CRYOLIFE INC
Form 10-K
February 26, 2019
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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, 2018

OR

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

For the transition period from to

Commission file number 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

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

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

(Address of principal executive offices) (zip code)
Registrant s telephone number, including area code (770) 419-3355

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

Title of each class	**Name of each exchange on which registered**

Common Stock, $.01 par value	New York Stock Exchange

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

None

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

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

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

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

Indicate by check mark 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	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, 2018 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $974,083,772 computed using the closing price of $27.85 per share of Common Stock on June 30, 2018, 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 7, 2019 the number of outstanding shares of Common Stock of the registrant was 37,021,370.

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, 2018.	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 beliefs regarding 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 our expectation, as enrollment was completed in the pivotal clinical trial in January 2019, of Premarket Approval submission to the FDA in early 2020;

Our beliefs and expectations regarding the benefits of our marketing, training, and educational 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 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;

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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 that our relations with our employees are good;

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, and our On-X and JOTEC products, as well as 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 increase 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, and our expectation that this larger sales force will take market share and drive market expansion;

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 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 possibility that 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, and 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 for the next twelve months; 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.

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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); JOTEC endovascular and surgical products; On-X mechanical heart valves 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 and On-X Life Technologies Holdings, Inc. (On-X), an Austin, Texas-based, mechanical heart valve company acquired on January 20, 2016, as well as separate country entities to support direct sales operations in Brazil, Canada, France, Italy, Poland, Spain, Switzerland, and the U.K. Our subsidiary, CryoLife Asia Pacific, Pte. Ltd., (Asia Pacific), provides 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; JOTEC products; On-X 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 19 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 or non-vascular 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 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

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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 discuss each market in which we compete and our products, services, and/or technologies with which we compete in each 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 European Economic Area (EEA) for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). We also distribute BioGlue in Japan where it is approved for adhesion and support of hemostasis for aortotomy closure sites, suture/anastomosis sites (including aortic dissection and anastomosis sites with use of a prosthetic graft), and suture sites on the heart. Additional marketing approvals have been granted for specified

applications in several other countries throughout the world.

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

We distribute BioGlue throughout the U.S. and in approximately 85 other countries. Revenues from BioGlue accounted for 25%, 35%, and 35% of our total revenues in 2018, 2017, and 2016, respectively.

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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 CO2 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

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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 60% fewer 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 in January 2016. We distribute On-X heart valves throughout the U.S. and in approximately 90 other countries. Revenues from On-X products accounted for 17%, 19%, and 19% of total revenues in 2018, 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% re-operation rate, as compared to a 40% 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. (Admedus), 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.

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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. Revenues from cardiac tissue preservation services accounted for 14%, 17%, and 17% of total revenues in 2018, 2017, and 2016, respectively.

PhotoFix

PhotoFix is a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix has FDA 510(k) clearance and is indicated for use in intracardiac repair, great vessel repair, suture line buttressing, pericardial closure, and vascular repair and reconstruction (for example: the carotid, iliac, femoral, and tibial blood vessels and arteriovenous access revisions).

Our PhotoFix product line competes with bioprosthetic and synthetic cardiac patch offerings from several other companies, including Baxter, 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.

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

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.

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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 3% in 2018 and 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 patients, 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 tailor-made 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 DESIGN ENGINEERING

E-xtra DESIGN ENGINEERING is a comprehensive range of stent graft systems for the treatment of aortic vascular diseases that enables surgeons to quickly and efficiently respond to individual patient therapeutic requirements. The E-xtra DESIGN ENGINEERING is tailor-made for individual patients. There are currently only limited off-the-shelf product offerings to treat aneurysms in the thoraco-abdominal aorta due to the many side branches in this anatomy where blood flow to vital organs would be obstructed by unbranched stent grafts. JOTEC has pioneered a service whereby it manufactures a customized thoraco-abdominal stent graft within 3 weeks. E-xtra DESIGN ENGINEERING products are often used in conjunction with E-vita THORACIC 3G as well as the AAA offering, the E-tegra, or in combination with both.

We 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 customized product offerings from Cook Medical and Terumo Corp.

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 5% in 2018 and 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-

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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 3% in 2018 and 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 2% in 2018 and 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 2% in 2018 and 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.

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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 5% in 2018 and 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 15%, 20%, and 20% of our revenues in 2018, 2017, and 2016, respectively.

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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 2% in 2018 and 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 counter pulsation. Currently, the only directly competitive laser technology for the performance of TMR is the CO_2 Heart Laser

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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 accounted for 2%, 4%, and 5% of our total revenues in 2018, 2017, and 2016, 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 in the EEA and other markets. PerClot is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venular, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

PerClot competes with various hemostats including thrombin products from Pfizer, Inc., Baxter, and Ethicon, Inc., and surgical hemostats from Pfizer, Inc., BD, Baxter, Ethicon, Inc., and BioCer Entwicklungs-GmbH. Other competitive products may include argon beam coagulators, which provide an electrical source of hemostasis. A number of companies have surgical hemostat products under development. PerClot competes on the basis of safety, clinical efficacy, absorption rates, and ease of use.

In January 2019 we completed enrolling patients in a clinical trial for the purpose of obtaining FDA Premarket Approval (PMA) to sell PerClot in the U.S., as discussed further in Research and Development and Clinical Research below. We anticipate PMA submission to the FDA in early 2020. We distribute PerClot in approximately 70 countries. Revenues from PerClot accounted for 2% of our total revenues in each of the years 2018, 2017, and 2016.

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 accounted for 1% of our total revenues in 2016. There were no HeRO Graft revenues in 2018 or 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 accounted for less than 1% of our total revenues in 2016. There were no ProCol revenues in 2018 or 2017.

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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 60-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 staff 24 hours per day, 365 days per year, for OTPO support.

We market our products in the EEA, the Middle East, and Africa (EMEA) region through JOTEC, based in Hechingen, Germany, as well as in several other subsidiaries based throughout Europe. We employ approximately 95 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, Asia Pacific, provides sales and marketing support for the Asia Pacific region.

Suppliers, Sources, and Availability of Raw Materials and Tissues

We obtain a number of our raw materials and supplies from a small group of suppliers or a single- or sole-source supplier. Certain raw materials and components used in our products and tissue processing have stringent specifications. Supply interruptions or supplier quality, financial, or operational issues could cause us to have to temporarily reduce, temporarily halt, or permanently halt manufacturing, processing, or distribution activities. Ongoing efforts are in process to find alternative suppliers for single- or sole-source raw materials and supplies. 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.

