4,725)	(10,951)	(1,525)
Income (loss) before income taxes	$ 1,644	$ (6,391)	$ 3,561

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

	2019	2018	2017
Current:			
Federal	$ 48	$ 402	$ 521
State	80	246	110
Foreign	2,041	2,009	460
	2,169	2,657	1,091
Deferred:			
Federal	(850)	(2,188)	(714)
State	(131)	(154)	70
Foreign	(1,264)	(3,866)	(590)
	(2,245)	(6,208)	(1,234)
Income tax benefit	$ (76)	$ (3,551)	$ (143)

Our income tax benefit in 2019, 2018, and 2017 included our federal, state, and foreign tax obligations. Our effective income tax rate was a tax benefit of 5%, 56%, and 4% for the years ended December 31, 2019, 2018, and 2017, respectively. Our income tax rate for the year ended December 31, 2019 was primary 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. Our income tax rate for the year ended December 31, 2017 was primarily affected by excess tax benefits on stock compensation and the research and development tax credit, offset by nondeductible transaction costs related to the JOTEC Acquisition 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, 2019 and 2018 and 34% for the year ended December 31, 2017 to pretax income as a result of the following (in thousands):

	2019	2018	2017
Tax expense (benefit) at statutory rate	$ 345	$ (1,340)	$ 1,211
Increase (reduction) in income taxes resulting from:			
Nondeductible executive compensation	778	320	145
Foreign income taxes	425	(250)	364
Foreign deferred items	365	--	--
Net operating losses	355	--	--
Foreign interest disallowance	292	--	--
Nondeductible entertainment expenses	201	206	258
Valuation allowance change	153	719	54
Prior year provision to return adjustments	43	--	--
State income taxes, net of federal benefit	(108)	(8)	212
Impact of Tax Cuts and Jobs Act	(155)	(238)	(255)
Unrealized income on investments	(203)	(337)	(163)
Net change in uncertain tax positions	(360)	(154)	(67)
Research and development credit	(400)	(557)	(525)
Equity compensation	(1,921)	(2,081)	(2,664)
Nondeductible transaction costs	--	--	1,676
Federal tax rate differential	--	--	(100)
Foreign tax credit	--	--	(133)
Domestic production activities deduction	--	--	(174)
Other	114	169	18
Total income tax benefit	$ (76)	$ (3,551)	$ (143)

Tax Cuts and Jobs Act of 2017

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 Bulletin 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 its 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.

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.

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

	2019	2018
Deferred tax assets:		
Loss carryforwards	$ 7,030	$ 8,266
Finance and operating leases	7,497	1,824
Excess interest carryforward	4,544	4,786
Stock compensation	2,153	2,138
Accrued expenses	1,890	2,723
Deferred compensation	1,107	778
Property	1,147	--
Credit carryforwards	710	939
UNICAP	425	404
Inventory and deferred preservation costs write-downs	299	289
Tax benefit of tax reserves	52	217
Other	1,659	310
Less valuation allowance	(3,218)	(3,372)
Total deferred tax assets	25,295	19,302

	2019	2018
Deferred tax liabilities:		
Intangible assets	(35,555)	(38,414)
Finance and operating leases	(7,048)	--
Debt costs	(1,917)	(2,331)
Property	(28)	(1,060)
Prepaid items	(494)	(477)
Other	(616)	(176)
Total deferred tax liabilities	(45,658)	(42,458)
Total net deferred tax liabilities	$ (20,363)	$ (23,156)

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, 2018 we maintained a total of $3.4 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 $23.2 million.

As of December 31, 2019 we had approximately $2.7 million tax-effected federal net operating loss carryforwards related to the acquisitions of Cardiogenesis and Hemosphere that we anticipate fully utilizing before expiration, $2.8 million of tax-effected state net operating loss carryforwards, that will begin to expire in 2022, approximately $1.6 million of foreign net operating loss carryforwards that will begin to expire in 2024, $631,000 in research and development tax credit carryforwards that begin to expire in 2026, and $128,000 in credits from the state of Texas that expire in 2027.

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) Income. 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. The Company has recorded approximately $35,000 of a deferred tax liability for the tax effects of this outside basis difference in its Consolidated Statements of Operations and Comprehensive (Loss) Income.

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):

	2019	2018	2017
Beginning balance	$ 3,889	$ 4,328	$ 3,390
Increases related to current year tax positions	691	368	143
Decreases due to the lapsing of statutes of limitations	(880)	(467)	(254)
Decreases related to prior year tax positions	(154)	--	(106)
(Decreases) increases for foreign exchange differences	(22)	16	--
(Decreases) increases related to prior year tax positions	(1)	249	1,155
Decreases related to settlements	--	(605)	--
Ending balance	$ 3,523	$ 3,889	$ 4,328

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

	2019	2018	2017
Beginning balance	$ 402	$ 315	$ 208
Accrual of interest and penalties	227	161	169
Decreases related to prior year tax positions	(195)	(74)	(62)
Ending balance	$ 434	$ 402	$ 315

As of December 31, 2019 our uncertain tax liability of $4.0 million, including interest and penalties, was recorded as a reduction to deferred tax assets of $300,000, and a non-current liability of $3.7 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, 2018 our total uncertain tax liability, including interest and penalties of $4.3 million, was recorded as a reduction to deferred tax assets of $286,000 and as a non-current liability of $4.0 million on our Consolidated Balance Sheets.

We believe it is reasonably possible that approximately $1.0 million 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 2016 and forward generally remain open to examination by the major taxing jurisdictions to which we are subject. However, certain returns from years prior to 2016, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

9. Leases

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.

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

Operating leases:	**December 31, 2019**
Operating lease right-of-use assets	$ 27,007
Accumulated amortization	(5,013)
Operating lease right-of-use assets, net	**$ 21,994**
Current maturities of operating leases	$ 5,487
Non-current maturities of operating lease	17,918
Total operating lease liabilities	$ **23,405**
Finance leases:	
Property and equipment, at cost	$ 7,161
Accumulated amortization	(1,279)
Property and equipment, net	**$ 5,882**
Current maturities of finance leases	$ 597
Non-current maturities of finance leases	5,415
Total finance lease liabilities	$ **6,012**
Weighted average remaining lease term (in years):	
Operating leases	5.5
Finance leases	10.6
Weighted average discount rate:	
Operating leases	5.4%
Finance leases	2.0%

Assets recorded as finance leases as of December 31, 2018 are as follows (in thousands):

	Gross Carrying Value	**Accumulated Amortization**	**Net Book Value**
Equipment	$ 1,066	$ 375	$ 691
Leasehold improvements	6,608	507	6,101
Total	$ 7,674	$ 882	$ 6,792

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) Income are as follows (in thousands):

	2019
Amortization of property and equipment	$ 771
Interest expense on finance leases	124
Total finance lease expense	895
Operating lease expense[a]	6,624
Sublease income	(905)
Total lease expense	**$ 6,614**

[a] Total rental expense for operating leases was $6.4 million in 2018 and $4.9 million in 2017.

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

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

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

	Finance Leases	Operating Leases	Sublease Income
2020	$ 712	$ 6,585	$ 905
2021	658	6,280	905
2022	613	3,809	306
2023	612	2,584	--
2024	610	2,570	--
Thereafter	3,467	5,027	--
Total minimum lease payments	$ 6,672	$ 26,855	$ 2,116
Less amount representing interest	660	3,450	
Present value of net minimum lease payments	6,012	23,405	
Less current maturities	597	5,487	
Finance lease obligations, less current maturities	$ 5,415	$ 17,918	

10. Debt

Credit Agreement

On December 1, 2017 we entered into a credit and guaranty agreement for a new $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 previously announced 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 existing credit facility under the Amended Debt Agreement. The Revolving Credit Facility is undrawn following the JOTEC Acquisition and 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.

Loans under the Term Loan Facility are repayable on a quarterly basis according to the amortization provisions set forth in the Credit Agreement. We have the right to prepay loans under the Credit Agreement in whole or in part at any time. Amounts repaid in respect of loans under the Term Loan Facility may not be reborrowed. Amounts repaid in respect of loans 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, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loans under the Term Loan Facility bear 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 loans under the Revolving Credit Facility bear 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 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, 2019 the aggregate interest rate was 5.19%. We were obligated to pay an unused commitment fee equal to 0.50% of the un-utilized 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, merge or consolidate, change their 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 prohibits the payment of certain restricted payments, including cash dividends.

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.

Government Supported Bank Debt

In June 2015, JOTEC GmbH obtained two loans of 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 1.4%.

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

	As of December 31,	
	2019	**2018**
Term loan balance	$ 220,500	$ 222,750
2.45% Sparkasse Zollernalb (KFW Loan 1)	1,061	1,318
1.40% Sparkasse Zollernalb (KFW Loan 2)	1,615	1,885
Total loan Balance	223,176	225,953
Less unamortized loan origination costs	(7,441)	(9,072)
Total borrowed	215,735	216,881
Less short-term loan balance	(1,164)	(1,160)
Long-term loan balance	$ 214,571	$ 215,721

At December 31, 2019 the aggregate maturities of long-term debt for the next five years is as follows (in thousands):

	2020	**2021**	**2022**	**2023**	**2024**	**Thereafter**	**Total**
Maturities	$ 2,780	$ 2,780	$ 2,780	$ 2,780	$ 211,843	$ 213	$ 223,176

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

Total interest expense was $14.9 million, $15.8 million, and $4.9 million in 2019, 2018, and 2017, respectively. Interest expense includes interest on debt and uncertain tax positions in all periods.

11. Commitments and Contingencies

Liability Claims

At December 31, 2019 and 2018 our unreported loss liability was $1.9 million and $1.7 million, respectively. As of December 31, 2019 and 2018, the related insurance recoverable amounts were $935,000 and $693,000, 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, 2019 could be estimated to be as high as $3.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreements

In July 2014 our Board of Directors appointed Mr. James P. Mackin as President and Chief Executive Officer ("CEO"), and we and Mr. Mackin entered into an employment agreement, which became effective September 2, 2014. The employment agreement has an initial three-year term. Beginning on the second anniversary of the effective date, and subject to earlier termination pursuant to the agreement, the employment term will, on a daily basis, automatically extend by one day. The agreement 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 paid $500,000 to SMI in January 2015 related to the achievement of a contingent milestone. 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 second half of 2020.

As of December 31, 2019 we had $1.5 million in prepaid royalties, $2.0 million in net intangible assets, and $1.3 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. Shareholders' Equity

In December 2017 we issued 2,682,754 shares of CryoLife common stock, as part of the consideration for the JOTEC Acquisition. The stock had a value of $53.1 million as determined on the date of the closing. See Note 3 for further discussion of the JOTEC Acquisition.

13. 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 2019 and 3% in 2018 and 2017. Our contributions approximated $1.6 million, $1.4 million, and $1.4 million for the years

ended 2019, 2018, and 2017, 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

On January 1, 2011 we initiated a nonqualified Deferred Compensation Plan ("Deferred Plan"). The 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.

14. 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, 2019, 2018, and 2017 the sources of revenue were as follows (in thousands):

	2019	2018	2017
Domestic hospitals	$ 144,538	$ 138,432	$ 128,240
International hospitals	85,241	81,203	23,791
International distributors	40,427	36,989	30,805
CardioGenesis cardiac laser therapy	6,016	6,217	6,866
Total sources of revenue	**$ 276,222**	**$ 262,841**	**$ 189,702**

Also see segment and geographic disclosure in Note 18 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, 2019 and 2018.

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, 2019 and 2018 were not material.

15. Stock Compensation

Overview

We are currently authorized to grant and have available for grant the following number of shares under our stock plans as of December 31, 2019 and 2018:

Plan	Authorized Shares	Available for Grant	
		2019	2018
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	234,000	295,000
2009 Equity and Cash Incentive Plan	9,000,000	2,100,000	958,000
Total	10,900,000	2,334,000	1,253,000

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 2019 the Compensation Committee of our Board of Directors (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 adjusted earnings before interest, taxes, depreciation, and amortization, ("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. The first performance period under the LTIP will not conclude until December 31, 2021.

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.

In 2017 the Committee authorized awards from approved stock incentive plans of RSAs to non-employee Directors, RSUs to certain employees, and RSAs, PSAs, and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 426,000 shares of common stock and had an aggregate grant date market value of $7.1 million. The performance component of PSU awards granted in 2017 was based on attaining specified levels of adjusted EBITDA, adjusted inventory levels, and adjusted trade accounts receivable days' sales outstanding, each as defined in the PSU grant documents, for the 2017 calendar year. The PSUs granted in 2017 earned approximately 92% of the target number of shares.

