CRYOLIFE INC
Form 10-K
March 09, 2018

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, 2017

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K Section 229.405 of this chapter is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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	(Do not check if a smaller reporting company)	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, 2017 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $629,872,572 computed using the closing price of $19.95 per share of Common Stock on June 30, 2017, 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 28, 2018 the number of outstanding shares of Common Stock of the registrant was 36,494,127.

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, 2017.	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). Forward-looking statements give our current expectations or forecasts of future events. The words could, may, might, will, would, shall, should, pro forma, potential, pending, intend, believe, expect, anticipate, estimate, plan, future, assume, 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 beliefs and estimates regarding the potential benefits and additional applications of our surgical adhesives, sealants, hemostats, CardioGenesis cardiac laser therapy, On-X heart valves, JOTEC products, and PhotoFix products;

Our estimates regarding specific country and worldwide market opportunities for certain types of procedures and products, and our products and tissues;

Our beliefs and estimates regarding our competitors in various geographic, procedure, and product markets, including non-profit competitors, the number of domestic tissue banks that offer vascular tissue in competition with us, and our beliefs regarding how effectively our products and services will compete with competitors products and services;

Our beliefs regarding the potential for competitive products and services to affect the market for our products and services;

Competitors with superior resources and capabilities could develop competing products in the future and our competitive disadvantages could materially, adversely affect us;

Our beliefs regarding the enhanced efficacy of certain procedures provided by using our surgical sealants;

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 expectation that we will terminate our minimum purchase requirements after regulatory approval of PerClot; and assuming enrollment proceeds as anticipated, we could receive Premarket Approval

from the FDA in the second half of 2019;

Our beliefs and expectations regarding the benefits of our marketing, educational, and technical support efforts;

Our beliefs regarding the advantages and competitive benefits of the human tissues, heart valves, and other products we preserve and distribute;

The anticipated effect of suppliers /sources inability to deliver critical raw materials or tissues and/or us having to source supply from an alternate supplier;

Our beliefs regarding the importance of, and competitive advantages associated with, our relationships with tissue procurement organizations;

Our belief regarding our compliance with The National Organ Transplant Act of 1984, or NOTA , state licensing requirements, and environmental laws and regulations;

Our belief that countries in which we distribute our products and tissue may perform inspections of our facilities to ensure compliance with local country regulations;

Our plans to continue to ship tissues to Germany under a special access program, which is subject to continued support from German authorities;

Our potential attempt to license certain products to corporate partners for further development or seek funding from outside sources to continue commercial development when additional applications for such products are identified, and our potential attempt to acquire or license additional technologies from third-parties to supplement our product lines;

Our plans and expectations regarding research and development of new technologies and products;

Our plans and expectations regarding clinical trials;

Our beliefs regarding the adequacy of, and competitive advantages conferred by, our intellectual property protections;

Management s beliefs regarding the state of relations with our employees;

Our expectations regarding the impact of U.S. and international healthcare policy;

Regulatory changes and our failure to comply with regulations could materially and adversely affect our business;

The potential impact of the FDA s classification of CryoValve SGPV as a class III device;

Our beliefs and expectations regarding the limitations on the recoverability of our acquired net operating loss carryforwards in future periods;

Our plans regarding acquisition and investment opportunities of complementary product lines and companies;

Our beliefs and assessments of the effects of adopting new accounting standards regarding the recognition of revenue from contracts with customers, lease accounting, and the balance sheet classification of deferred taxes;

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 estimates regarding yields for tissues in process and in quarantine and the portion of tissues that will ultimately become implantable;

Our potential plan to pursue expanded U.S. indications for BioGlue and our beliefs regarding the international growth opportunities that would be provided by obtaining regulatory approval for BioGlue in China;

Various risks related to BioGlue, our tissue preservation services, our On-X and JOTEC products, future acquisitions, supply, regulatory compliance, competitors, tax law changes, healthcare industry and professionals, purchase accounting, foreign currency fluctuations, litigation, and intellectual property that could affect our revenues, financial condition, profitability, and cash flows;

Our belief that the growth rate for JOTEC products will accelerate in future years due to the selling efforts of a larger, realigned international sales force as they undertake additional training and become more experienced with selling JOTEC products and due to our anticipated introduction of certain JOTEC products into the U.S. market;

Various factors related to our JOTEC acquisition that could adversely affect our business, financial condition, profitability, cash flows and earnings per share, and the price of our common stock;

Our indebtedness could adversely affect our ability to raise capital to fund our operations and limit our ability to react to changes in the economy or our industry, and our failure to comply with credit agreement covenants could result in a default and adversely affect our business, financial condition, and profitability;

Our plans to improve tissue processing throughput and reduce costs;

Our plans to pursue new and previous vascular tissue customers to broaden our revenue base for vascular preservation services, and our belief that we now have sufficient vascular tissue supply;

Our beliefs regarding the seasonal nature of the demand for some of our products and services;

The adequacy of our financial resources and our belief that we will have sufficient cash to meet our operational liquidity needs for at least the next twelve months;

The anticipated impact on cash flows of undertaking significant business development activities and the potential need to obtain additional borrowing capacity or financing;

The future cash requirements that we anticipate may have a significant effect on our cash flows during 2018;

Issues that may affect our future financial performance and cash flows;

Our plans to transfer the manufacturing of PhotoFix from GBI to our facility in Kennesaw, Georgia; and

Other statements regarding future plans and strategies, anticipated events, or trends.

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), incorporated in 1984 in Florida, is a leader in the manufacturing processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures focused on aortic repair. Our medical devices and processed tissues primarily include four product families: BioGlue® Surgical Adhesive (BioGlue); On-X mechanical heart valves and surgical products; JOTEC endovascular and surgical products; and cardiac and vascular human tissues including the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch (CryoPatch SG), both of which are processed using our proprietary SynerGraft® technology. Additional products include CardioGenesis cardiac laser therapy, PerClot® and PhotoFix™.

Corporate Structure

Our main operating subsidiaries include JOTEC GmbH (JOTEC), a Hechingen, Germany-based endovascular and surgical products company acquired on December 1, 2017, along with six JOTEC direct sales operations in Brazil, Italy, Poland, Spain, Switzerland, and the U.K.; On-X Life Technologies Holdings, Inc. (On-X), an Austin, Texas-based, mechanical heart valve company acquired on January 20, 2016; CryoLife Europa Ltd. (Europa), established in 2000 to provide marketing and distribution support in the European Economic Area (EEA), the Middle East, and Africa (collectively, EMEA); CryoLife France, SAS (CryoLife France), established in 2015 to provide direct sales operations in France; CryoLife Canada, Inc. (CryoLife Canada) established in Canada in 2017 to provide direct sales operating in Canada; and CryoLife Asia Pacific, Pte. Ltd. (CryoLife Asia Pacific), established in Singapore in 2013 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; On-X products; JOTEC products; CardioGenesis cardiac laser therapy; PerClot; and PhotoFix. The Preservation Services segment includes services revenues from the preservation of cardiac and vascular tissues. See also Part II, Item 8, Note 20 of the Notes to Consolidated Financial Statements for further information on our segments and for our geographic information.

Strategy

Our strategic plan is focused on four growth areas in the cardiac and vascular surgery space that we expect to drive our business expansion in the near term. These four growth areas and their key elements are described below:

New Products Drive growth through new products, including JOTEC and On-X products;

New Indications Drive growth by broadening the reach of some of our products and services, including the JOTEC, On-X, and BioGlue products, and preserved cardiac and vascular tissues, with new or expanded approvals and indications in the U.S. or in international markets;

Global Expansion Drive growth by expanding our current products and services into new markets, including emerging markets, and developing new direct sales territories overseas; and

Business Development Drive growth through business development by selectively pursuing potential acquisitions, licensing, or distribution rights of companies or technologies that complement our existing products, services, and infrastructure and expand our footprint in the cardiac and vascular surgery spaces, as we did with the recent acquisitions of JOTEC and On-X; and licensing of products developed internally with non-cardiac indications. 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.

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, peripheral vascular disease and other conditions. We

discuss each market in which we compete and describe our products and/or services with which we compete in each market below.

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 technology obsolete and non-competitive. Any of these competitive disadvantages could materially, adversely affect us. We specifically discuss our products that are currently on the market 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 content leakage resulting from surgical procedures can lead to prolonged hospitalization, higher levels of 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 product, BioGlue, 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 has a tensile strength that is four to five times that of fibrin sealants, and it is stronger than other cardiovascular sealants. BioGlue begins to polymerize within 20 to 30 seconds and reaches its bonding strength within two minutes. BioGlue is dispensed by a controlled delivery system that consists of a disposable syringe and various applicator tips. BioGlue is pre-filled in 2ml, 5ml, and 10ml volumes.

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 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, Ethicon, Inc. (a Johnson & Johnson Company), Integra LifeSciences Holdings Corporation, and Bard (Bard), previously C. R. Bard, Inc. and now a subsidiary of Becton, Dickinson, and Company (BD). BioGlue competes with these products based on its features and benefits, such as strength and ease of use.

We distribute BioGlue throughout the U.S. and in approximately 85 other countries. Revenues from BioGlue represented 35%, 35%, and 40% of our total revenues in 2017, 2016, and 2015, 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. Cardiac surgery can include the implantation of mechanical heart valves, bioprosthetic (animal-derived or xenograft) heart valves and tissues, synthetic tissues, or donated human tissues.

Mechanical heart valves are durable and are often a solution that will last for the remainder of a patient s life without replacement. Mechanical valves are readily available and are a relatively inexpensive solution for those requiring a valve replacement. These valves contain a synthetic sewing ring to facilitate implantation. Patients who receive mechanical heart valves are required to undergo long-term blood thinning or anticoagulation drug therapy to minimize the risk of complications from blood clots.

Bioprosthetic tissues include bovine, equine, or porcine tissue valves, and surgical patches. Bioprosthetic valves are readily available and are a relatively inexpensive solution for those requiring a valve replacement. 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 patient populations. Bioprosthetic tissues are typically processed with glutaraldehyde, which may result in progressive calcification, or hardening of the tissue over time. These valves often contain a synthetic sewing ring to facilitate 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.

Synthetic surgical patches are available for use in cardiac repair and synthetic materials are used in sewing rings for mechanical and bioprosthetic heart valves. These synthetic sewing rings may harbor bacteria and lead to an infection (endocarditis), which can be difficult to treat with antibiotics. Patients with an infected mechanical or bioprosthetic valve may require valve replacement surgery.

Human heart valves are available for use in valve replacement procedures. Human heart valves allow for more normal blood flow and often provide higher cardiac output than mechanical and bioprosthetic heart valves. Human tissue responds better to treatment for infections, such as endocarditis, and is not as susceptible to progressive calcification as glutaraldehyde-fixed bioprosthetic tissues. Human heart valves do not require anticoagulation drug therapy. 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.

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.

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 catalogue of products 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 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.

The On-X heart valve is a bileaflet mechanical valve composed of a graphite substrate coated with On-X s pyrolytic carbon coating. The On-X heart valve is available for both aortic and mitral indications and with a variety of sewing ring

options to suit physician s preferences. 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 an aortic graft.

As discussed above, all mechanical valve patients require anticoagulation drug therapy with warfarin, which creates a risk of harmful bleeding. The On-X aortic heart valve is the only mechanical valve FDA approved to be marketed as, and clinically proven to be, safer for use by the patient with less anticoagulation. 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 65% fewer and minor harmful bleeding events without an increase in stroke risk.

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., and LivaNova PLC (LivaNova) based on the On-X heart valves 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 distributing On-X heart valves throughout the U.S. and in approximately 95 other countries in January 2016 when we acquired On-X. Revenues from On-X products represented 19% of total revenues in 2017 and 2016.

Cardiac Preservation Services

Our proprietary preservation process involves dissection, processing, preservation, and storage of donated human tissues by us until they are shipped to an implanting physician. The cardiac tissues currently preserved by us include aortic and pulmonary heart valves and cardiac patches in three primary anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch. 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 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 advantages of our heart valves include more natural blood flow properties, the ability to use the valve with patients who have endocarditis, the elimination of a need for long-term drug therapy to prevent excessive blood clotting, and a reduced risk of catastrophic failure, thromboembolism (stroke), or calcification.

Our cardiac tissues include the CryoValve SGPV and the CryoPatch SG, both processed with our proprietary SynerGraft decellularization technology. A multi-center study showed that at 10 years, patients with our proprietary SynerGraft valves had a 17 percent re-operation rate, as compared to a 40 percent re-operation rate for patients with non-SynerGraft valves. We use the SynerGraft technology in pulmonary valve and pulmonary cardiac patch tissue processing.

We believe that at least one domestic tissue bank, LifeNet Health, Inc. (LifeNet), offers preserved human heart valves and patches in competition with us. 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, Inc., Edwards Life Sciences, Inc., LivaNova, and Abbott Laboratories. Alternatives to our human cardiac patches include xenograft small intestine submucosa (SIS) and glutaraldehyde fixed bovine pericardial patches. We compete with xenograft products from companies including Aziyo Biologics, Edwards Life Sciences, Inc., Admedus, Inc., Abbott Laboratories, and Baxter.

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 SIS and glutaraldehyde fixed bovine pericardial patches, due to the benefits of human tissue discussed above. Human tissue is the preferred 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.

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

We distribute 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 distribute tissues in Canada and have limited distribution through a special access program in Germany. Revenues from cardiac tissue preservation services accounted for 17%, 17%, and 19% of total revenues in 2017, 2016, and 2015, respectively.

PhotoFix

In 2014 we entered into an exclusive supply and distribution agreement with Genesee Biomedical, Inc. (GBI) to acquire the distribution rights to PhotoFix, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. In April 2016 we exercised our right to acquire the PhotoFix technology from GBI and are in the process of transferring manufacturing of PhotoFix to our headquarters facility. 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, Admedus, Aziyo Biologics, and Abbott Laboratories based on PhotoFix s features and benefits, such as the photo-oxidation cross-linking process that does not use glutaraldehyde.

We began distributing PhotoFix in the U.S. in January 2015. Revenues from PhotoFix represented approximately 1% of our total revenues in each of 2017, 2016, and 2015.

Hybrid 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.

Aortic dissection occurs when the innermost layer of the aorta tears and blood surges through the tear. 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, 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 it to 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. When the aneurysm gets too large, the wall of the aorta can split or tear, resulting in a ruptured aorta or an aortic dissection. Left untreated, aortic aneurysms can result in death.

Often, the dissection in the aortic arch and the condition in the descending thoracic aorta are repaired in a two-stage procedure, one open surgical procedure to repair the arch followed by another procedure to repair the descending thoracic aorta. We market the E-vita OPEN PLUS 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 distribute the E-vita OPEN PLUS under CE Mark in the EEA. Additional marketing approvals have been granted in other countries throughout the world. With this product, we compete with Terumo Corp. and two smaller competitors outside of the U.S., and, to our knowledge, there are no competitive products currently being commercialized in the U.S. The E-vita OPEN PLUS competes primarily on its proven stent graft technology and long-term clinical data.

Through our acquisition of JOTEC, we began distributing 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 less than 1% of total revenues in 2017.

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 people part of the aorta can become abnormally large or bulge and this is referred to as an aneurysm.

An aneurysm results from a weakening in the wall of an aorta, which causes it to 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. When the aneurysm gets too large, the wall of the blood vessel 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 results in reasonable long-term survival, but can be risky 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 transdermally 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 marketing a broad portfolio of endovascular products for aortic repair. These include highly differentiated products, such as the E-xtra DESIGN ENGINEERING, a portfolio of stent grafts custom designed for a patient s anatomy for TAAA repair, the E-liac for repair of aneurysms in the iliac arteries, and less differentiated products, including the E-vita THORACIC 3G for TAA repair and the E-tegra for AAA repair.

E-xtra

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 therapeutic requirements. The E-xtra DESIGN ENGINEERING is custom made for individual patients. There are currently no off-the-shelf products to treat aneurysms in the thoraco-abdominal aorta due to the many side branches in this anatomy where blood flow to vital organs would be obstructed by unbranched stent grafts. JOTEC has pioneered a service whereby it manufactures a customized thoraco-abdominal stent graft within 3 weeks. E-xtra DESIGN ENGINEERING products are often used in conjunction with JOTEC s E-vita THORACIC 3G as well as the AAA offering, the E-tegra, or in combination with both.

We distribute the 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 a customized product offering from Cook Medical.

Through our acquisition of JOTEC, we began distributing the E-xtra DESIGN ENGINEERING portfolio in many markets outside the United States in December 2017. Revenues from E-xtra DESIGN ENGINEERING accounted for

less than 1% of total revenues in 2017.

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 which 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 as well as 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., Gore & Associates (Gore), and BD.

Through our acquisition of JOTEC, we began distributing the E-ventus BX in many markets outside of the United States in December 2017. Revenues from the E-ventus BX accounted for less than 1% of total revenues in 2017.

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 distribute 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 Medical.

Through our acquisition of JOTEC, we began distributing the E-liac in many markets outside of the United States in December 2017. Revenues from the E-liac accounted for less than 1% of total revenues in 2017.

E-vita THORACIC 3G

The E-vita THORACIC 3G is a stent graft system that enables endovascular treatment of TAA s. 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 as well as E-xtra DESIGN ENGINEERING.

We distribute 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 products from Medtronic, Inc., Gore, Terumo Corp., and Cook Medical.

Through our acquisition of JOTEC, we began distributing the E-vita THORACIC 3G in many markets outside of the United States in December 2017. Revenues from the E-vita THORACIC 3G accounted for less than 1% of total revenues in 2017.

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 developed products and the E-liac.

We distribute 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, Inc., Gore, Terumo Corp., Endologix, Antegraft, Inc., and Cook Medical.

Through our acquisition of JOTEC, we began distributing the E-tegra in many markets outside of the United States in

December 2017. Revenues from the E-tegra accounted for approximately less than 1% of total revenues in 2017.

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 infected abdominal aortic grafts, insufficient vascular access, carotid endarterectomy, or vessel repair. These procedures may include the use of bioprosthetic 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. However, synthetic grafts and patches 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. 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, acquired through our acquisition of JOTEC, for peripheral vascular reconstruction surgeries.

Vascular Preservation Services

Our proprietary preservation process involves dissection, processing, preservation, and storage of tissues by us, until they are shipped to an implanting physician. The vascular tissues currently preserved by us include saphenous veins, aortoilliac 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.

We believe that only two other domestic tissue banks, LifeNet, and LeMaitre Vascular, Inc. (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, Inc.

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 distribute human vascular tissues to implanting institutions throughout the U.S. We also distribute vascular tissues in Canada and have limited distribution through a special access program in Germany. Revenues from vascular preservation services accounted for 20%, 20%, and 24% of total Company revenues in 2017, 2016, and 2015, 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 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 BD, Gore, LeMaitre, Vascutek, and Maquet, Inc.

Through our acquisition of JOTEC, we began distributing synthetic surgical vascular grafts in many markets outside of the United States in December 2017. Revenues from synthetic surgical vascular grafts accounted for less than 1% of total revenues in 2017.

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 distribute the SoloGrip® III disposable handpieces, which consist of multiple, fine fiber-optic strands in a one millimeter diameter bundle and are designed to work with the console. The SoloGrip III 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.

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 distributing 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 commercial distribution 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 counterpulsation. Currently, the only directly competitive laser technology for the performance of TMR is the CO_2 Heart

Laser System manufactured by Novadaq Technologies, Inc. Our revascularization technology 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 distribute handpieces and CardioGenesis laser consoles primarily in the U.S. Revenues from CardioGenesis cardiac laser therapy represented 4%, 5%, and 6% of our total revenues in 2017, 2016, and 2015, 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 market 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.

PerClot has a CE Mark allowing commercial distribution into 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.

We are actively enrolling patients in a clinical trial for the purpose of obtaining FDA Premarket Approval (PMA) to distribute PerClot in the U.S., as discussed further in Research and Development and Clinical Research below. We distribute PerClot in approximately 70 countries. Revenues from PerClot represented 2%, 2%, and 3% of our total revenues in 2017, 2016, and 2015, 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.

HeRO Graft and ProCol

We began distributing the HeRO Graft in the U.S. in May 2012 when we acquired Hemosphere, Inc. and distributed the product until we divested the product line in February 2016. Revenues from the HeRO Graft represented 1% and 5% of our total revenues in 2016 and 2015, respectively. There were no HeRO Graft revenues in 2017.

We began distributing ProCol in the U.S. in March 2014 under a distribution agreement with Hancock Jaffe and distributed the product until we divested the product line in March 2016. Revenues from ProCol represented less than 1% of our total revenues in each of 2016 and 2015. There were no HeRO or ProCol revenues in 2017.

Marketing and Distribution

In the U.S and Canada, we market our products and preservation services primarily to physicians, and distribute our products through our approximately 55-person direct sales team to hospitals and other healthcare facilities. We also have a team of region managers, 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.

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 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 through organ and tissue procurement organizations (OTPOs). To assist OTPOs, we provide educational materials and training on procurement, dissection, packaging, and shipping techniques. We produce educational videos and coordinate laboratory sessions for OTPO personnel to improve their recovery techniques and increase the yield of usable tissue. We also maintain a staff 24 hours per day, 365 days per year for OTPO support.

We market our products in the EMEA region through JOTEC, based in Hechingen, Germany, and Europa, based in Guildford, England, as well as several other subsidiaries based throughout Europe. We employ approximately 105 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.

We market and distribute our products through our direct organization in certain parts of Brazil, and in other international markets through independent distributors in Asia Pacific and the Americas. Our Singapore subsidiary, CryoLife Asia Pacific, provides sales and marketing support for the Asia Pacific region.