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

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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 assembling of injection molded parts and machine drilled parts, suturing of stent grafts, processing of Nitinol, and weaving of textiles.

The conventional polyester grafts consist of two main product components: polyester fabric and collagen coating.

The polyester fabric is manufactured by JOTEC 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, BioFoam, and PhotoFix and process human tissues at our headquarters facility. 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 consists of combined manufacturing, warehousing, and office space in Hechingen, Germany and is our EMEA headquarters.

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

In all of our facilities, we are subject to regulatory standards for good manufacturing practices, including current Quality System Regulations, which are the FDA regulatory requirements for medical device manufacturers, and current Good Tissue Practices (cGTPs), which are the FDA regulatory requirements for the processing of human tissue. We also operate according to International Organization for Standardization (ISO) 13485 Quality System Requirements, an internationally recognized voluntary system of quality management for companies that design, develop, manufacture, distribute, and service medical devices. We maintain a Certification of Approval to the ISO 13485. The Medical Device Directive (MDD) is the governing document for the EEA that details requirements for safety and risk. Effective May 26, 2020 the Medical Device Regulation (MDR) will replace MDD and will impose more stringent requirements on manufacturers and European Notified Bodies, who have already begun the transition to these new requirements.

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We work with three Notified Bodies that are officially recognized by the European Union to perform assessments of compliance with ISO 13485 and the MDD. 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, BioFoam, and PhotoFix product line, and Deutscher Kraftfahrzeug-Überwachungs-Verein (DEKRA) acts as our Notified Body for our JOTEC product line. G-Med, LRQA, 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 government regulations.

U.S. Federal Regulation of Medical Devices

The Federal Food, Drug, and Cosmetic Act (FDCA) provides that, unless exempted by regulation, medical devices may not be distributed in the U.S. unless they have been approved or cleared for marketing by the FDA. Medical devices may receive clearance through either a 510(k) process or an approval through an investigational device exemption (IDE) and PMA process.

Under a Section 510(k) process, a medical device manufacturer provides premarket notification that it intends to begin 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

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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.

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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 CE Marks for BioGlue, BioFoam, On-X heart valves, On-X Chord-X sutures, CardioGenesis cardiac laser therapy consoles and handpieces, E-vita OPEN PLUS, E-vita THORACIC 3G, E-tegra, E-liac, and other devices. An application to approve a CE Mark for On-X AAP, which was temporarily suspended, is currently under review by our Notified Body. See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Our revenues for the On-X AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP s CE Mark. Additionally, E-ventus, which we distribute, has a CE Mark.

Backlog

As of December 31, 2018, we did not have a firm backlog of orders related to BioGlue, the JOTEC product line, On-X heart valves, CardioGenesis cardiac laser therapy, PerClot, or PhotoFix. The limited supply of certain types or sizes of preserved tissue can result in a backlog of orders for these tissues. The amount of backlog fluctuates based on the tissues available for shipment and varies based on the surgical needs of specific cases. Our backlog of human tissue consists mostly of pediatric tissues that have limited availability. Our backlog is generally not considered firm and must be confirmed with the customer before shipment.

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

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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 2018, 2017, and 2016 we spent approximately $23.1 million, $19.5 million, and $13.4 million, respectively, on research and development activities on new and existing products. These amounts accounted for approximately 9%, 10%, and 7% of our revenues for each of 2018, 2017, and 2016, 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 and complete the submission for market approval. Enrollment was completed in the third quarter of 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 2019.

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 2019.

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 2019.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate PMA submission to the FDA in early 2020. See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S. either directly or indirectly.

Patents, Licenses, and Other Proprietary Rights

We rely on a combination of patents, trademarks, confidentiality agreements, and security procedures to protect our proprietary products, preservation technology, trade secrets, and know-how. We believe that our patents, trade secrets, trademarks, and technology licensing rights provide us with important competitive advantages. We have also obtained additional rights through license and distribution agreements for additional products and technologies, including PerClot. We own or have licensed rights to 39 U.S. patents and 135 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 32 pending U.S. patent applications and 69 pending foreign applications that relate to our legacy CryoLife products and services, On-X products, and JOTEC products. There can be no assurance that any patent applications pending will ultimately be issued as patents.

The remaining duration of our issued patents ranges from 1 year to 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.

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

See Part I, Item 1A, Risk Factors 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, 2018 we had approximately 1,100 employees. None of our employees are covered by a collective bargaining agreement, and we have never experienced a work stoppage or interruption due to labor disputes. We believe our relations with our employees 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 with applicable laws and regulations the disposal of our waste regarding tissue preservation activities, as well as in our other production activities, the failure by us, or the companies with which we contract, to comply fully with any such regulations could result in an imposition of penalties, fines, or sanctions, which could materially, adversely affect our business.

Risk Factors

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

Available Information

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

We also make available on the Corporate Governance portion of our website: (i) our Code of Conduct; (ii) our Corporate Governance Guidelines; and (iii) the charter of each active committee of our Board of Directors. We also intend to disclose any amendments to our Code of Conduct, or waivers of our Code of Conduct on behalf of our Chief Executive Officer, Chief Financial Officer, or Chief Accounting Officer, on the Corporate Governance portion of

website. All of these corporate governance materials are also available free of charge in print to shareholders who request them in writing to: Jean F. Holloway, General Counsel, Chief Compliance Officer, and Corporate Secretary, 1655 Roberts Blvd NW, Kennesaw, GA 30144.

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

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

The continued growth of the global market for stent grafts used in endovascular and open repair of aortic disease;

Our ability to leverage our global infrastructure, 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 Conformité Européene Mark product certification (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, including any related to intellectual property rights.

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

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

Our current and future levels of indebtedness could:

Limit our ability to borrow money for our working capital, capital expenditures, development projects, strategic initiatives, or other purposes;

Require us to dedicate a substantial portion of our cash flow from operations to the repayment of our indebtedness, thereby reducing funds available to us for other purposes;

Limit our flexibility in planning for, or reacting to, changes in our operations or business;

Make us more vulnerable to downturns in our business, the economy, or the industry in which we operate;

Restrict us from making strategic acquisitions, introducing new technologies, or exploiting business opportunities; and

Expose us to the risk of increased interest rates as most of our borrowings are at a variable rate of interest.