A summary of stock grant activity for the years ended December 31, 2019, 2018, and 2017 for RSAs, PSAs, 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, 2016	392,000	$ 10.64
Granted	138,000	17.00
Vested	(129,000)	10.84
Forfeited	(18,000)	11.78
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

PSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2016	250,000	$ 10.18
Granted	--	--
Vested	(250,000)	10.18
Forfeited	--	--
Unvested at December 31, 2017	--	--
Granted	--	--
Vested	--	--
Forfeited	--	--
Unvested at December 31, 2018	-	--
Granted	--	--
Vested	--	--
Forfeited	--	--
Unvested at December 31, 2019	-	--

RSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2016	178,000	1.24	$ 3,405,000
Granted	196,000		
Vested	(64,000)		
Forfeited	(24,000)		
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
Vested and expected to vest	226,000	0.93	$ 6,131,000

PSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2016	188,000	0.77	$ 3,603,000
Granted	126,000		
Vested	(128,000)		
Forfeited	(17,000)		
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
Vested and expected to vest	347,000	2.33	$ 9,400,000

During the years ended December 31, 2019, 2018, and 2017 the total fair value of $9.8 million, $7.3 million, and $11.1 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 169,000, 219,000, and 260,000 shares in 2019, 2018, and 2017, 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, 2019, 2018, and 2017 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2016	1,911,000	$ 8.59	3.55	$ 20,179,000
Granted	260,000	16.30		
Exercised	(394,000)	6.30		
Forfeited	(31,000)	12.47		
Expired	(5,000)	7.01		
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		
Expired	--	--		
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		
Expired	--	--		
Outstanding at December 31, 2019	1,129,000	16.14	3.67	12,763,000
Vested and expected to vest	1,129,000	$ 16.14	3.67	$ 12,763,000
Exercisable at December 31, 2019	782,000	$ 12.55	2.89	$ 11,371,000

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

	2019	2018	2017
Weighted-average fair value of options granted	$ 11.47	$ 8.38	$ 5.97
Intrinsic value of options exercised	6,519,000	9,961,000	4,748,000

Employees purchased common stock totaling 61,000, 83,000, and 93,000 shares in 2019, 2018, and 2017, respectively, through our ESPP.

Stock Compensation Expense

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

	2019		2018		2017	
	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	4.75 Years	0.50 Years
Expected stock price volatility	0.40	0.39	0.40	0.34	0.40	0.39
Risk-free interest rate	2.54%	2.35%	2.64%	1.73%	1.87%	0.85%

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

	2019	2018	2017
RSA, PSA, RSU, and PSU expense	$ 7,451	$ 5,076	$ 5,335
Stock option and ESPP option expense	1,960	1,732	1,978
Total stock compensation expense	$ 9,411	$ 6,808	$ 7,313

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 $612,000, $484,000, and $394,000 in the years ended December 31, 2019, 2018, and 2017, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of December 31, 2019 we had total unrecognized compensation costs of $11.9 million related to RSAs, RSUs, and PSUs and $2.0 million related to unvested stock options. As of December 31, 2019 this expense is expected to be recognized over a weighted-average period of 1.5 years for RSUs, 1.4 years for stock options, 1.0 years for RSAs, and 2.3 years for PSUs.

16. Income (Loss) 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 income (loss) per common share	**2019**	**2018**	**2017**
Net income (loss)	$ 1,720	$ (2,840)	$ 3,704
Net (income) loss allocated to participating securities	(12)	27	(63)
Net income (loss) allocated to common shareholders	$ 1,708	$ (2,813)	$ 3,641
Basic weighted-average common shares outstanding	37,118	36,412	33,008
Basic income (loss) per common share	$ 0.05	$ (0.08)	$ 0.11

Diluted income (loss) per common share	**2019**	**2018**	**2017**
Net income (loss)	$ 1,720	$ (2,840)	$ 3,704
Net (income) loss allocated to participating securities	(12)	27	(61)
Net income (loss) allocated to common shareholders	$ 1,708	$ (2,813)	$ 3,643
Basic weighted-average common shares outstanding	37,118	36,412	33,008
Effect of dilutive options and awards[a]	742	-	1,155
Diluted weighted-average common shares outstanding	37,860	36,412	34,163
Diluted income (loss) per common share	$ 0.05	$ (0.08)	$ 0.11

[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, 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 and 2017 stock options to purchase 131,000 and 227,000 shares, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

17. Transactions with Related Parties

A member of our Board of Directors and a shareholder of the Company, who retired from the Board of Directors during 2018, was the former Chief of Thoracic Surgery of a university hospital that generated product and preservation services revenues of $499,000, $443,000, and $133,000 for us in 2019, 2018, and 2017, respectively. Additionally, the son of this former member of our Board of Directors received a retainer for performing heart and lung transplants from a medical center that generated product and preservation services revenues of $1.1 million, $745,000, and $793,000 for us in 2019, 2018, and 2017, respectively.

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 $341,000 and $296,000 in 2019 and 2018, respectively.

18. Segment and Geographic Information

We have two reportable segments organized according to our products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue, JOTEC products, 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):

	2019	2018	2017
Revenues:			
Medical devices	$ 197,246	$ 187,394	$ 119,631
Preservation services	78,976	75,447	70,071
Total revenues	276,222	262,841	189,702
Cost of products and preservation services:			
Medical devices	55,022	53,772	29,798
Preservation services	38,187	36,085	31,262
Total cost of products and preservation services	93,209	89,857	61,060
Gross margin:			
Medical devices	142,224	133,622	89,833
Preservation services	40,789	39,362	38,809
Total gross margin	$ 183,013	$ 172,984	$ 128,642

Net revenues by product for the years ended December 31, 2019, 2018, and 2017 were as follows (in thousands):

	2019	2018	2017
Products:			
BioGlue	$ 68,611	$ 66,660	$ 65,939
JOTEC	64,974	63,341	4,136
On-X	50,096	44,832	37,041
CardioGenesis cardiac laser therapy	6,016	6,217	6,866
PerClot	3,795	3,767	3,533
PhotoFix	3,754	2,577	2,116
Total products	197,246	187,394	119,631
Preservation services:			
Cardiac tissue	40,879	35,683	32,510
Vascular tissue	38,097	39,764	37,561
Total preservation services	78,976	75,447	70,071
Total revenues	$ 276,222	$ 262,841	$ 189,702

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2019, 2018, and 2017 were as follows (in thousands):

	2019	2018	2017
U.S.	$ 150,553	$ 144,651	$ 135,102
International	125,669	118,190	54,600
Total revenues	$ 276,222	$ 262,841	$ 189,702

For the years ended December 31, 2019 and 2018, revenues attributed to customers in Germany accounted for 10% of total revenues as a result of the acquisition of JOTEC in December 2017. During December 31, 2017 revenues attributed to customers in any individual country outside the U.S. were 10% or less of total revenues.

At December 31, 2019 and 2018, 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 $14.1 million as of December 31, 2019, of which 97% were located in Hechingen, Germany. Our long-lived international assets were $13.1 million as of December 31, 2018, of which 98% were located in Hechingen, Germany. At December 31, 2019 and 2018, $186.7 million and $188.8 million, respectively, of our goodwill was allocated entirely to our Medical Devices segment.

SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)
(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE:				
2019	$ 67,505	$ 71,139	$ 67,881	$ 69,697
2018	61,948	68,496	64,598	67,799
2017	45,059	47,818	43,999	52,826 *
GROSS MARGIN:				
2019	$ 44,273	$ 46,966	$ 45,222	$ 46,552
2018	39,228	45,851	42,714	45,191
2017	29,512	32,905	29,862	36,363 *
NET (LOSS) INCOME:				
2019	$ (297)	$ 2,832	$ (134)	$ (681)
2018	(3,855)	226	1,565	(776)
2017	2,223	3,163	1,325	(3,007)*
(LOSS) INCOME PER COMMON SHARE—DILUTED:				
2019	$ (0.01)	$ 0.07	$ 0.00	$ (0.02)
2018	(0.11)	0.01	0.04	(0.02)
2017	0.06	0.09	0.04	(0.09)*

* In December 2017 we completed our acquisition of JOTEC, which is operated as a wholly-owned subsidiary of CryoLife.

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, 2019, 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 70 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 71 of this report.

Changes in Internal Control over Financial Reporting

On November 1, 2019, we were notified that we had become a victim of a business e-mail compromise. During the fourth quarter, 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. The impersonator had taken a number of steps to deceive our employees and reduce the likelihood of detection. We expect our cyber-insurance to cover all but a de minimis amount of the unrecovered losses from this compromise.

We believe the fraudulent breach occurred as a result of a significant deficiency in our controls relating to certain electronic payments. During the fourth quarter of 2019, we made enhancements to our controls relating to electronic payments. These enhancements included additional verification and documentation procedures to be followed prior to our initiation and approval of electronic payments. We believe these enhancements increase the ability of our personnel to identify and block attempts by third parties to fraudulently initiate electronic payments from us. We believe that the foregoing actions improved our internal controls over financial reporting. Our management has concluded the significant deficiency associated with this fraudulent breach has been remediated.

During the quarter ended December 31, 2019, other than as discussed above, there were no other 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, 2019, with the exception of information concerning executive officers listed below.

The following table lists the executive officers of CryoLife as of December 31, 2019 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	53	Chairman, President, and Chief Executive Officer
Thomas J. Bogenschütz	Since 2018	53	Senior Vice President, EMEA, General Manager, Hechingen
Scott B. Capps	Since 2007	53	Vice President, Clinical Research
John E. Davis	Since 2015	55	Senior Vice President, Global Sales and Marketing
Matthew A. Getz	Since 2019	51	Vice President, Human Resources
Jean F. Holloway, Esq.	Since 2015	62	Senior Vice President, General Counsel, Chief Compliance Officer, and Secretary
Amy D. Horton, CPA	Since 2006	49	Vice President and Chief Accounting Officer
D. Ashley Lee, CPA	Since 2000	55	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Dennis B. Maier	Since 2017	46	Vice President, Operations
Michael S. Simpson	Since 2018	52	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.

Thomas J. Bogenschütz was appointed to the position of Senior Vice President, Europe, Middle East, and Africa and General Manager of JOTEC GmbH in Hechingen, Germany. Mr. Bogenschütz has 25 years of experience in the cardiac and vascular business. Over the past 16 years, while Mr. Bogenschütz served as CEO of the JOTEC Group, he developed the business into a leading European company in the vascular and endovascular industry. Prior to joining JOTEC, Mr. Bogenschütz worked as Investment Manager at LSmedcap GmbH where he developed and managed several medical startup companies. He began his career in the cardiac industry in various sales and marketing leadership roles. Mr. Bogenschütz received his Bachelor of Science in Industrial Engineering from the University of Applied Science, Esslingen, 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 20 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 will oversee 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 Bachelor of Science 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, 2019.

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, 2019.

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, 2019.

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, 2019.

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 74.

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 19, 2020 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 19, 2020
/s/ D. Ashley Lee **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 19, 2020
/s/ Amy D. Horton **Amy D. Horton**	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 19, 2020
/s/ Thomas F. Ackerman **Thomas F. Ackerman**	Director	February 19, 2020
/s/ Daniel J. Bevevino **Daniel J. Bevevino**	Director	February 19, 2020
/s/ Marna P. Borgstrom **Marna P. Borgstrom**	Director	February 19, 2020
/s/ James W. Bullock **James W. Bullock**	Director	February 19, 2020
/s/ Jeffrey H. Burbank **Jeffrey H. Burbank**	Director	February 19, 2020
/s/ Ronald D. McCall **Ronald D. McCall**	Director	February 19, 2020
/s/ Harvey Morgan **Harvey Morgan**	Director	February 19, 2020
/s/ Jon W. Salveson **Jon W. Salveson**	Director	February 19, 2020

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.)
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, 2019)
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.
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.
10.2(c)†*	Form of 2019 Long Term Incentive Program Performance Share Award Agreement pursuant to the CryoLife, Inc. Equity and Cash Incentive Plan.
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.)
10.3	CryoLife, Inc. Employee Stock Purchase Plan. (Incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement filed April 10, 1996.)
10.3(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.)

Exhibit Number	Description
10.4†	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.)
10.5†*	Summary of 2019 Compensation Arrangements with Non-Employee Directors.
10.6†	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.)
10.7†	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.)
10.8†	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.)
10.9†	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.)
10.10†	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.)
10.11†	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	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.)
10.12 (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.)
10.12 (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.)
10.12 (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.)
10.13++	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.)