Suppliers, Sources, and Availability of Raw Materials and Tissues

We obtain many of our raw materials and supplies from a small group of suppliers or a single-source supplier. Certain raw materials and components used in our products and tissue processing have stringent specifications. Supply interruptions or supplier quality, financial, or operational issues could cause us to have to temporarily reduce, temporarily halt, or permanently halt manufacturing, processing, or distribution activities. 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 a significant 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 maintain an inventory of grafts to help mitigate the effects of a potential supply interruption. We also purchase various components for our On-X valves from single suppliers. We maintain inventories of these components to help mitigate the effects of a potential supply interruption. Ongoing efforts are in process to find alternative suppliers for these components.

We purchase laser consoles and handpieces for our CardioGenesis cardiac laser therapy product line each from a separate single-source contract manufacturer. Using a secondary supplier for the laser consoles may be difficult because of the current manufacturer s patent rights. In addition, these two manufacturers obtain certain laser and fiber-optic components and subassemblies from single sources. Our business is subject to interruption if either of these contract manufacturers or their suppliers became unable or unwilling to do business with us.

We purchase PerClot for distribution from SMI pursuant to a distribution agreement. We maintain an extra supply of 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 OTPOs. We must rely on the OTPOs that we work with to educate the public on the need for donation, to foster a willingness to donate tissue, to follow our donor screening and procurement procedures, and to send donated tissue to us. We have active relationships with approximately 55 OTPOs 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 injection molded parts and machine drilled parts.

The conventional polyester grafts consist of two main product components: polyester fabric and collagen coating. The polyester fabric is manufactured by JOTEC internally 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 an external 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 BioFoam and process human tissues at our headquarters facility. We expect to complete the transfer of the manufacturing of PhotoFix to our headquarters facility in 2018. Our headquarters also includes a CardioGenesis cardiac laser therapy 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, which contains our EMEA headquarters and houses manufacturing, warehouse, and office space, is in Hechingen, Germany.

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

In all of the 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 is the governing document for the EEA that details requirements for safety and risk.

We work with three Notified Bodies that are officially recognized by the EU to perform assessments of compliance with ISO 13485 and the Medical Device Directive. LNE/G-Med (G-Med) acts as our Notified Body for the On-X product line, Lloyd s Register Quality Assurance Limited (LRQA) acts as our Notified Body for our BioGlue and CardioGenesis product line, and Deutscher Kraftfahrzeug-Überwachungs-Verein (DEKRA) acts as our Notified Body for our JOTEC product line. LRQA, G-Med and DEKRA perform periodic on-site inspections to independently review our compliance with systems and regulatory requirements. G-Med, LRQA and DEKRA also perform assessments of compliance with the Canadian Medical Devices Conformity Assessment System (CMDCAS).

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, and 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 produce products meeting 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. OTPOs must follow our policies 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 is 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 in 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 healthcare policy changes.

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 marketing 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. Marketing 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. Marketing 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, BioFoam, On-X heart valve, On-X AAP, PerClot, CardioGenesis cardiac laser therapy, E-vita OPEN PLUS, E-vita THORACIC 3G, E-xtra, E-tegra and E-liac. CryoPatch SG is classified as Class II medical devices. We obtained 510(k) clearance from the FDA to market 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 MMM allograft heart valves 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. If the FDA issues a proposal for reclassification of MMM allograft heart valves, it will be subject to a public comment period before finalization. After publication of the reclassification rule, we expect to have thirty months to submit for a PMA, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers. To date, the FDA has not issued a proposed reclassification for 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, 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 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, called a 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. LRQA, G-Med and DEKRA 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 been issued CE Marks for BioGlue, BioFoam, On-X heart valve, On-X AAP, CardioGenesis cardiac laser therapy consoles and handpieces, E-vita OPEN PLUS, E-vita THORACIC 3G, E-tegra, E-liac, and other devices. See Certifications, Accreditations, and Inspections below for further discussion of the On-X AAP CE Mark. Additionally, PerClot and E-ventus, which we distribute, have a CE Mark.

The EU Tissue and Cells Directives (EUTCD) established an approach to the regulation of tissues and cells across Europe. Pursuant to the EUTCD, each country in the EEA has responsibility for regulating tissues and cells and the procurement and distribution of tissues and cells for use in humans through a Competent Authority. The Competent Authority in the U.K. is the Human Tissue Authority (HTA). Europa was a Licensed Establishment under HTA Directions. In 2013 the HTA temporarily suspended Europa s licenses but shortly thereafter reinstated them subject to certain conditions, which allowed Europa to continue importing tissues into Europe. Subsequently, the HTA imposed certain additional tissue processing requirements for tissues imported into Europe through the HTA license. We did not believe those requirements were necessary in order to ensure the safety of the processed tissue, and, as a result, we ceased importing tissues into Europe through the HTA licenses as of March 31, 2014.

We currently distribute tissues through a special access program in Germany. In the first half of 2015, Germany s regulatory authorities and Europa were in discussions regarding requirements to allow Europa to market tissue in Germany. Europa was unable to reach a satisfactory agreement with the German authorities regarding those requirements, and although nominal shipments under the special access program have continued in 2017, there can be no assurance that the German authorities will continue to allow shipments of tissues under this program in the future. We are currently in discussions with authorities in Germany to secure approval for broad distribution of some of our processed tissues in Germany, although there is no guarantee that we will secure such approval.

Recent Regulatory Approvals

New country listings were obtained during 2017 to allow additional distribution of certain On-X products into international markets.

Certifications, Accreditations, and Inspections

During 2017 the following inspections were conducted in our Kennesaw, Georgia manufacturing facility:

In November 2017 the Therapeutic Goods Administration (TGA) representing the Australian government conducted an on-site inspection as part of their routine recertification process. Any nonconformities identified during the audit were subsequently resolved.

In November 2017 the Ukraine FDA conducted an on-site inspection as part of their routine recertification process. No nonconformities were identified during the audit.
In November and December 2017 LRQA conducted a routine surveillance assessment to ISO 13485:2003 and CMDCAS requirements. Any minor nonconformities identified during the audit were subsequently resolved.

During 2017 the following inspections were conducted in our Austin, Texas manufacturing facility:

In July 2017 the FDA conducted an on-site inspection as part of their routine Quality Systems Inspection Technique (QSIT) process. No observations were identified during the audit.
In August 2017 the FDA conducted an on-site inspection as part of a pre-approval process to implement an internal sterilization process. No observations were identified during the audit.
In September 2017 the Ukraine FDA conducted an on-site inspection as part of their routine recertification process. No nonconformities were identified during the audit.
In September 2017 G-MED, which acts as our Notified Body for the On-X product line conducted a routine surveillance assessment to ISO 13485:2003 and Canadian CMDCAS requirements. Any minor nonconformities identified during the audit were subsequently resolved.

All other registrations, licensures, certifications, and accreditations have been renewed or continued, or are in the process of being renewed or continued, and no regulatory actions are pending from state inspections.

Backlog

We currently do not have a firm backlog of orders related to BioGlue, On-X heart valves, CardioGenesis cardiac laser therapy, PerClot, PhotoFix, of the JOTEC product line. 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.

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 2017, 2016, and 2015 we spent approximately $19.5 million, $13.4 million, and $10.4 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 10%,

7%, and 7% of our revenues for each of 2017, 2016, and 2015, 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. We are working with the Chinese regulatory authorities and our consulting partners to conduct this ongoing study. Enrollment is expected to be completed during 2018.

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 is expected to continue throughout 2018.

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 is expected to continue throughout 2018.

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 throughout 2018.

We are currently conducting a 10 patient, post-market, prospective study to evaluate NeoPatch® as a tissue cover for chronically injured tendons requiring surgical revision. NeoPatch is an allograft derived from human chorioamniotic membrane which is indicated for use as a tissue covering to replace or supplement damaged tissue, such as diabetic foot ulcers, or surgically manipulated soft tissue, such as tendons and nerves. The study is expected to be completed in 2019.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. We resumed enrollment into the PerClot U.S. clinical trial in the fourth quarter of 2016, and assuming enrollment proceeds as anticipated, we could receive PMA from the FDA in the second half of 2019. 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. We own or have licensed rights to 41 U.S. patents and 114 foreign patents for legacy CryoLife, 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 21 pending U.S. patent applications and 59 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 2 months to 18 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, several of 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 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 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, 2017 we had approximately 1,000 employees. None of our employees are represented by a labor organization or 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 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 in the disposal of our waste with applicable laws and regulations promulgated by the U.S. Environmental Protection Agency, the Georgia Department of Natural Resources, Environmental Protection Division, and the Texas Commission on Environmental Quality, 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 of the anticipated benefits of the JOTEC acquisition.

On December 1, 2017 we acquired JOTEC for $168.8 million in cash and 2,682,754 shares of CryoLife common stock with an estimated value of $53.1 million as determined on the date of closing, for a total purchase price of approximately $221.9 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 institutional term loan B and a $30.0 million undrawn 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, including in the markets in which JOTEC is already direct; minimize difficulties and costs associated with transitioning away from distributors in key markets; and accelerate our ability to go direct in Europe in developed markets with the CryoLife and JOTEC product portfolios;

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 CE Mark for pipeline products;

Our ability to drive gross margin expansion;

Our ability to successfully integrate the JOTEC business with ours, including integrating the combined European sales force;

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.

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 the Company s, 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 than 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 implementation costs, which are expensed immediately.

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

BioGlue® Surgical Adhesive (BioGlue) is currently a significant source of our revenues, representing approximately 35%, 35%, and 40% of revenues for the twelve months ended December 31, 2017, 2016, and 2015, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- 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;
- Another company launched competitive products in 2016 and another is in the process of doing so. These companies have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets. Companies other than these may also pursue regulatory approval for competitive products;

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 increasingly subject to 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

BioGlue is subject to potential adverse developments with regard to its safety, efficacy, or reimbursement practices.

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 currently a significant source of our revenues, representing 37%, 37%, and 43% of revenues in the twelve months ended December 31, 2017, 2016, and 2015, respectively. 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;

Process donated tissue cost effectively or at all due to factors such as employee turnover, ineffective or inefficient operations, or an insufficiently skilled workforce;

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:

NOTA 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;

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; and

The EUTCD which require that countries in the eEEA take responsibility for regulating tissues and cells through a Competent Authority.

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 On-X and are subject to a variety of risks affecting them.

On-X is a significant source of our revenues, representing 20% and 19% of revenues in the twelve months ended December 31, 2017 and 2016, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

Our ability to achieve anticipated On-X revenue in international markets outside the U.S., particularly in markets with large legacy inventories;

Our ability to capitalize on the FDA s approved reduced INR indication;

Our ability to compete effectively with our major competitors, as they may have advantages over us in terms of cost structure, 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;

Changes in technology that may impact the market for mechanical heart valves, such as transcatheter aortic valve replacement, or TAVR devices; and

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.

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 product with a goal of returning the product to the European market in the third quarter of 2018. Failure to obtain CE Mark for the On-X AAP in the EEA could have a material adverse effect on EEA revenues in 2018 and beyond.

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.

In 2010 and 2011, we entered into various agreements with SMI pursuant to which, among other things, we (a) may distribute PerClot in certain international markets and are licensed to manufacture PerClot in the U.S.; (b) acquired some technology to assist in the production of a potentially key component in PerClot; and (c) obtained the exclusive right to pursue, obtain, and maintain FDA 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 assuming enrollment proceeds as anticipated, we could receive PMA from the FDA in the second half of 2019. 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, the pace of enrollment in the pivotal clinical trial and the approval process may be delayed because of unforeseen scheduling difficulties and unfavorable results at various stages in the pivotal clinical trial or the 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, SMI s breach 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.

PerClot sold in the EEA has a CE Mark owned by a third party, who informed us in the fourth quarter of 2017 that its CE Mark will expire in the second quarter of 2018. If that CE Mark is not timely renewed, we may be unable to distribute PerClot in the EEA and other countries that recognize the CE Mark, which could materially, adversely affect our future revenues.

Reclassification by the FDA of 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 MMM allograft heart valves from an unclassified medical device to a Class III medical device. The class of MMM allograft heart valves 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. We expect that the FDA will issue a proposal for reclassification of MMM allograft heart valves, which will be subject to a public comment period before finalization. After publication of the reclassification rule, we expect to have thirty months to submit for an FDA PMA, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers. To date, the FDA has not issued a proposed reclassification for 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, we anticipate requesting a meeting with the FDA to determine the specific requirements to file for and obtain a PMA, and we will determine an appropriate course of action in light of those requirements. 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 infeasible, necessitating that we 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 new products, including JOTEC and On-X products;

New Indications Drive growth by broadening the reach of some of our products and services, including the JOTEC, On-X, and BioGlue products, and preserved cardiac and vascular tissues, with new or expanded approvals and indications in the U.S. or in international markets;

Global Expansion Drive growth by expanding our current products and services into new markets, including emerging markets, and developing new direct sales territories overseas; and

Business Development Drive growth through business development by selectively pursuing potential acquisitions, licensing, or distribution rights of companies or technologies that complement our existing products, services, and infrastructure and expand our footprint in the cardiac and vascular surgery space, as we did with the recent acquisitions of JOTEC and On-X; and licensing of products developed internally with non-cardiac indications. 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.

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.

As noted above, we are currently engaged in an IDE clinical trial for PerClot, as well as a clinical trial in China for BioGlue and in the U.S. for the On-X valve. We also anticipate commencing in 2018 and 2019 U.S. trials for certain JOTEC products. Each of these trials is subject to the risks outlined herein.

We cannot give assurance that the relevant regulatory agencies will clear or approve these or any new products and services, or new indications, in a timely basis, if ever, or that the new 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, and quality may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials 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 programs;
Inability to manufacture or acquire sufficient quantities of the products, tissues, or any other components required for clinical trials;
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, and Office of Foreign Asset Control administered sanction programs;

- 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 British Pound and Euro as compared to the U.S. Dollar, including any fluctuations in exchange rates due to the exit of the U.K. from the European Union;

- Differing local product preferences and product requirements;

- Adverse economic or political changes or political instability;

Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs; and

Potential adverse tax consequences of overlapping tax structures.

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 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, we recently acquired JOTEC, which we financed by incurring further debt, using cash on hand, and issuing additional equity securities. This acquisition poses 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 to provide quality materials and supplies.

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 or the related suppliers and/or their facilities are shut down temporarily or permanently, whether by government order, natural disaster, or otherwise, there may not be sufficient materials or supplies available for purchase to allow us to manufacture our products or process tissues. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

We are dependent on single source suppliers and single facilities.

Some of the materials, supplies, and services that are key components of our product manufacturing or our tissue processing are sourced from single vendors. As a result, our ability to negotiate favorable terms with those vendors may be limited, and if those vendors experience operational, financial, quality, or regulatory difficulties, or those vendors 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 vendors resume operations or alternative vendors 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. We also conduct substantially all of 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.

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. 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;

Regulatory agencies could reclassify, reevaluate, or suspend our clearances and approvals to sell our products and distribute tissues;

European Notified Bodies have recently engaged in more rigorous regulatory enforcement activities and may continue to do so, and the European Union has adopted a new Medical Device Regulation (MDR 2017/745), which could result in product reclassifications or more stringent commercialization requirement that adversely impact our clearances and approvals; 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.

As an example of these risks, 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 re-inspection by the FDA 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. Despite an FDA re-inspection in the first quarter of 2015, after which the FDA closed out the warning letter issued in 2013, we remain subject to further inspections and oversight by the FDA and, if the FDA is not satisfied with our quality and regulatory compliance, it could institute a wide variety of enforcement actions, ranging from issuing additional Form 483s or warning letters, to more severe sanctions such as fines; injunctions; civil penalties; recalls of our products and/or tissues; operating restrictions; suspension of production; non-approval or withdrawal of approvals or clearances for new products or existing products; and criminal prosecution. Any further Form 483s, warning letters, recalls, holds, or other adverse action from the FDA may decrease demand for our products or tissues or cause us to write down our inventories or deferred preservation costs and 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 mechanical, synthetic, and animal-based tissue valves for implantation;
- The sale of endovascular and surgical stents;
- 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, Ethicon (a Johnson & Johnson Company), Medtronic, Inc., Abbott Laboratories, LivaNova PLC, Edwards Life Sciences Corp., BD, Integra Life Sciences Holdings, LifeNet, Admedus, Inc., Aziyo Biologics, Cook Medical, Gore, Terumo Corp., Endologix, Antegraft, Inc., LeMaitre, 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.

Significant disruptions of information technology systems or breaches of information security 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 infrastructure 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 service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors. Our information technology and information security systems 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 motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. For example, although we have taken security precautions and are assessing additional precautions to provide greater data security, certain data may be vulnerable to loss in a catastrophic event. We have only limited cyber-insurance coverage that will not cover a number of the events described above and this insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. We thus have no insurance for most of the claims that could be raised and, for those where we have coverage, those claims could exceed the limits of our coverage. Any interruption or breach in our systems 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 EEA in May 2018 could adversely affect our business.

The European Commission has approved a data protection regulation, known as the General Data Protection Regulation (GDPR), which takes 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) and significant penalties for noncompliance. GDPR, as well as any related government enforcement activities, may be costly to comply with, result in negative publicity, increase our operating costs, require significant management time and energy, 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 or reductions for medical devices that incorporate components produced by us. 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.

Our sales are affected by challenging domestic and international economic and geopolitical conditions and their constraining effect on hospital budgets, and demand for our products and tissue preservation services could decrease in the future, which could materially, adversely affect our business.

The demand for our products and tissue preservation services can fluctuate from time to time. In challenging economic environments, hospitals attempt to control costs by reducing spending on consumable and capital items, which can result in reduced demand for some of our products and services. If demand for our products or tissue preservation services decreases significantly in the future, our revenues, profitability, and cash flows would likely decrease, possibly materially. In addition, the manufacturing throughput of our products and the processing throughput of our preservation services would necessarily decrease, which would likely adversely impact our margins and, therefore, our profitability, possibly materially. Further, if

demand for our products and/or tissue preservation services materially decreases in the future, we may not be able to ship our products and/or tissues before they expire, which would cause us to write down our inventories and/or deferred preservation costs.

Our sales may also be affected by challenging economic and geopolitical conditions in countries around the world, in addition to the U.S., particularly in countries where we have significant BioGlue, On-X product, or JOTEC product sales or where BioGlue, On-X products, or JOTEC products are still in a growth phase. These factors could materially, adversely affect our revenues, financial condition, and profitability.

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.

If healthcare providers are not adequately reimbursed for procedures conducted with our products, or if reimbursement policies change adversely, we may not be successful in marketing and selling our products or preservation services.

Most of our customers, and the healthcare providers to whom our customers supply medical devices, rely on third-party payors, including government programs and private health insurance plans, to reimburse some or all of the cost of the procedures in which medical devices that incorporate components we manufacture or assemble are used. Healthcare providers, facilities, and government agencies are unlikely to purchase our products or implant our tissues if they are not adequately reimbursed for these procedures. Unless a sufficient amount of peer-reviewed clinical data about our products and preservation services has been published, third-party payors, including insurance companies and government agencies, may refuse to provide reimbursement. The continuing efforts of governmental authorities, insurance companies, and other payors of healthcare costs to contain or reduce these costs could lead to patients being unable to obtain approval for payment from these third-party payors. Furthermore, even if reimbursement is provided, it may not be adequate to fully compensate the clinicians or hospitals. Some third-party payors may impose restrictions on the procedures for which they will provide reimbursement. If healthcare providers cannot obtain sufficient reimbursement from third-party payors for our products or preservation services or the screenings conducted with our products, we may not achieve significant market acceptance. Acceptance of our products in international markets will depend upon the availability of adequate reimbursement or funding within prevailing healthcare payment systems. Reimbursement, funding, and healthcare payment systems vary significantly by country. We may not obtain approvals for reimbursement in a timely manner or at all.

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 FDCA. 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.

Tax reform could have a material adverse effect on us.

The December 2017 legislation commonly referred to as the Tax Cuts and Jobs Act (the Tax Act) made significant changes to federal income tax law including, among other things, reducing the statutory corporate income tax rate to 21 percent from 35 percent and changing the U.S. taxation of our non-U.S. business activities. We may be adversely affected by these changes in U.S. tax laws and regulations, and it is possible that governmental authorities in the U.S. and/or other countries could further amend tax laws that would adversely affect us. In addition, we are required to evaluate the impact of the Tax Act on our operations and financial statements, and to the extent we initially do so inaccurately, we may not provide investors or the public with advance notice of any adverse effect. Currently, we have accounted for the effects of the Tax Act using reasonable estimates based on currently available information and our interpretations thereof. This accounting may change due to, among other things, changes in interpretations we have made and the issuance of new tax or accounting guidance.

Certain changes in tax law implemented by the Tax Act will be partially effective in the current 2018 fiscal year and fully effective in the 2019 fiscal year. The primary impacts to us include repeal of the alternative minimum tax regime, decrease of the corporate income tax rate structure, net operating loss limitations, and changes to the limits on executive compensation deductions. These changes will have a material impact to the value of deferred tax assets and liabilities, and our future taxable income and effective tax rate. Although we currently anticipate the enacted changes in the corporate tax rate and calculation of taxable income will have a favorable effect on our financial condition, profitability, and/or cash flows, we are still analyzing the Tax Act with our professional advisers. Until such analysis is complete and verified, the full impact of the Tax Act on us in future periods is uncertain, and no assurances can be made by us that it will not have any negative impacts on us.

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, Inc. (Hemosphere) and Cardiogenesis Corporation, 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, 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 the acquisition of On-X Life Technologies that are limited under Section 382. We believe, however, that such net operating loss carryforwards from On-X will be fully realizable prior to expiration. 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 federal and state anti-kickback, self-referral, false claims privacy, and transparency laws, 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 federal anti-kickback, self-referral, false claims, privacy, and transparency laws, and similar laws, often referred to collectively as healthcare compliance laws. Healthcare compliance laws are broad, can be ambiguous, and are complex, and even minor inadvertent violations can give rise to claims that the relevant law has been violated. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal

penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers compensation programs, and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents and retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions. Any government investigation or a finding of a violation of these laws could result in a material, adverse effect on our business, financial condition, and profitability.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid, or other government-sponsored healthcare programs. We have

entered into consulting agreements, speaker agreements, research agreements, and product development agreements with healthcare professionals, 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 laws, including state anti-referral laws and other applicable anti-kickback 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 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 have conducted 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 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, 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 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 federally funded healthcare programs, including Medicare and Medicaid, for noncompliance.