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

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

Incur or guarantee additional debt;

Pay dividends on or make distributions in respect of our share capital, including repurchasing or redeeming capital stock or make other restricted payments, including restricted junior payments;

Enter into agreements that restrict our subsidiaries ability to pay dividends to us, repay debt owed to us or our subsidiaries, or make loans or advances to us or our other subsidiaries;

Comply with certain financial ratios set forth in the agreement;

Enter into any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary;

Create liens on certain assets;

Enter into certain transactions with our affiliates;

Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement;

Amend, supplement, waive, or otherwise modify our organizational documents or the organizational documents of a subsidiary in a manner that would be materially, adverse to the interests of the lenders, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lenders;

Change our, or permit a subsidiary to change its, fiscal year without notice to the administrative agent under the agreement;

Enter into agreements which restrict our ability to incur liens;

Engage in any line of business substantially different from that in which we are currently engaged; and

Make certain investments, including strategic acquisitions or joint ventures.

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

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

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

Will not be required to lend any additional amounts to us;

Could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable; or

Could require us to apply all of our available cash to repay such indebtedness.

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against the collateral granted to them to secure that indebtedness. If the indebtedness under our existing debt agreements were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

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

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

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

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

Tissue preservation services are a significant source of our revenues, accounting for 29%, 37%, and 37% of revenues in the years ended December 31, 2018, 2017, and 2016, 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;

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

Mitigate sufficiently the risk that processed tissue cannot be sterilized and hence carries an inherent risk of infection or disease transmission; there is no assurance that our quality controls will be adequate to mitigate such risk.

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

National Organ Transplant Act, (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; and

U.S. Department of Labor, Occupational Safety and Health Administration, and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment.

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

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

BioGlue® Surgical Adhesive (BioGlue) is a significant source of our revenues, accounting for approximately 25%, 35% and 35% of revenues in the years ended December 31, 2018, 2017, and 2016, 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;

- Some companies have launched competitive products and others may pursue regulatory approval for competitive products in the future. These companies may have greater financial, technical, manufacturing, and marketing resources than we do and may be better established in their markets;

- We may be unable to obtain regulatory approvals to commercialize BioGlue in certain countries other than the U.S. at the same rate as our competitors or at all. We also may not be able to capitalize on new regulatory approvals we obtain for BioGlue in countries other than the U.S., including approvals for new indications;

- BioGlue contains a bovine blood protein. Animal-based products are subject to increased scrutiny from the public and regulators, who may have concerns about the use of animal-based products or concerns about the transmission of disease from animals to humans. These concerns could lead to additional regulations or product bans in certain countries;

- Changes to components in the BioGlue product, including in the delivery system require regulatory approval, which if delayed, could cause prolonged disruptions to our ability to supply BioGlue; and

- Our European Notified Body for BioGlue, Lloyd s Register Quality Assurance Limited (LRQA), is headquartered in the U.K. If the U.K. withdraws from the European Union on March 29, 2019, the effective date of Brexit, without an agreement, and if LRQA is unsuccessful in qualifying a subsidiary in the EEA or if we are unable to timely update our BioGlue labels to reflect this newly qualified subsidiary in the EEA, we may be unable to sell BioGlue in the EEA until the situation is resolved.

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

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

- Our ability to achieve anticipated JOTEC revenue in international markets outside the U.S.;

Our ability to 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 develop innovative and in-demand products in the aortic surgery space; and

Our ability to contend with enhanced regulatory enforcement activities.

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

On-X is a significant source of our revenues, accounting for 17%, 19%, and 19% of revenues in the years ended December 31, 2018, 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 the U.S. and in international markets outside the U.S.;

Our ability to capitalize on the U.S. Food and Drug Administration (FDA) s approved reduced International Normalized Ratio (INR) indication;

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

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Enhanced regulatory enforcement activities or failure to receive renewed certifications that could cause interruption in our ability to sell On-X products in certain markets; and

Our ability to execute and complete the FDA mandated post-approval study to assess the occurrence of adverse events with the On-X Aortic Prosthetic Heart Valve when targeted at an INR level of 1.8 (1.5-2.0 range) during a 5-year follow-up.

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

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

Our products and tissues may be recalled or placed on hold by us, the FDA, or other regulatory bodies;

Our products and tissues allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose, us to product and tissue processing liability claims, and such claims could lead to additional regulatory scrutiny and inspections;

Our manufacturing and tissue processing operations are subject to regulatory scrutiny and inspections, including by the FDA and foreign regulatory agencies, and these agencies could require us to change or modify our manufacturing operations, processes, and procedures or take other adverse action. For example, in January 2013 we received a warning letter from the FDA related to the manufacture of our products and our processing, preservation, and distribution of human tissue, as well as a subsequent 2014 Form 483, after a FDA re-inspection related to the warning letter that included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training. After an FDA re-inspection in the first quarter of 2015, the FDA closed out the warning letter issued in 2013;

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

Local and international regulatory and quality laws and standards are subject to change, which could adversely affect our clearances and approvals to sell our products and distribute tissues; and

Adverse publicity associated with our products or processed tissues or our industry could lead to a decreased use of our products or tissues, additional regulatory scrutiny, and/or product or tissue processing liability lawsuits.

Further, on May 25, 2017, the European Union adopted a new Medical Device Regulation (MDR 2017/745) (MDR), which takes effect on May 26, 2020. Among other changes, MDR places more stringent requirements on manufacturers and European Notified Bodies regarding product classifications, pre- and post-market clinical studies,

and other regulatory requirements for product clearances and approvals. These changes could result in product reclassifications and the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the EEA. In addition, we or our Notified Bodies (or both) might be unable to timely meet the requirements of MDR. If either of the foregoing were to occur, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

At the same time, European Notified Bodies have begun engaging in more rigorous regulatory enforcement activities and may continue to do so. For example, our Notified Body for the On-X product line temporarily suspended the CE Mark for the On-X AAP in the EEA. See the risk factor below entitled Our revenues for the On-X AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP s CE Mark for further discussion. Further, in anticipation of MDR, Notified Bodies have begun establishing deadlines in 2019 after which they will no longer review routine submissions unless they are submitted in accordance with MDR. Our inability to timely adapt to these new requirements of our Notified Bodies could adversely impact our clearances and approvals, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

We own patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that we believe provide us with important competitive advantages. We cannot be certain that our pending patent applications will issue as patents or that no one will challenge the validity or enforceability of any patent that we own or license. Furthermore, competitors may independently develop similar technologies, or duplicate our technologies, or design around the patented aspects of such technologies.

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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 also 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.

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 ascending aortic prosthesis (AAP) in the European Economic Area (EEA), due to an allegedly untimely and allegedly deficient plan by us to address certain technical documentation issues found by G-Med during a review and renewal of the design examination certificate for the On-X AAP. On July 26, 2017, we received a letter from G-Med indicating that it was continuing the suspension of the CE Mark for the AAP product for a period of up to 18 months pending further assessment. We have since withdrawn our application from G-Med for certification of the AAP product and are currently pursuing another pathway to CE Mark for the AAP. Failure to obtain CE Mark for the On-X AAP in the EEA could have a material adverse effect on EEA revenues for the remainder of 2019 and beyond.