Exhibit Number	Description
10.13 (a)++	First Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated November 15, 2012. (Incorporated herein by reference to Exhibit 10.14(a) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.13 (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.)
10.13 (c)++	Third Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated January 29, 2015. (Incorporated herein by reference to Exhibit 10.14(c) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
10.14	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.)
10.14(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.)
10.15++	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.)
10.15(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.)
10.16	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.)
10.16(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.)
10.17	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.)
10.18+	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.)
10.19*+	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

*Filed herewith.

**Furnished herewith.

† Indicates management contract or compensatory plan or arrangement.

∞ Indicates that the 2018 form was used in 2019.

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

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

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Description of Capital Stock

CryoLife Inc., a Florida corporation (the "Company"), is authorized to issue up to 75,000,000 shares of common stock and 5,000,000 shares of preferred stock.

The Company's common stock, par value $0.01 per share ("common stock"), is registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is the only class of the Company's securities that was registered under Section 12 of the Exchange Act as of the end of the fiscal year covered by the Company's Annual Report on Form 10-K to which this Exhibit is filed, or incorporated by reference, as an exhibit.

The following summary of the terms of the common stock is qualified in its entirety by reference to the complete text of the Company's Amended and Restated Articles of Incorporation, as amended (the "Articles of Incorporation"), the Company's Amended and Restated Bylaws, as amended (the "Bylaws"), and the Florida Business Corporation Act (the "FBCA").

Common Stock

Holders of common stock are entitled to one vote per share of common stock held of record on all matters to be voted upon by the Company's shareholders generally. Holders of common stock are not entitled to cumulative voting rights.

Holders of common stock are entitled to receive, on a pro rata basis, such dividends and distributions, if any, as may be declared from time to time by the Board of Directors out of funds legally available therefor, subject to any preferential dividend right of any issued and outstanding shares of preferred stock. In the event of liquidation, dissolution or winding up of the Company, after payment of creditors, holders of common stock are entitled to share ratably in all assets of the Company, subject to the payment of any liquidation preference of any issued and outstanding shares of preferred stock. Furthermore, holders of common stock have no conversion, sinking fund or redemption rights, or preemptive rights to subscribe for any of the Company's securities. The shares of common stock currently outstanding are validly issued, fully paid and non-assessable.

Preferred Stock

The Board of Directors of the Company is empowered, without approval of the Company's shareholders, to cause shares of preferred stock to be issued in one or more series and to fix and determine the relative rights and preferences of the shares of any such series, subject to the limitations of the FBCA. Because the Board of Directors has the power to establish the preferences and rights of each series, it may afford the holders of any series of preferred stock rights and preferences, voting or otherwise, senior to the rights of holders of common stock.

While providing desirable flexibility for possible acquisitions and other corporate purposes, and eliminating delays associated with a shareholder vote on specific issuances, the issuance of preferred stock could adversely affect the voting, dividend and liquidation rights of holders of common stock.

Articles of Incorporation and Bylaws

Certain provisions of the Articles of Incorporation, the Bylaws and the FBCA, which are summarized below, could have the effect of making it more difficult to change the composition of the Company's Board of Directors or for any person or entity to acquire control of the Company.

Preferred Stock

As noted above, the Board of Directors may issue preferred stock without shareholder approval. Consequently, the Company's preferred stock could be issued quickly and utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company or make removal of management and directors more difficult.

Special Meetings

Pursuant to the Articles of Incorporation and Bylaws, special meetings of the shareholders may be called only by the President or Secretary at the request in writing of a majority of the Board of Directors then in office or at the request in writing of shareholders owning not less than 50% of all votes entitled to be cast at the special meeting. Only business within the purpose or purposes described in the special meeting notice may be conducted at the special meeting.

Prohibition of Shareholder Action Without a Meeting

Under the Articles of Incorporation, the Company's shareholders may not take action by written consent. Any and all action by the shareholders must be taken at either the annual shareholders' meeting or at a special shareholders' meeting.

Advance Notice of Shareholder Proposals and Nominations for Directors

Shareholders who seek to nominate directors or to bring business before a shareholder meeting must comply with specified timing requirements and submit to the Company certain information in advance of such meeting, as set forth in the Bylaws. These provisions may impede a shareholder's ability to bring matters before an annual or special meeting or make nominations for directors.

Effect of Florida Affiliated Transactions and Anti-Takeover Statutes

As a Florida corporation, the Company is subject to certain anti-takeover provisions that apply to public corporations under the FBCA. Pursuant to Section 607.0901 of the FBCA, a publicly held Florida corporation may not engage in a broad range of business combinations or other extraordinary corporate transactions with an interested shareholder for a period of three (3) years following the time that such shareholder became an interested shareholder, unless:

- such business combination or other extraordinary corporate transaction (including a transaction which resulted in the shareholder becoming an interested shareholder) is approved by a majority of disinterested directors before the subject shareholder becomes an interested shareholder;
- upon consummation of such a business combination or extraordinary corporate transaction that resulted in the subject shareholder becoming an interested shareholder, such shareholder owned at least 85% of the outstanding voting shares of the corporation at the time such transaction commenced, exclusive of shares owned by directors, officers and certain employee stock plans; or
- at or subsequent to the time the subject shareholder became an interested shareholder, such business combination or other extraordinary corporate transaction is approved by the Board of Directors and authorized by an affirmative vote of the holders of two-thirds of the voting shares of the corporation (excluding shares held by the interested shareholder) at an annual or special meeting of shareholders, and not by written consent.

The above requirements do not apply to such business combinations or other extraordinary corporate transactions with an interested shareholder if:

- the corporation has not had more than 300 shareholders of record at any time during the three years preceding the announcement date of any such business combination;
- the interested shareholder has owned at least 80% of the corporation's outstanding voting shares for at least three (3) years preceding the announcement date of any such business combination;

- the interested shareholder is the beneficial owner of at least 90% of the outstanding voting shares of the corporation, exclusive of shares acquired directly from the corporation in a transaction not approved by a majority of the disinterested directors; or

- the consideration paid to the holders of the corporation's voting stock is at least equal to certain fair price criteria.

An interested shareholder is generally defined as a person who, together with affiliates and associates, beneficially owns more than 15% of a corporation's outstanding voting shares. The Company has not made an election in the Articles of Incorporation to opt out of Section 607.0901.

In addition, the Company is subject to Section 607.0902 of the FBCA, which prohibits the voting of shares in a publicly held Florida corporation that are acquired in a control share acquisition unless (i) the Board of Directors approved such acquisition prior to its consummation or (ii) after such acquisition, in lieu of prior approval by the Board of Directors, the holders of a majority of the corporation's voting shares, exclusive of shares owned by officers of the corporation, employee directors or the acquiring party, approve the granting of voting rights as to the shares acquired in the control share acquisition. A control share acquisition is defined as an acquisition that immediately thereafter entitles the acquiring party to 20% or more of the total voting power in an election of directors.

Although the FBCA permits a corporation to opt out of these requirements, the Company has not elected to opt out, which may have the effect of making it more difficult for any person or group to acquire the Company or substantial amounts of the Company's common stock, or engage in any "affiliated transaction," including the acquisition of a substantial amount of the Company's assets.

Ability to Consider Other Constituencies

The directors of the Company are subject to the "general standards for directors" provisions set forth in Section 607.0830 of the FBCA. These provisions provide that, among other things, in discharging his or her duties and determining what is in the best interests of the Company, a director may consider such factors as the director deems relevant, including the long-term prospects and interests of the Company and its shareholders, and the social, economic, legal or other effects of any proposed action on the employees, suppliers or customers of the Company or its subsidiaries, the communities and society in which the Company or its subsidiaries operate, and the economy of the state and the nation. Consequently, in connection with any proposed corporate action, the Board of Directors is empowered to consider interests of other constituencies in addition to the interests of the Company's shareholders. Shareholders should be aware that directors who take into account these other factors may make decisions which are less beneficial to the shareholders than if the law did not permit consideration of such other factors.

Shareholder Action

Except as otherwise provided by the FBCA or in the Articles of Incorporation or Bylaws, if a quorum is present at any annual or special meeting of shareholders, the approval by holders of a majority of the shares of common stock present in person or represented by proxy at such meeting and entitled to vote is sufficient to authorize, affirm, ratify or consent to a matter voted on by shareholders. The FBCA requires the approval of the holders of a majority of the outstanding stock entitled to vote for certain extraordinary corporate transactions, such as a merger, share exchange, conversion, sale of substantially all assets or dissolution.

Transfer Agent and Registrar

The Transfer Agent and Registrar for the common stock is American Stock Transfer & Trust Company, LLC. It is located at 6201 15th Avenue, Brooklyn, NY 11219, and its telephone number is (718) 921-8124.

Listing

The common stock is listed on the New York Stock Exchange under the symbol "CRY."

CERTAIN INFORMATION HAS BEEN OMITTED FROM THE VERSION OF THISEXHIBIT FILED WITH THE SECURITIES AND EXCHANGE COMMISSIONBECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELYHARMFUL IF PUBLICLY DISCLOSED

CLINICAL RESEARCH AGREEMENT

This Clinical Research Agreement ("**Agreement**") is entered into this 10th day of October, 2019, ("**Effective Date**") by and between CryoLife, Inc. ("**Sponsor**"), a corporation with its principal place of business at 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, and Duke University, a tax-exempt research and educational institution acting for and on behalf of its Duke Clinical Research Institute ("**Duke**"), with an office at 300 West Morgan Street, Suite 800, Durham, North Carolina 27701 (individually, a "**Party**" and collectively, the "**Parties**").

R E C I T A L S

WHEREAS Sponsor wishes to conduct a program of clinical research and development entitled, "*Clinical Trial of the On-X® Aortic Valve Using Alternative Anticoagulation Prospective Randomized On-X Anticoagulation Clinical Trial with a Factor Xa Inhibitor (PROACT-Xa)*" (the "**Study**"); and,

WHEREAS, Duke has the facilities and the personnel with the requisite skills, experience, and knowledge as an Academic Research Organization to coordinate the Study; and

WHEREAS, Sponsor and Duke enter into this Agreement to set forth the terms and conditions upon which Sponsor and Duke will conduct the Study; and

WHEREAS, the Study contemplated by this Agreement shall be of mutual interest and benefit to Sponsor and Duke, and shall further the instructional and research objectives of Duke in a manner consistent with its status as a nonprofit research, education, and healthcare institution; and

NOW, THEREFORE, in consideration of the foregoing facts and the mutual covenants set forth herein, the Parties hereto agree as follows:

1. Scope of Work.

1.1. Study. The research to be conducted by Duke under this Agreement shall be conducted as set forth in the scope of work ("**Scope of Work**"), attached hereto as **Appendix A** and incorporated by reference. The Study shall be conducted in accordance with the Study protocol (the "**Protocol**"), attached hereto as **Appendix B** and incorporated herein by reference, as may be amended from time to time by Sponsor, which fully details the clinical research activities and responsibilities to be undertaken as part of the Study; provided, however, that Duke's obligation to conduct the Study is expressly conditioned upon the approval of its Institutional Review Board ("**IRB**"), as set forth in Section 14.2 below.

1.2. Transfer of Obligations. Pursuant to 21 CFR 312.52, this Agreement, and the Appendices annexed hereto shall serve as the written description of the obligations of Sponsor being transferred to Duke under the terms and conditions hereof.

1.3. Coordinating Investigator. The research activities to be conducted by Duke hereunder shall be under the direction of Tracy Wang, MD, ("**Coordinating Investigator**,") who is a full-time faculty member at Duke University.

1.4. Participating Investigators and Institutions. Sponsor shall be responsible for selecting and contracting with the clinical sites conducting the Study ("**Participating Institutions**") and the investigators participating in the Study at each Participating Institution ("**Participating Investigators**").

1.5. Enrollment of Study Subjects. Participating Institutions shall coordinate the enrollment of subjects as participants in the Study ("**Study Subjects**") in accordance with the terms and conditions of the Protocol.

1.6. Supply and Use of the Study Material.

1.6.1. Supply. Duke shall be responsible for sourcing sufficient amounts of any drug, placebo, or comparator drug as applicable (the "**Study Materials**").

1.6.2. Order Placement. Prior to placement, all orders for any Study Materials shall be submitted by Duke to Sponsor for approval, such approval shall not unreasonably be withheld or delayed.