The Federal False Claims Act (FCA) imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. Government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice (DOJ) on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers, including the off-label promotion of products or the payment of prohibited kickbacks to doctors, violated the FCA, resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts, and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

The Physician Payments Sunshine Act and similar state laws require us to annually report in detail certain payments and transfer of value from us to healthcare professionals, such as reimbursement for travel and meal expenses or compensation for services provided such as training, consulting, and research and development. This information is then posted on the website of the Center of Medicare and Medicaid Services (CMS). Certain states also prohibit some forms of these payments, require adoption of marketing codes of conduct, and regulate our relationships with physicians and other referral sources.

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 federal or state 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 state or federal 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, including U.S. healthcare reform legislation signed in 2010, 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.

The Patient Protection and Affordable Care Act (ACA) and the Health Care and Education Affordability Reconciliation Act of 2010 imposed significant new taxes on medical device makers in the form of a 2.3 percent excise tax on all U.S. medical device sales that commenced in January 2013. While this tax was suspended for 2016 and 2017, and just

recently suspended again for 2018 and 2019, and while efforts are being continued to repeal or delay this tax further, there is no guarantee that the excise tax will not be reinstated or that the underlying legislation might not be repealed or replaced.

Efforts to repeal and replace the ACA have been ongoing since the 2016 election, but it is unclear if these efforts will be successful. On January 20, 2017, President Trump issued an executive order titled Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal. In addition, as part of the Tax Act, the individual mandate, which required individuals to purchase insurance, was repealed. The impact of the executive order and the repeal of the individual mandate, as well as the future of the ACA itself, remain unclear. There are many programs and requirements for which the details have not yet been fully established or the consequences are not fully understood. 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.

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 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;

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;

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.

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

The majority of our foreign product and tissue processing revenues are denominated in Euros and British Pounds 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 and British Pounds 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.

If we experience decreasing prices for our goods and services and we are unable to reduce our expenses, our results of operations will suffer.

We may experience decreasing prices for our goods and services due to pricing pressure experienced by our customers from managed care organizations and other third-party payors, increased market power of our customers as the medical device industry consolidates, and increased competition among medical engineering and manufacturing services providers. If the prices for our goods and services decrease and we are unable to reduce our expenses, our results of operations will be adversely affected.

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.

We have obtained licenses from third parties for certain patents and patent application rights, including rights related to our PerClot technologies. 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.

Furthermore, competitors may independently develop similar technologies, or duplicate our technologies, or design around the patented aspects of such technologies. In addition, 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. For example, in 2015 we resolved a patent infringement case with Medafor related to technology we licensed from SMI. The settlement of that patent infringement case resulted in the continuation of an injunction prohibiting us from marketing, selling, or distributing PerClot in the U.S. until February 8, 2019. We incurred substantial attorneys fees and costs in pursuing and defending that case, and only a portion of those fees and costs are subject to recovery through indemnification. Should we be forced to sue a potential infringer, if we are unsuccessful in prohibiting infringements of our patents, should the validity of our patents be successfully challenged by others, or if we are sued by another party for alleged infringement (whether we ultimately prevail or not), our revenues, financial condition, profitability, and cash flows could be materially, adversely affected.

We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets of others.

Some of our employees were previously employed at other medical device or tissue companies. We may also hire additional employees who are currently employed at other medical device or tissue companies, including our competitors. Additionally, consultants or other independent agents with which we may contract may be or have been in a contractual arrangement with one or more of our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or independent contractors have used or disclosed any party s trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to us. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to market existing or new products, which could severely harm our business.

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 the 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 BioFoam, and process and preserve tissues from our Preservation Services segment at our headquarters facility. We began limited manufacturing of PhotoFix in the fourth quarter of 2017 and expect to fully establish manufacturing operations in 2018. 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 located on a 335,000 square foot campus. One 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, England, Italy, Poland, Spain, and Switzerland.

Item 3. Legal Proceedings.

We are currently involved in litigation with the representative of the former shareholders of On-X over our indemnification claims under the On-X purchase agreement and the approximately $10 million of the purchase price paid into escrow. The On-X shareholder representative filed a complaint in Delaware Chancery Court on June 1, 2017, seeking declaratory relief that our indemnification claims were invalid. We timely filed an answer and counterclaim on June 22, 2017, and discovery is underway.

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.

2017	High	Low
First quarter	$ 19.60	$ 15.20
Second quarter	20.30	14.03
Third quarter	23.35	17.60
Fourth quarter	24.00	18.25

2016	High	Low
First quarter	$ 11.33	$ 8.94
Second quarter	13.00	10.64
Third quarter	18.64	11.69
Fourth quarter	20.15	16.40

As of February 28, 2018 we had 259 shareholders of record.

Dividends

We initiated a cash dividend in the third quarter of 2012 and paid the dividend quarterly until, in December 2015, our Board of Directors discontinued dividend payments for the foreseeable future.

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 13 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, 2017 of equity securities that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934.

Issuer Purchases of Equity Securities

Common Stock

	Total Number of Common Shares	Dollar Value

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Purchased as Part of Publicly Announced Plans or Programs	of Common Shares That May Yet Be Purchased Under the Plans or Programs
10/01/17 - 10/31/17	--	--	--	--
11/01/17 - 11/30/17	731	$ 19.55	--	--
12/01/17 - 12/31/17	--	--	--	--
Total	731	$ 19.55	--	--

The common shares purchased during the quarter ended December 31, 2017 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,				
	2017 [1]	2016 [2]	2015	2014	2013
Operations					
Revenues	$ 189,702	$ 180,380	$ 145,898	$ 144,641	$ 140,763
Operating income	7,970	21,820	5,354	8,838	13,820
Net income[3]	3,704	10,778	4,005	7,322	16,172
Net income applicable to common shareholders diluted[3]	3,643	10,576	3,918	7,164	15,813
Research and development expense as a percentage of revenues	10%	7%	7%	6%	6%
Income Per Common Share[3]					
Basic	$ 0.11	$ 0.33	$ 0.14	$ 0.26	$ 0.59
Diluted	$ 0.11	$ 0.32	$ 0.14	$ 0.25	$ 0.57
Dividend Declared Per Common Share	$ --	$ --	$ 0.120	$ 0.118	$ 0.108
Year-End Financial Position					
Total assets	$ 589,693	$ 316,140	$ 181,179	$ 176,157	$ 174,683
Working capital	136,340	117,131	90,058	85,401	85,605
Long-term liabilities	269,695	77,055	6,323	6,845	9,214
Shareholders equity	277,058	208,983	155,251	148,685	144,747
Current ratio[4]	4:1	5:1	6:1	5:1	5:1

1 In December 2017 we completed our acquisition of JOTEC AG, 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 The 2013 net income and income per common share includes the favorable effect of a $12.7 million pre-tax gain on the sale of an investment in the common stock of Medafor, Inc. as a result of Bard completing its acquisition of the outstanding common shares of Medafor, Inc.

[4] 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), incorporated in 1984 in Florida, is a leader in the manufacturing processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures focused on aortic repair. Our medical devices and processed tissues primarily include four product families: BioGlue® Surgical Adhesive (BioGlue); On-X mechanical heart valves and surgical products; JOTEC endovascular and surgical products; and cardiac and vascular human tissues including the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch (CryoPatch SG), both of which are processed using our proprietary SynerGraft® technology. Additional products include CardioGenesis cardiac laser therapy, PerClot® and PhotoFix™.

For the year ended December 31, 2017 we reported record annual revenues of $189.7 million, increasing 5% over the prior year, which includes revenues from the acquisition of JOTEC GmbH (JOTEC), a Hechingen, Germany-based endovascular and surgical products company in December 2017. We generated $10.8 million in cash flows from operations during 2017. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2017 results. See Part I, Item 1, Business, for further discussion of our business and activities during 2017.

Recent Events

Acquisition of JOTEC

On October 10, 2017 we announced that we entered into a definitive agreement to acquire JOTEC AG (JOTEC), a Swiss entity (the Acquisition), which we converted to JOTEC GmbH, for approximately $225.0 million, subject to certain adjustments. The transaction closed on December 1, 2017 and JOTEC is being operated as a wholly owned subsidiary of CryoLife. In connection with the closing of the JOTEC acquisition, CryoLife entered into a Credit and Guaranty Agreement (Credit Agreement) with certain financial institutions as lenders, and Deutsche Bank AG New York Branch, as administrative and collateral agent, for 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.

Pro Forma Results

JOTEC revenues were $4.1 million and the net loss was $1.5 million from the date of acquisition through December 31, 2017. Our unaudited pro forma results of operations for the years ended December 31, 2017 and 2016, assuming the JOTEC acquisition had occurred as of January 1, 2016, are presented for comparative purposes below. These amounts are based on available information from the results of operations of JOTEC prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the acquisition been completed on January 1, 2016. Differences between the preliminary and final purchase price allocation could have an impact on the pro forma financial information presented below and that impact could be material. This unaudited pro forma information does not project operating results post acquisition.

	Twelve Months Ended December 31,	
	2017	**2016**
Total revenues	$ 236,209	$ 224,896
Net loss	(736)	(1,966)

Pro forma loss per common share - basic	$	(0.02)	$	(0.06)
Pro forma loss per common share - diluted	$	(0.02)	$	(0.06)

Pro forma net loss was calculated using a normalized tax rate of approximately 38%.

The pro forma amortization of intangible assets acquired, as reported in our 8-K/A filed on February 16, 2018, was incorrect due to a clerical error. The corrected pro forma amortization is included in the determination of pro forma loss per common share for the twelve months ended December 31, 2016 presented above. The result of this correction increased the pro forma amortization adjustment by $4.3 million to a total of $5.5 million for the twelve month ended December 31, 2016. This adjustment reduced the results per common share for the twelve months ended December 31, 2016 by $0.08 per common

share from $0.02 per common share originally reported in the 8-K/A, resulting in an adjusted pro forma net loss per common share of ($0.06) on a fully diluted basis.

The results for the twelve months ended December 31, 2017 presented above include pro forma amortization of intangible assets acquired of $4.9 million.

The result of this correction on pro forma results of operations, as reported in the 8-K/A referenced for the nine months ended September 30, 2017, also increased the pro forma amortization adjustment by $3.2 million for the nine months ended September to a total of $3.8 million. This adjustment reduced the pro forma net income per common share by $0.06 from $0.13 per common share to an adjusted pro forma net income per common share of $0.07 on a fully diluted basis for the nine months ended September 30, 2017.

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, including: cash equivalents, certain marketable securities, certain restricted securities, contingent consideration, and derivative instruments. We may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis, although as of December 31, 2017 we have not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

We also measure certain non-financial assets at fair value on a non-recurring basis. These non-recurring valuations include evaluating assets such as cost method investments, long-lived assets, and non-amortizing intangible assets for impairment; allocating value to assets in an acquired asset group; applying accounting for business combinations; and allocating goodwill to divested components of a business. 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 rehandling 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 (OTPOs), which consign the tissue to us for processing, preservation, and distribution. Deferred preservation costs consist primarily of the procurement fees charged by the OTPOs, 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 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 $922,000, $897,000, and $483,000 for the years ended December 31, 2017, 2016, and 2015, 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 acquired net operating loss carryforwards in the acquisition of On-X; the majority of which have been realized. We also acquired net operating loss carryforwards in certain foreign jurisdictions in our recent acquisition of JOTEC. While our analysis is still on-going, 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

In February 2016 the Financial Accounting Standards Board (FASB) amended its Accounting Standards Codification 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 leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to the current Topic 840, *Leases*. It is effective for fiscal years and interim periods beginning after December 15, 2018, and early adoption is permitted. We are evaluating the impact the adoption of this standard will have on our financial position, results of operations, and cash flows.

In May 2014 the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers.* Since ASU 2014-09 was issued, several additional ASUs have been issued to clarify various elements of the guidance. 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. As required, we have adopted the new standard effective January 1, 2018. We are using the modified retrospective method and under this method we will have a cumulative catch up adjustment and will be providing additional disclosures in future filings including a comparison of results under the new standard to the previous standard. We have completed an initial evaluation of the potential impact from adopting the new standard, including a detailed review of performance obligations for all material revenue streams. We currently believe the most significant impacts may include the following items:

- Certain distributor agreements included inventory buyback provisions under defined change of business conditions, which under the new standard, would not qualify as a completed revenue transaction because these provisions could prevent us from transferring control to the distributor and would, therefore, result in a reversal of revenue and recording of deferred revenue until the proper criteria are met. We have modified most of our agreements to remove the buyback provisions effective on or before January 1, 2018. As of January 1, 2018, there were certain remaining agreements with buyback provisions that had not been modified. We expect to record a cumulative effect adjustment upon adoption of the new standard to record the deferred revenue associated with these agreements. The deferred revenue will be recognized over future periods as the medical devices are implanted during the remaining term of the agreement.

- Certain JOTEC products are manufactured to order, have no alternative use, and contain an enforceable right to payment for the performance completed. The revenue impact of these agreements is not material, but it is anticipated the sale of these products will increase over time. We expect to record a cumulative effect adjustment upon adoption of the new standard to record the deferred revenue associated with these agreements.

Based on the procedures and calculations completed to date, we do not expect that the combined cumulative effect adjustments will be material to our financial statements. In addition, we have not identified other matters related to the adoption of the standard that we believe would have a material impact on our financial position, results of operations, or cash flows.

Results of Operations

(In thousands)

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2017	**2016**	**2017**	**2016**
Products:				
BioGlue and BioFoam	$ 17,845	$ 15,982	34%	36%
On-X	9,993	9,073	19%	20%
JOTEC	4,136	--	8%	--%
CardioGenesis cardiac laser therapy	1,736	2,367	3%	5%
PerClot	892	1,038	2%	2%
PhotoFix	510	465	1%	1%
Total products	35,112	28,925	67%	64%
Preservation services:				
Cardiac tissue	8,599	7,442	16%	17%
Vascular tissue	9,115	8,662	17%	19%
Total preservation services	17,714	16,104	33%	36%
Total	$ 52,826	$ 45,029	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2017	**2016**	**2017**	**2016**
Products:				
BioGlue and BioFoam	$ 65,939	$ 63,461	35%	35%
On-X	37,041	34,232	19%	19%
JOTEC	4,136	--	2%	--%
CardioGenesis cardiac laser therapy	6,866	7,864	4%	5%
PerClot	3,533	4,021	2%	2%
PhotoFix	2,116	1,871	1%	1%
HeRO Graft	--	2,325	--%	1%
ProCol	--	218	--%	--%

Total products	119,631	113,992	63%	63%
Preservation services:				
Cardiac tissue	32,510	29,697	17%	17%
Vascular tissue	37,561	36,691	20%	20%
Total preservation services	70,071	66,388	37%	37%
Total	$ 189,702	$ 180,380	100%	100%

Revenues increased 17% and 5% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2017 is presented below.

Products

Revenues from products increased 21% and 5% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. These increases were primarily due to increased revenues from the sale of BioGlue and On-X products and the acquisition of JOTEC during the fourth quarter of 2017. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; On-X; JOTEC; CardioGenesis cardiac laser therapy; PerClot; PhotoFix; Hemodialysis Reliable Outflow Graft (HeRO® Graft); and ProCol® Vascular Bioprosthesis (ProCol) is presented below.

Sales of certain products through our direct sales force and distributors across Europe, the U.K., and various other countries are denominated in a variety of currencies, with a concentration in Euros and British Pounds, which are subject to exchange rate fluctuations. During 2017, the U.S. Dollar generally weakened in comparison to these currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into U.S. Dollars. Future changes in currency exchange rates could have a material, adverse effect on our revenues denominated in foreign currencies. Additionally, our sales to many distributors worldwide are denominated in U.S. Dollars and, although these sales are not directly impacted by currency exchange rates, we believe that 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 12% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. This increase was primarily due to a 5% increase in the volume of milliliters sold, which increased revenues by 8%, the favorable impact of foreign exchange rates, which increased revenues by 2%, and an increase in average sales prices, which increased revenues by 2%.

Revenues from the sale of surgical sealants increased 4% for the twelve months ended December 31, 2017, as compared to the twelve months ended December 31, 2016. This increase was primarily due to a 4% increase in the volume of milliliters sold, which increased revenues by 3%, and an increase in average sales prices, which increased revenues by 1%.

The increase in sales volume of surgical sealants for the three and twelve months ended December 31, 2017 was primarily due to an increase in sales of BioGlue in international markets, primarily Japan and direct European countries, partially offset by a decrease in BioGlue sales in domestic markets.

Sales of BioGlue increased due to market penetration in certain international markets and to the timing of distributor ordering patterns. We are currently seeking regulatory approval for BioGlue in China and, if this effort is successful, we believe this will provide an additional international growth opportunity for BioGlue in future years.

Domestic BioGlue revenues accounted for 51% and 53% of total BioGlue revenues for the three and twelve months ended December 31, 2017, respectively, and 58% and 56% of total BioGlue revenues for the three and twelve months ended December 31, 2016, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2017 and 2016. BioFoam is currently approved for sale in certain international markets.

On-X

On-X product revenues increased 10% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. This increase was primarily due to the combined effect of a favorable product mix,

which increased revenues by 8%, an increase in average sales prices, which increased revenues by 1%, and an increase due to the favorable impact of foreign exchange rates of 1%. The increase of On-X products was primarily due to an increase in volume in the U.S. and an increase in Canadian revenues after establishing a direct market in July 2017, partially offset by a decrease in volume internationally, reduced On-X AAP shipments due to the delay in obtaining re-certification of the On-X AAP CE Mark in Europe, and reduced shipments to certain Asia Pacific distributors.

On-X product revenues increased 10% for the twelve months ended December 31, 2017, as compared to the eleven months ended December 31, 2016. On January 20, 2016 we acquired On-X Life Technologies Holdings, Inc. This increase in sales of On-X products was primarily due to volume increases in the U.S. and our direct markets in Europe, partially offset by revenue reversals related to the distributor inventory buybacks as a result of going direct in certain markets, reduced On-X AAP shipments due to the delay in obtaining re-certification of the On-X AAP CE Mark in Europe, and reduced shipments to certain Asia Pacific distributors. On-X product revenues,

excluding the revenue reversal of $1.0 million related to inventory buybacks, increased 13% for the twelve months ended December 31, 2017, as compared to the eleven months ended December 31, 2016.

On-X OEM revenues increased 33% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. On-X OEM revenues decreased 23% for the twelve months ended December 31, 2017, as compared to the eleven months ended December 31, 2016. On-X OEM revenues were $325,000 and $244,000 for the three months ended December 31, 2017 and 2016, respectively and $1.3 million and $1.7 million for the twelve months ended December 31, 2017 and eleven months ended December 31, 2016, respectively. On-X OEM revenues decreased for the twelve months ended December 31, 2017, compared to the eleven months ended December 31, 2016, due to an anticipated decrease in OEM activities for a major OEM customer.

JOTEC

On December 1, 2017 CryoLife acquired JOTEC, a German-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 combined pre- and post-acquisition revenues for the three and twelve months ended December 31, 2017 increased 26% and 14%, respectively, when compared to JOTEC pre-acquisition revenues for the three and twelve months ended December 31, 2016, respectively.

We believe that the growth rate for JOTEC products will achieve double digit growth over the next five years due to the selling efforts of our larger, realigned international sales force as they undertake additional training and become more experienced in selling JOTEC products. We expect this larger sales force will take market share and drive market expansion, including opening additional hospitals to using JOTEC products, based on the technological and clinically advanced benefits of JOTEC products.

CardioGenesis Cardiac Laser Therapy

Revenues from our CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from cardiac laser therapy decreased 27% for the three months ended December 31, 2017 as compared to the three months ended December 31, 2016. Revenues from the sale of laser consoles were $118,000 and $507,000 for the three months ended December 31, 2017 and 2016, respectively. Revenues from the sale of handpieces decreased 13% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. This decrease was primarily due to a 17% decrease in unit shipments of handpieces, which decreased revenues by 17%, partially offset by an increase in average sales prices, which increased revenues by 4%.

Revenues from cardiac laser therapy decreased 13% for the twelve months ended December 31, 2017, as compared to the twelve months ended December 31, 2016. Revenues from the sale of laser consoles were $550,000 and $507,000 for the twelve months ended December 31, 2017 and 2016, respectively. Revenues from the sale of handpieces decreased 13% for the twelve months ended December 31, 2017 as compared to the twelve months ended December 31, 2016. This decrease was primarily due to a 13% decrease in unit shipments of handpieces, which decreased revenues by 13%.

The major contributing factors to the decrease in handpiece revenues included the de-emphasis on this product line since 2016, emphasis on On-X and JOTEC product lines acquired in business acquisitions, 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. Revenues from laser console sales are difficult to predict and can vary significantly from quarter to quarter.

PerClot

Revenues from the sale of PerClot decreased 14% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. This decrease was primarily due to a 14% decrease in the volume of grams sold, which decreased revenues by 11%, and a decrease in average selling prices, which decreased revenues by 7%, partially offset by the favorable effect of foreign currency exchange, which increased revenues by 4%.

Revenues from the sale of PerClot decreased 12% for the twelve months ended December 31, 2017, as compared to the twelve months ended December 31, 2016. This decrease was primarily due to an 11% decrease in sales volume, which decreased revenues by 9%, and a decrease in average selling prices, which decreased revenues by 3%.