Our investment in PerClot is subject to significant risks, including our ability to fully realize our investment by obtaining FDA approval and to successfully commercialize PerClot in the U.S. either directly or indirectly.

In 2010 and 2011, we entered into various agreements with SMI pursuant to which, among other things, we (i) may distribute PerClot in certain international markets and are licensed to manufacture PerClot in the U.S.; (ii) acquired some technology to assist in the production of a potentially key component in PerClot; and (iii) obtained the exclusive right to pursue, obtain, and maintain FDA Pre-Market Approval (PMA) for PerClot. We are currently conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S., and we completed enrollment in 2019. We anticipate submission to the FDA in early 2020. There is no guarantee, however, that we will obtain FDA approval when anticipated or at all. The estimated timing of regulatory approval for PerClot is based on factors beyond our control, including but not limited to, unforeseen scheduling difficulties and unfavorable results at various stages in the PMA application process. We may also decide to delay or terminate our pursuit of U.S. regulatory approval for PerClot at any time due to changing conditions at CryoLife, in the marketplace, or in the economy in general.

Further, even if we receive FDA PMA for PerClot, we may be unsuccessful in selling PerClot in the U.S. By the time we secure approvals, competitors may have substantial market share or significant market protections due to contracts,

among other things. We may also be unsuccessful in selling in countries other than the U.S. due, in part, to a proliferation in other countries of multiple generic competitors, 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 that is owned by a third party and that expired in the second quarter of 2018. If that CE Mark is not timely renewed, we may be unable to purchase additional PerClot to distribute in the EEA and other countries that recognize the CE Mark after our distributors inventories of approved PerClot are depleted, which could materially, adversely affect our future revenues.

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

In October 2014 the FDA convened an advisory committee meeting to consider the FDA s recommendation to re-classify more than minimally manipulated (MMM) allograft heart valves from an unclassified medical device to a Class III medical device. The class of 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 too onerous, leading us to discontinue distribution of these tissues.

Our key growth areas may not generate anticipated benefits.

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

New Products Drive growth through 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 or non-vascular 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 Investigational Device Exemption clinical trial for PerClot, as well as clinical trials in China for BioGlue and in the U.S. for the On-X valve. We also have begun efforts to initiate future U.S. clinical 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, on a timely basis, if ever, or that the new products and services or new indications, will

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adequately meet the requirements of the applicable market or achieve market acceptance. We may encounter delays or rejections during any stage of the regulatory approval process if clinical or other data fails to demonstrate satisfactorily compliance with, or if the service or product fails to meet, the regulatory agency s requirements for safety, efficacy, and quality, or the regulatory agency otherwise has concerns about our quality or regulatory compliance. Regulatory requirements for safety, efficacy, quality, and the conduct of clinical trials 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, Office of Foreign Asset Control administered sanction programs, and the European Union s General Data Protection Regulation;

- Broader exposure to corruption;

- Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement policies and programs;

- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;

- Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;

- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the U.S. Dollar;

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Differing local product preferences and product requirements;

Differing local labor and employment laws, including those related to terminations, unionization, and the formation of works councils or other similar employee organizations;

Adverse economic or political changes or political instability;

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

Potential adverse tax consequences of overlapping tax structures; and

Potential adverse financial consequences resulting from the scheduled exit of the U.K. from the European Union, or Brexit on March 29, 2019, including a potential disruption of sales into the U.K.

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

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

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

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

As an example of these risks, in December 2017 we acquired JOTEC, which we financed by incurring further debt, using cash on hand, and issuing additional equity securities. This acquisition 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 and sole source suppliers and single facilities.

Some of the materials, supplies, and services that are key components of our product manufacturing or our tissue processing, as well as some of our products, are sourced from single- or sole-source suppliers. As a result, our ability to negotiate favorable terms with those suppliers may be limited, and if those suppliers experience operational, financial, quality, or regulatory difficulties, or if those suppliers and/or their facilities refuse to supply us or cease operations

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temporarily or permanently, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. We also conduct nearly all our operations at three facilities: Austin, Texas for our On-X product line, Hechingen, Germany for our JOTEC product line, and Kennesaw, Georgia for all our other products. If one of these facilities ceases operations temporarily or permanently, due to natural disaster or other reason, our business could be substantially disrupted.

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

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

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

A significant percentage of market revenues from these products was generated by Baxter, 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.

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Tax reform could have a material adverse effect on us.

The December 2017 tax reform legislation known as the H.R. 1, 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% from 35% 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. 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.

Changes in tax law implemented by the Tax Act primarily became effective in 2018 and certain changes will become 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 and interest 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.

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;
- Unanticipated costs and expenses;
- Effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- The divestiture or discontinuation of a product line or other revenue generating activity;
- The relocation and integration of manufacturing operations and other strategic restructuring;
- Regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
- Failure of government and private health plans to adequately and timely reimburse the users of our products or changes in reimbursement policies;
- Costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;
- Our ability to collect outstanding accounts receivable in selected countries outside of the U.S.;
- The expiration or utilization of deferred tax assets such as net operating loss carryforwards;
- Market reception of our new or improved product offerings; and
- The loss of any significant customer, especially in regard to any product that has a limited customer base.

We have based our current and future expense levels largely on our investment plans and estimates of future events, although some of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely

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

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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 took effect in May 2018. GDPR includes significant new requirements for companies that receive or process the personal data of residents of the European Union (including company employees), which increase our operating costs and require significant management time and energy. GDPR also includes significant penalties for noncompliance. Any GDPR related government enforcement activities may be costly to comply with, result in negative publicity, and subject us to significant penalties, any of which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

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

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

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

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

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

Our business and future growth depend on the continued use of our products for specific approved uses. Generally, unless the products are approved or cleared by the FDA for the alternative uses, the FDA contends that we may not make claims about the safety or effectiveness of our products, or promote them, for such uses. Such limitations present a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing, and/or support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the Federal Food, Drug, and Cosmetic Act, (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.

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

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

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

Our relationships with physicians, hospitals, and other healthcare providers are subject to scrutiny under various U.S. and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, often referred to collectively as healthcare compliance laws. Healthcare compliance laws are broad, sometimes ambiguous, complex, and subject to changing interpretations. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal penalties, exclusion from government healthcare programs, and forfeiture of amounts collected in violation of such prohibitions. Any government investigation or a finding of a violation of these laws, despite our compliance efforts, could result in a material, adverse effect on our business, financial condition, and profitability.