1.6.3. Use. Duke agrees that the Study Materials shall be used only for the Study. As specified in the Scope of Work, Duke shall be responsible for preparing, labeling, and shipping Study Materials to Participating Institutions and Study Subjects as needed to conduct the Study, or contracting with a third-party vendor to do the same.

1.6.4. Expense. Sponsor shall be responsible for reimbursing Duke for the Study Materials.

1.6.5. Unused Materials. Any unused Study Materials that have been delivered to a Participating Institution that remains at the end of that institution's participation in the Study, or that remains at a Participating Institution or Duke at the end of the Study, shall be disposed of in accordance with Sponsor instructions.

2. Inspections and Audits.

2.1 Regulatory Inspections. Authorized representatives of Sponsor may, upon reasonable advance notice, and representatives of the U.S. Food and Drug Administration (the "**FDA**") or any other international health agency having regulatory authority over the subject matter of the Study may, at reasonable times, examine and inspect the facilities being used to conduct the Study, and review all records, procedures and other materials (including case report forms and patient medical records to the extent allowed by the informed consent document or other legal disclosure authorizations) related to the Study, and have access to the Coordinating Investigator to discuss the Study. If Duke is found deficient in any manner by Sponsor and reasonable efforts to correct the deficiency are ineffectual, Sponsor shall either terminate Duke's continued participation in the Study in accordance with the termination provisions of this Agreement or take such corrective actions as may be agreed between Sponsor and Duke. It is further agreed that if Duke is notified that the Study is to be the subject of an audit, Duke shall promptly inform Sponsor. If a formal response to any audit is required, Duke agrees to permit representatives of Sponsor to review and comment on such response and shall give Sponsor reasonable time to do so.

2.2. Compliance Audits. Sponsor has the right to conduct on-site Study compliance audits of Duke at mutually agreed upon times. Audits shall be at no additional cost to Sponsor provided such audits are at mutually agreed intervals and do not significantly alter Duke's ability to meet any deadlines delineated in this Agreement. Sponsor may only request records or documents that are within the scope of the documents Duke is required to maintain under the obligations of this Agreement or otherwise related to the research activities conducted by Duke under this Agreement and the Scope of Work.

3. Debarment.

Duke hereby certifies that it has not been debarred under Article 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §335a(a) or (b). In the event that Duke becomes debarred, Duke agrees to notify Sponsor immediately. Duke hereby certifies that it has not and shall not use in any capacity related to the Study the services of any individual, corporation, partnership, or association which has been debarred under Article 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §335a(a) or (b). In the event that Duke becomes aware of or receives notice of the debarment of any individual, corporation, partnership, or association providing services to Duke which relate to the research conducted under this Agreement, Duke agrees to notify Sponsor immediately.

4. Payment.

4.1. Amount. Sponsor shall compensate Duke according to the Budget and Payment Terms attached hereto as **Appendix C** and incorporated herein by reference.

4.2. Payee. Any payment due from Sponsor set forth in Appendix C shall be tendered in the form of a check payable to Duke University at one of the following addresses:

Duke University Accounts Receivable Lockbox
P.O. Box 602651
Charlotte, NC 28260-2651

Where a physical address is required, checks should be mailed to:

Wells Fargo Lockbox
Duke University Accounts Receivable
Lockbox 602651
1525 West WT Harris Blvd – 2C2
Charlotte, NC 28262

Duke University's Tax ID Number [OMITTED].

4.3. Delays. In the event of Force Majeure (as defined in Section 21 herein) the Parties agree to revise the Budget and Payment Schedule as necessary to reflect cost increases or decreases resulting from said Force Majeure.

4.4. Payment of Invoices. Duke shall invoice Sponsor on a monthly basis for activities set forth in the applicable Budget. Sponsor shall be responsible for paying invoices within thirty (30) calendar days of receipt. Sponsor shall notify Duke of any disputed invoices within twenty (20) calendar days of receiving such invoice and shall pay any undisputed amounts as set forth above. Provided that Sponsor pays undisputed amounts as set forth above, Duke shall continue to conduct research during which time the Parties shall use best efforts to resolve the disputed amount. In the event

that the Parties cannot resolve the disputed amount within twenty (20) calendar days of Duke receiving the invoice dispute notice from Sponsor, Duke shall have the right to stop work upon ten (10) calendar days' written notice to Sponsor. Both Parties agree to continue good faith efforts to resolve the dispute prior to such stoppage of work.

4.5. Default. [Purposely deleted.]

4.6. Reporting. In accordance with the Physician Payment Sunshine Act (a provision of the Patient Protection and Affordable Care Act), Duke agrees that Sponsor shall have the right to publicly disclose Duke's name and the aggregate amount of payment under this Agreement. Sponsor shall designate Duke as the recipient of all payments made in accordance with this Agreement as payments to Duke for research rather than payments to an individual.

5. Modifications and Amendments.

This Agreement may be amended from time to time upon the written agreement of the Parties. The Parties agree to exert good faith efforts to incorporate any revisions required by law, FDA or other international health authorities. Any changes to a Scope of Work or Budget and/or Payment Terms shall be incorporated into this Agreement by means of a written amendment. Duke shall be under no obligation to commence work on any change to the Scope of Work until such amendment is executed.

6. Data.

6.1. Study Data. All data, and results arising out of the study, including the final report, case report forms and other relevant information generated during the Study (collectively, the "**Study Data**") shall be promptly and fully disclosed to Sponsor and shall be freely usable by Sponsor so long as such use is in accordance with applicable laws and this Agreement. In addition, upon Sponsor's request, Duke will promptly provide other documentation arising out of the Study or under this Agreement (including clinical and non-clinical data, study plans and communications, and documents relating to investigator qualifications) to the extent they may be reasonably necessary for purposes of an audit, regulatory submission, Sponsor's management of the Study, or Sponsor's use of the Study results. The Parties agree to cooperate in good faith to narrowly tailor any such requests. Sponsor shall ensure that Duke receives data transfers and/or a final data set of any Study Data developed and/or maintained by Sponsor or any third party in privity of contract with Sponsor that is reasonably required for Duke to fulfill its obligations and exercise its rights pursuant to this Agreement. Except in the event of Sponsor's termination for breach, Duke shall be free to maintain copies of the Study Data and to use the Study Data and results of Duke's research contemplated hereunder for its own teaching, research, education, clinical and publication purposes, and Sponsor shall ensure that Duke receives a copy of the closed, locked, clinical database for the Study for its use prior to the unblinding of the data unless any of the foregoing is prohibited by any applicable privacy or confidentiality obligations or applicable law.

6.2. Data Security. In those instances where 1) Sponsor is requiring Duke to send PHI or Personally Identifiable Information ("**PII**") through Sponsor's system or the system of any third party in privity of contract with Sponsor, or 2) Sponsor or any third party in privity of contract with Sponsor will be connecting to one of Duke's electronic record systems, Sponsor is responsible for ensuring the security of the PHI or PII under Sponsor's or any third party in privity of contract with Sponsor 's possession, custody, or control. Sponsor shall ensure that it or any third party in privity of contract with Sponsor adopts, implements, and maintains appropriate security controls (including encryption in transit) to protect against unauthorized access of any such PHI or PII (including PHI or PII of Duke employees). Sponsor shall notify Duke promptly in the event of

any breach of data security or unauthorized release of any such PHI or PII. Sponsor represents that it has no intention to connect to a Duke secure wifi network but agrees to install whatever endpoint clients are required in the event a connection becomes necessary. Notwithstanding anything in this Agreement to the contrary, any connection to an unsecured network for Study purposes by Sponsor or any third party in privity of contract with Sponsor is not recommended.

6.3. Regulatory Filings. Any and all Study Data and other findings obtained as a result of the Study shall be communicated to Sponsor which shall be free to incorporate such findings in any regulatory filing concerning the Study. Duke and the Coordinating Investigator(s) understand and agree that they shall have no ownership, license, or access rights in, or to, such regulatory filings solely based upon the inclusion of such findings therein, nor shall they acquire any interest whatsoever, except as provided herein, in the Study Data as a result of performing the Study.

7. Inventions.

7.1 Prior Inventions. It is recognized and understood that certain existing inventions and technologies are the separate property of Sponsor or Duke and are not affected by this Agreement, and neither Party shall have any claims to or rights in such prior, separate inventions and technologies, or improvements thereto, except only to the extent required for the conduct of the Study.

7.2 Title. Inventorship of new inventions, developments, or discoveries arising out of the Study (hereinafter "**Invention**") shall be determined in accordance with U.S. patent law or by mutual agreement if the invention is not patentable. All rights, title and interest in and to any Invention that is not a Sponsor Invention, as defined below, shall be based upon inventorship with Sponsor holding sole title to any Invention made solely by Sponsor personnel, Duke holding sole title to any Invention made solely by Duke personnel, and the Parties holding joint title to any Invention made jointly by their personnel during the conduct of the Study (a "**Joint Invention**"). Duke shall promptly disclose to Sponsor in writing on a confidential basis any Invention made solely by Duke personnel or jointly with Sponsor personnel. Sponsor shall promptly disclose to Duke on a confidential basis any Invention jointly made by Sponsor personnel together with Duke personnel.

7.3 Prosecution. Each Party may, with the prior written consent of the other Party, and at its sole expense, prepare and file appropriate U.S. and foreign patent applications for any Joint Invention ("**Joint Application**"). The filing Party will provide the other Party, on a confidential basis, a copy of any such Joint Application filed and any documents received or filed during prosecution thereof, and will provide the other Party an opportunity to comment thereon. A filing Party shall not abandon or allow to be abandoned any Joint Application without first allowing the other Party an opportunity to assume the expense of and responsibility for prosecution. Each Party agrees that, during the term of this Agreement and subsequent to the completion or termination of this Agreement, they will, at the other Party's request and expense, cooperate and take such other actions as may be reasonably necessary to obtain the full benefits, enjoyment, rights, title, and interest in the U.S. and throughout the world in the Joint Invention. Neither Party may license, assign, transfer, pledge, or otherwise encumber any Joint Invention, or enter into any agreement with any third party which conflicts with the other Party's rights in the Joint Invention, without the prior written consent of the other Party.

7.4 Sponsor Inventions. All rights, title, and interest in and to any Invention arising out of Sponsor's documented conception prior to the Effective Date and subsequent reduction to practice, or improvements thereon, shall be owned solely by Sponsor ("**Sponsor Invention**"). Sponsor shall

reimburse Duke or Coordinating Investigator(s) for any reasonable expenses incurred at Sponsor's request to secure title or legal protection for any such Sponsor Invention.

7.5 Grant of Option. Duke hereby grants Sponsor, without option fee other than the consideration of the Study sponsored herein and the reimbursement of all reasonable patent expenses related to the Invention incurred by Duke prior to and during the option period, an option to acquire an exclusive, worldwide, royalty-bearing license to Duke's rights to any Invention which option shall extend for four (4) months after Sponsor's receipt of an Invention disclosure. If Sponsor notifies Duke in writing of its exercise of the option within the option period, then the Parties will have sixty (60) days after such notice to negotiate in good faith a license agreement on commercially reasonable terms unless the Parties mutually agree to extend such time in good faith. If Sponsor does not exercise this option, or notifies Duke that it will not exercise this option, or if the Parties fail to sign a license agreement within said sixty (60) day negotiation period, then Sponsor shall no longer have any claim or interest in Duke's rights in the subject Invention, except that if the Parties are unable to reach agreement on licensing terms then for a period of one year after the negotiation period, Duke will not offer to license the Duke Invention to a third party on terms more favorable to the licensee than those last offered to Sponsor without first giving Sponsor thirty (30) days to accept such terms.

7.6 Reserved Rights. Duke shall reserve the right to use any Invention licensed by Duke to Sponsor for Duke's research, educational, clinical and publication purposes.