The sales volume decrease for the twelve months ended December 31, 2017 was primarily due to a decline in sales of PerClot in Europe due to competitive pressures. The decrease in average selling prices for the twelve months ended December 31, 2017 was primarily due to price reductions extended to certain customers in Europe as a result of pricing pressures from competitive products.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. We resumed enrollment into the PerClot U.S. clinical trial in the fourth quarter of 2016, and assuming enrollment proceeds as anticipated, we could receive Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) in the second half of 2019.

PhotoFix

PhotoFix revenues increased 10% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. This increase was primarily due to an 8% increase in units sold, which increased revenues by 8% and an increase in average sales prices which increased revenues by 2%. PhotoFix revenues increased 13% for the twelve months ended December 31, 2017, as compared to the twelve months ended December 31, 2016. This increase was primarily due to a 12% increase in units sold, which increased revenues by 12%, and an increase in average sales prices, which increased revenues by 1%. The increase in volume for both the three and twelve months ended December 31, 2017 is primarily due to an increase in the number of implanting physicians when compared to the prior year period.

HeRO Graft

On February 3, 2016 we sold our HeRO Graft product line to Merit Medical Systems, Inc. (Merit), and we agreed to continue to manufacture the HeRO Graft for Merit for up to six months under a transition supply agreement. Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. Revenues include sales to hospitals through February 3, 2016 and to Merit from that date through the second quarter of 2016. The sales transfer to Merit was completed in the second quarter of 2016, at which time we ceased sales of the HeRO Graft.

ProCol

On March 18, 2016 we sold our ProCol product line to LeMaitre Vascular, Inc. (LeMaitre), at which time we ceased sales of these products.

Preservation Services

Revenues from preservation services increased 10% and 6% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. 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 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, 2017.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of human heart valves and cardiac patch tissues increased 16% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. This increase was primarily due to a 16% increase in unit shipments of cardiac tissues, which increased revenues by 15% and an increase in average service fees, which increased revenues by 1%.

Revenues from cardiac preservation services increased 9% for the twelve months ended December 31, 2017, as compared to the twelve months ended December 31, 2016. This increase was primarily due to a 7% increase in unit

shipments of cardiac tissues, which increased revenues by 7%, and an increase in average service fees, which increased revenues by 2%.

The increase in volume for the three months ended December 31, 2017 was primarily due to an increase in the volume of cardiac valve shipments. The increase in volume for the twelve months ended December 31, 2017 was primarily due to an increase in the volume of cardiac valve and patch shipments. The increase in average service fees for the three and twelve months ended December 31, 2017 was primarily due to list fee increases in domestic markets 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 5% for the three months ended December 31, 2017, as compared to the three months ended December 31, 2016. This increase was primarily due to a 7% 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 3%.

Revenues from vascular preservation services increased 2% for the twelve months ended December 31, 2017, as compared to the twelve months ended December 31, 2016. This increase was primarily due to a 4% increase in unit shipments of vascular tissues, which increased revenues by 4%, partially offset by a decrease in average service fees, which decreased revenues by 2%.

The increase in shipments of vascular tissues for the three and twelve months ended December 31, 2017 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, 2017 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,	
	2017	**2016**	**2017**	**2016**
Cost of products	$ 8,601	$ 6,734	$ 29,798	$ 28,033

Cost of products increased 28% and 6% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. Cost of products in 2017 and 2016 includes costs related to BioGlue and BioFoam, On-X products, CardioGenesis cardiac laser therapy, PerClot, PhotoFix, HeRO Graft through the second quarter of 2016, and ProCol through the first quarter of 2016. Cost of

products in the fourth quarter of 2017 also included costs related to JOTEC.

The increase in cost of products in the three and twelve months ended December 31, 2017 was primarily due to increased revenues from the sale of BioGlue and On-X products and revenues related to JOTEC which we acquired during the fourth quarter of 2017, partially offset by a reduction in cost of products following the sale of the HeRO Graft and ProCol product lines in the first half of 2016. Cost of products in the three and twelve months ended December 31, 2017 includes $584,000 and $2.7 million, respectively, in acquisition inventory basis step-up expense, related to JOTEC and On-X inventory fair value adjustments recorded in purchase accounting and distributor buybacks. The three and twelve months ended December 31, 2016 includes $822,000 and $3.0 million, respectively, in acquisition inventory basis step-up expense, related to On-X inventory fair value adjustments recorded in distributor buybacks and purchase accounting.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Cost of preservation services	$ 7,862	$ 7,100	$ 31,262	$ 33,448

Cost of preservation services increased 11% and decreased 7% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three months ended December 31, 2017 primarily due to an increase in the unit shipment of tissues. Cost of preservation services decreased in the twelve months ended December 31, 2017 primarily due to a decrease in the unit cost of tissues, partially offset by an increase in the number of tissue shipments. The unit cost of preservation services decreased during 2017 when compared to 2016, primarily resulting from the impact of higher volume on the unit cost of processing tissues during 2016, which shipped during 2017.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Gross margin	$ 36,363	$ 31,195	$ 128,642	$ 118,899
Gross margin as a percentage of total revenues	69%	69%	68%	66%

Gross margin increased 17% and 8% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. These increases were primarily due to the addition of margins related to the JOTEC product line and increases in revenues from BioGlue and On-X products. For the twelve months ended December 31, 2017, the increase is due to increased revenues of major products and higher tissue margins due to a decrease in the unit cost of tissues sold. The increases were partially offset by decreases in margins for the divested HeRO Graft and ProCol product lines and a decrease in margins for CardioGenesis cardiac laser therapy due to decreased revenues.

Gross margin as a percentage of total revenues was flat and increased in the three and twelve months ended December 31, 2017, as compared to the three and twelve months ended December 31, 2016, respectively. The increase was primarily due to increases in tissue margins, as a result of a decrease in the unit cost of tissues sold, and a reduction of inventory basis step-up expense as compared to the prior year period.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
	$ 30,195	$ 22,246	$ 101,211	$ 91,548

General, administrative, and marketing expenses				
General, administrative, and marketing expenses as a percentage of total revenues	57%	49%	53%	51%

General, administrative, and marketing expenses increased 36% and 11% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively.

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. General, administrative, and marketing expenses for the three and twelve months ended December 31, 2016

included $832,000 and $7.9 million, respectively, in business development costs primarily related to the acquisition of On-X in January 2016, which include, among other costs, expenses related to the termination of international and domestic distribution agreements. We also incurred additional general, administrative, and marketing expenses during 2016 related to the expanded sales force and the ongoing operations of On-X.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Research and development expenses	$ 6,363	$ 3,844	$ 19,461	$ 13,446
Research and development expenses as a percentage of total revenues	12%	9%	10%	7%

Research and development expenses increased 66% and 45% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. Research and development spending in these periods was primarily on clinical trials for PerClot in the U.S., our tissue processing, On-X products, BioGlue in China, and the purchase of commercial rights to an early stage technology.

Interest Expense

Interest expense was $2.4 million and $4.9 million for the three and twelve months ended December 31, 2017, respectively, and interest expense was $787,000 and $3.0 million for the three and twelve months ended December 31, 2016, respectively. Interest expense in the 2017 and 2016 periods included interest on debt and uncertain tax positions. Interest expense in both the three and twelve months ended December 31, 2017 and 2016 includes interest on borrowings under the $75.0 million term loan we entered into in January 2016 to finance, in part, the acquisition of On-X. Interest expense in the three and twelve months ended December 31, 2017 also included 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 and to pay the remaining balance of the previous $75.0 million term loan.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
(Loss) income before income taxes	$ (2,348)	$ 3,759	$ 3,561	$ 18,412
Income tax expense (benefit)	659	862	(143)	7,634
Net (loss) income	$ (3,007)	$ 2,897	$ 3,704	$ 10,778
Diluted income per common share	$ (0.09)	$ 0.09	$ 0.11	$ 0.32
Diluted weighted-average common shares outstanding	34,025	33,443	34,163	32,822

Income before income taxes decreased 162% and 81% for the three and twelve months ended December 31, 2017, respectively, as compared to the three and twelve months ended December 31, 2016, respectively. The decrease in

income before income taxes for the three and twelve months ended December 31, 2017 was due to an increase in operating expenses and interest expense, partially offset by an increase in gross margins, as discussed above as well as the gain on sale of business components recorded in the twelve months ended December 31, 2016.

Our effective income tax rate was -28% and -4% for the three and twelve months ended December 31, 2017, respectively, as compared to 23% and 41% for the three and twelve months ended December 31, 2016, respectively. 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 twelve months ended December 31, 2017 was favorably affected by excess tax benefits on stock compensation and the R&D Tax Credit, partially offset by nondeductible transaction costs and nondeductible meals & entertainment expenses.

Our income tax rate for the twelve months ended December 31, 2016 was favorably affected by the reversal of $869,000 in uncertain tax positions, primarily related to research and development tax credits for which the statute of limitations has expired, partially offset by the expiration of certain state net operating losses and other permanent differences.

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. We have elected to follow the guidance in SEC Staff Accounting Bulletin 118 (SAB 118), which provides additional clarification regarding the application of ASC 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. SAB 118 provides for a measurement period beginning in the reporting period that includes the Tax Act s enactment date and ending when we have obtained, prepared, and analyzed the information needed in order to complete the accounting requirements but in no circumstances should the measurement period extend beyond one year from the enactment date.

We have 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. We have recorded a one-time estimated deemed repatriation transition tax resulting in a nominal tax benefit to us, based on the interplay of the transition tax and the foreign tax credit. The provisional amount is based on information currently available, including information from our recent acquisition of JOTEC. We continue to gather and analyze information, including historical adjustments to earnings and profits of foreign subsidiaries, in order to complete the accounting for the effects of the estimated transition tax.

As a result of the Tax Act, we have also recorded a nominal tax benefit related to the remeasurement of domestic deferred tax assets and liabilities from 35% to 21%. We continue to analyze other impacts of the Tax Act, but the effects based on current information do not have a material impact on the financial statements for the year ended December 31, 2017. We intend to complete the necessary analysis within the measurement period. We expect the impact of the Tax Act may have a material impact on our effective income tax rate in future periods.

Net income decreased for the three months and twelve months ended December 31, 2017, as compared to the three and twelve months ended December 31, 2016, primarily due to a decrease in income before income taxes, partially offset by a decrease in income tax expense, as discussed above.

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

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Products:				
BioGlue and BioFoam	$ 15,982	$ 16,488	36%	41%
On-X	9,073	--	20%	--%
CardioGenesis cardiac laser therapy	2,367	3,487	5%	9%
PerClot	1,038	1,096	2%	3%
PhotoFix	465	437	1%	1%
HeRO Graft	--	2,008	--%	5%
ProCol	--	397	--%	1%
Total products	28,925	23,913	64%	60%
Preservation services:				
Cardiac tissue	7,442	6,970	17%	18%
Vascular tissue	8,662	8,955	19%	22%
Total preservation services	16,104	15,925	36%	40%
Total	$ 45,029	$ 39,838	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Products:				
BioGlue and BioFoam	$ 63,461	$ 59,332	35%	41%
On-X	34,232	--	19%	--%
CardioGenesis cardiac laser therapy	7,864	9,419	5%	6%
PerClot	4,021	4,083	2%	3%
PhotoFix	1,871	1,396	1%	1%
HeRO Graft	2,325	7,546	1%	5%
ProCol	218	1,305	--%	1%
Total products	113,992	83,081	63%	57%

Cardiac tissue	29,697	28,059	17%	19%
Vascular tissue	36,691	34,758	20%	24%
Total preservation services	66,388	62,817	37%	43%
Total	$ 180,380	$ 145,898	100%	100%

Revenues increased 13% and 24% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2016 is presented below.

Products

Revenues from products increased 21% and 37% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. These increases were primarily due to the acquisition of On-X during the first quarter of 2016. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; On-X; CardioGenesis cardiac laser therapy; PerClot; PhotoFix; HeRO; and ProCol is presented below.

Our sales of certain products through our direct sales force to U.K. hospitals are denominated in British Pounds, and our sales to German, Austrian, French, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. During 2015, the U.S. Dollar strengthened materially, as compared to the British Pound and Euro and, as a result, our revenues denominated in these currencies decreased when translated into U.S. Dollars. This trend continued during the twelve months ended December 31, 2016. Additionally, our sales to many distributors around the world are denominated in U.S. Dollars and, although these sales are not directly impacted by the strong U.S. Dollar, we believe that our distributors may have been delaying or reducing purchases of products in U.S. Dollars due to 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, decreased 3% for the three months ended December 31, 2016, as compared to the three months ended December 31, 2015. This decrease was primarily due to a 4% decrease in the volume of milliliters sold, which decreased revenues by 3%, and the unfavorable impact of foreign exchange rates, which decreased revenues by 1%, partially offset by an increase in average sales prices, which increased revenues by 1%.

Revenues from the sale of surgical sealants increased 7% for the twelve months ended December 31, 2016, as compared to the twelve months ended December 31, 2015. This increase was primarily due to a 7% increase in the volume of milliliters sold, which increased revenues by 7%.

The decrease in sales volume of surgical sealants for the three months ended December 31, 2016 was primarily due to a decrease in sales of BioGlue in Japan, partially offset by an increase in BioGlue sales in domestic markets. The increase in sales volume of surgical sealants for the twelve months ended December 31, 2016 was primarily due to sales of BioGlue in France. In October 2015 we transitioned the French market from a distributor to a direct sales model, and as a result, there were no shipments of BioGlue into France for the first three quarters of the comparable period in 2015. To a lesser extent, BioGlue revenues in the twelve months ended December 31, 2016 were affected by an increase in sales volume in Europe and domestic markets and a decrease in sales volume in Japan. Sales of BioGlue in Japan decreased due to the timing of distributor ordering patterns.

Domestic BioGlue revenues accounted for 58% and 56% of total BioGlue revenues for the three and twelve months ended December 31, 2016, respectively, and 55% and 58% of total BioGlue revenues for the three and twelve months ended December 31, 2015, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2016 and 2015. BioFoam is currently approved for sale in certain international markets.

On-X

On January 20, 2016 CryoLife acquired On-X, an Austin, Texas-based, privately held mechanical heart valve company. The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis (AAP). On-X product revenues also include revenues from the distribution of CarbonAid CO_2 diffusion catheters, the sale of Chord-X ePTFE sutures for mitral chordal replacement, and revenue from

pyrolytic carbon coating services to other medical device manufacturers. On-X products are distributed in both domestic and international markets.

On-X combined pre- and post-acquisition revenues for the three and twelve months ended December 31, 2016 increased 9% and 7%, respectively, when compared to On-X s pre-acquisition revenues for the three and twelve months ended December 31, 2015, respectively, despite disruptions in the sales channel caused by the transition to direct selling in various domestic and international markets that On-X previously served through distributors.

CardioGenesis Cardiac Laser Therapy

Revenues from our CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from cardiac laser therapy decreased 32% for the three months ended December 31, 2016, as compared to the three months ended December 31, 2015. Revenues from the sale of laser consoles were $507,000 and $1.1 million for the three months ended December 31, 2016 and 2015, respectively. Revenues from the sale of handpieces decreased 25% for the three months ended December 31, 2016 as compared to the three months ended December 31, 2015. This decrease was primarily due to a 22% decrease in unit shipments of handpieces, which decreased revenues by 23%, and a decrease in average sales prices, which decreased revenues by 2%.

Revenues from cardiac laser therapy decreased 17% for the twelve months ended December 31, 2016, as compared to the twelve months ended December 31, 2015. Revenues from the sale of laser consoles were $507,000 and $1.2 million for the twelve months ended December 31, 2016 and 2015, respectively. Revenues from the sale of handpieces decreased 13% for the twelve months ended December 31, 2016 as compared to the twelve months ended December 31, 2015. This decrease was primarily due to a 14% decrease in unit shipments of handpieces, which decreased revenues by 14%, partially offset by an increase in average sales prices, which increased revenues by 1%.

The decrease in revenues from both handpiece and laser console sales was due in part to the deemphasizing of this product line during 2016, during the On-X integration period and the realignment of our sales force, and due to a reduction in procedure volume, which can vary from quarter to quarter due to physician case volume and patient-specific factors, which determine whether cardiac laser therapy can be used adjunctively with cardiac bypass surgery.

PerClot

Revenues from the sale of PerClot decreased 5% for the three months ended December 31, 2016, as compared to the three months ended December 31, 2015. This decrease was primarily due to the unfavorable effect of foreign currency exchange, which decreased revenues by 3%, a 5% decrease in the volume of grams sold, which decreased revenues by 1%, and a decrease in average selling prices, which decreased revenues by 1%.

Revenues from the sale of PerClot decreased 2% for the twelve months ended December 31, 2016, as compared to the twelve months ended December 31, 2015. This decrease was primarily due to a decrease in average selling prices, which decreased revenues by 3%, and the unfavorable effect of foreign currency exchange, which decreased revenues by 2%, partially offset by favorable sales volume, which increased revenues by 3%.

The sales volume increase for the twelve months ended December 31, 2016 was primarily due to sales of PerClot in France, due to our transition to a direct sales model in this market in October 2015. The decrease in average selling prices for the twelve months ended December 31, 2016 was primarily due to price reductions to certain customers in Europe as a result of pricing pressures from competitive products.

PhotoFix

PhotoFix revenues increased 6% for the three months ended December 31, 2016, as compared to the three months ended December 31, 2015. This increase was primarily due to an increase in units sold, which increased revenues by 6%. PhotoFix revenues increased 34% for the twelve months ended December 31, 2016, as compared to the twelve months ended December 31, 2015. This increase was primarily due to an increase in units sold, which increased revenues by 36%, partially offset by a decrease in average sales prices, which decreased revenues by 2%. The increase in volume for both the three and twelve months ended December 31, 2016 is primarily due to an increase in the number of implanting physicians when compared to the prior year period, as we launched our distribution of PhotoFix

in the first quarter of 2015.

HeRO Graft

On February 3, 2016 we sold our HeRO Graft product line to Merit, and we agreed to continue to manufacture the HeRO Graft for Merit for up to six months under a transition supply agreement. Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. Revenues include sales to hospitals through February 3, 2016 and to Merit from that date through the second quarter of 2016. The sales transfer to Merit was completed in the second quarter of 2016, at which time we ceased sales of the HeRO Graft.

ProCol

On March 18, 2016 we sold our ProCol product line to LeMaitre, at which time we ceased sales of these products.

Preservation Services

Revenues from preservation services increased 1% and 6% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. A detailed discussion of the changes in cardiac and vascular preservation services revenues is presented below.

During 2014 we made significant changes to various tissue processing and quality procedures, which resulted in a decrease in tissue processing throughput and an increase in our cost of processing tissues. These factors adversely impacted revenues and costs during 2015 as we continued to ship tissues that were processed in 2014. In 2015 we reviewed and modified our procedures as part of our ongoing compliance efforts and in an effort to improve tissue processing throughput and reduce costs, and we continued these efforts during 2016. As a result of these efforts, tissue availability began to increase in the second half of 2015, particularly vascular tissue availability as discussed further below, and the cost of tissue processing decreased.

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, 2016.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of human heart valves and cardiac patch tissues increased 7% for the three months ended December 31, 2016, as compared to the three months ended December 31, 2015. This increase was primarily due to a 6% increase in unit shipments of cardiac tissues, which increased revenues by 4% and an increase in average service fees, which increased revenues by 3%.

Revenues from cardiac preservation services increased 6% for the twelve months ended December 31, 2016, as compared to the twelve months ended December 31, 2015. This increase was primarily due to a 6% increase in unit shipments of cardiac tissues, which increased revenues by 3% and an increase in average service fees, which increased revenues by 3%.

The increase in volume for the three months ended December 31, 2016 was primarily due to an increase in the volume of cardiac valve and patch shipments. The increase in volume for the twelve months ended December 31, 2016 was primarily due to an increase in the volume of cardiac patch shipments. The increase in average service fees for the three and twelve months ended December 31, 2016 was primarily due to list fee increases in domestic markets 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 decreased 3% for the three months ended December 31, 2016, as compared to the three months ended December 31, 2015. This decrease was primarily due to a 2% decrease in unit shipments of vascular tissues, which decreased revenues by 4%, partially offset by an increase in average service fees, which increased revenues by 1%.

Revenues from vascular preservation services increased 6% for the twelve months ended December 31, 2016, as compared to the twelve months ended December 31, 2015. This increase was primarily due to an increase in average service fees, which increased revenues by 3%, and the combined effect of favorable tissue mix and a 3% decrease in unit shipments of vascular tissues, which in the aggregate increased revenues by 3%.

Our vascular preservation services revenues benefited in the second half of 2015 and the first half of 2016 from an increase in vascular tissue availability, due to factors discussed above. We used this increase in available tissue to meet the previously unmet demand from our existing vascular tissue customers. Although our vascular tissue customers continue to receive tissue shipments, the volume of these requests has normalized. The decrease in shipments of vascular tissues for the three and twelve months ended December 31, 2016 was primarily due to these factors.

The increase in average service fees for the three and twelve months ended December 31, 2016 was primarily due to fee differences due to physical characteristics of vascular tissues, list fee increases in domestic markets, and the routine negotiation of pricing contracts with certain customers.

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. 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,	
	2016	**2015**	**2016**	**2015**
Cost of products	$ 6,734	$ 5,108	$ 28,033	$ 18,663

Cost of products increased 32% and 50% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. Cost of products in 2016 and 2015 includes costs related to BioGlue, BioFoam, CardioGenesis cardiac laser therapy, PerClot, PhotoFix, HeRO Graft through the second quarter of 2016, and ProCol through the first quarter of 2016. Cost of products in 2016 also includes costs related to On-X.