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

We have also adopted the AdvaMed Code of Conduct and the MedTech Europe Code of Ethical Business Practice into our Code of Business Conduct, which governs our relationships with healthcare professionals, including our payment of travel and lodging expenses, research and educational grant procedures, and sponsorship of third-party conferences. In addition, we conduct training sessions on these principles. There can be no assurance, however, that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws or that one or more of our employees or agents will not disregard the rules we have established. Because our strategy relies on the involvement of healthcare professionals who consult with us on the design of our products, perform clinical research on our behalf, or

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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 government funded healthcare programs, including Medicare and Medicaid, for noncompliance.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the scarcity of applicable precedent and regulations. There can be no assurance that regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material, adverse effect on our business, financial condition, and profitability. Any regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going-forward basis only.

Healthcare policy changes, 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% 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, the excise tax may be reinstated.

Efforts to repeal and replace the ACA altogether 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.

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

The majority of our foreign product revenues are denominated in Euros and, as such, are sensitive to changes in exchange rates. In addition, a portion of our dollar-denominated product sales are made to customers in other countries who must convert local currencies into U.S. Dollars in order to purchase these products. We also have

balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Fluctuations in exchange rates of Euros or other local currencies in relation to the U.S. Dollar could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

Our products and tissues allegedly have caused, and may in the future cause, injury to patients using our products or tissues, and we have been, and may be, exposed to product and tissue processing liability claims. We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. In addition, our product and tissue processing liability insurance policies do not include coverage for any

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punitive damages. Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, it is possible that:

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

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

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

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

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

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

Risks Related to Ownership of our Common Stock

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

In December 2015 our Board of Directors discontinued dividend payments on our common stock for the foreseeable future. If we do not pay cash dividends, our shareholders may receive a return on their investment in our common stock only if the market price of our common stock has increased when they sell shares of our common stock that they own. Future dividends, if any, will be authorized by our Board of Directors and declared by us based upon a variety of factors deemed relevant by our directors, including, among other things, our financial condition, liquidity, earnings projections, and business prospects. In addition, restrictions in our credit facility limit our ability to pay future dividends. We can provide no assurance of our ability to pay cash dividends in the future.

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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, BioFoam, and PhotoFix, and process and preserve tissues from our Preservation Services segment at our headquarters facility. Our corporate headquarters also includes a CardioGenesis cardiac laser therapy maintenance and evaluation laboratory space.

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

Our primary European subsidiary, JOTEC, located in Hechingen, Germany, maintains facilities that consist of approximately 80,000 square feet of leased manufacturing, administrative, laboratory, and warehouse space. A nearby building contains approximately 53,000 square feet of additional empty space that could be leased for future growth.

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

We also lease a facility, which consists of 15,600 square feet of combined manufacturing and office space in Atlanta, Georgia, and a facility, which consists of approximately 25,000 square feet of additional office space in Kennesaw, Georgia, both of which we sublet to a third party. Our Atlanta facility was sublet beginning in 2018.

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

Item 3. Legal Proceedings.

From time to time, we are involved in legal proceedings concerning matters arising in connection with the conduct of our business activities. We regularly evaluate the status of legal proceedings in which we are involved in order to assess whether a loss is probable or there is a reasonable possibility that a loss or additional loss may been incurred, and to determine if

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accruals are appropriate. We further evaluate each legal proceeding to assess whether an estimate of possible loss of range of loss can be made.

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

Item 4. Mine Safety Disclosures.

Not applicable.

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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.

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

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

As of February 7, 2019 we had 232 shareholders of record.

Dividends

No dividends were paid in 2018, 2017, or 2016.

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 11 of the Notes to Consolidated Financial Statements for further discussion of the Credit Agreement.

Issuer Purchases of Equity Securities

The following table provides information about purchases we made during the quarter ended December 31, 2018 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934.

Issuer Purchases of Equity Securities

Common Stock

Period

	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
10/01/18 - 10/31/18	--	--	--	--
11/01/18 - 11/30/18	407	$ 30.79	--	--
12/01/18 - 12/31/18	--	--	--	--
Total	407	30.79	--	--

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The common shares purchased during the quarter ended December 31, 2018 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.

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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,				
	2018	**2017 [1]**	**2016 [2]**	**2015**	**2014**
Operations					
Revenues	$ 262,841	$ 189,702	$ 180,380	$ 145,898	$ 144,641
Operating income	9,312	7,970	21,820	5,354	8,838
Net (loss) income	(2,840)	3,704	10,778	4,005	7,322
Net (loss) income applicable to common shareholders -diluted	(2,813)	3,643	10,576	3,918	7,164
Research and development expense as a percentage of revenues	9%	10%	7%	7%	6%
(Loss) Income Per Common Share					
Basic	$ (0.08)	$ 0.11	$ 0.33	$ 0.14	$ 0.26
Diluted	$ (0.08)	$ 0.11	$ 0.32	$ 0.14	$ 0.25
Dividend Declared Per Common Share	$ --	$ --	$ --	$ 0.120	$ 0.118
Year-End Financial Position					
Total assets	$ 571,091	$ 589,693	$ 316,140	$ 181,179	$ 176,157
Working capital	144,645	136,340	117,131	90,058	85,401
Long-term liabilities	261,501	269,695	77,055	6,323	6,845
Shareholders equity	275,067	277,058	208,983	155,251	148,685
Current ratio[3]	5:1	4:1	5:1	6:1	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 Current assets divided by current liabilities.

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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); JOTEC endovascular and surgical products; On-X mechanical heart valves 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, 2018 we reported record annual revenues of $262.8 million, increasing 39% over the prior year and we generated $9.9 million in cash flows from operations during 2018. Revenues for December 31, 2018 includes a full year of revenues from the December 2017 acquisition of JOTEC GmbH (JOTEC), a Hechingen, Germany-based endovascular and surgical products company. For the year ended December 31, 2018 we reported a net loss of $2.8 million, largely due to an increase in interest expense on net borrowings and business development costs primarily related to integration of JOTEC. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2018 results. See Part I, Item 1, Business, for further discussion of our business and activities during 2018.

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, 2018 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.

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Although we believe that the recorded fair value of our financial instruments is appropriate, these fair values may not be indicative of net realizable value or reflective of future fair values.