8. Confidential Information.

8.1 Confidential Information. "**Confidential Information**" shall mean all non-public, confidential or proprietary information, data, files, documents, or materials of or related to one Party, its affiliates, or its subsidiaries, provided by one Party (the "**Disclosing Party**"), obtained, or accessed by the other Party, whether directly related to the Study or not, whether disclosed to or accessed by the recipient in writing, orally, electronically, visually, or in any other form or medium, and whether clearly identified as "Confidential" by the Disclosing Party at the time of disclosure or not, including, without limitation: (i) unpatented inventions, ideas, methods, and discoveries, know-how, unpublished patent applications, and other confidential intellectual property; (ii) designs, specifications, documentation, components, source code, object code, protocols, and processes; (iii) other information that would reasonably be considered non-public, confidential, or proprietary given the nature of the information and the parties' businesses; and (iv) all notes, analyses, summaries, and other materials prepared by or for a receiving Party or its representatives that contain, are based on or otherwise reflect, to any degree, any of the foregoing. Notwithstanding any of the foregoing, the Disclosing Party shall make a reasonable attempt to disclose Confidential Information in a writing that has been clearly marked and identified as confidential at the time of disclosure; and if such disclosure is made orally, shall make a reasonable attempt to promptly reduce such disclosure to writing and provide the other Party with a record of the disclosure. Specifically excepted from Confidential Information is all information that: (a) was previously known by the receiving Party; (b) is publicly disclosed except by breach of this Agreement either prior to or subsequent to the receiving Party's receipt of such information; (c) is rightfully received by the receiving Party from a third party without an express obligation of confidence; or (d) is independently developed by personnel of the receiving Party without use of Confidential Information of the Disclosing Party.

8.2 Nondisclosure. Subject to the provisions of the section headed "Publication" hereunder (Section 9), the receiving Party shall not disclose Confidential Information of the Disclosing Party to any

third party without prior written authorization from the Disclosing Party. This provision shall remain in effect for five (5) years following the termination of the Study.

8.3 Patient Information. Each Party shall be provided with patient information as allowed by law and the patient consent and authorization documents and shall maintain the confidentiality of all such patient information, unless specifically required to disclose such information by law.

8.4 Legally Required Disclosure. Nothing set forth herein shall operate to prohibit or prevent a Party from disclosing Confidential Information pursuant to any judicial or government request, requirement, or order, provided that the Disclosing Party takes reasonable steps to provide the other Party with sufficient prior notice in order to allow the other Party to contest such request, requirement or order.

9. Publication.

9.1. Sponsor recognizes the importance of communicating medical research and scientific data and its obligations to patients enrolled in the Study and therefore, encourages publication of such material in reputable scientific journals and at professional and/or academic seminars or conferences.

9.2. Neither Duke nor the Coordinating Investigator shall publish or submit for publication, directly or indirectly, any manuscript regarding any aspect of the Study until the earlier of (i) Sponsor or a designee of Sponsor publishes an article in a peer reviewed scientific journal summarizing the data generated by all of the Participating Institutions, (ii) no such article is published within twelve (12) months of the finalization of the Study, or (iii) Sponsor informs Duke that no such article will be published, in which case Duke may publish a manuscript without further delay.

9.3. Duke shall submit to Sponsor for its review and comment a copy of any proposed publication resulting from the Study at least thirty (30) calendar days prior to submission for publication, or at least fifteen (15) calendar days prior to submission for an abstract. Duke shall consider in good faith all comments received from Sponsor during the review period; provided, however, nothing in this Agreement shall prohibit Duke from the publication of all information necessary for the accurate interpretation and presentation of said medical research and scientific data.

9.4. If Sponsor determines that the proposed publication contains patentable subject matter which requires protection, Sponsor may require the delay of publication for an additional period of time not to exceed seventy-five (75) days for the purpose of filing patent applications.

9.5. Duke and the Coordinating Investigator shall give Sponsor and/or Sponsor's personnel appropriate credit for any direct contribution made by them, and shall acknowledge Sponsor's support in all publications and presentations.

9.6. Sponsor shall register the Study with www.clinicaltrials.gov, or an equivalent registry, and all Publications shall be consistent with usual academic standards in a manner compliant with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals guidelines of the International Committee of Medical Journal Editors (http://www.icmje.org).

10. Use of Name.

No Party shall use the name, trademarks, logos, physical likeness or other symbol of any other Party, or its employees, for any marketing, advertising or public relations purposes without the prior written

consent of the affected Party, except as otherwise required by applicable laws. Notwithstanding anything herein to the contrary, Duke shall have the right to post Sponsor's name, the Study name, and the Study period, on Duke's publicly accessible lists of research conducted at Duke and as may be required in submissions to funding agencies. Notwithstanding anything herein to the contrary, Sponsor may use Duke's and Coordinating Investigator's name in any submission to any regulatory authority. Notwithstanding anything herein to the contrary, in the event that Sponsor determines that the Study must be registered on clinicaltrials.gov, it shall be free to disclose the information required by such website, in accordance with applicable laws.

11. Medical Care Costs.

[Purposely Deleted]

12. Indemnification.

12.1 Indemnification by Sponsor. Sponsor agrees to indemnify, hold harmless and defend Duke, its trustees, officers, employees, and agents (collectively, "**Duke Indemnitees**") from and against any and all claims, suits, losses, damages, costs, fees, expenses (including attorneys' fees and discovery and other pre-litigation expenses), and other liabilities asserted by third parties, both government and non–government, resulting from or arising out of the Study under this Agreement (the "**Liabilities**"). Notwithstanding the forgoing, Sponsor shall not be liable to the Duke Indemnitees to the extent Liabilities result from (i) Duke's failure to obtain the prior approval of an IRB in accordance with the IRB's approved procedures; (ii) Duke's failure to follow the Protocol in any material respect or to comply with federal, state, local or international health authority law or regulation in connection with the Study; (iii) Duke's negligence or willful misconduct in connection with the Study; or (iv) any unauthorized warranties by any Duke Indemnitee relating to the Study, Study Materials, or any other drug, device, or procedure used in the Study.

12.2 Indemnification by Duke. Duke agrees to indemnify, hold harmless and defend Sponsor, its directors, officers, employees, and agents to the extent the Liabilities result from (i) Duke's failure to obtain the prior approval of the IRB in accordance with the IRB's approved procedures; (ii) Duke's failure to follow the Protocol in any material respect or to comply with federal, state, local or international health authority law or regulation in connection with the Study; (iii) Duke's negligence or willful misconduct in connection with the Study; (iv) any unauthorized warranties by any Duke Indemnitee relating to the Study, Study Materials, or any other drug, device, or procedure used in the Study; or (v) breach by a Duke Indemnitee of any term, representation or warranty set forth in this Agreement. Notwithstanding the forgoing, Duke shall not be liable to Sponsor in the event of Sponsor's negligence or willful misconduct.

12.3 Indemnification Process. A Party seeking indemnification hereunder shall give notice to the other Party promptly upon receipt of written notice of the potential claim. The Party seeking indemnification shall permit the indemnifying party to assume the defense and/or disposition of any such claim or related litigation, provided that counsel is reasonably acceptable to the Party seeking indemnification. The Party seeking indemnification shall cooperate with the indemnifying Party in all reasonable respects with respect to the defense of any such claim, with the out-of-pocket costs of the Party seeking indemnification to be reimbursed by the indemnifying Party.

12.4 Indemnification for Participating Institutions and Participating Investigators. Sponsor agrees to indemnify, defend and hold harmless Participating Institutions and Participating Investigators,

and their employees, officers, directors and agents from any third party claims, demands, losses, costs or expenses (including reasonable attorneys' expenses) arising as a direct result of the Study which is not due to their failure to obtain any necessary prior approval prior to enrolling Study Subjects or participating in the Study, their failure to follow the Protocol in any material respect, their failure to comply with federal, state, local or international health authority law or regulation in connection with the Study, or the negligence or willful misconduct of the Participating Institutions and Participating Investigators. The form of that indemnification shall be in a document addressed from Sponsor to each Participating Institutions participating in the Study.

12.5 Disclaimer of Warranty. Duke and Sponsor understand and agree that the conduct of the Study is experimental in nature and that no warranty, either expressed or implied, is made regarding the results of any research conducted under this Agreement. Neither party shall be liable for incidental or consequential damages under this Agreement.

13. Insurance.

The Parties hereto warrant that they shall maintain during the term hereof policies of liability insurance with minimum coverage as follows:

13.1 As to Sponsor: Sponsor represents that it carries Commercial Form General Liability Insurance with limits not less than one million dollars ($1,000,000) per occurrence and two million dollars ($2,000,000) annual aggregate and Products and Completed Operations Liability Insurance with limits not less than one million dollars ($1,000,000) per occurrence and three million dollars ($3,000,000) annual aggregate. If Sponsor or any third party in privity of contract with Sponsor will have electronic access to a Duke database holding PHI or PII, or if Sponsor or any third party in privity of contract with Sponsor will manage clinical data, then Sponsor represents that it carries Cyber Liability Insurance with limits not less than two million dollars ($2,000,000) per occurrence and two million dollars ($2,000,000) annual aggregate. Coverage shall provide for a retroactive date of placement coinciding with or prior to the effective date of this Agreement. Sponsor agrees to furnish to Duke upon request a certificate of insurance or evidence of self-insurance acceptable to Duke indicating the required coverage.

13.2 As to Duke: Duke represents that it carries Comprehensive Form General and Professional Liability Insurance with limits of not less than three million dollars ($3,000,000) per occurrence combined single limit and ten million dollars ($10,000,000) annual aggregate. Duke agrees to furnish to Sponsor upon request a certificate of insurance or evidence of self-insurance acceptable to Sponsor indicating the required coverage prior to commencement of the Study.

14. Compliance.

14.1 The Study shall be conducted in compliance with all applicable federal, state, local, international health authority and institutional laws, regulations, and guidelines, including, without limitation, the Health Insurance Portability and Accountability Act (“HIPAA”) of 1996 and all requirements imposed by legally constituted IRBs. Sponsor agrees to collect, use and disclose information with respect to the Study Subjects only in accordance with the informed consents and legal disclosure authorizations obtained from such Study Subjects as part of the Study, unless otherwise required by law.

14.2 Duke shall apply for approval to conduct the Study with Duke's IRB. Sponsor shall cooperate with Duke in preparing and filing the Study protocol, informed consent form, and other information with the IRB.

14.3 During and for a period of at least two (2) years after completion of the Study, Sponsor shall promptly, which should not exceed thirty (30) days, report to Duke and the Coordinating Investigator any information, including data and safety monitoring findings or information contained in site monitoring reports, which could directly affect the safety of past or current Study Subjects or influence the conduct of the Study. In each case, the Coordinating Investigator and Duke shall be free to communicate these findings to each Participating Institution, Study Subject and the IRB.

15. Term.

Term. The term of this Agreement shall commence as of the Effective Date and terminate upon completion of all research contemplated under this Agreement, unless terminated sooner in accordance with the terms herein.

16. Termination.

16.1 Termination by Sponsor. This Agreement may be terminated by Sponsor, or Sponsor may terminate or suspend enrolment of Study Subjects, immediately upon written notice to Duke, in the following circumstances:

(a) Authorization and approval to perform the Study in the United States is withdrawn by the FDA on a permanent or temporary basis;

(b) Sponsor becomes aware of any efficacy or safety information that could significantly affect or alter continuation of the Study;

(c) A material event adversely affecting Sponsor's ability to finance the Study; or

(d) Duke, a Participating Institution, or the Coordinating Investigator commit a violation or suspected violation of any applicable laws and regulations, the Protocol, or this Agreement.

Notwithstanding anything in this Agreement to the contrary, Sponsor may terminate the conduct of the Study under this Agreement for any reason or no reason at all, upon at least 30 days prior written notice to Duke. The date of termination in such case shall be the date specified in such notice.

16.2 Termination for Breach. This Agreement may be terminated by either Party upon the occurrence of any material breach or default by the other Party, provided that the breaching or defaulting party shall be given not less than thirty (30) days prior written notice and the opportunity to cure the breach or default during such period. Excluding the process related to disputed invoices as set forth in Section 4.5, if Sponsor breaches the payment terms set forth in Section 4 of this Agreement, Duke shall have the right to give a written notice of breach ("**Payment Notice**") immediately after such breach. Unless Sponsor cures such breach, Duke shall have the right to stop work after fifteen (15) calendar days of a Payment Notice to Sponsor.

16.3 Wind-Down Plan Upon Termination. Both Duke and Sponsor recognize that early termination of this Agreement requires both discussion and coordination between the Parties to ensure patient safety, continuity of treatment, if appropriate, and compliance with all applicable regulations. Upon early termination of this Agreement, the Parties shall cooperate to provide for an orderly

cessation of the Study or transfer of Duke's responsibilities hereunder to Sponsor or its designee. Each Party further agrees to take no action or forego taking action if such action or forbearance would in any manner jeopardize patient safety or the utility, quality, or integrity of the Study, or violate or cause the other Party to violate any applicable laws. In addition, Duke shall promptly conduct such activities as are reasonably necessary in connection with the orderly wind-down of the Study or the transfer of Duke's responsibilities to Sponsor or its designee. Based upon Sponsor's written instructions regarding the scope of activities to be conducted by Duke in connection with termination of the Study or transfer of Duke's responsibilities hereunder, to be delivered to Duke as soon as possible after notice of termination is received, Duke shall submit to Sponsor a wind-down, close out, or transfer plan to accomplish the tasks or research identified by Sponsor's written instructions together with a budget to be mutually agreed in writing ("**Plan**").