The increase in cost of products in the three and twelve months ended December 31, 2016 was primarily due to sales of On-X products following our acquisition of On-X in January 2016, partially offset by a reduction in cost of products following the sale of the HeRO Graft and ProCol product lines. Cost of products in the three and twelve months ended December 31, 2016 includes $822,000 and $3.0 million, respectively, in acquisition inventory basis step-up expense, related to the On-X inventory fair value adjustment recorded in purchase accounting. Cost of products in the twelve months ended December 31, 2015 included the write-down of PerClot inventory manufactured for the U.S. market following our cessation of marketing, sales, and distribution of PerClot in the U.S. during the first quarter of 2015.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Cost of preservation services	$ 7,100	$ 8,214	$ 33,448	$ 36,516

Cost of preservation services decreased 14% and 8% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. Cost of

preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services decreased in the three and twelve months ended December 31, 2016 primarily due to a decrease in the per unit cost of processing tissues, as a result of processing changes implemented in 2015, as discussed in Preservation Services above.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Gross margin	$ 31,195	$ 26,516	$ 118,899	$ 90,719
Gross margin as a percentage of total revenues	69%	67%	66%	62%

Gross margin increased 18% and 31% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. These increases were primarily due to the addition of margins related to the On-X product line; increases in tissue margins due to a decrease in the per unit cost of processing tissues; and, for the twelve months ended December 31, 2016, an increase in BioGlue margins due to increased revenues. The increases were partially offset by decreases in margins for the divested HeRO Graft and ProCol product lines and a decrease in margins for CardioGenesis cardiac laser therapy due to decreased revenues.

Gross margin as a percentage of total revenues increased in the three and twelve months ended December 31, 2016, as compared to the three and twelve months ended December 31, 2015, respectively. These increases were primarily due to increases in tissue margins, due to a decrease in the per unit cost of processing tissues, partially offset by the unfavorable impact of the On-X acquisition inventory basis step-up expense discussed above. The gross margin and gross margin as a percentage of total revenues for the twelve months ended December 31, 2015 were impacted by the write-down of PerClot inventory, as discussed above.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
General, administrative, and marketing expenses	$ 22,246	$ 19,139	$ 91,548	$ 74,929
General, administrative, and marketing expenses as a percentage of total revenues	49%	48%	51%	51%

General, administrative, and marketing expenses increased 16% and 22% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively.

General, administrative, and marketing expenses for the three and twelve months ended December 31, 2016 included $832,000 and $7.9 million, respectively, in business development costs primarily related to the acquisition of On-X in January 2016, which include, among other costs, expenses related to the termination of international and domestic distribution agreements. We also incurred additional general, administrative, and marketing expenses during 2016 related to the expanded sales force and the ongoing operations of On-X. General, administrative, and marketing expenses for the twelve months ended December 31, 2015 included severance and termination benefits of approximately $3.0 million, related to one-time expenses associated with certain employee departures, including the retirement of Mr. Anderson, our former President, Chief Executive Officer, and Executive Chairman, in April 2015. General, administrative, and marketing expenses included $1.1 million and $3.0 million for the three and twelve months ended December 31, 2015, respectively, in business development expenses, primarily related to the

acquisition of On-X.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	**2015**	**2016**	**2015**
Research and development expenses	$ 3,844	$ 2,540	$ 13,446	$ 10,436
Research and development expenses as a percentage of total revenues	9%	6%	7%	7 %

Research and development expenses increased 51% and 29% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. Research and development spending in these periods was primarily focused on clinical work with respect to PerClot, our tissue processing, On-X products, and BioGlue.

Gain from Sale of Business Components

Gain on sale of business components for the twelve months ended December 31, 2016 consisted of the net of an $8.8 million gain on the HeRO Sale and an $845,000 loss on the ProCol Sale. We sold our HeRO Graft and ProCol product lines during the first quarter of 2016.

Gain on Sale of Medafor Investment

On October 1, 2013 BD completed its acquisition of all outstanding shares of Medafor common stock. We recorded gain on sale of investment of zero and $891,000 for the three and twelve months ended December 31, 2015, respectively. The gain on the sale of Medafor investment in 2015 represents additional consideration received by us in April 2015 related to the release of transaction consideration from escrow.

Interest Expense

Interest expense was $787,000 and $3.0 million for the three and twelve months ended December 31, 2016, respectively, and interest expense was a favorable $44,000 and $62,000 for the three and twelve months ended December 31, 2015, respectively. Interest expense in the 2016 and 2015 periods included interest on debt and uncertain tax positions. The increase in interest expense in 2016 was due to borrowings under the $75 million term loan we entered into in January 2016 to finance, in part, the acquisition of On-X. In the three and twelve months ended December 31, 2015 interest expense was favorable due to the reversal of interest on uncertain tax positions.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Income before income taxes	$ 3,759	$ 4,617	$ 18,412	$ 5,868
Income tax expense	862	1,981	7,634	1,863
Net income	$ 2,897	$ 2,636	$ 10,778	$ 4,005
Diluted income per common share	$ 0.09	$ 0.09	$ 0.32	$ 0.14
Diluted weighted-average common shares outstanding	33,443	28,687	32,822	28,542

Income before income taxes decreased 19% and increased 214% for the three and twelve months ended December 31, 2016, respectively, as compared to the three and twelve months ended December 31, 2015, respectively. The decrease in income before income taxes for the three months ended December 31, 2016 was due to an increase in operating expenses and interest expense, partially offset by an increase in gross margins, as discussed above. The increase in income before income taxes for the twelve months ended December 31, 2016 was primarily due to an increase in gross margins and the gain on sale of business components, partially offset by increases in operating expenses and

interest expense, as discussed above.

Our effective income tax rate was 23% and 41% for the three and twelve months ended December 31, 2016, respectively, as compared to 43% and 32% for the three and twelve months ended December 31, 2015, respectively. Our income tax rate for the three months ended December 31, 2016 was favorably affected by increases in pretax book income and the tax deduction for domestic manufacturers as compared to prior estimates. Our income tax rate for the twelve months ended December 31, 2016 was unfavorably impacted by the tax treatment of certain expenses related to the On-X acquisition, which had a larger impact on the tax rate in the first quarter of 2016, and by book/tax basis differences related to the HeRO Sale.

Our income tax rate for the twelve months ended December 31, 2015 was favorably affected by the reversal of $869,000 in uncertain tax positions, primarily related to research and development tax credits for which the statute of limitations has expired, partially offset by the expiration of certain state net operating losses and other permanent differences.

Net income increased for the three months ended December 31, 2016, as compared to the three months ended December 31, 2015, primarily due to a decrease in income tax expense, partially offset by a decrease in income before income taxes, as discussed above. Net income and diluted income per common share increased for the twelve months ended December 31, 2016, as compared to the twelve months ended December 31, 2015, primarily due to the increase in income before income taxes, partially offset by an increase in income tax expense, as discussed above.

Seasonality

We believe the demand for BioGlue 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 for BioGlue may be due to the summer holiday seasons in Europe and the U.S. We believe that demand for BioGlue in Japan may continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by the slower summer holiday season in Japan.

We are uncertain whether the demand for On-X products, PerClot, or PhotoFix will be seasonal, as these products have not fully penetrated many markets and, therefore, the nature of any seasonal trends may be obscured.

We do not believe the demand for CardioGenesis cardiac laser therapy is seasonal, as our data does not indicate a significant trend.

Demand for our cardiac preservation services has traditionally been seasonal, with peak demand generally occurring in the third quarter. We believe that 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, 2017 net working capital (current assets of $179.3 million less current liabilities of $42.9 million) was $136.4 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of $117.1 million and a current ratio of 5 to 1 at December 31, 2016.

Overall Liquidity and Capital Resources

Our largest cash requirement for the twelve months ended December 31, 2017 was cash used to fund the acquisition of JOTEC. To a lesser extent, our cash requirements included debt issuance costs and principal payments on our borrowings, and capital expenditures for facilities and equipment. We funded our cash requirements by issuing debt in the form of a new $225 million secured term loan, discussed further below, our existing cash reserves, and our operating activities, which generated cash during the period.

We believe 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 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. 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

On December 1, 2017 we completed our acquisition of JOTEC for $168.8 million in cash and 2,682,754 shares of CryoLife common stock, with an estimated value of $53.1 million as determined on the date of the closing, for a total purchase price of approximately $221.9 million, including debt and cash acquired as determined on the date of closing.

In connection with the closing of the JOTEC acquisition, we entered into a credit agreement with 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 previously announced acquisition of JOTEC and its subsidiaries (the Acquisition), (ii) pay certain fees and expenses related to the Acquisition and the Credit Agreement and (iii) pay the outstanding balance of our existing credit facility under the Third Amended and Restated Credit Agreement, dated as of January 20, 2016 (as amended), among CryoLife and On-X Holdings, as borrowers, the financial institutions party thereto from time to time as lenders, and Healthcare Financial Solutions, LLC, as agent.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. We resumed enrollment into the PerClot U.S. clinical trial in the fourth quarter of 2016, and assuming enrollment proceeds as anticipated, we could receive PMA from the FDA in the second half of 2019. 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.

We believe utilization of net operating loss carryforwards from our acquisitions of Hemosphere and Cardiogenesis will reduce required cash payments for federal income taxes by approximately $600,000 for the 2017 tax year. We acquired net operating losses from the acquisition of JOTEC that we believe will reduce foreign income taxes by approximately $830,000 for the 2017 tax year.

As of December 31, 2017 approximately 28% of our cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $10.8 million for the twelve months ended December 31, 2017, as compared to $19.7 million for the twelve months ended December 31, 2016.

We use the indirect method to prepare our cash flow statement, and accordingly, the operating cash flows are based on our net income, which is then adjusted to remove non-cash items, items classified as investing and financing cash flows, and for changes in operating assets and liabilities from the prior year end. For the twelve months ended December 31, 2017 these items included $9.7 million in depreciation and amortization expenses and $6.9 million in non-cash compensation.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the twelve months ended December 31, 2017 these changes included an unfavorable adjustment of $9.4 million due to

increases in inventory balances and deferred preservation costs and $7.3 million due to the timing difference between recording receivables and the receipt of cash, partially offset by a favorable effect of $8.7 million due to timing differences between the recording of accounts payable and other current liabilities and the payment of cash.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $171.0 million for the twelve months ended December 31, 2017, as compared to $73.9 million for the twelve months ended December 31, 2016. The current year cash used was primarily due to $164.7 million for the acquisition of JOTEC, net of cash acquired, and $6.6 million in capital expenditures.

Net Cash Flows from Financing Activities

Net cash provided by financing activities was $143.2 million for the twelve months ended December 31, 2017, as compared to net cash provided of $73.4 million for the twelve months ended December 31, 2016. The current year cash provided was primarily due to $225.0 million in proceeds from the issuance of a term loan, which was used to finance, in part, the acquisition of JOTEC, and $3.1 million in proceeds from the exercise of stock options and issuance of common stock under our employee stock purchase plan, partially offset by $67.2 million in repayment of debt agreement, $10.1 million in payments of debt issuance costs, $5.0 million in debt repayments.

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, 2017 are as follows (in thousands):

	Total	2018	2019	2020	2021	2022	Thereafter
Long-term debt obligations	$ 228,969	$ 2,814	$ 2,813	$ 2,813	$ 2,814	$ 2,813	$ 214,902
Interest payments	81,910	13,147	11,944	11,813	11,682	11,550	21,774
Operating leases	28,844	5,927	6,231	5,098	4,249	2,038	5,301
Research obligations	5,060	4,216	328	222	159	135	
Purchase commitments	4,669	2,930	1,739				
Contingent payments	1,000			1,000			
Other long-term liabilities	137	137					
Total contractual obligations	$ 350,589	$ 29,171	$ 23,055	$ 20,946	$ 18,904	$ 16,536	$ 241,977

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

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

Our purchase commitments include obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under a distribution agreement with Starch Medical, Inc. (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 2019, based on the assumption that we will not terminate the distribution agreement before its target date for receiving FDA approval for PerClot in 2019. However, if we do not obtain FDA approval for PerClot and 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 contingent payments obligation includes payments that we may make if certain U.S. regulatory approvals and certain commercial milestones are achieved related to our transaction with SMI for PerClot.

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 $4.6 million, as no specific assessments have been made by any taxing authorities.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2017 and 2016 were $6.6 million and $6.2 million, respectively. Capital expenditures in the twelve months ended December 31, 2017 were primarily related to the routine purchases of computer software, manufacturing and tissue processing equipment, computer and office equipment, CardioGenesis cardiac laser therapy laser consoles, and leasehold improvements needed to support our business.

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 $40.0 million as of December 31, 2017, 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, 2017, affecting our cash and cash equivalents, restricted cash and securities, $225.0 million secured Term Loan Facility, and Revolving Credit Facility would not have had a material impact on the 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.

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 Zloty, Canadian Dollars, and Brazilian Reals and a portion of our general, administrative, and marketing expenses are denominated in Euros, British Pounds, Swiss Francs, Polish Zloty, 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, 2017 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, 2017 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.

Our financial statements and supplementary data required by this item are submitted as a separate section of this annual report on Form 10-K. See Financial Statements commencing on page F-1.

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

None.

Item 9A. 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.

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, 2017, 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 Securities and Exchange Commission s general guidance permits the exclusion of an assessment of the effectiveness of a registrant s disclosure controls and procedures as they relate to its internal control over financial reporting for an acquired business during the first year following such acquisition if, among other circumstances and factors, there is not adequate time between the acquisition date and the date of assessment. As previously noted in this Form 10-K, we completed the acquisition of JOTEC during the fourth quarter of 2017. Management s assessment and conclusion on the effectiveness of our disclosure controls and procedures as of December 31, 2017 excludes an assessment of the internal control over financial reporting of JOTEC. See Part II, Item 8, Note 4, Notes to Consolidated Financial Statements contained in this Form 10-K for a description of the significance of the acquired business to us.

During the quarter ended December 31, 2017 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.

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 F-1 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 F-2 of this report.

Item 9B. Other Information.

None.

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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, 2017, with the exception of information concerning executive officers listed below.

The following table lists the executive officers of CryoLife as of December 31, 2017 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	51	Chairman, President, and Chief Executive Officer
Scott B. Capps	Since 2007	51	Vice President, Clinical Research
John E. Davis	Since 2015	53	Senior Vice President, Global Sales and Marketing
Jean F. Holloway	Since 2015	60	Senior Vice President, General Counsel, Chief Compliance Officer, and Secretary
Amy D. Horton, CPA	Since 2006	47	Vice President and Chief Accounting Officer
D. Ashley Lee, CPA	Since 2000	53	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
William R. Matthews	Since 2015	63	Senior Vice President, Operations, Quality, and Regulatory
Jim McDermid	Since 2016	58	Senior Vice President, Chief Human Resources Officer

J. Patrick Mackin assumed the position of President and Chief Executive Officer in September 2014, was appointed to the Board of Directors in October 2014 and was appointed Chairman in May 2015. Mr. Mackin has more than 20 years of experience in the medical device industry. Prior to joining 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.

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.

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 of 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.

William R. Matthews was appointed to the position of the Senior Vice President of Operations, Quality, and Regulatory in May 2015 and served in that role until February 28, 2018. Before joining CryoLife, he was the Managing Partner at BioDevice Solutions, a medical device consultancy firm from 2002 to 2014, where he served as a Senior Operations, Quality, and Regulatory Consultant, recognized for his experience in FDA compliance, manufacturing, new technology start-ups, and product submissions. Prior to that, he was Vice President of Government Affairs and Quality Systems for Cardinal Health s Viasys Healthcare, Executive Vice President of Operations, Regulatory Affairs, and Quality Systems at Xylum Corporation, and the Corporate Director of Regulatory, Quality, Manufacturing, and Engineering at Fresenius Medical Care (formerly Grace National Medical Care division). Mr. Matthews obtained a Bachelor s degree in Chemistry from St. Peter s University and also attended the Business Administration Programs at Rutgers University and Fairleigh Dickinson University.

Jim McDermid was appointed to the position of the Senior Vice President, Chief Human Resources Officer in September 2016. Mr. McDermid joined the company from Medtronic, Inc. where he was Group Vice President of Human Resources for the Cardiac and Vascular Group. Prior to joining the Cardiac and Vascular Group, Mr. McDermid was the Vice President of Human Resources for Medtronic s Spinal & Biologics Division, located in Memphis, TN. His other Medtronic positions included HR Director, U.S. Cardiovascular and HR Director, Structural Heart. Prior to Medtronic, Mr. McDermid worked for several Fortune 500 companies, including Rockwell International, Hudson Bay Company, Cooper Industries, and International Paper. Mr. McDermid holds a bachelor s from the University of Toronto and a Master of Arts from McMaster University in Ontario.

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, 2017.

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, 2017.

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, 2017.

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, 2017.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following are filed as part of this report:

(a) 1. Financial Statements.

Consolidated Financial Statements begin on page F-1.

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.

March 9, 2018 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)	March 9, 2018
/s/ D. ASHLEY LEE **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	March 9, 2018
/s/ AMY D. HORTON **Amy D. Horton**	Vice President and Chief Accounting Officer (Principal Accounting Officer)	March 9, 2018
/s/ THOMAS F. ACKERMAN **Thomas F. Ackerman**	Director	March 9, 2018
/s/ DANIEL J. BEVEVINO **Daniel J. Bevevino**	Director	March 9, 2018
/s/ JAMES W. BULLOCK **James W. Bullock**	Director	March 9, 2018
/s/ JEFFREY H. BURBANK **Jeffrey H. Burbank**	Director	March 9, 2018
/s/ RONALD C. ELKINS, M.D.	Director	March 9, 2018

Ronald C. Elkins, M.D.		
/s/ Ronald D. McCall	Director	March 9, 2018
Ronald D. McCall		
/s/ Harvey Morgan	Director	March 9, 2018
Harvey Morgan		
/s/ Jon W. Salveson	Director	March 9, 2018
Jon W. Salveson		

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 Current Report on Form 8-K filed November 23, 2015.)
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 fiscal year ended December 31, 1997.)
4.2	Form of Indenture for Senior Debt Securities (Incorporated herein by reference to Exhibit 4.7 to the Registrant s Registration Statement on Form S-3 filed August 5, 2015 (No. 333-206119).)
4.3	Form of Subordinated Indenture for Subordinated Debt Securities (Incorporated herein by reference to Exhibit 4.9 to the Registrant s Registration Statement on Form S-3 filed August 5, 2015 (No. 333-206119).)
10.1	CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.1(a)	First Amendment, dated July 24, 2012, to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.1(b)	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	Form of 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.7 to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.3(a)	Change of Control Severance Agreement between CryoLife, Inc. and Scott B. Capps dated November 21, 2016. (Incorporated herein by reference to Exhibit 10.1 to Registrant s Current Report on Form 8-K filed November 22, 2016.)
10.3(b)	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.)
10.3(c)	

		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.)
10.3(d)	*	Change of Control Severance Agreement between CryoLife, Inc. and John E. Davis 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.)
10.3(e)	*	Change of Control Severance Agreement between CryoLife, Inc. and William R. Matthews 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.)
10.4		Separation Agreement between CryoLife, Inc. and Steven G. Anderson dated April 9, 2015. (Incorporated herein by reference to Exhibit 10.1 to Registrant s Current Report on Form 8-K filed April 10, 2015.)

Exhibit Number	Description
10.5	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 fiscal year ended December 31, 2007.)
10.5(a)	First Amendment to Lease Agreement, dated April 18, 1995, 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 fiscal year ended December 31, 1999.)
10.5(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 fiscal year ended December 31, 2000.)
10.5(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 for the quarter ended June 30, 2010.)
10.6	CryoLife, Inc. 2004 Employee Stock Incentive Plan, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.6(a)	First Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated October 27, 2009. (Incorporated herein by reference to Exhibit 10.46 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009.)
10.6(b)	Second Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated May 24, 2011. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)
10.6(c)	Form of Incentive Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)
10.6(d)	Form of Non-Qualified Employee Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)
10.6(e)	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)
10.6(f)	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.35 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.6(g)	Form of Section 16 Officer Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current

	Report on Form 8-K filed February 27, 2006.)
10.7	International Distribution Agreement, dated September 17, 1998, between the Company and Century Medical, Inc. (Incorporated by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.8	Summary of Compensation Arrangements with Non-Employee Directors. (Incorporated by reference to Exhibit 10.24 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2015.)

Exhibit Number	Description
10.8(a)	Summary of 2016 Compensation Arrangements with Non-Employee Directors. (Incorporated by reference to Exhibit 10.2(a) to the Registrants Annual Report on Form 10-K for the fiscal year ended December 31, 2016.)
10.8(b)*	Summary of 2017 Compensation Arrangements with Non-Employee Directors.
10.9	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 for the quarter ended June 30, 2009.)
10.10	Form of 2013 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on 10-Q for the quarter ended March 31, 2013.)
10.11	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 for the quarter ended March 31, 2010.)
10.12+	Distribution Agreement between CryoLife, Inc. and Starch Medical, Inc., dated September 28, 2010. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed December 30, 2014.)
10.12(a)	First Amendment to the Distribution Agreement between CryoLife, Inc. and Starch Medical, Inc., dated May 18, 2011. (Incorporated herein by reference to Exhibit 10.7 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.)
10.12(b)	Second Amendment to the Distribution Agreement between CryoLife, Inc. and Starch Medical, Inc., dated September 20, 2013. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2013.)
10.13+	License Agreement between CryoLife, Inc. and Starch Medical, Inc., dated September 28, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed December 30, 2014.)
10.14	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.)
10.15	Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)
10.16	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)
10.17	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 February 18, 2015.)
10.18	Form of Performance Share Agreement with Named Executive Officers. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed March 22,

	2012.)
10.18(a)	First Amendment, dated July 23, 2012, to the 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.18(b)	Stock Option Grant Agreement, dated September 2, 2014, by and between CryoLife, Inc. and J. Patrick Mackin. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)
10.18(c)	Restricted Stock Award Agreement, dated September 2, 2014, by and between CryoLife, Inc. and J. Patrick Mackin. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)

Exhibit Number	Description
10.18(d)	Form of Performance Share Agreement with Named Executive Officers pursuant to the Second Amended and Restated CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to Registrant s Quarterly Report on Form 10-Q filed April 29, 2015.)
10.18(e)	Form of Amendment to Performance Share Agreement with Named Executive Officers. (Incorporated herein by reference to Exhibit 10.4 to Registrant s Quarterly Report on Form 10-Q filed July 28, 2015.)
10.19	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.)
10.19(a)	First Amendment, dated July 24, 2012, to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.19(b)	Second Amended and Restated CryoLife Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Appendix B to the Company s Definitive Proxy Statement filed April 8, 2014.)
10.20	Employment Agreement dated as of July 7, 2014, between CryoLife, Inc. and J. Patrick Mackin. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed July 11, 2014.)
10.21	Form of Non-Employee Directors Restricted Stock Award Agreement pursuant to the Second Amended and Restated CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.42 to the Registrant s Annual Report on Form 10-K filed February 16, 2016.)
10.22	Asset Purchase Agreement between Merit Medical System, Inc. and CryoLife, Inc., dated February 3, 2016. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 8, 2016.)
10.23	Form of Indemnification Agreement for Certain Officers. (Incorporated herein by reference to Exhibit 10.1 to Registrant s Current Report on Form 8-K filed February 21, 2017.)
10.24	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.)
10.25	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.)
14.1	Form of Code of Conduct, as amended (Incorporated herein by reference to Exhibit 14.1 to the Registrant s Current Report on Form 8-K filed November 23, 2015.)
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.