Deferred Preservation Costs

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

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations (OTPOs), that 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 $437,000, $922,000, and $897,000 for the years ended December 31, 2018, 2017, and 2016, 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;

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Timing and amounts of anticipated future taxable income;

Timing of the anticipated reversal of book/tax temporary differences;

Evaluation of statutory limits regarding usage of certain tax assets; and

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

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

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

Valuation of Acquired Assets or Businesses

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

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

We typically engage external advisors to assist in determining the fair value of acquired asset groups or business combinations, using valuation methodologies such as: the excess earnings, the discounted cash flow, or the relief from royalty methods. The determination of fair value in accordance with the fair value measurement framework requires

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

New Accounting Pronouncements

See Note 1 of Notes to Summary Consolidated Financial Statements for further discussion of new accounting standards that have been adopted or are being evaluated for future adoption.

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Results of Operations

(In thousands)

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

Revenues

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

	Revenues for the Twelve Months Ended December 31,			Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2018	2017	Percent Change	2018	2017
Products:					
BioGlue and BioFoam	$ 66,660	$ 65,939	1%	25%	35%

JOTEC	63,341	4,136	1431%	24%	2%
On-X	44,832	37,041	21%	17%	19%
CardioGenesis cardiac laser therapy	6,217	6,866	-9%	2%	4%
PerClot	3,767	3,533	7%	2%	2%
PhotoFix	2,577	2,116	22%	1%	1%
Total products	187,394	119,631	57%	71%	63%
Preservation services:					
Cardiac tissue	35,683	32,510	10%	14%	17%
Vascular tissue	39,764	37,561	6%	15%	20%
Total preservation services	75,447	70,071	8%	29%	37%
Total	$ 262,841	$ 189,702	39%	100%	100%

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

Products

Revenues from products increased 40% and 57% for the three and twelve months ended December 31, 2018, respectively, as compared to the three and twelve months ended December 31, 2017, respectively. These increases were primarily due to the acquisition of JOTEC in December 2017 as well as increased revenues from the sale of On-X products. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; JOTEC; On-X; CardioGenesis cardiac laser therapy; PerClot; and PhotoFix is presented below.

Sales of certain products through our direct sales force and distributors across Europe and various other countries are denominated in a variety of currencies, with a concentration denominated in Euros in addition to British Pounds, Polish Zloty, Swiss Francs, Brazilian Real, and Canadian Dollars which are subject to exchange rate fluctuations. For the three months ended December 31, 2018 compared to the three months ended December 31, 2017 the U.S. Dollar strengthened in comparison to these currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into U.S. Dollars. For the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017, the U.S. Dollar weakened in comparison to the major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into U.S. Dollars. The year-over-year average change in these currencies and the net impact on the results of operations from translations to reporting currency was not material in either period. The impact of currency translation adjustments are substantially mitigated by natural hedges which reduce our revenue and expense net exposure by currency. Future changes in these exchange rates could have a material, adverse effect on our revenues denominated in these currencies. Additionally, our sales to many distributors around the world are denominated in U.S. Dollars and, although these sales are not directly impacted by currency exchange rates, we believe that some of our distributors may delay or reduce purchases of products in U.S. Dollars depending on the relative price of these goods in their local currencies.

BioGlue and BioFoam

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

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

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

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

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

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JOTEC

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

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

We believe that the 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 continued 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 use JOTEC products, based on the technologically and clinically advanced benefits of JOTEC products.

On-X

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

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

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

CardioGenesis Cardiac Laser Therapy

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

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

prices for the twelve months ended December 31, 2018, as compared to the twelve months ended December 31, 2017.

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

PerClot

Revenues from the sale of PerClot increased 6% for the three months ended December 31, 2018, as compared to the three months ended December 31, 2017. This increase was primarily due to a 16% increase in the volume of grams sold, which increased revenues by 3%, and an increase in average selling prices, which increased revenues by 3%. The volume

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increase included a larger proportion of products that have lower prices and, therefore, did not have as large of an effect on total PerClot revenues.

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

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

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate Premarket Approval (PMA) submission to the U.S. Food and Drug Administration (FDA) in early 2020.

PhotoFix

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

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

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

Preservation Services

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

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, 2018.

Cardiac Preservation Services

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

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

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

Our cardiac valves are primarily used in cardiac replacement and reconstruction surgeries, including the Ross procedure, for patients with endocarditis or congenital heart defects. Our cardiac tissues are primarily distributed in domestic markets.

Vascular Preservation Services

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

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

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

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

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

Cost of Products and Preservation Services

Cost of Products

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

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

cardiac laser therapy, PerClot, and PhotoFix.

Cost of products for the twelve months ended December 31, 2018 includes $2.8 million in inventory basis step-up expense, primarily related to the JOTEC inventory fair value adjustment recorded in purchase accounting, all included prior to the three months ended December 31, 2018. Cost of products for the three and twelve months ended December 31, 2017 included $584,000 and $2.7 million, respectively, in inventory basis step-up expense related to costs for On-X products repurchased from previous international and domestic distributors in excess of the unit cost to manufacture the inventory, in addition to fair value adjustments recorded in purchase accounting for JOTEC products.

The increase in cost of products for the three and twelve months ended December 31, 2018 was primarily due to having a full year of revenues related to JOTEC, which we acquired in December 2017, partially offset by a decrease in acquisition

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inventory basis step-up expense for the three months ended December 31, 2018, as compared to the prior year period as discussed above.

Cost of Preservation Services

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

Cost of preservation services increased 15% for both three and twelve months ended December 31, 2018, as compared to the three and twelve months ended December 31, 2017. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

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

Gross Margin

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

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

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

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,	Twelve Months Ended December 31,

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

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

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twelve months ended December 31, 2017 included $6.6 million and $10.9 million, respectively, in business development costs primarily related to the acquisition of JOTEC in December 2017, which include, among other costs, expenses related to the termination of international distribution agreements.

Research and Development Expenses

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

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

Interest Expense

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

Earnings

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

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

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

Our income tax rate for the year ended December 31, 2018 was affected by excess tax benefits on stock compensation, the research and development tax credit and non-includable income related to the On-X settlement which increased our

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

On December 22, 2017 the United States enacted tax reform legislation known as the H.R. 1, commonly referred to as the Tax Cuts and Jobs Act (the Tax Act), resulting in significant modifications to existing law. For 2017, we elected to follow the guidance in SEC Staff Accounting Bulletin 118 (SAB 118), which provides additional clarification regarding the application of Accounting Standards Codification Topic 740 in situations where we do not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act for the reporting period in which the Tax Act was enacted. We estimated the accounting for the effects of the Tax Act to be included in our 2017 Consolidated Balance Sheets and Statements of Operations and Comprehensive Income, and, as a result, our financial statements for the year ended December 31, 2017 reflect these effects of the Tax Act as provisional based on a reasonable estimate of the income tax effects and recorded a one-time estimated deemed repatriation transition tax resulting in a nominal tax impact to us, based on the interplay of the transition tax and the foreign tax credit. At December 31, 2018 after further analyses of the Tax Act, notices, and regulations issued and proposed by the U.S. Department of the Treasury and the Internal Revenue Service, we have now completed our accounting for all of the enactment-date income tax effects of the Tax Act. As further discussed below, during 2018, certain immaterial adjustments to the provisional amounts recorded at December 31, 2017 are included as a component of income tax expense.