16.4 Handling Data Upon Termination. The Parties agree that the transfer of the Study Data and outstanding reports are critically important to both Parties. The Plan shall include the procedures and responsibilities of each Party including but not limited to the orderly collection of all patient data outstanding at participating sites, data analysis and entry of such data into the Study database, and any manuscript resulting therefrom.

16.5 Compensation Upon Termination. Upon early termination of this Agreement, Sponsor shall promptly compensate Duke for all work and research performed under this Agreement up to the effective date of termination, and reimburse Duke for any non-cancelable commitments and all activities in connection with the orderly wind-down and close out of the Study pursuant to the Plan. In the event of early termination hereunder, Sponsor shall compensate Duke for the processing of any data collected, analyzed, and entered into the applicable database in accordance with a Plan.

16.6 Termination Survival. Notwithstanding any termination or expiration of this Agreement, or any Study Addendum hereto, Sections 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 19 shall survive any termination of this Agreement.

17. Notices.

Any notice or other communication required or permitted under this Agreement shall be in writing and shall be deemed given as of the date it is received by the receiving Party. Notice shall be given to the Parties at the addresses listed below, or such alternative address as may be provided by one Party to the other in writing:

As to Duke:
Office of Research Contracts
Attn: Director
2200 West Main Street, Suite 900
Durham, NC 27705

With a copy to:
Duke Clinical Research Institute
Attn: Contracts Management
300 West Morgan Street, Suite 800
Durham, NC 27701

As to Sponsor:
Attention: Scott B. Capps
Vice President, Clinical Research
1655 Roberts Blvd., NW
Kennesaw, GA 30144

With a copy to:
Attention: General Counsel
1655 Roberts Blvd., NW
Kennesaw, GA 30144

18. Relationship of the Parties.

Duke's relationship to Sponsor under this Agreement shall be that of an independent contractor and not an agent, joint venture, or partner of Sponsor. No Party hereto shall have, or shall represent that it has, any power, right or authority to bind the other Party hereto to any obligation or liability without express authorization from such other Party.

19. Arbitration.

The Parties agree to attempt to resolve promptly any dispute arising out of or relating to this Agreement by good faith negotiation; provided, however, if such attempts at dispute resolution shall fail, disputes relating to the terms and conditions of this Agreement shall be exclusively resolved, upon written request by either Party, by final and binding arbitration in a mutually agreed location, or a location chosen by the chair of the arbitration panel if the Parties cannot agree, pursuant to the commercial arbitration rules of the American Arbitration Association, in accordance with the following procedures:

(a) The arbitration tribunal shall consist of three arbitrators. The Parties shall respectively nominate one arbitrator in the request for arbitration and one arbitrator in the answer thereto, and the two arbitrators so named will then jointly appoint a third arbitrator as chairperson of the arbitration tribunal.

(b) The decision of the arbitration tribunal shall be final and binding upon the Parties hereto, and judgment upon such decision may be entered in any competent court for juridical acceptance of such an award and order of enforcement. Each Party hereby submits itself to the courts of the place of arbitration, but only for the entry of judgment with respect to the decision of the arbitrators hereunder.

20. Similar Research.

Nothing in this Agreement shall be construed to limit the freedom of Duke or its researchers who are participants under this Agreement, from engaging in similar research made under other grants, contracts or agreements with parties other than the Sponsor subject to the confidentiality provisions herein.

21. Force Majeure.

If either Party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such Parties direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather or other reason beyond the Party's control (a "**Disability**") then such Party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The Party affected by the Disability shall notify the other Party of such Disability as provided for herein.

22. Non-Solicitation.

[Purposely deleted]

23. Entire Agreement.

This Agreement constitutes the full and complete understanding of the Parties hereto with respect to the subject matter hereof and supersedes all prior understandings and agreements with respect to such subject

matter. Any handwritten modifications to this Agreement shall be null and void unless such modifications are initialed by both Parties.

24. No Waivers.

No delay or omission by a Party hereto to exercise any right under this Agreement shall impair any such right or power or be construed to be a waiver thereof. A waiver by any of the Parties hereto of any of the covenants, conditions or agreements herein contained shall not be construed to be a waiver of any succeeding breach thereof or of any covenant, condition or agreement herein contained. No waiver or discharge of any provisions of this Agreement shall be valid unless it is in writing and is executed by the Party against whom such change or discharge is sought to be enforced.

25. Severability.

If a judicial determination is made that any of the provisions contained in this Agreement constitute an unreasonable restriction against a Party or are otherwise unenforceable, such provision or provisions shall be rendered void or invalid only to the extent that such judicial determination finds such provision or provisions to be unreasonable or otherwise unenforceable, and the remainder of this Agreement shall remain operative and in full force and effect.

26. Headings.

The headings contained in this Agreement do not form a substantive part of this Agreement and shall not be construed to limit or otherwise modify its provisions.

27. Governing Law.

[Purposely deleted.]

IN WITNESS WHEREOF, this Agreement is entered into as of the date first written above.

CryoLife, Inc.:		**Duke University:**	
By:	/s/James P. Mackin	By:	/s/Cory Puryear
Name:	James P. Mackin	Name:	Cory Puryear
Title:	CEO	Title:	Senior Agreement Administration Manager
Date:	10/29/2019	Date:	11/6/19

Appendix A
Scope of Work
[OMITTED]

Appendix B

Study Protocol

[OMITTED]

Appendix C

Budget and Payment Terms

[OMITTED]

Name:	%%FIRST_NAME%-% %%LAST_NAME%-%
Total No. of Units:	%%TOTAL_SHARES_GRANTED%-%

Exhibit 10.2(b)

CRYOLIFE, INC.
EQUITY AND CASH INCENTIVE PLAN
PERFORMANCE SHARE AWARD AGREEMENT

Unless otherwise defined herein, the terms defined in the CryoLife, Inc. Equity and Cash Incentive Plan (the "Plan') will have the same defined meanings in this Performance Share Award Agreement, including the Notice of Stock Unit Grant (the "Notice of Grant") and the Terms and Conditions of Performance Share Award, attached hereto as Exhibit A, together the ("Award Agreement").

NOTICE OF PERFORMANCE STOCK UNIT GRANT

The undersigned Participant has been granted a Performance Share Unit, subject to the terms and conditions of the Plan and this Award Agreement, as follows:

Grant Date: %%OPTION_DATE%-%.

Total Number of Units of Stock Unit Award: %%TOTAL_SHARES_GRANTED%-%

Vesting Schedule:

Performance Stock Units	**Vest Date**
%%SHARES_PERIOD1%-%	%%VEST_DATE_PERIOD1%-%
%%SHARES_PERIOD2%-%	%%VEST_DATE_PERIOD2%-%
%%SHARES_PERIOD3%-%	%%VEST_DATE_PERIOD3%-%

The Award will vest, and common stock ("Shares") of CryoLife, Inc. (the "Company") will be issued, based on a combination of (i) attaining specified levels of 2019 adjusted EBITDA and (ii) the satisfaction of time-based service vesting requirements, as more specifically described below. The weighting of the performance goals (i.e., the percentage of the Target Number of Performance Shares eligible to vest based on the achievement of each goal) shall be as follows: EBITDA component (100%) The Company calculates adjusted EBITDA as GAAP Net Income before interest, taxes, depreciation and amortization, as further adjusted by removing the impact of the following: stock-based compensation; R&D (excluding salaries and related expense); grant revenue; litigation expense or revenue; acquisition, license, and business development expense; integration costs (including any litigation costs or revenue related to assumed litigation); unbudgeted executive severance expenses and on-boarding costs; and GAAP other income or expense.

Adjusted EBITDA Vesting Schedule

If adjusted EBITDA of at least $57,258,000 achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 60% of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of Grant Date.

If adjusted EBITDA of at least $59,279,000 is achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 68 % of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of the Grant Date.

If adjusted EBITDA of at least $61,299,000 achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 76% of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of Grant Date.

If adjusted EBITDA of at least $63,320,000 is achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 84 % of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of the Grant Date.

If adjusted EBITDA of at least $65,341,000 is achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 92 % of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of the Grant Date.

If adjusted EBITDA of at least $67,262,000 achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 100 % of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of Grant Date.

If adjusted EBITDA of at least $69,383,000 is achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 110% of

the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of the Grant Date.

If adjusted EBITDA of at least $71,404,000 achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 120 % of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of Grant Date.

If adjusted EBITDA of at least $73,425,000 is achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 130% of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of the Grant Date.

If adjusted EBITDA of at least $75,445,000 is achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 140 % of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of the Grant Date.

If adjusted EBITDA of at least $77,466,000 is achieved, the Company will fix the number of Shares that may be issued pursuant to the adjusted EBITDA component of the Award at 150 % of the target number of Shares related to adjusted EBITDA; 50% of the fixed Shares will vest on the anniversary of the Grant Date, 25% of the fixed Shares will vest on the second anniversary of the Grant Date, and the final 25% of the fixed Shares will vest on the third anniversary of the Grant Date.

By Participant's electronic acceptance and the electronic signature of the CryoLife, Inc (the "Company") representative below, Participant and the Company agree that this Award is granted under and governed by the terms and conditions of the Plan and this Award Agreement, including exhibits hereto, all of which are made a part of this document. Should the Plan and this Award Agreement conflict, the Plan governs. Participant has reviewed the Plan and this Award Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Award Agreement and fully understands all provisions of the Plan and Award Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Company upon any questions relating to the Plan and Award Agreement. Participant further agrees to notify the Company upon any change in the residence address indicated below.

After reviewing the documents noted above, please accept this Performance Share Award online where indicated on ETrade.com and retain a copy for your files. Please note that your electronic acceptance of this Performance Share Award is required. The Performance Share Award will be cancelled if not accepted within 30 days of the Grant Date noted above.

GRANTED BY:

CRYOLIFE, INC.

//James P. Mackin//
President and CEO

GRANTED TO:

%%FIRST_NAME%-% %%LAST_NAME%-%
%%ADDRESS_LINE_1%-%
%%ADDRESS_LINE_2%-%
%%CITY%-% %%STATE%-% %%ZIPCODE%-%
%%SOCIAL_SECURITY_NUMBER%-%

EXHIBIT A

TERMS AND CONDITIONS OF PERFORMANCE SHARE AWARD

1. Effect of Termination of Service. Participant must be an employee of the Company, CryoLife International, Inc., or another eligible employer approved by the Company's Compensation Committee (the "Committee") of its Board of Directors (each, an "Eligible Employer") on the applicable vesting date to be entitled to the vesting of the Award on such date. If Participant ceases to be an employee of an Eligible Employer for any reason (including, without limitation, by reason of death, disability, or retirement), then the portion of the Award that has not vested as of the date of termination of service shall automatically be forfeited and cancelled as of the date of such termination of service, unless the Committee waives this employment requirement or accelerates the vesting as permitted by the Plan.