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

++ 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.

Management s Report on Internal Control over Financial Reporting under Sarbanes-Oxley Section 404.

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

On December 1, 2017 we completed the acquisition of 100% of the outstanding equity of JOTEC GmbH (JOTEC), a privately held company. As permitted by SEC guidance, we excluded JOTEC from management s assessment of internal control over financial reporting as of December 31, 2017. JOTEC, which is included in the 2017 consolidated financial statements of CryoLife, constituted $280.9 million and $193.8 million of total assets and net assets, respectively, as of December 31, 2017 and $4.1 million and $2.2 million of revenues and gross margin, respectively, for the year then ended. JOTEC will be included in management s assessment of the internal control over financial reporting as of December 31, 2018.

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, 2017. 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, 2017, 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, 2017.

CryoLife, Inc.

March 9, 2018

Report of Independent Registered Public Accounting Firm on the Financial Statements

The Board of Directors and Shareholders 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, 2017 and 2016, the related consolidated statements of operations and comprehensive income, shareholders equity and cash flows for each of the three years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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, 2017, 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 March 9, 2018 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.

Ernst & Young LLP

We have served as the Company s auditor since 2013

Atlanta, Georgia

March 9, 2018

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

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, 2017, 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, 2017, based on the COSO criteria.

As indicated in the accompanying Management s Report on Internal Control Over Financial Reporting, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of JOTEC GmbH (JOTEC), which is included in the 2017 consolidated financial statements of the Company and constituted $280.9 million and $193.8 million of total and net assets, respectively, as of December 31, 2017 and $4.1 million and $2.2 million of revenues and gross margin, respectively, for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of JOTEC.

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, 2017 and 2016, the related consolidated statements of operations and comprehensive income, shareholders equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and our report dated March 9, 2018 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.

Ernst & Young LLP

Atlanta, Georgia

March 9, 2018

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,977	$ 56,642
Restricted securities	776	699
Receivables:		
Trade accounts, net	47,525	27,769
Other	3,916	2,327
Total receivables	**51,441**	**30,096**
Inventories	46,684	26,293
Deferred preservation costs	35,671	30,688
Prepaid expenses and other	4,731	2,815
Total current assets	**179,280**	**147,233**
Property and equipment:		
Equipment and software	47,899	37,086
Furniture and fixtures	4,916	4,670
Leasehold improvements	40,280	31,981
Total property and equipment	93,095	73,737
Less accumulated depreciation and amortization	59,516	55,235
Net property and equipment	**33,579**	**18,502**
Other assets:		
Goodwill	188,305	78,294
Patents, less accumulated amortization of $2,819 in 2017 and $2,702 in 2016	793	1,008
Trademarks and other intangibles, less accumulated amortization of $15,326 in 2017 and $10,733 in 2016	178,637	65,633
Deferred income taxes	1,610	--
Other	7,489	5,470
Total assets	**$ 589,693**	**$ 316,140**

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2017	**2016**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accrued expenses	$ 11,646	$ 5,054
Accrued compensation	10,208	8,815
Accounts payable	9,767	5,744
Taxes payable	4,020	2
Accrued procurement fees	3,577	4,806
Current portion of capital lease obligation	578	--
Current portion of long-term debt	718	4,562
Other	2,426	1,119
Total current liabilities	**42,940**	**30,102**
Long-term debt	218,236	67,012
Deferred income taxes	30,431	7
Capital lease obligation	6,856	11
Deferred compensation liability	3,390	2,600
Deferred rent obligations	2,895	2,355
Other	7,887	5,070
Total liabilities	**312,635**	**107,157**
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, 37,618 shares issued in 2017 and 34,230 shares issued in 2016	376	342
Additional paid-in capital	249,935	187,061
Retained earnings	37,609	34,143
Accumulated other comprehensive income (loss)	1,857	(429)
Treasury stock at cost, 1,387 shares in 2017 and 1,356 shares in 2016	(12,719)	(12,134)

Total shareholders equity		**277,058**		**208,983**
Total liabilities and shareholders equity	**$**	**589,693**	**$**	**316,140**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

(in thousands, except per share data)

	Year Ended December 31,		
	2017	**2016**	**2015**
Revenues:			
Products	$ 119,631	$ 113,992	$ 83,081
Preservation services	70,071	66,388	62,817
Total revenues	**189,702**	**180,380**	**145,898**
Cost of products and preservation services:			
Products	29,798	28,033	18,663
Preservation services	31,262	33,448	36,516
Total cost of products and preservation services	**61,060**	**61,481**	**55,179**
Gross margin	**128,642**	**118,899**	**90,719**
Operating expenses:			
General, administrative, and marketing	101,211	91,548	74,929
Research and development	19,461	13,446	10,436
Total operating expenses	**120,672**	**104,994**	**85,365**
Gain from sale of business components	--	(7,915)	--
Operating income	**7,970**	**21,820**	**5,354**
Interest expense	4,881	3,043	(62)
Interest income	(212)	(72)	(45)
Gain on sale of Medafor investment	--	--	(891)
Other (income) expense, net	(260)	437	484
Income before income taxes	**3,561**	**18,412**	**5,868**
Income tax (benefit) expense	(143)	7,634	1,863
Net income	**$ 3,704**	**$ 10,778**	**$ 4,005**

Income per common share:			
Basic	**$ 0.11**	**$ 0.33**	**$ 0.14**
Diluted	**$ 0.11**	**$ 0.32**	**$ 0.14**
Dividends declared per common share	**$ --**	**$ --**	**$ 0.120**
Weighted-average common shares outstanding:			
Basic	33,008	31,855	27,744
Diluted	34,163	32,822	28,542
Net income	**$ 3,704**	**$ 10,778**	**$ 4,005**
Other comprehensive income (loss)	2,286	(353)	45
Comprehensive income	**$ 5,990**	**$ 10,425**	**$ 4,050**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2017	**2016**	**2015**
Net cash flows from operating activities:			
Net income	$ 3,704	$ 10,778	$ 4,005
Adjustments to reconcile net income to net cash from operating activities:			
Gain from sale of business components	--	(7,915)	--
Gain on sale of Medafor investment	--	--	(891)
Depreciation and amortization	9,745	8,384	5,863
Non-cash compensation	6,919	6,328	5,089
Write-down of inventories and deferred preservation costs	2,110	1,364	1,341
Deferred income taxes	(1,483)	595	3,681
Other non-cash adjustments to income	676	268	268
Changes in operating assets and liabilities:			
Receivables	(7,258)	4,142	(3,809)
Inventories and deferred preservation costs	(9,369)	(9,460)	(2,262)
Prepaid expenses and other assets	(2,968)	515	(1,187)
Accounts payable, accrued expenses, and other liabilities	8,727	4,720	(656)
Net cash flows provided by operating activities	**10,803**	**19,719**	**11,442**
Net cash flows used in investing activities:			
Acquisition of JOTEC, net of cash acquired	(164,661)	--	--
Acquisition of On-X, net of cash acquired	--	(91,152)	--
Acquisition of PhotoFix technology	(409)	(1,226)	--
Acquisition of French distribution business	--	--	(1,349)
Capital expenditures	(6,632)	(6,198)	(3,490)
Proceeds from sale of business components	740	19,795	--
Proceeds from sale of Medafor investment	--	--	891
Decrease in restricted cash	--	5,000	--
Sales and maturities of restricted securities and investments	1,010	1,067	1,157
Purchases of restricted securities and investments	(954)	(1,014)	(1,085)
Other	(86)	(126)	(610)
Net cash flows used in investing activities	**(170,992)**	**(73,854)**	**(4,486)**
Net cash flows from financing activities:			
Proceeds from issuance of term loan	225,000	75,000	--

Payoff of debt agreement	(67,219)	--	--
Payment of debt issuance costs	(10,144)	(2,289)	--
Repayment of term loan	(4,994)	(1,406)	--
Proceeds from exercise of stock options and issuance of common stock	3,126	2,203	1,526
Cash dividends paid	--	--	(3,408)
Redemption and repurchase of stock to cover tax withholdings	(1,614)	(697)	(1,386)
Other	(910)	617	458
Net cash flows provided by (used in) financing activities	**143,245**	**73,428**	**(2,810)**
Effect of exchange rate changes on cash	279	(239)	67
(Decrease) increase in cash and cash equivalents	**(16,665)**	**19,054**	**4,213**
Cash and cash equivalents, beginning of year	56,642	37,588	33,375
Cash and cash equivalents, end of year	**$ 39,977**	**$ 56,642**	**$ 37,588**

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, 2014	**29,229**	**$ 292**	**$ 135,227**	**$ 22,768**	**$ (121)**	**(1,101)**	**$ (9,481)**	**$ 148,685**
Net income	--	--	--	4,005	--	--	--	4,005
Other comprehensive income:								
Foreign currency translation gain	--	--	--	--	45	--	--	45
Comprehensive income								4,050
Cash dividends paid ($0.120 per share)	--	--	--	(3,408)	--	--	--	(3,408)
Equity compensation	271	3	5,323	--	--	--	--	5,326
Exercise of options	248	2	1,837	--	--	(93)	(1,002)	837
Employee stock purchase plan	78	1	688	--	--	--	--	689
Excess tax benefit	--	--	458	--	--	--	--	458
Redemption and repurchase of stock to cover tax withholdings	(60)	--	(645)	--	--	(71)	(741)	(1,386)
Balance at December 31, 2015	**29,766**	**$ 298**	**$ 142,888**	**$ 23,365**	**$ (76)**	**(1,265)**	**$ (11,224)**	**$ 155,251**

Net income	--	--	--	10,778	--	--	--	10,778
Other comprehensive income:								
Foreign currency translation loss	--	--	--	--	(353)	--	--	(353)
Comprehensive income								10,425
Stock Issued for On-X transaction	3,704	37	34,556	--	--	--	--	34,593
Equity compensation	342	3	6,599	--	--	--	--	6,602
Exercise of options	372	3	2,083	--	--	(69)	(712)	1,374
Employee stock purchase plan	90	1	828	--	--	--	--	829
Excess tax benefit	--	--	606	--	--	--	--	606
Redemption and repurchase of stock to cover tax withholdings	(44)	--	(499)	--	--	(22)	(198)	(697)
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	2,683	27	53,092	--	--	--	--	53,119

transaction								
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**

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), incorporated in 1984 in Florida, is a leader in the manufacturing processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures focused on aortic repair. Our medical devices and processed tissues primarily include four product families: BioGlue® Surgical Adhesive (BioGlue); On-X mechanical heart valves and surgical products; JOTEC endovascular and surgical products; and cardiac and vascular human tissues including the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch (CryoPatch SG), both of which are processed using our proprietary SynerGraft® technology.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and our wholly owned subsidiaries. All significant inter-company accounts and transactions have been eliminated in consolidation.

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 gains and losses on foreign currency transactions are recorded as a component of other (income) expense, net on our Consolidated Statements of Operations and Comprehensive Income. 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 income (loss) in the shareholders equity section of our Consolidated Balance Sheets.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Estimates and assumptions are used when accounting for investments, allowance for doubtful accounts, inventory, deferred preservation costs, acquired assets or businesses, long-lived tangible and 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), contingent consideration liability, and other items as appropriate.

Revenue Recognition

Revenues for products, including: BioGlue, On-X products, JOTEC products, CardioGenesis cardiac laser therapy, PerClot®, PhotoFix ™ and other medical devices, are typically recognized at the time the product is shipped, at which time 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 services are completed and tissue is shipped to the customer. Revenues from upfront licensing agreements are recognized ratably

over the period we expect to fulfill our obligations.

Revenues from the sale of laser consoles are considered multiple element arrangements, and such revenues are allocated to the elements of the sale. We allocate revenues based primarily on the revenue these individual elements would generate if sold separately. Revenues from the sales of domestic laser consoles are typically recognized when the laser is installed at a customer site and all materials for the laser console s use are delivered. Revenues from the sales of laser consoles to international distributors are evaluated individually based on the terms of the sale and collectability to determine when revenue has been earned and can be recognized.

Shipping and Handling Charges

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

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 Income was $606,000, $384,000, and $521,000 for the years ended December 31, 2017, 2016, and 2015, 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. 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. 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 ASU 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 on our Consolidated Statement of Operations and Comprehensive 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

Cash dividends approved by our Board of Directors were paid every three months in the amount of $0.03 per share in 2015. In December 2015 the Board of Directors undertook a review of our dividend policy and determined that it would be in the best interest of the shareholders to discontinue dividend payments for the foreseeable future. We did not pay quarterly dividends in 2016 or 2017 and do not currently anticipate paying out further quarterly dividends.

Financial Instruments

Our financial instruments include cash equivalents, marketable securities, restricted securities, accounts receivable, notes receivable, accounts payable, debt obligations, contingent consideration, and derivatives. We typically value financial assets and liabilities such as receivables, accounts payable, and debt obligations at their carrying values, which approximate fair value due to their generally short-term duration. Other financial instruments are recorded as discussed in the sections below.

Fair Value Measurements

We record certain financial instruments at fair value, including: cash equivalents, certain marketable securities, certain restricted securities, contingent consideration, and derivative instruments. We may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis, although as of December 31, 2017 we have not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

We also measure certain non-financial assets at fair value on a non-recurring basis. These non-recurring valuations include evaluating assets such as cost method investments, long-lived assets, and non-amortizing intangible assets for impairment; allocating value to assets in an acquired asset group; applying accounting for business combinations; and allocating goodwill to divested components of a business. 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):

	2017	2016	2015
Cash paid during the year for:			
Interest	$ 2,561	$ 2,446	$ 1
Income taxes	3,358	2,501	145
Non-cash investing and financing activities:			
Issuance of common stock for acquisition of JOTEC intangible assets	$ 53,119	$ --	$ --
Issuance of common stock for acquisition of On-X intangible assets	--	34,593	--

Marketable Securities and Other Investments

We typically invest our excess cash for short-term periods in large, well-capitalized financial institutions, and our policy excludes investment in any securities rated less than investment-grade by national rating services, unless specifically approved by the Board of Directors. We sometimes make longer term strategic investments in medical device companies, and these investments must be approved by the Board of Directors.

We determine the classification of our investments as trading, available-for-sale, or held-to-maturity at the time of purchase and reevaluate such designations quarterly. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Debt securities are classified as held-to-maturity when we have the intent and ability to hold the securities to maturity. Any securities not designated as trading or held-to-maturity are considered available-for-sale. We typically state our investments at their fair values; however, for held-to-maturity securities or when current fair value information is not readily available, investments are recorded using the cost method. The cost of securities sold is based on the specific identification method.

Under the fair value method, we adjust each investment to its market price and record the unrealized gains or losses in other (income) expense, net for trading securities, or accumulated other comprehensive income (loss), for

available-for-sale securities. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in other (income) expense, net. Under the cost method, investments are recorded at cost, with subsequent dividends received recognized as income. Cost method investments are reviewed for impairment if factors indicate that a decrease in the value of the investment has occurred.

We review our contracts to determine if they require any restrictions to cash or investments. If there is a contractual agreement restricting the availability of our cash or investments, we will classify these amounts as current or long-term restricted cash or investments.

Accounts and Notes 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 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 $697,000 and $503,000 as of December 31, 2017 and 2016, respectively.

We may lend money from time-to-time through a note receivable, which may be made in conjunction with a longer term strategic investment in a medical device company, as approved by the Board of Directors. We assess the likelihood of collection of our notes receivable based on a number of factors, including past transaction history, credit worthiness, and the liquidity position of the recipient as well as the expected value of any collateral. Our notes receivable balance was zero as of December 31, 2017 and 2016, respectively.

Inventories

Inventories are comprised of finished goods for our major product lines including: BioGlue; On-X products; JOTEC 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 rehandling costs.

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

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

We recorded write-downs to our inventory totaling $1.2 million, $467,000, and $858,000 for the years ended December 31, 2017, 2016, and 2015, respectively. The 2017 write-down is primarily related to the write-down of our On-X ascending aortic prosthesis (AAP) as a result of inventory not expected to ship prior to the expiration date of the packaging and continued delay in obtaining European re-certification. The 2016 write-down is primarily related to the write-down of PerClot inventory as a result of inventory not expected to ship prior to the expiration date. The 2015 write-down is primarily related to the write-down of PerClot Topical inventory following our cessation of marketing, sales, and distribution of PerClot Topical in the U.S. See Note 8 for further discussion of PerClot Topical.

Deferred Preservation Costs

Deferred preservation costs includes 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 rehandling 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 (OTPOs), which consign the tissue to us for processing, preservation, and distribution. Deferred preservation costs consist primarily of the procurement fees charged by the OTPOs, 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 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 $922,000, $897,000, and $483,000 for the years ended December 31, 2017, 2016, and 2015, 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):

	2017	2016	2015
Depreciation expense	$ 4,648	$ 3,958	$ 3,728

Goodwill and Other Intangible Assets

Our intangible assets consist of goodwill, patents, trademarks, and other intangible assets, as discussed in Note 11. 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.

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 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, 2017, 2016, and 2015 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, 2017 our non-amortizing intangible assets consisted of goodwill, acquired procurement contracts and agreements, trademarks, and other acquired technology. We performed an analysis of our non-amortizing intangible assets as of October 31, 2017 and 2016, 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 OTPOs, which consign the tissue to us for processing, preservation, and distribution. We reimburse the OTPOs 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 OTPOs at the time tissues are received based on contractual agreements between us and the OTPOs.

Leases

We have operating and capital 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 14. Certain of our leases contain escalation clauses, rent concessions, and renewal options for additional periods. Rent expense is computed on the straight-line method over the lease term and the related liability is recorded as deferred rent obligations on our Consolidated Balance Sheets.

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 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 (income) expense, net on our Consolidated Statements of Operations and Comprehensive Income. See Note 12 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 acquired net operating loss carryforwards in the acquisition of On-X, the majority of which have been realized. We also acquired net operating loss carryforwards in certain foreign jurisdictions in our recent acquisition of JOTEC. While our analysis is still on-going, 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 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.

Derivative Instruments

We determine the fair value of our stand-alone and embedded derivative instruments at issuance and record any resulting asset or liability on our Consolidated Balance Sheets. Changes in the fair value of the derivative instruments are recognized in other (income) expense on our Consolidated Statements of Operations and Comprehensive Income.

New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) amended its Accounting Standards Codification 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 leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to the current Topic 840, *Leases*. It is effective for fiscal years and interim periods beginning after December 15, 2018, and early adoption is permitted. We are evaluating the impact the adoption of this standard will have on our financial position, results of operations, and cash flows.

In May 2014 the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers.* Since ASU 2014-09 was issued, several additional ASUs have been issued to clarify various elements of the guidance. 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. As required, we have adopted the new standard effective January 1, 2018. We are using the modified retrospective method and under this method we will have a cumulative catch up adjustment and will be providing additional disclosures in future filings including a comparison of results under the new standard to the previous standard. We have completed an initial evaluation of the potential impact from adopting the new standard, including a detailed review of performance obligations for all material revenue streams. We currently believe the most significant impacts may include the following items:

Certain distributor agreements included inventory buyback provisions under defined change of business conditions which, under the new standard, would not qualify as a completed revenue transaction because these provisions could prevent us from transferring control to the distributor and would, therefore, result in a reversal of revenue and recording of deferred revenue until the proper criteria are met. We have modified most of our agreements to remove the buyback provisions effective on or before January 1, 2018. As of January 1, 2018, there were certain remaining agreements with buyback provisions that had not been modified. We expect to record a cumulative effect adjustment upon adoption of the new standard to record the deferred revenue associated with these agreements. The deferred revenue will be recognized over future periods as the medical devices are implanted during the remaining term of the agreement.

Certain JOTEC products are manufactured to order, have no alternative use, and contain an enforceable right to payment for the performance completed. The revenue impact of these agreements is not material, but it is anticipated the sale of these products will increase over time. We expect to record a cumulative effect adjustment upon adoption of the new standard to record the deferred revenue associated with these agreements.

Based on the procedures and calculations completed to date, we do not expect that the combined cumulative effect adjustments will be material to our financial statements. In addition, we have not identified other matters related to the adoption of the standard that we believe would have a material impact on our financial position, results of operations, or cash flows.

2. Financial Instruments

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

December 31, 2017	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 372	--	--	$ 372
Restricted securities:				
Money market funds	776	--	--	776
Total assets	$ 1,148	$ --	$ --	$ 1,148

December 31, 2016	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 3,466	$ --	$ --	$ 3,466
Restricted securities:				
Money market funds	699	--	--	699
Total assets	$ 4,165	$ --	$ --	$ 4,165

We used prices quoted from our investment management companies to determine the Level 1 valuation of our investments in money market funds.