As of December 31, 2017 we remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future (which was generally from 35% to 21%), which resulted in a nominal provisional amount for 2017. Upon further analysis of certain aspects of the Tax Act and refinement of our calculations during the year ended December 31, 2018, we made immaterial adjustments to our provisional estimate, which are included as a component of income tax expense from continuing operations.

We elected to account for the global intangible low-taxed income (GILTI) tax in the period in which it is incurred, and therefore, have not provided any deferred tax impacts of GILTI in its consolidated financial statements for the years ended December 31, 2018 and 2017. For the year ending December 31, 2018 our GILTI inclusion was nominal.

The Tax Act also created a new provision, foreign derived intangible income (FDII), whereby certain sales made from the U.S. to overseas markets is taxed at a lower U.S. rate. We are favorably impacted by the new FDII provision and as of December 31, 2018 our FDII deduction was $1.1 million.

We are also affected by the new interest deductibility rule under the Tax Act. This rule disallows interest expense to the extent it exceeds 30% of adjusted taxable income. For the year ending December 31, 2018 our interest deduction was limited to $4.9 million. The excess interest not deducted in 2018 of $21.1 million can be carried forward indefinitely for use in future years.

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

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

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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	Percent Change	2017	2016
Products:					
BioGlue and BioFoam	$ 17,845	$ 15,982	12%	34%	36%
On-X	9,993	9,073	10%	19%	20%
JOTEC	4,136	--	100%	8%	--%
CardioGenesis cardiac laser therapy	1,736	2,367	-27%	3%	5%
PerClot	892	1,038	-14%	2%	2%
PhotoFix	510	465	10%	1%	1%
Total products	35,112	28,925	21%	67%	64%
Preservation services:					
Cardiac tissue	8,599	7,442	16%	16%	17%
Vascular tissue	9,115	8,662	5%	17%	19%
Total preservation services	17,714	16,104	10%	33%	36%
Total	$ 52,826	$ 45,029	17%	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	Percent Change	2017	2016
Products:					
BioGlue and BioFoam	$ 65,939	$ 63,461	4%	35%	35%
On-X	37,041	34,232	8%	19%	19%
JOTEC	4,136	--	100%	2%	--%
CardioGenesis cardiac laser therapy	6,866	7,864	-13%	4%	5%
PerClot	3,533	4,021	-12%	2%	2%
PhotoFix	2,116	1,871	13%	1%	1%

HeRO Graft	--	2,325	-100%	--%	1%
ProCol	--	218	-100%	--%	--%
Total products	119,631	113,992	5%	63%	63%
Preservation services:					
Cardiac tissue	32,510	29,697	9%	17%	17%
Vascular tissue	37,561	36,691	2%	20%	20%
Total preservation services	70,071	66,388	6%	37%	37%
Total	$ 189,702	$ 180,380	5%	100%	100%

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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.

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.

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 approved for sale in certain international markets.

On-X

On-X product revenues, excluding OEM, 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, excluding OEM, 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 ascending aortic prosthesis (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 OEM, 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, excluding OEM, 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 OEM and 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.

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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 Germany-based, privately held developer of technologically differentiated endovascular stent grafts, and cardiac and vascular surgical grafts, focused on aortic repair. JOTEC products are distributed in a variety of international markets.

JOTEC 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.

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.

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.

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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.

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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 for 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.

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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
General, administrative, and marketing expenses	$ 30,195	$ 22,246	$ 101,211	$ 91,548
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.

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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 included 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 (loss) 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 an expense of 28% and a benefit of 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 Research and Development Tax Credit, partially offset by nondeductible transaction costs related to the JOTEC acquisition and nondeductible meals and 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 Act, resulting in significant modifications to existing law. We have elected to follow the guidance in SAB 118, which provides additional clarification regarding the application of ASC Topic 740 in situations where we do not have the

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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 available, including information from our acquisition of JOTEC.

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%.

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.

Seasonality

We believe the demand for BioGlue and On-X products is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. We believe that this trend may be due to the summer holiday season in Europe and the U.S. We further 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, although this trend could vary somewhat from year to year. We believe the seasonality for On-X products may be obscured as the On-X products have not fully penetrated many markets.

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

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

We are uncertain whether the demand for 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.

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

Demand for our vascular preservation services is seasonal, with the 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, 2018 net working capital (current assets of $179.2 million less current liabilities of $34.5 million) was $144.7 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $136.4 million and a current ratio of 4 to 1 at December 31, 2017.

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Overall Liquidity and Capital Resources

Our largest cash requirement for the twelve months ended December 31, 2018 was cash used for interest and principal payments on our debt agreement. To a lesser extent, our cash requirements included cash used for business development costs, largely due to the integration of JOTEC, expenditures for clinical trials and other research and development expenditures, and capital expenditures for facilities and equipment. We funded our cash requirements through 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

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. As of December 31, 2018 the balance under the Term Loan Facility was $222.8 million and the balance under the secured revolving credit facility was zero and $30.0 million was available for borrowing.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate PMA submission to the FDA in early 2020. See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S. either directly or indirectly.

We believe the utilization of net operating loss carryforwards from our acquisitions of Hemosphere and Cardiogenesis will reduce required cash payments for federal income taxes by approximately $360,000 for the 2018 tax year. We acquired net operating losses from the acquisition of JOTEC that we believe will reduce foreign income taxes by approximately $650,000 for the 2018 tax year.

As of December 31, 2018 approximately 30% of our cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $9.9 million for the twelve months ended December 31, 2018, as compared to $10.8 million for the twelve months ended December 31, 2017.