2. The Company's Obligation to Pay. Each Performance Share represents the right to receive one (1) share of Company common stock at the target level, and subject to adjustment up or down based upon the Company's adjusted EBITDA performance for 201 8 as further described in the Notice of Grant, on the date the Performance Share vests in accordance with the vesting schedules described in the Notice of Grant (or at such later time as indicated in this Award Agreement or the Plan). Unless and until the Award vests, Participant will have no right to payment of Shares with respect to any such Performance Shares. Prior to actual payment of any Shares with respect to any Performance Shares, such Performance Shares will represent an

unfunded, unsecured obligation of the Company, payable (if at all) only from the general assets of the Company. The number of Shares subject to the Award, i.e., the relevant percentage of target shares that will be issued if time vesting requirements are satisfied, will be determined on and as of the date of filing of the Company's Form 10-K for fiscal 2018 with the Securities and Exchange Commission. Shares will be rounded down to the nearest whole number. No fractional Shares will be issued. **Notwithstanding anything to the contrary contained herein, at any time prior to the first anniversary of the Grant Date, the Committee, in its sole discretion, may reduce the number of Shares to be issued hereunder, but in no event may the number of Shares to be issued be reduced below the target number of Shares. Participant will receive written notice of any such reduction.**

3. Time of Payment.

a. Payment After Vesting. Except as otherwise provided in the Plan, any Performance Shares that vest in accordance with this Award Agreement shall be paid to Participant (or in the event of Participant's death, to Participant's estate), in whole Shares within thirty (30) days after the date on which such Performance Shares vest or as soon as administratively practicable thereafter, but in no event later than the date that is two and one-half months following the later of (i) the end of the Company's taxable year; or (ii) the end of Participant's taxable year that includes the vesting date. Notwithstanding anything in the Plan or this Award Agreement to the contrary, payment to Participant of Shares upon the vesting of a Performance Share shall be delayed to the extent required by Section 409A of the Internal Revenue of 1986, as amended (the "Code").

b. Accelerated Vesting Upon a Change of Control. If the vesting of the balance, or some lesser portion of the balance, of the Performance Shares subject to this Award Agreement is accelerated upon a Change of Control, as such term is defined in the Plan, of the Company, and such Change of Control is not a "change in the ownership or effective control" or "change in the ownership of a substantial portion of the assets" of the Company within the meaning of Section 1.409A-3(i)(5) of the United States Treasury Regulations, then such accelerated Performance Shares shall not be paid until the applicable vesting date of such Performance Shares, as set forth on the Notice of Grant, or if earlier, the date of Participant's death, disability or "separation from service" within the meaning of Section 409A of the Code from the Company (a "Separation from Service"); *provided, however*, that if the payment pursuant to this Section (b) is to be made upon Participant's Separation from Service and as of the date of Participant's Separation from Service Participant is a "specified employee" within the meaning of Section 409A of the Code then payment of the Shares with respect to the Performance Shares subject to this Section (b) shall not be made until the date that is six (6) months and one day following the date of Participant's Separation from Service if earlier payment would result in the imposition of the additional tax under Section 409A of the Code.

4. Rights with Respect to Performance Shares Prior to Vesting. Participant may not transfer or otherwise assign the Award or the Shares subject to the Award prior to vesting. As this Award vests, Participant may receive certificates representing the vested portion or the Shares to be issued or the Shares may be issued in uncertificated form. Prior to issuance of Shares, Participant is not entitled to any rights as a shareholder with respect to the Shares underlying this Award. As a result, subject to the provisions of the Plan, Participant will have no rights to vote such Shares or to receive dividends or other distributions, if any, payable with respect to such Shares after the Grant Date but prior to the issuance of the Shares subsequent to vesting.

5. Withholding of Taxes. Notwithstanding any contrary provision of this Award Agreement, no Shares will be issued to Participant unless and until satisfactory arrangements (as determined by the Committee) have been made by Participant with respect to the payment of federal, state, local or foreign income, employment and other taxes which the Committee determines must be withheld ("Tax Related Items") with respect to the Shares so issuable. The Committee hereby allows Participant, pursuant to such procedures as the Committee may specify from time to time, to satisfy such Tax Related Items, in whole or in part (without limitation) by one or more of the following: (a) paying cash; or (b) electing to have the Company withhold otherwise deliverable Shares having a Fair Market Value, as defined in the Plan, equal to the amount of the Tax Related Items required to be withheld. If the obligation for Tax Related Items is satisfied by withholding a number of Shares as described above, Participant will be deemed to have been issued the full number of Shares subject to the vested Performance Shares, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax Related Items due as a result of any aspect of the Award. If Participant fails to make satisfactory arrangements for the payment of the Tax Related Items at the time any portion of the Award is scheduled to vest, Participant will permanently forfeit such portion of the Award and no Shares will be issued to Participant pursuant to them.

6. Notices. All notices delivered pursuant to this Award Agreement shall be in writing and shall be (i) delivered by hand, (ii) mailed by United States certified mail, return receipt requested, postage prepaid, (iii) sent by an internationally recognized courier which maintains evidence of delivery and receipt, or (iv) sent by email to corpsecretary@cryolife.com. All notices or other communications shall be directed to the following addresses (or to such other addresses as such parties may designate by notice to the other parties):

To the Company: CryoLife, Inc.
1655 Roberts Blvd., NW
Kennesaw, GA 30144
Attention: Corporate Secretary

To Participant: The address set forth in the Notice of Grant.

7. Miscellaneous. Failure by Participant or the Company at any time or times to require performance by the other of any provisions in this Award Agreement will not affect the right to enforce those provisions. Any waiver by Participant or the Company of any condition or of any breach of any term or provision in this Award Agreement, whether by conduct or otherwise, in any one or more instances, shall apply only to that instance and will not be deemed to waive conditions or breaches in the future. If any court of competent jurisdiction holds that

any term or provision of this Award Agreement is invalid or unenforceable, the remaining terms and provisions will continue in full force and effect, and this Award Agreement shall be deemed to be amended automatically to exclude the offending provision. This Award Agreement may be executed in multiple copies and each executed copy shall be an original of this Award Agreement. This Award Agreement shall be subject to and governed by the laws of the State of Georgia. No change or modification of this Award Agreement shall be valid unless it is in writing and signed by the party against which enforcement is sought, except where specifically provided to the contrary herein. This Award Agreement shall be binding upon, and inure to the benefit of, the permitted successors, assigns, heirs, executors and legal representatives of the parties hereto. The headings of each section of this Award Agreement are for convenience only. This Award Agreement, together with the Plan, contains the entire agreement of the parties hereto, and no representation, inducement, promise, or agreement or other similar understanding between the parties not embodied herein shall be of any force or effect, and no party will be liable or bound in any manner for any warranty, representation, or covenant except as specifically set forth herein or in the Plan.

8. Section 409A. This Award Agreement and the Award granted hereunder are intended to comply with, or otherwise be exempt from, Section 409A of the Code. This Award Agreement and the Award shall be administered, interpreted and construed in a manner consistent with such Code section. Should any provision of this Award Agreement or the Award be found not to comply with, or otherwise be exempt from, the provisions of Section 409A of the Code, it shall be modified and given effect, in the sole discretion of the Committee and without requiring Participant's consent (notwithstanding any other provisions hereof), in such manner as the Committee determines to be necessary or appropriate to comply with, or effectuate an exemption from, Section 409A of the Code. Each amount payable under this Award Agreement as a payment upon vesting of a Performance Share is designated as a separate identified payment for purposes of Section 409A of the Code.

Exhibit 10.2(c)

PERFORMANCE SHARE AWARD AGREEMENT

This Performance Share Award Agreement (together with the Performance Share Award Grant Notice to which this Agreement is attached, the "***Agreement***") is made as of the Date of Grant set forth in the Grant Notice by and between CryoLife, Inc., a Florida corporation (the "***Company***"), and _____ (the "***Participant***"). Capitalized terms used but not specifically defined herein shall have the meanings specified in the Plan, the Grant Notice, or this Performance Share Award Agreement.

1. **Award**. Effective as of the Date of Grant set forth in the Grant Notice above (the "***Date of Grant***"), the Company hereby grants to the Participant the target number of PSUs set forth in the Grant Notice (the "***Target PSUs***") on the terms and conditions set forth in the Grant Notice, the Performance Share Award Agreement, and the Plan, which is incorporated herein by reference as a part of this Agreement. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control, except as to treatment upon a Change of Control Event in which the terms of this Agreement control. To the extent earned, each PSU represents the right to receive one share of Stock, subject to the terms and conditions set forth in the Grant Notice, the Performance Share Award Agreement, and the Plan; provided, however, that, depending on the level of performance determined to be attained with respect to the Performance Goal, the number of shares of Stock that may be earned hereunder in respect of this Award may range from ___% to ___% of the Target PSUs. Unless and until the PSUs have become vested in the manner set forth in the Grant Notice, the Participant will have no right to receive any Stock or other payments in respect of the PSUs. Prior to settlement of this Award, the PSUs and this Award represent an unsecured obligation of the Company, payable only from the general assets of the Company.

2. **Vesting of PSUs**. Except as otherwise set forth in Section 3(b), the PSUs shall vest and become Earned PSUs in accordance with the Participant's satisfaction of the vesting requirements and schedule set forth in the Grant Notice and based on the extent to which the Company has satisfied the Performance Goals set forth in the Grant Notice, which shall be determined by the Committee in its sole discretion following the end of the Performance Period (and any PSUs that do not become Earned PSUs shall be automatically forfeited). Unless and until the PSUs have vested and become Earned PSUs as described in the preceding sentence, the Participant will have no right to receive any dividends or other distribution with respect to the PSUs.

3. **Effect of Termination of Employment or Service**. **[EFFECT OF TERMINATION OF EMPLOYMENT WILL BE DETERMINED BY THE COMMITTEE FOR EACH AGREEMENT.]**

4. **Settlement of PSUs**. As soon as administratively practicable following the date on which the PSUs vest, but in no event later than **[DATE]** of the calendar year following the vesting date, the Company shall deliver to the Participant (or the Participant's permitted transferee, if applicable), a number of shares of Stock equal to the number of Earned PSUs; provided, however, that any fractional PSU that becomes earned hereunder shall be rounded down at the time shares of Stock are issued in settlement of such PSU. No fractional shares of Stock, nor the cash value of any fractional shares of Stock, shall be issuable or payable to the Participant pursuant to this Agreement. All shares of Stock, if any, issued hereunder shall be delivered either by delivering one or more certificates for such shares to the Participant or by entering such shares in book-entry form, as determined by the Committee in its sole discretion. The value of shares of Stock shall not bear any interest owing to the passage of time. Neither this Section 4 nor any action taken pursuant to or in accordance with this Agreement shall be construed to create a trust or a funded or secured obligation of any kind.

5. **Tax Withholding**. Unless and until satisfactory arrangements (as determined by the Committee) have been made by Participant with respect to the payment of federal, state, local, or foreign income, the Company will withhold employment and other taxes which the Committee determines must be withheld ("***Tax Related Items***") with respect to the Stock so issuable. The Committee hereby allows Participant, pursuant to such procedures as the Committee may specify from time to time, to satisfy such Tax Related Items, in whole or in part (without limitation) by one or more of the following: (a) paying cash; or (b) electing to have the Company withhold otherwise deliverable shares of Stock having a Fair Market Value, as defined in the Plan, equal to the amount of the Tax Related Items required to be withheld. If the obligation for Tax Related Items is satisfied by withholding a number of shares of Stock as described above, Participant will be deemed to have been issued the full number of shares of Stock subject to the vested PSUs, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax Related Items due as a result of any aspect of the Award. If Participant fails to make satisfactory arrangements for the

payment of the Tax Related Items at the time any portion of the Award is scheduled to vest, Participant will permanently forfeit such portion of the Award and no shares of Stock will be issued to Participant pursuant to them.

6. **Non-Transferability**. During the lifetime of the Participant, the PSUs may not be sold, pledged, assigned, or transferred in any manner other than by will or the laws of descent and distribution, unless and until the shares of Stock underlying the PSUs have been issued, and all restrictions applicable to such shares have lapsed. Neither the PSUs nor any interest or right therein shall be liable for the debts, contracts, or engagements of the Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment, or any other means, whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

7. **Compliance with Applicable Law**. Notwithstanding any provision of this Agreement to the contrary, the issuance of shares of Stock hereunder will be subject to compliance with all applicable requirements of applicable law with respect to such securities and with the requirements of any stock exchange or market system upon which the Stock may then be listed. No shares of Stock will be issued hereunder if such issuance would constitute a violation of any applicable law or regulation or the requirements of any stock exchange or market system upon which the Stock may then be listed. In addition, shares of Stock will not be issued hereunder unless: (a) a registration statement under the Securities Act is in effect at the time of such issuance with respect to the shares to be issued or (b) in the opinion of legal counsel to the Company, the shares to be issued are permitted to be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary for the lawful issuance and sale of any shares of Stock hereunder will relieve the Company of any liability in respect of the failure to issue such shares as to which such requisite authority has not been obtained. As a condition to any issuance of Stock hereunder, the Company may require the Participant to satisfy any requirements that may be necessary or appropriate to evidence compliance with any applicable law or regulation and to make any representation or warranty with respect to such compliance as may be requested by the Company.

8. **Legends**. If a stock certificate is issued with respect to shares of Stock issued hereunder, such certificate shall bear such legend or legends as the Committee deems appropriate in order to reflect the restrictions set forth in this Agreement and to ensure compliance with the terms and provisions of this Agreement, the rules, regulations, and other requirements of the SEC, any applicable laws or the requirements of any stock exchange on which the Stock is then listed. If the shares of Stock issued hereunder are held in book-entry form, then such entry will reflect that the shares are subject to the restrictions set forth in this Agreement.