During the years ended December 31, 2017 and 2016, the Company initially recoded certain non-financial assets at fair value related to the acquisition JOTEC and On-X. Disclosures of these initial fair value determinations are included in Note 4 and Note 5 below.

3. Cash Equivalents and Restricted Cash and Securities

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

December 31, 2017	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value
Cash equivalents:			
Money market funds	$ 372	--	$ 372
Restricted securities:			
Money market funds	776	--	776

December 31, 2016	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value

Cash equivalents:			
Money market funds	$ 3,466	$ --	$ 3,466
Restricted securities:			
Money market funds	699	--	699

As of December 31, 2017 and 2016 $776,000 and $699,000, 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, 2017, 2016, and 2015. As of December 31, 2017 $537,000 of our restricted securities had a maturity date within three months and $239,000 had a maturity date between three months and one year. As of December 31, 2016 $490,000 of our restricted securities had a maturity date within three months and $209,000 of our restricted securities had a maturity date between three months and one year.

4. Acquisition of JOTEC

Overview

On October 10, 2017 we announced that we entered into a definitive agreement to acquire JOTEC AG (JOTEC), a Swiss entity (the Acquisition), which we converted to JOTEC GmbH, for approximately $225.0 million, subject to certain adjustments. The transaction closed on December 1, 2017 and JOTEC is being operated as a wholly owned subsidiary of CryoLife. In connection with the closing of the JOTEC acquisition, CryoLife entered into a Credit and Guaranty Agreement (Credit Agreement) with certain financial institutions as lenders, and Deutsche Bank AG New York Branch, as administrative and collateral agent, for 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 13 for further discussion of the Credit Agreement.

JOTEC is a German-based, privately held developer of technologically differentiated endovascular stent grafts, and cardiac and vascular surgical grafts, focused on aortic repair. We believe our the acquisition of JOTEC will create a company with a broad and highly competitive product portfolio focused on aortic surgery, and will position us to compete strongly in the important and growing endovascular surgical markets.

Accounting for the Transaction

Based on our preliminary analysis, the purchase price of the transaction totaled approximately $221.9 million, including debt and cash acquired as determined on the date of closing, consisting of $168.8 million in cash and 2,682,754 shares of CryoLife common stock, with an estimated value of $53.1 million as determined on the date of the closing. Upon closing of the Acquisition, $22.5 million was paid into an escrow account for any amounts payable for indemnification claims or other payment obligations. Our preliminary allocation of the $221.9 million purchase consideration was allocated to JOTEC s tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of December 1, 2017. Goodwill was preliminarily recorded based on the amount by which the purchase price exceeded the fair value of the net assets acquired and is not deductible for tax purposes. Goodwill from this transaction has been allocated to our Medical Devices segment. The estimated allocation of assets acquired and liabilities assumed is based on the information available to us. If new information regarding these values is received that would result in a material adjustment to the values recorded, we will recognize the adjustment, which may include the recognition of additional expenses, impairments, or other allocation adjustments, in the period this determination is made.

The preliminary purchase consideration acquired as of December 1, 2017, is as follows (in thousands):

		Opening Balance Sheet
Cash and cash equivalents	$	4,089
Receivables		13,204
Inventories		17,341

Intangible assets		115,820
Property and equipment		12,921
Goodwill		110,100
Other assets		3,893
Debt acquired		(3,770)
Liabilities assumed		(51,729)
Total purchase consideration	$	221,869

We incurred transaction and integration costs of $8.9 million for the year ended December 31, 2017 primarily related to the acquisition, which included, among other costs, expenses related to the termination of international and domestic

distribution 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 Income.

Pro Forma Results - Unaudited

JOTEC revenues were $4.1 million and the net loss was $1.5 million from the date of acquisition through December 31, 2017. Our unaudited pro forma results of operations for the years ended December 31, 2017 and 2016, assuming the JOTEC acquisition had occurred as of January 1, 2016, are presented for comparative purposes below. These amounts are based on available information from the results of operations of JOTEC prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the acquisition been completed on January 1, 2016. Differences between the preliminary and final purchase price allocation could have an impact on the pro forma financial information presented below and that impact could be material. This unaudited pro forma information does not project operating results post acquisition.

This unaudited pro forma information is as follows (in thousands, except per share amounts):

	Twelve Months Ended December 31,	
	2017	**2016**
Total revenues	$ 236,209	$ 224,896
Net loss	(736)	(1,966)
Pro forma loss per common share - basic	$ (0.02)	$ (0.06)
Pro forma loss per common share - diluted	$ (0.02)	$ (0.06)

Pro forma net loss was calculated using a normalized tax rate of approximately 38%.

The pro forma amortization of intangible assets acquired, as reported in our 8-K/A filed on February 16, 2018, was incorrect due to a clerical error. The corrected pro forma amortization is included in the determination of pro forma loss per common share for the twelve months ended December 31, 2016 presented above. The result of this correction increased the pro forma amortization adjustment by $4.3 million to a total of $5.5 million for the twelve month ended December 31, 2016. This adjustment reduced the results per common share for the twelve months ended December 31, 2016 by $0.08 per common share from $0.02 per common share originally reported in the 8-K/A, resulting in an adjusted pro forma net loss per common share of ($0.06) on a fully diluted basis.

The results for the twelve months ended December 31, 2017 presented above include pro forma amortization of intangible assets acquired of $4.9 million.

The result of this correction on pro forma results of operations, as reported in the 8-K/A referenced for the nine months ended September 30, 2017, also increased the pro forma amortization adjustment by $3.2 million for the nine months ended September to a total of $3.8 million. This adjustment reduced the pro forma net income per common share by $0.06 from $0.13 per common share to an adjusted pro forma net income per common share of $0.07 on a fully diluted basis for the nine months ended September 30, 2017.

5. Acquisition of On-X Life Technologies

Overview

On December 22, 2015 we entered into an Agreement and Plan of Merger (On-X Agreement) to acquire On-X Life Technologies Holdings, Inc. (On-X), an Austin, Texas-based, privately held mechanical heart valve company, for approximately $130.0 million, subject to certain adjustments. The transaction closed on January 20, 2016, and On-X is being operated as a wholly owned subsidiary of CryoLife.

The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis. On-X also distributes CarbonAid CO_2 diffusion catheters and manufactures Chord-X ePTFE sutures for mitral chordal replacement. On-X also generates revenue from pyrolytic carbon coating products produced for other medical

device manufacturers. We believe that the On-X products fit well into our product portfolio of medical devices for cardiac surgery and that we are capitalizing on the significant opportunity for our sales team to expand utilization of the On-X valves in the U.S. and internationally.

Accounting for the Transaction

The purchase price of the On-X transaction totaled approximately $128.2 million, consisting of $93.6 million in cash and 3,703,699 shares of CryoLife common stock, with a value of $34.6 million as determined on the date of the closing. We recorded an allocation of the $128.2 million purchase price to On-X s tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of January 20, 2016. Goodwill was recorded based on the amount by which the purchase price exceeded the fair value of the net assets acquired and is not deductible for tax purposes. Goodwill from this transaction has been allocated to our Medical Devices segment.

The purchase price allocation was as follows (in thousands):

		Opening Balance Sheet
Cash and cash equivalents	$	2,472
Receivables		6,826
Inventories		12,889
Intangible assets		53,950
Goodwill		68,229
Other assets		6,891
Liabilities assumed		(23,040)
Total purchase price	$	128,217

We incurred transaction and integration costs of $7.4 million for the year ended December 31, 2016 related to the acquisition, which included, among other costs, expenses related to the termination of international and domestic distribution agreements. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on our Consolidated Statements of Operations and Comprehensive Income.

We paid approximately $10.0 million of the purchase price into an escrow account upon closing of the On-X transaction. We are currently in litigation with the shareholder representative of On-X concerning the resolution of these escrow funds. We believe that we are entitled to recover the escrow funds, but the outcome of litigation is inherently uncertain, and we may not recover any of the escrow funds.

Pro Forma Results - Unaudited

Our pro forma results of operations for the years ended December 31, 2016 and 2015, assuming the On-X acquisition had occurred as of January 1, 2015, are presented for comparative purposes below. These amounts are based on available information of the results of operations of On-X prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the acquisition been completed on January 1, 2015. This unaudited pro forma information does not project operating results post acquisition.

This unaudited pro forma information is as follows (in thousands, except per share amounts):

	Twelve Months Ended December 31,	
	2016	**2015**
Total revenues	$ 182,007	$ 179,266
Net income (loss)	17,692	(4,787)
Pro forma income (loss) per common share - basic	$ 0.54	$ (0.15)
Pro forma income (loss) per common share - diluted	$ 0.53	$ (0.15)

Pro forma net income (loss) was calculated using a normalized tax rate of approximately 38%.

6. Sale of Business Components

Divestiture of the HeRO Graft Product Line

On February 3, 2016 we sold our Hemodialysis Reliable Outflow Graft (HeRO® Graft) product line to Merit Medical Systems, Inc. (Merit) for $18.5 million in cash (HeRO Sale), of which $17.8 million was received on the transaction date and the remaining $740,000 was received in the first quarter of 2017. Under terms of the agreement, Merit acquired the HeRO Graft product line, including worldwide marketing rights, customer relationships, intellectual property, inventory, and certain property and equipment. We continued to manufacture the HeRO Graft under a transition supply agreement until the manufacturing transfer to Merit was completed in the second quarter of 2016. Sales prices under the transition supply agreement were at lower average prices than our previous sales to hospitals at end-user prices. The HeRO Graft product line was included as part of our Medical Devices segment. We recorded a pre-tax gain of approximately $8.8 million on the HeRO Sale.

ProCol Distribution Agreement and Divestiture of the ProCol Product Line

In 2014 we acquired the exclusive worldwide distribution rights to ProCol® Vascular Bioprosthesis (ProCol) from Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). In accordance with the terms of the agreement, we made payments to Hancock Jaffe totaling $3.4 million for which we obtained the right to receive a designated amount of ProCol inventory for resale. As of March 18, 2016 we had received $1.7 million in inventory. The remaining $1.7 million in prepayments for inventory not yet delivered to us were settled as part of the ProCol Sale, described below.

On March 18, 2016 we sold our ProCol distribution rights and purchase option to LeMaitre Vascular, Inc. (LeMaitre) for $2.0 million in cash (ProCol Sale), all of which was received by March 31, 2016. Under the terms of the agreement, LeMaitre acquired the ProCol related assets, including inventory, customer lists, related marketing assets, and our purchase option to acquire ProCol. LeMaitre exercised the option to acquire ProCol from Hancock Jaffe. The ProCol product was included as part of our Medical Devices segment. We recorded a pre-tax loss of approximately $845,000 on the ProCol Sale.

Disclosure of the HeRO Sale and the ProCol Sale

Financial Accounting Standards Board ASU 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity,* (ASU 2014-08) defines the criteria for reporting discontinued operations and requires additional disclosures about discontinued operations. The standard requires that an entity report a disposal as a discontinued operation only if the disposal represents a strategic shift in operations that has a major effect on our operations and financial results.

In the first quarter of 2016 we completed and recorded the HeRO Sale and the ProCol Sale and received cash for these transactions. Therefore, as of March 31, 2016 both transactions met the disposed of by sale criteria under ASU 2014-08.

We evaluated the impact of the HeRO Sale and the ProCol Sale on our business to determine whether these disposals represent a strategic shift that has, or will have, a major effect on our financial position, results of operations, or cash flows. As the HeRO Graft and ProCol product lines combined represented less than 10% of both our total revenues for the year ended December 31, 2015 and our total assets as of December 31, 2015, we believe that these transactions did not have a major effect on our operations and financial condition, either individually or in the aggregate, and therefore, we did not disclose these transactions as discontinued operations. The combined net gain from the HeRO Sale and ProCol Sale was, therefore, reported as gain from sale of business components on our Consolidated Statements of Operations and Comprehensive Income.

7. PhotoFix Distribution Agreement and Acquisition

Overview

In 2014 CryoLife entered into an exclusive supply and distribution agreement with Genesee Biomedical, Inc. (GBI) to acquire the distribution rights to PhotoFix , a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix has received U.S. Food and Drug Administration (FDA) 510(k) clearance and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line

buttressing, and pericardial closure. We believe that PhotoFix fits well into our product portfolio of medical devices for cardiac surgery. In January 2015 we received our initial shipments and launched our distribution of PhotoFix.

The agreement between CryoLife and GBI (the GBI Agreement) had an initial five-year term and was renewable for two one-year periods at CryoLife s option. Under the terms of the GBI Agreement, we began purchasing PhotoFix inventory for resale at an agreed upon transfer price and had the option, which became effective in March 2015, to acquire the PhotoFix product line from GBI.

Accounting for the Transaction

On April 13, 2016 we exercised our right to acquire the PhotoFix technology from GBI for approximately $2.3 million, of which $1.2 million was paid in cash at closing, approximately $600,000 was previously provided to GBI as an advance under the distribution agreement, and approximately $400,000 was paid to GBI in October 2017. Our allocation of the purchase price to the tangible and identifiable intangible assets acquired, based on their estimated fair values, resulted in the allocation of the majority of the purchase price to amortizable intangible assets. We began limited manufacturing of PhotoFix in the fourth quarter of 2017. GBI will continue to manufacture PhotoFix until we are able to fully establish manufacturing operations, which is expected to occur in 2018.

8. Medafor Matters

Investment in Medafor Common Stock

In 2009 and 2010 we purchased shares of common stock in Medafor, a developer and supplier of plant based hemostatic agents. We initially recorded our investment using the cost method as a long-term asset, investment in equity securities, on our Consolidated Balance Sheets.

On October 1, 2013 Bard (Bard), previously C. R. Bard, Inc. and its subsidiaries, now a wholly owned subsidiary of Becton, Dickinson and Company (BD) and a developer, manufacturer, and marketer of medical technologies in the fields of vascular, urology, oncology, and surgical specialty products completed its acquisition of all outstanding shares of Medafor common stock. We received an initial payment of approximately $15.4 million in 2013, $530,000 in 2014, and $891,000 in 2015 for our 2.4 million shares of Medafor common stock.

Legal Action

In April 2014 we filed a declaratory judgment lawsuit against Bard, and its subsidiaries Davol, Inc. (Davol), and Medafor (collectively, Defendants), in the District Court for the District of Delaware (the Court). We requested that the Court declare that our manufacture, use, offer for sale, and sale of PerClot in the U.S. does not, and would not, infringe BD s U.S. Patent No. 6,060,461 (the 461 Patent). In addition, we requested that the Court declare that the claims of the 461 Patent are invalid. We also requested injunctive relief and an award of attorneys fees.

In August 2014 Medafor filed a counterclaim against us for infringement of the 461 Patent. In September 2014 Medafor filed a motion for a preliminary injunction, asking the Court to enjoin our marketing and sale of PerClot in the U.S. In March 2015 the Court ruled that our declaratory judgment lawsuit against Medafor may proceed but dismissed Bard from the lawsuit. The Court also granted Medafor s motion for a preliminary injunction, which prohibited us from marketing, selling, and distributing PerClot in the U.S. while the litigation proceeded. In March 2015 we ceased all marketing, sales, and distribution of PerClot in the U.S., including PerClot Topical, in accordance with the Court s order. In April 2015 we appealed the Court s ruling on the preliminary injunction motion to the U.S. Court of Appeals for the Federal Circuit. We dismissed this appeal in June 2015. On November 18, 2015, the lawsuit was resolved by entry by the Court of the Parties Joint Stipulation for Dismissal, which resulted in the dismissal with prejudice of all parties claims and counterclaims in the lawsuit, the continuation of the preliminary injunction

prohibiting us from marketing, selling and distributing PerClot in the U.S. until expiration of the 461 Patent on February 8, 2019, each party bearing its own attorneys fees and costs associated with the lawsuit, and the continuation of the Court s jurisdiction over the parties to enforce the resolution.

9. Direct Sales in France

In June 2015 we signed a Business Transfer Agreement with our French distribution partner to facilitate an orderly transition to a direct sales model in France. In October 2015 we completed the acquisition of a portion of the business of our French distribution partner. We acquired in the transaction certain intangible assets, including commercial and business information, assignment of contracts, and a non-compete agreement with our former French distribution partner for a purchase price of 1.2 million or $1.3 million. During the third quarter of 2015 we established a wholly owned subsidiary in France, CryoLife France SAS, and certain members of the distributor s sales team who were responsible for selling our products in France became employees of the our newly created subsidiary.

10. Inventories and Deferred Preservation Costs

Inventories at December 31, 2017 and 2016 are comprised of the following (in thousands):

	2017	2016
Raw materials and supplies	$ 16,328	$ 9,321
Work-in-process	5,504	3,321
Finished goods	24,852	13,651
Total inventories	$ 46,684	$ 26,293

Deferred preservation costs at December 31, 2017 and 2016 are comprised of the following (in thousands):

	2017	2016
Cardiac tissues	$ 16,988	$ 15,768
Vascular tissues	18,683	14,920
Total deferred preservation costs	$ 35,671	$ 30,688

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 this consignment inventory until the device is implanted, at which time we invoice the hospital. As of December 31, 2017 we had $9.3 million in consignment inventory, with approximately 58% in domestic locations and 42% in foreign locations. As of December 31, 2016 we had $4.9 million in consignment inventory, with approximately 80% in domestic locations and 20% in foreign locations.

11. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of December 31, 2017 and 2016 the carrying values of our indefinite lived intangible assets are as follows (in thousands):

	2017	2016

Goodwill	$ 188,305	$ 78,294
In-process R&D	13,954	--
Procurement contracts and agreements	2,013	2,013
Trademarks	841	841

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, 2017 and 2016 the value of our goodwill, all of which is related to our Medical Devices segment, is as follows (in thousands):

	2017	2016
Balance as of January 1,	$ 78,294	$ 11,365
Goodwill from JOTEC acquisition	110,100	--
Goodwill from On-X acquisition	--	68,229
Goodwill allocated to sale of HeRO Graft product line	--	(1,200)
Goodwill allocated to sale of ProCol distribution rights and purchase option	--	(100)
Revaluation of goodwill denominated in foreign currency	(89)	--
Balance as of December 31,	$ 188,305	$ 78,294

Definite Lived Intangible Assets

As of December 31, 2017 and 2016 gross carrying values, accumulated amortization, and approximate amortization periods of our definite lived intangible assets are as follows (dollars in thousands):

December 31, 2017	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 139,045	8,685	11 22 Years
Patents	3,612	2,819	17 Years
Distribution and manufacturing rights and know-how	4,059	1,820	11 15 Years
Customer lists and relationships	32,419	3,552	13 23 Years
Other	1,439	1,076	3 Years

December 31, 2016	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 38,478	5,956	11 22 Years
Patents	3,710	2,702	17 Years
Distribution and manufacturing rights and know-how	4,059	1,532	11 15 Years
Customer lists and relationships	29,140	2,141	13 22 Years
Non-compete agreement	381	381	10 Years
Other	1,262	531	3 Years

The increase in gross carrying value of our intangible assets as of December 31, 2017 when compared to December 31, 2016 is primarily due to our acquisition JOTEC. See Note 4 for further discussion of the acquisition of JOTEC.

Amortization Expense

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

	2017	2016	2015
Amortization expense	$ 5,085	$ 4,426	$ 2,135

As of December 31, 2017 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2018	2019	2020	2021	2022	Total
Amortization expense	$ 10,810	$ 10,468	$ 10,304	$ 10,283	$ 9,755	$ 51,620

12. Income Taxes

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. We have elected to follow the guidance in SEC Staff Accounting Bulletin 118 (SAB 118), which provides additional clarification regarding the application of ASC 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. SAB 118 provides for a measurement period beginning in the reporting period that includes the Tax Act s enactment date and ending when we have obtained, prepared, and analyzed the information needed in order to complete the accounting requirements but in no circumstances should the measurement period extend beyond one year from the enactment date.

We have 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. We have 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. The provisional amount is based on information currently available, including information from our recent acquisition of JOTEC. We continue to gather and analyze information, including historical adjustments to earnings and profits of foreign subsidiaries, in order to complete the accounting for the effects of the estimated transition tax.

As a result of the Tax Act, we have also recorded a nominal tax benefit related to the remeasurement of domestic deferred tax assets and liabilities from 35% to 21%. We continue to analyze other impacts of the Tax Act, but the effects based on current information do not have a material impact on the financial statements for the year ended December 31, 2017. We intend to complete the necessary analysis within the measurement period. We expect the impact of the Tax Act may have a material impact on our effective income tax rate in future periods.

We have provisionally 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 provisional deferred tax impacts of GILTI in its consolidated financial statements for the year ended December 31, 2017.

Income Tax Expense

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

	2017	2016	2015
Domestic	$ 5,086	$ 17,874	$ 5,701
Foreign	(1,525)	538	167
Income before income taxes	$ 3,561	$ 18,412	$ 5,868

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

	2017	2016	2015
Current:			
Federal	$ 521	$ 3,948	$ 231
State	110	626	142
Foreign	460	353	160
	1,091	4,927	533
Deferred:			
Federal	(714)	2,836	1,011
State	70	(9)	319
Foreign	(590)	(120)	--
	(1,234)	2,707	1,330
Income tax (benefit) expense	$ (143)	$ 7,634	$ 1,863

Our income tax (benefit) expense in 2017, 2016, and 2015 included our federal, state, and foreign tax obligations. Our effective income tax rate was approximately -4%, 41%, and 32% for the years ended December 31, 2017, 2016, and 2015, respectively. 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, offset by nondeductible transaction costs related to the JOTEC acquisition and nondeductible meals and entertainment expenses. The Company s income tax rate for the twelve months ended December 31, 2016 was unfavorably impacted by the tax treatment of certain expenses related to the On-X acquisition, which had a larger impact on the tax rate in the first quarter of 2016, and by book/tax basis differences related to the HeRO Sale. Our income tax rate for the twelve months ended December 31, 2015 was favorably affected by the reversal of $869,000 in uncertain tax positions, primarily related to research and development tax credits for which the statute of limitations has expired, partially offset by the expiration of certain state net operating losses and other permanent differences.