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, 2018 these items included $18.1 million in depreciation and amortization expenses and $6.3 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, 2018 these changes included an unfavorable effect of $8.9 million due to timing differences between the recording of accounts payable and other current liabilities and the payment of cash and $1.1 million

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due to the timing difference between recording receivables and the receipt of cash, partially offset by a favorable adjustment of $2.4 million due to increases in inventory balances and deferred preservation costs.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $6.7 million for the twelve months ended December 31, 2018, as compared to $171.0 million for the twelve months ended December 31, 2017. The current year cash used was primarily related to $5.8 million in capital expenditures. The prior year cash used was primarily due to $164.7 million for the acquisition of JOTEC, net of cash acquired.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $2.6 million for the twelve months ended December 31, 2018, as compared to net cash provided of $143.2 million for the twelve months ended December 31, 2017. The current year cash used was primarily due to $2.8 million in principal payments on borrowings and $2.1 million related to the redemption and repurchase of stock to cover tax withholdings, partially offset by $3.9 million in proceeds from the exercise of stock options and issuance of common stock under our employee stock purchase plan. The prior 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, partially offset by $67.2 million in repayment of debt agreement, $10.1 million in payments of debt issuance costs, and $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, 2018 are as follows (in thousands):

	Total	2019	2020	2021	2022	2023	Thereafter
Long-term debt obligations	$ 225,953	$ 2,726	$ 2,791	$ 2,791	$ 2,791	$ 2,791	$ 212,063
Interest payments	77,610	13,477	13,330	13,184	13,037	12,891	11,691
Operating leases	26,741	6,122	5,555	4,758	2,461	1,456	6,389
Capital leases	7,457	857	688	641	586	586	4,099
Purchase commitments	6,097	4,130	1,821	82	64	--	--
Research obligations	3,112	2,456	322	199	135	--	--
Contingent payments	1,000	--	--	1,000	--	--	--
Total contractual obligations	$ 347,970	$ 29,768	$ 24,507	$ 22,655	$ 19,074	$ 17,724	$ 234,242

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

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 2020, based on the assumption that we will not terminate the distribution agreement before our target date for receiving FDA approval for PerClot in 2020. 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.

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

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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 $4.3 million, as no specific assessments have been made by any taxing authorities.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2018 and 2017 were $5.8 million and $6.6 million, respectively. Capital expenditures in the twelve months ended December 31, 2018 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 $41.5 million as of December 31, 2018, 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, 2018, affecting our cash and cash equivalents, restricted securities, $225.0 million secured Term Loan Facility, and Revolving Credit Facility would not have had a material impact on our financial position, profitability, or cash flows.

Foreign Currency Exchange Rate Risk

We have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency denominated balances are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of cash or funds that we will receive in payment for assets or that we would have to pay to settle liabilities. As a result, we could be required to record these changes as gains or losses on foreign currency translation. Realized gains and losses were a loss of $2.6 million, gain of $257,000, and a loss of $170,000 for the years ended December 31, 2018, 2017, and 2016, respectively. Losses incurred during 2018 were primarily related to cross currency intercompany receivables and payables resulting from large inventory transfers during the JOTEC integration phase, impacted by fluctuations in the Brazilian Real and the British Pound relative to other currencies.

We have revenues and expenses that are denominated in foreign currencies. Specifically, a portion of our international BioGlue, On-X, PerClot, and JOTEC revenues are denominated in Euros, British Pounds, Swiss Francs, Polish 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, 2018 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, 2018 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.

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Item 8. Financial Statements and Supplementary Data.

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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.

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, 2018. 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, 2018, 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, 2018.

CryoLife, Inc.

February 26, 2019

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Report of Independent Registered Public Accounting Firm on the Financial Statements

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CryoLife, Inc. and subsidiaries (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive (loss) income, cash flows, and shareholders equity for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 26, 2019 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

February 26, 2019

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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, 2018, 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, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive (loss) income, cash flows, and shareholders equity for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 26, 2019 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

February 26, 2019

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,489	$ 39,977
Restricted securities	747	776
Receivables:		
Trade accounts, net	47,108	47,525
Other	4,324	3,916
Total receivables	**51,432**	**51,441**
Inventories	45,478	46,684
Deferred preservation costs	33,174	35,671
Prepaid expenses and other	6,848	4,731
Total current assets	**179,168**	**179,280**
Property and equipment:		
Equipment and software	48,323	47,899
Furniture and fixtures	5,369	4,916
Leasehold improvements	41,906	40,280
Total property and equipment	95,598	93,095
Less accumulated depreciation and amortization	64,570	59,516
Net property and equipment	**31,028**	**33,579**
Other assets:		
Goodwill	188,781	188,305
Acquired technology, less accumulated amortization of $16,815 in 2018 and $8,685 in 2017	118,184	130,359
Other intangibles, less accumulated amortization of $10,572 in 2018 and $9,459 in 2017	41,897	49,071
Deferred income taxes	4,111	1,610
Other	7,922	7,489

Total assets	**$ 571,091**	**$ 589,693**

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2018	**2017**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accrued expenses	$ 7,193	$ 11,646
Accrued compensation	10,733	10,208
Accounts payable	7,547	9,767
Taxes payable	2,250	4,020
Accrued procurement fees	3,308	3,577
Current portion of capital lease obligation	729	578
Current portion of long-term debt	1,160	718
Other	1,603	2,426
Total current liabilities	**34,523**	**42,940**
Long-term debt	215,721	218,236
Deferred income taxes	27,267	30,431
Capital lease obligation	5,937	6,856
Deferred compensation liability	3,250	3,390
Deferred rent obligations	2,457	2,895
Other	6,869	7,887
Total liabilities	**296,024**	**312,635**
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, 38,463 shares issued in 2018 and 37,618 shares issued in 2017	385	376
Additional paid-in capital	260,361	249,935
Retained earnings	34,984	37,609
Accumulated other comprehensive (loss) income	(6,072)	1,857

Treasury stock at cost, 1,484 shares in 2018 and 1,387 shares in 2017	(14,591)	(12,719)
Total shareholders equity	**275,067**	**277,058**
Total liabilities and shareholders equity	**$ 571,091**	**$ 589,693**

See accompanying Notes to Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

(in thousands, except per share data)

	Year Ended December 31,		
	2018	**2017**	**2016**
Revenues:			
Products	$ 187,394	$ 119,631	$ 113,992
Preservation services	75,447	70,071	66,388
Total revenues	**262,841**	**189,702**	**180,380**
Cost of products and preservation services:			
Products	53,772	29,798	28,033
Preservation services	36,085	31,262	33,448
Total cost of products and preservation services	**89,857**	**61,060**	**61,481**
Gross margin	**172,984**	**128,642**	**118,899**
Operating expenses:			
General, administrative, and marketing	140,574	101,211	91,548
Research and development	23,098	19,461	13,446
Total operating expenses	**163,672**	**120,672**	**104,994**
Gain from sale of business components	--	--	(7,915)