9. **Rights as a Stockholder**. The Participant shall have no rights as a stockholder of the Company with respect to any shares of Stock that may become deliverable hereunder unless and until the Participant has become the holder of record of such shares of Stock, and no adjustments shall be made for dividends in cash or other property, distributions, or other rights in respect of any such shares of Stock.

10. **Execution of Receipts and Releases**. Any issuance or transfer of shares of Stock or other property to the Participant or the Participant's legal representative, heir, legatee, or distributee, in accordance with this Agreement shall be in full satisfaction of all claims of such Person hereunder. As a condition precedent to such payment or issuance, the Company may require the Participant or the Participant's legal representative, heir, legatee, or distributee to execute (and not revoke within any time provided to do so) a release and receipt therefor in such form as it shall determine appropriate; provided, however, that any review period under such release will not modify the date of settlement with respect to Earned PSUs.

11. **No Right to Continued Employment, Service or Awards**. Nothing in the adoption of the Plan, nor the award of the PSUs hereunder pursuant to the Grant Notice or the Performance Share Award Agreement, shall confer upon the Participant the right to continued employment by any Eligible Employer, or any other entity, or affect in any way the rights of an Eligible Employer to terminate such employment relationship at any time. The grant of the PSUs is a one-time benefit and does not create any contractual or other right to receive a grant of Awards or benefits in lieu of Awards in the future. Any future Awards will be granted at the sole discretion of the Company.

12. **Legal and Equitable Remedies**. The Participant acknowledges that a violation or attempted breach of any of the Participant's covenants and agreements in this Agreement will cause such damage as will be irreparable, the exact amount of which would be difficult to ascertain and for which there will be no adequate remedy at law, and accordingly, the parties hereto agree that the Company and its Affiliates shall be entitled as a matter of right to an injunction issued by any court of competent jurisdiction, restraining the Participant or the affiliates, partners, or agents of the Participant from such breach or attempted violation of such covenants and agreements, as well as to recover from the Participant any and all costs and expenses sustained or incurred by the Company or any Affiliate in obtaining such an injunction, including, without limitation, reasonable attorneys' fees. The parties to this Agreement agree that no bond or other security shall be required in connection with such injunction. Any exercise by either of the parties to this Agreement of its rights pursuant to this Section 12 shall be cumulative and in addition to any other remedies to which such party may be entitled.

13. **Notices**. Any notices or other communications provided for in this Agreement shall be sufficient if in writing. In the case of Participant, such notices or communications shall be effectively delivered if hand delivered to Employee at Employee's principal place of employment or if sent by registered or certified mail to Employee at the last address Employee has filed with the Company. In the case of the Company, such notices or communications shall be effectively delivered if sent by registered or certified mail to the Company at its principal business address.

14. **Consent to Electronic Delivery; Electronic Signature**. In lieu of receiving documents in paper format, the Participant agrees, to the fullest extent permitted by law, to accept electronic delivery of any documents that the Company may be required to deliver (including, but not limited to, prospectuses, prospectus supplements, grant or award notifications and agreements, account statements, annual and quarterly reports and all other forms of communications) in connection with this and any other Award made or offered by the Company. Electronic delivery may be via the Company's electronic mail system or by reference to a location on the Company intranet to which the Participant has access. The Participant hereby consents to any and all procedures the Company has established or may establish for an electronic signature system for delivery and acceptance of any such documents that the Company may be required to deliver, and agrees that his or her electronic signature is the same as, and shall have the same force and effect as, his or her manual signature.

15. **Agreement to Furnish Information**. The Participant agrees to furnish to the Company all information requested by the Company to enable it to comply with any reporting or other requirement imposed upon the Company by or under any applicable statute or regulation.

16. **Entire Agreement; Amendment**. This Agreement constitutes the entire agreement of the parties with regard to the subject matter hereof, and contains all the covenants, promises, representations, warranties, and agreements between the parties with respect to the PSUs granted hereby; provided, however, that the terms of this Agreement shall not modify and shall be subject to the terms and conditions of any employment, consulting, and/or severance agreement between the Company (or an Affiliate or other entity) and the Participant in effect as of the date a determination is to be made under this Agreement. Without limiting the scope of the preceding sentence, except as provided therein, all prior understandings and agreements, if any, among the parties hereto relating to the subject matter hereof are hereby null and void and of no further force and effect. The Committee may, in its sole discretion, amend this Agreement from time to time in any manner that is not inconsistent with the Plan.

17. **Severability and Waiver**. If a court of competent jurisdiction determines that any provision of this Agreement is invalid or unenforceable, then the invalidity or unenforceability of such provision shall not affect the validity or enforceability of any other provision of this Agreement, and all other provisions shall remain in full force and effect. Waiver by any party of any breach of this Agreement or failure to exercise any right hereunder shall not be deemed to be a waiver of any other breach or right. The failure of any party to take action by reason of such breach or to exercise any such right shall not deprive the party of the right to take action at any time while or after such breach or condition giving rise to such rights continues.

18. **Clawback**. Notwithstanding any provision in the Grant Notice, this Performance Share Award Agreement, or the Plan to the contrary, to the extent required by (a) applicable law, including, without limitation, the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, any SEC rule or any applicable securities exchange listing standards and/or (b) any policy that may be adopted or amended by the CryoLife,

Inc. Board of Directors from time to time, all shares of Stock issued hereunder shall be subject to forfeiture, repurchase, recoupment and/or cancellation to the extent necessary to comply with such law(s) and/or policy.

19. **Governing Law**. THIS AGREEMENT, THE RIGHTS OF THE PARTIES AND ALL ACTIONS ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION HEREWITH, SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE UNITED STATES OF AMERICA AND OF THE STATE OF GEORGIA, WITHOUT GIVING EFFECT TO ANY CHOICE OR CONFLICT OF LAW PROVISION OR RULE (WHETHER OF THE STATE OF GEORGIA OR OF ANY OTHER JURISDICTION) THAT WOULD CAUSE THE APPLICATION OF THE LAWS OF ANY OTHER JURISDICTION OTHER THAN THOSE OF THE STATE OF GEORGIA.

20. **Successors and Assigns**. The Company may assign any of its rights under this Agreement without the Participant's consent. This Agreement will be binding upon and inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth herein and in the Plan, this Agreement will be binding upon the Participant and the Participant's beneficiaries, executors, administrators and the Person(s) to whom the PSUs may be transferred by will or the laws of descent or distribution.

21. **Headings**. Headings are for convenience only and are not deemed to be part of this Agreement.

22. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument. Delivery of an executed counterpart of this Agreement by facsimile or portable document format (.pdf) attachment to electronic mail shall be effective as delivery of a manually executed counterpart of the Agreement.

23. **Section 409A**. The PSUs are intended to be exempt from or compliant with Section 409A of the Code and the Treasury regulations and other interpretive guidance issued thereunder (collectively, "***Section 409A***"). If the Participant is deemed to be a "specified employee" within the meaning of Section 409A, as determined by the Committee, at a time when the Participant becomes eligible for settlement of the PSUs or payment of Dividend Equivalents upon his "separation from service" within the meaning of Section 409A, then to the extent necessary to prevent any accelerated or additional tax under Section 409A, such settlement will be delayed until the earlier of: (a) the date that is six months following Employee's separation from service and (b) the Participant's death. Notwithstanding the foregoing, the Company makes no representations that the payments provided under this Agreement are exempt from or compliant with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by the Participant on account of non-compliance with Section 409A.

Exhibit 10.5

SUMMARY OF 2019 COMPENSATION ARRANGEMENTS WITH NON-EMPLOYEE DIRECTORS
(Effective as of December 31, 2019)

The following summarizes the compensation and benefits received by the non-employee Directors of CryoLife as of December 31, 2019. It is intended to be a summary of compensation arrangements, and in no way is intended to provide any additional rights to any non-employee Director.

Annual Retainer and Committee Chair Fees

Each of the non-employee Directors of the Board of Directors of CryoLife (the "Board") receives an annual cash retainer of $45,000. Each committee chair also receives a fee in addition to the annual cash retainer in the amounts shown in the following table.

Annual Fees For Committee Chairs	
Audit Committee	$ 20,000
Compensation Committee	$ 15,000
Corporate Governance Committee	$ 10,000
Compliance Committee	$ 10,000

The Presiding Director also receives $25,000 retainer paid in cash. Currently, the Presiding Director is also the Chairman of the Corporate Governance Committee, and he does not receive any additional compensation for his position as Chairman of that committee. CryoLife pays all cash retainers on a monthly basis.

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

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

Restricted Stock Grants

Non-employee Directors of CryoLife are eligible for equity grants, which are generally made in May of each year. The annual equity portion of non-employee Director compensation for fiscal 2019 was paid in the form of a grant of4,163 shares of restricted stock. These shares were issued following the annual meeting of stockholders and vest on the first anniversary of issuance. The size and terms of the annual equity grant are subject to annual reevaluation by the Compensation Committee. If a Director ceases to serve as a Director as a result of death or disability or chooses not to stand for reelection following the completion of a full term of service, the equity grant will become fully vested on the date the Director ceases to be a member of the Board. If the Director ceases to be a member of the Board for any other reason, and their equity grant has not fully vested as of the date of termination of Board service, the equity grant shall automatically be forfeited and cancelled as of the date of such termination of Board service. The Compensation Committee, however, has discretion under CryoLife's Equity and Cash Incentive Plan to cause the equity grant to fully vest for certain conditions.

Exhibit 21.1

SUBSIDIARIES OF CRYOLIFE, INC.

Subsidiary	Jurisdiction
CryoLife Europa, Ltd	England and Wales
AuraZyme Pharmaceuticals, Inc.	Florida
CryoLife International, Inc.	Florida
CryoLife Asia Pacific, PTE. Ltd	Singapore
CryoLife France, SAS	France
On-X Life Technologies Holdings, Inc.	Delaware
On-X Life Technologies, Inc.	Delaware
Valve Special Purpose Co., LLC	Delaware
CryoLife Canada, Inc.	Canada
CryoLife Germany TopCo GmbH	Germany
CryoLife Germany HoldCo GmbH.	Germany
Jolly Buyer Acquisition GmbH	Switzerland
JOTEC GmbH	Germany
JOTEC s.r.l.	Italy
JOTEC Cardiovascular S.L.	Spain
JOTEC Polska Sp. z.o.o	Poland
JOTEC UK Ltd.	England
JOTEC Sales GmbH	Switzerland
JOTEC do Brasil	Brazil
CryoLife Beijing Medical Device Ltd.	China
CryoLife Korea Co., Ltd.	Korea
CryoLife Medical (Thailand) Co., Ltd.	Thailand
CryoLife Vietnam Co., Ltd.	Vietnam

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement No. 333-229881 on Form S-8 pertaining to the CryoLife, Inc. Equity and Cash Incentive Plan,
(2) Registration Statement No. 333-227473 on Form S-3 filed on September 21, 2018,
(3) Registration Statement No. 333-197545 on Form S-8 pertaining to the CryoLife, Inc. Second Amended and Restated 2009 Stock Incentive Plan,
(4) Registration Statement No. 333-182296 on Form S-8 pertaining to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan,
(5) Registration Statement No. 333-182297 on Form S-4 filed on June 22, 2012,
(6) Registration Statement No. 333-167065 on Form S-8 pertaining to the CryoLife, Inc. Employee Stock Purchase Plan,
(7) Registration Statement No. 333-159608 on Form S-8 pertaining to the CryoLife, Inc. 2009 Employee Stock Incentive Plan,
(8) Registration Statement No. 333-119137 on Form S-8 pertaining to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, and
(9) Registration Statement No. 333-104637 on Form S-8 pertaining to the CryoLife, Inc. 2002 Stock Incentive Plan;

of our reports dated February 19, 2020, with respect to the consolidated financial statements of CryoLife, Inc. and subsidiaries and the effectiveness of internal control over financial reporting of CryoLife, Inc. and subsidiaries included in this Annual Report (Form 10-K) of CryoLife, Inc. and subsidiaries for the year ended December 31, 2019.

Atlanta, Georgia
February 19, 2020

Exhibit 31.1

I, James Patrick Mackin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 19, 2020

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

Exhibit 31.2

I, David Ashley Lee, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 19, 2020

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

Exhibit 32

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

In connection with the Annual Report of CryoLife, Inc. (the "Company") on Form 10-K for the year ending December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of James Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

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

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

/s/ J. PATRICK MACKIN
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
February 19, 2020

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and Chief Financial Officer
February 19, 2020