The income tax expense amounts differ from the amounts computed by applying the U.S. federal statutory income tax rate of 34% for the year ended December 31, 2017, 35% for the year ended December 31, 2016, and 34% for the year ended December 31, 2015 to pretax income as a result of the following (in thousands):

	2017	2016	2015
Tax expense at statutory rate	$ 1,211	$ 6,444	$ 1,995
Increase (reduction) in income taxes resulting from:			
Nondeductible transaction costs	1,676	908	--
State income taxes, net of federal benefit	212	531	499
Nondeductible loss on unit disposals	--	455	--
Nondeductible entertainment expenses	258	221	184
Foreign income taxes	364	130	118
Limitation of future deductibility of stock awards	145	--	--
Provision to return adjustments	96	29	122
State valuation allowance adjustment	54	(84)	(19)
Impact of Tax Cuts and Jobs Act	(255)	--	--
Equity compensation	(2,664)	135	144
Net change in uncertain tax positions	(67)	(153)	(869)
Federal tax rate differential	(100)	--	--
Foreign tax credit	(133)	(178)	(92)
Unrealized income on investments	(163)	(111)	63
Domestic production activities deduction	(174)	(456)	(87)
Research and development credit	(525)	(296)	(281)
Other	(78)	59	86
Total income tax (benefit) expense	$ (143)	$ 7,634	$ 1,863

Deferred Taxes

We generate deferred tax assets primarily as a result of write-downs of inventory and deferred preservation costs; accruals for product and tissue processing liability claims; asset impairments; stock compensation, and net operating losses. We acquired significant deferred tax assets, primarily net operating losses, from our acquisitions of JOTEC in 2017, On-X in 2016, Hemosphere in 2012, and Cardiogenesis in 2011. We recorded significant deferred tax liabilities in 2017 and 2016 related to the intangible assets acquired in the JOTEC and On-X acquisitions, respectively.

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

	2017	2016
Deferred tax assets:		
Allowance for bad debts	$ 101	$ 208
Inventory and deferred preservation costs write-downs	570	708
Investment in equity securities	36	58
Property	--	1,780
Intangible assets	1,306	2,034
Accrued expenses	4,719	4,215
Loss carryforwards	8,369	8,760
Credit carryforwards	771	1,001
Stock compensation	2,213	3,678
Transaction costs	--	122
Deferred compensation	1,010	973
UNICAP	390	371
Tax benefit of tax reserves	229	333
Other	402	409
Less valuation allowance	(2,469)	(2,157)
Total deferred tax assets	17,647	22,493

	2017	2016
Deferred tax liabilities:		
Prepaid items	(285)	(436)
Intangible assets	(43,647)	(21,665)
Property	(1,632)	--
Other	(904)	(399)
Total deferred tax liabilities	(46,468)	(22,500)
Total net deferred tax liabilities	$ (28,821)	$ (7)

As of December 31, 2017 we maintained a total of $2.5 million in valuation allowances against deferred tax assets, related primarily to state net operating loss carryforwards, and a net deferred tax liability of $28.8 million. As of December 31, 2016 we maintained a total of $2.2 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax liability of $7,000.

As of December 31, 2017 we had approximately $3.4 million tax-effected federal net operating loss carryforwards related to the acquisitions of Cardiogenesis and Hemosphere that will begin to expire in 2018, $2.8 million of tax-effected state net operating loss carryforwards, that will begin to expire in 2022, $2.2 million of foreign net operating loss carryforwards related to the acquisition of JOTEC that do not expire, $490,000 in research and development tax credit carryforwards that begin to expire in 2022, and $164,000 in credits from the state of Texas that will fully expire by 2027.

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):

	2017	2016	2015
Beginning balance	$ 3,390	$ 969	$ 1,437
Increases related to current year tax positions	143	86	103
Increases related to prior year tax positions	1,155	2,668	403
Decreases related to prior year tax positions	(106)	(40)	(70)
Decreases related to settlements	--	(66)	--
Decreases due to the lapsing of statutes of limitations	(254)	(227)	(904)
Ending balance	$ 4,328	$ 3,390	$ 969

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

	2017	2016	2015
Beginning balance	$ 208	$ 210	$ 366
Accrual of interest and penalties	169	92	50
Decreases related to prior year tax positions	(62)	(94)	(206)
Ending balance	$ 315	$ 208	$ 210

As of December 31, 2017 our uncertain tax liability, including interest and penalties, of $4.6 million, was recorded as a reduction to deferred tax assets of $146,000, and a non-current liability of $4.5 million on our Consolidated Balance Sheets. The uncertain tax position increase related to prior year tax positions is primarily due to our preliminary analysis of positions taken by JOTEC on tax returns in prior years. As of December 31, 2016 our total uncertain tax liability, including interest and penalties of $3.6 million, was recorded as a reduction to deferred tax assets of $234,000, and a non-current liability of $3.4 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.

We believe it is reasonably possible that approximately $817,000 of our uncertain tax liability will be recognized in 2018 due to settlement with various taxing authorities and the lapsing of various federal and state statutes of limitations, of this amount approximately $433,000 would affect the tax rate.

Other

Our tax years 2014 through 2016 generally remain open to examination by the major taxing jurisdictions to which we are subject. However, certain returns from years prior to 2014, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

13. 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 acquisition of JOTEC and its subsidiaries (the Acquisition), (ii) pay certain fees and expenses related to the 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 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.

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 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, 2017 the aggregate interest rate was 5.36%. 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 9 years and the interest rates are 2.45% and 1.4%.

Amended Debt Agreement

In connection with the closing of the On-X acquisition on January 20, 2016 we and certain of our subsidiaries entered into the Third Amended and Restated Credit Agreement (Amended Debt Agreement) with Capital One, National Association, who acquired GE Capital s Healthcare Financial Services lending business in late 2015. The designated credit parties were Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association, collectively the (Lending Parties). The Amended Debt Agreement amended and restated the prior GE Credit Agreement and provided us with a senior secured credit facility in an aggregate principal amount of $95 million, which included a $75 million term loan and a $20 million revolving credit facility (including a $4 million letter of credit sub-facility and a $3 million swing-line sub-facility). The $75 million term loan was used to finance, in part, the acquisition of On-X and was set to mature on January 20, 2021.

We and our domestic subsidiaries, subject to certain exceptions and exclusions, had guaranteed the obligations of the Amended Debt Agreement. Borrowings under the Amended Debt Agreement were secured by substantially all of our real and personal property. As of December 31, 2016 the aggregate interest rate was 3.50%. 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 Amended Debt Agreement prohibited us from exceeding a maximum consolidated leverage ratio during the term of the Amended Debt Agreement and requires us to maintain a minimum interest coverage ratio. In addition, the

Amended Debt Agreement contained certain customary affirmative and negative covenants, including covenants that limit our ability, and the ability of our subsidiaries that are parties to the loan agreement to, among other things, grant liens; incur debt; dispose of assets; make loans and investments; make acquisitions; make certain restricted payments; merge or consolidate; and change their business and accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. As of December 31, 2017 and 2016 the balance of the term loan under the amended debt agreement was zero and $67.0 million.

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

	As of December 31,	
	2017	2016
Term loan balance	$ 225,000	$ 73,594
2.45% Sparkasse Zollernalb (KFW Loan 1)	2,312	--
1.4% Sparkasse Zollernalb (KFW Loan 2)	1,657	--
Total loan Balance	228,969	73,594
Less unamortized loan origination costs	(10,015)	(2,020)
Total borrowed	218,954	71,574
Less short-term loan balance	(718)	(4,562)
Long-term loan balance	$ 218,236	$ 67,012

At December 31, 2017 the aggregate maturities of long-term debt for the next five years is as follows (in thousands):

	2018	2019	2020	2021	2022	Thereafter	Total
Maturities	$ 2,814	$ 2,813	$ 2,813	$ 2,814	$ 2,813	$ 214,902	$ 228,969

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 $4.9 million and $3.0 million in 2017 and 2016, respectively, and a favorable $62,000 in 2015. Interest expense was favorable in 2015 due to the reversal of accrued interest on uncertain tax positions as discussed in Note 12 above. Interest expense includes interest on debt and uncertain tax positions in all periods.

14. Commitments and Contingencies

Leases

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

We had deferred rent obligations of $2.9 million and $2.4 million as of December 31, 2017 and 2016, respectively, primarily related to the lease on our corporate headquarters, which expires in 2022. Total rental expense for operating leases was $4.9 million in 2017, $4.3 million in 2016, and $3.4 million in 2015. The increase in rent expense in 2017 is due to the acquisition and our lease of equipment and manufacturing, warehouse, and office space in Hechingen, Germany. The increase in rent expense in 2016 is due to the acquisition of On-X and our lease for manufacturing, warehouse, and office space in Austin, Texas. We began subleasing some of our additional office space late in December 2016 and earned $564,000 of sublease income in 2017 and nominal sublease income in 2016.

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

	Capital Leases	Operating Leases	Sublease Income
2018	$ 1,034	$ 5,927	$ 512
2019	1,061	6,231	525
2020	874	5,098	538
2021	838	4,249	552
2022	781	2,038	--
Thereafter	6,243	5,301	--
Total minimum lease payments	$ 10,831	$ 28,844	$ 2,127
Less amount representing interest	3,415		
Present value of net minimum lease payments	7,416		
Less current maturities	580		
Capital lease obligations, less current maturities	$ 6,836		

Assets acquired under capital leases are as follows (in thousands):

	Gross Carrying Value	Accumulated Amortization	NBV
Equipment	$ 1,306	$ 594	$ 712
Leasehold improvements	6,908	256	6,652
Total	$ 8,214	$ 850	$ 7,364

Liability Claims

At December 31, 2017 and 2016 our unreported loss liability was $1.8 million and $1.5 million, respectively. As of December 31, 2017 and 2016, the related insurance recoverable amounts were $692,000 and $626,000, 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, 2017 could be estimated to be as high as $2.9 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.

The employment agreement of our former President, CEO, and Executive Chairman, Mr. Steven G. Anderson, conferred certain benefits on Mr. Anderson upon his retirement or termination of employment in conjunction with certain change in control events. On April 9, 2015 Mr. Anderson retired from service as our employee and Chair of our Board of Directors, and entered into a separation agreement with us. We recorded expenses of approximately $1.4 million related to Mr. Anderson s separation agreement in the second quarter of 2015. We had remaining obligations due under Mr. Anderson s separation agreement of $77,000 and $83,000 as of December 31, 2017 and December 31, 2016, respectively.

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. We resumed enrollment into the PerClot U.S. clinical trial in the fourth quarter of 2016, and assuming enrollment proceeds as anticipated, we could receive Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) in the second half of 2019.

As of December 31, 2017 we had $1.5 million in prepaid royalties, $2.6 million in net intangible assets, and $1.4 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.

15. Cash Dividends

We initiated a cash dividend in the third quarter of 2012 and paid the dividend quarterly until our Board of Directors discontinued dividend payments for the foreseeable future in December 2015. We paid dividend payments of $3.4 million from cash on hand for the year ended December 31, 2015. The dividend payments were recorded as a reduction to retained earnings on our Consolidated Balance Sheet.

16. 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% of each participant s salary in 2017. We made matching contributions of 40% of each participant s contribution for up to 5% of each participant s salary in 2016 and 2015. Our contributions approximated $1.4 million, $750,000, and $573,000 for the years ended 2017, 2016, and 2015, respectively. The increase in expenses in 2017 was primarily due to the increase in our matching contribution. The increase in expenses in 2016 was due, in part, to the addition of participants related to the acquisition of On-X. Additionally, 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 or 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.

17. 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, 2017 and 2016:

Plan	Authorized Shares	Available for Grant 2017	Available for Grant 2016
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	377,000	469,000
2009 Equity and Cash Incentive Plan	7,100,000	1,422,000	2,194,000
Total	9,000,000	1,799,000	2,663,000

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 2017 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 426,000 shares and had an aggregate grant date market value of $7.1 million. The PSUs granted in 2017 represented the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2016 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 2016 calendar year. The PSUs granted in 2017 earned 92% of the target number of shares.

In 2016 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 490,000 shares of common stock and had an aggregate grant date market value of $5.5 million. The PSUs granted in 2016 earned approximately 142% of the target number of shares.

In 2015 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 405,000 shares of common stock and had an aggregate market value of $4.3 million. The PSUs granted in 2015 earned approximately 127% of the target number of shares.

A summary of stock grant activity for the years ended December 31, 2017, 2016, and 2015 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, 2014	495,000	$ 7.65
Granted	207,000	10.33
Vested	(278,000)	8.10
Forfeited	(110,000)	8.49
Unvested at December 31, 2015	314,000	9.31
Granted	216,000	10.84
Vested	(138,000)	7.92
Forfeited	--	--
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

PSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2014	250,000	$ 10.18
Granted	--	--
Vested	--	--
Forfeited	--	--
Unvested at December 31, 2015	250,000	10.18
Granted	--	--
Vested	--	--
Forfeited	--	--
Unvested at December 31, 2016	250,000	10.18
Granted	--	--
Vested	(250,000)	10.18
Forfeited	--	--
Unvested at December 31, 2017	--	--

RSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2014	61,000	1.21	$ 687,000
Granted	88,000		
Vested	(36,000)		
Forfeited	(10,000)		
Unvested at December 31, 2015	103,000	1.17	1,110,000
Granted	146,000		
Vested	(44,000)		
Forfeited	(27,000)		
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
Vested and expected to vest	286,000	1.26	$ 5,477,000

PSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Unvested at December 31, 2014	257,000	0.73	$ 2,907,000
Granted	125,000		
Vested	(139,000)		
Forfeited	(108,000)		
Unvested at December 31, 2015	135,000	0.74	1,455,000
Granted	144,000		
Vested	(83,000)		
Forfeited	(8,000)		
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
Vested and expected to vest	169,000	0.71	$ 3,236,000

During the years ended December 31, 2017, 2016, and 2015, the total fair value of $11.1 million, $2.9 million, and $4.8 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 260,000, 387,000, and 328,000 shares in 2017, 2016, and 2015, 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, 2017, 2016, and 2015 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2014	2,021,000	$ 7.43	3.54	$ 8,021,000
Granted	328,000	10.83		
Exercised	(248,000)	7.42		
Forfeited	(112,000)	9.93		
Expired	(93,000)	12.08		
Outstanding at December 31, 2015	1,896,000	7.65	3.31	5,992,000
Granted	387,000	10.34		
Exercised	(372,000)	5.60		
Forfeited	--	--		
Expired	--	--		
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
Vested and expected to vest	1,741,000	$ 10.19	3.64	$ 15,598,000
Exercisable at December 31, 2017	1,167,000	$ 8.81	2.76	$ 12,057,000

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

	2017	2016	2015
Weighted-average fair value of options granted	$ 5.97	$ 3.68	$ 3.82
Intrinsic value of options exercised	4,748,000	2,422,000	761,000

Employees purchased common stock totaling 93,000, 90,000, and 78,000 shares in 2017, 2016, and 2015, respectively, through our ESPP.

Stock Compensation Expense

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

	2017		2016		2015	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	4.75 Years	0.5 Years	4.75 Years	0.5 Years	4.5 Years	0.5 Years
Expected stock price volatility	0.40	0.39	0.40	0.30	0.44	0.32
Dividend yield	--%	--%	--%	--%	1.12%	1.06%
Risk-free interest rate	1.87%	0.85%	1.20%	0.43%	1.41%	0.12%

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

	2017	2016	2015
RSA, PSA, RSU, and PSU expense	$ 5,335	$ 4,966	$ 3,955
Stock option and ESPP option expense	1,978	1,636	1,371
Total stock compensation expense	$ 7,313	$ 6,602	$ 5,326

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 $394,000, $274,000 and $237,000 in the years ended December 31, 2017, 2016, and 2015, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of December 31, 2017 we had total unrecognized compensation costs of $6.1 million related to RSAs, PSAs, RSUs, and PSUs and $1.6 million related to unvested stock options. As of December 31, 2017 this expense is expected to be recognized over a weighted-average period of 1.9 years for RSUs, 1.5 years for stock options, 1.1 years for RSAs, and 0.7 years for PSUs.

18. Income Per Common Share

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

Basic income per common share	**2017**	**2016**	**2015**
Net income	$ 3,704	$ 10,778	$ 4,005
Net income allocated to participating securities	(63)	(208)	(87)
Net income allocated to common shareholders	$ 3,641	$ 10,570	$ 3,918
Basic weighted-average common shares outstanding	33,008	31,855	27,744
Basic income per common share	$ 0.11	$ 0.33	$ 0.14

Diluted income per common share	**2017**	**2016**	**2015**
Net income	$ 3,704	$ 10,778	$ 4,005
Net income allocated to participating securities	(61)	(202)	(87)
Net income allocated to common shareholders	$ 3,643	$ 10,576	$ 3,918
Basic weighted-average common shares outstanding	33,008	31,855	27,744
Effect of dilutive options and awards[a]	1,155	967	798
Diluted weighted-average common shares outstanding	34,163	32,822	28,542
Diluted income per common share	$ 0.11	$ 0.32	$ 0.14

[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 income per common share. Accordingly, stock options to purchase 227,000, 1,000, and 710,000 shares for the years ended December 31, 2017, 2016, and 2015, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

19. Transactions with Related Parties

A member of our Board of Directors and a shareholder of the Company is an employee of an investment banking services company. On January 20, 2016 we acquired On-X. The investment banking company represented On-X, not us, in that acquisition, for which that investment banking services company earned $3.0 million in fees upon the close of the acquisition. We paid these fees directly to the investment banking company on behalf of On-X from the acquisition sales proceeds otherwise due On-X shareholders.

A member of our Board of Directors and a shareholder of the Company was the former Chief of Thoracic Surgery of a university hospital that generated product and preservation services revenues of $133,000, $316,000, and $329,000 for us in 2017, 2016, and 2015, respectively. Additionally, the son of this member of our Board of Directors receives a retainer for performing heart and lung transplants from a medical center that generated product and preservation services revenues of $793,000, $479,000, and $617,000 for us in 2017, 2016, and 2015, respectively.

We expensed $34,000, $39,000, and $35,000 in 2017, 2016, and 2015, respectively, relating to supplies for clinical trials purchased from a company whose former Chief Financial Officer is a member of the Company s Board of Directors and a shareholder of the Company.

We expensed $53,000, $44,000, and $43,000 in 2017, 2016, and 2015, respectively, relating to membership fees to a medical device trade association where our President and CEO is a current member of the Board of Directors.

20. 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, BioFoam, On-X products, JOTEC products, CardioGenesis cardiac laser therapy, PerClot, PhotoFix, HeRO Graft through the second quarter of 2016, and ProCol through the date of the sale of the ProCol product line in the first quarter of 2016. 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):

	2017	2016	2015
Revenues:			
Medical devices	$ 119,631	$ 113,992	$ 83,081
Preservation services	70,071	66,388	62,817
Total revenues	189,702	180,380	145,898
Cost of products and preservation services:			
Medical devices	29,798	28,033	18,663
Preservation services	31,262	33,448	36,516
Total cost of products and preservation services	61,060	61,481	55,179
Gross margin:			
Medical devices	89,833	85,959	64,418
Preservation services	38,809	32,940	26,301
Total gross margin	$ 128,642	$ 118,899	$ 90,719

Net revenues by product for the years ended December 31, 2017, 2016, and 2015 were as follows (in thousands):

	2017	2016	2015
Products:			
BioGlue and BioFoam	$ 65,939	$ 63,461	$ 59,332
On-X	37,041	34,232	--
JOTEC	4,136	--	--
CardioGenesis cardiac laser therapy	6,866	7,864	9,419
PerClot	3,533	4,021	4,083
PhotoFix	2,116	1,871	1,396
HeRO Graft	--	2,325	7,546
ProCol	--	218	1,305
Total products	119,631	113,992	83,081
Preservation services:			
Cardiac tissue	32,510	29,697	28,059
Vascular tissue	37,561	36,691	34,758
Total preservation services	70,071	66,388	62,817
Total revenues	$ 189,702	$ 180,380	$ 145,898

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2017, 2016, and 2015 were as follows (in thousands):

	2017	2016	2015
U.S.	$ 135,102	$ 131,727	$ 114,978
International	54,600	48,653	30,920
Total revenues	$ 189,702	$ 180,380	$ 145,898

At December 31, 2017 and 2016 60% and 99%, respectively, of our long-lived assets were held in the U.S., where the corporate headquarters and a portion of our manufacturing facilities are located. At December 31, 2017 $13.3 million of our long-lived assets were located internationally, of which 99% were located in Hechingen, Germany. At December 31, 2017 and 2016 $188.3 million and $78.3 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:				
2017	$ 45,059	$ 47,818	$ 43,999	$ 52,826 *
2016	43,016 **	47,083 **	45,252 **	45,029 **
2015	33,831	35,526	36,703	39,838
GROSS MARGIN:				
2017	$ 29,512	$ 32,905	$ 29,862	$ 36,363 *
2016	27,621 **	30,301 **	29,782 **	31,195 **
2015	19,667	21,554	22,982	26,516
NET INCOME (LOSS):				
2017	$ 2,223	$ 3,163	$ 1,325	$ (3,007)*
2016	2,541 **	2,347 **	2,993 **	2,897 **
2015	(274)	(502)	2,145	2,636
INCOME (LOSS) PER COMMON SHARE DILUTED:				
2017	$ 0.06	$ 0.09	$ 0.04	$ (0.09)*
2016	0.08 **	0.07 **	0.09 **	0.09 **
2015	(0.01)	(0.02)	0.07	0.09

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

** In January 2016 we completed our acquisition of On-X Life Technologies Holdings, Inc., 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.