CRYOLIFE INC
Form 10-K
February 18, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

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**
Preferred Share Purchase Rights	**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 x

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 x

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

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

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

As of June 30, 2014 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $224,797,669 computed using the closing price of $8.95 per share of Common Stock on June 30, 2014, 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 13, 2015 the number of outstanding shares of Common Stock of the registrant was 28,206,511.

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, 2014.	Part III

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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 medical device manufacturing and distributio and in the processing and distribution of implantable human tissues for use in cardiac and vascular surgeries. CryoLife s surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot®, an absorbable powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI), and PerClot Topical, which is being marketed in the U.S. primarily for use in ENT applications. CryoLife s CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used for the treatment of coronary artery disease in patients with severe angina. CryoLife markets the Hemodialysis Reliable Outflow Graft (HeRO® Graft) and exclusively distributes ProCol® Vascular Bioprosthesis (ProCol), both of which are solutions for end-stage renal disease (ESRD) in certain hemodialysis patients. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both of which are processed using CryoLife s proprietary SynerGraft® technology.

Corporate Structure

CryoLife s main operating subsidiaries include CryoLife Europa Ltd. (Europa), established in 2000 to provide marketing and distribution support in the European Economic Area (EEA), the Middle East, and Africa (collectively EMEA), and CryoLife Asia Pacific, Pte. Ltd. (CryoLife Asia Pacific), established in Singapore in November 2013 to provide sales and marketing support for the Asia Pacific region. CryoLife acquired Cardiogenesis Corporation and its cardiac laser therapy product line in May 2011 and Hemosphere, Inc. (Hemosphere) and its HeRO Graft product in May 2012. These companies were operated as subsidiaries of CryoLife from their respective acquisition dates until December 31, 2014, when they were merged into the CryoLife, Inc. parent entity.

Segments and Geographic Information

CryoLife has two reportable segments organized according to its products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Graft, and ProCol. The Preservation Services segment includes external 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 the Company s segments and for the Company s geographic information.

Strategy

The Company s strategic plan is focused on four growth vectors which are expected to drive the Company s business expansion in the near term. These growth vectors and their key elements are described below:

New Products Drive growth through the rollout of the Company s new products including ProCol, PerClot, and PhotoFix™

New Indications Broaden the reach of the Company s flagship products, including BioGlue and PerClot, with new and expanded approvals and indications.

Global Expansion Expand the Company s current products and services into new markets, including emerging markets, and accelerate growth by developing new direct sales territories overseas.

Business Development Selectively pursue potential acquisition, licensing, or distribution rights of companies or technologies that complement CryoLife s existing products, services, and infrastructure.

Products, Services, Markets, and Competition

The Company s products and preservation services are used to treat a variety of medical conditions. A discussion of each market in which the Company competes and a detailed description of the Company s products and/or services that compete within each market are discussed below.

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The Company faces competition from several domestic and international medical device, pharmaceutical, and biopharmaceutical companies and from both for profit and non-profit tissue banks. Many of the Company s current and potential competitors have substantially greater financial and personnel resources than the Company. These competitors may also have greater experience in developing products, procuring tissues, conducting clinical trials, and obtaining regulatory approvals and may have large contracts with hospitals under which they can impose purchase requirements that place the Company s products at a disadvantage. Certain of these competitors may obtain patent protection or approval or clearance by the U.S. Food and Drug Administration (FDA) or foreign regulators earlier than the Company. The Company may also compete with companies that have superior manufacturing efficiency, tissue processing capacity, and/or marketing capabilities. Additional competitive products may be under development which could compete with the Company s products or services in the future. There can be no assurance that the Company s 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 the Company or that would render the Company s products or technology obsolete and non-competitive. Any of these competitive disadvantages could materially, adversely affect the Company. Specific competitive products currently on the market are discussed in the sections below. See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Rapid Technological Change Could Cause Our Products And Services To Become Obsolete.

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 effectively seal surgical wounds 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 a higher mortality rate.

Sutures and staples facilitate healing by joining wound edges to allow the body to heal naturally. However, sutures and staples 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 the ability to achieve 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. The Company believes that the use of surgical adhesives and sealants with or without sutures and staples could enhance the efficacy of these procedures through more effective and rapid wound closure. In order to address the inherent limitations of sutures and staples, the Company developed and commercialized its protein hydrogel technology (PHT) platform. The PHT platform is based on a bovine protein that mirrors an array of amino acids that perform complex functions in the human body. Together with a cross-linker, the protein forms a hydrogel, a water-based biomaterial somewhat similar to human tissue. Materials and implantable replacement devices created with PHT may have the potential to provide structure, form, and function similar to certain human tissues. CryoLife developed and currently markets the surgical sealants BioGlue and BioFoam from its PHT platform.

BioGlue

CryoLife s 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, which may be used with or without a multi-use delivery device, and various applicator tips. BioGlue is pre-filled in 2ml, 5ml, and 10ml volumes. Applicator tips are available in standard size, 12mm and 16mm spreader tips, 10cm and 27cm flexible extender tips, and 10cm, 27cm, and 35cm delivery tip extenders.

BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue under Conformité Européene Mark product certification (CE Mark) in the EEA for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). CryoLife also distributes BioGlue in Japan for use in the repair of aortic dissections. Additional marketing approvals have been granted for specified applications in several other countries throughout the world.

CryoLife distributes BioGlue throughout the U.S. and in approximately 75 other countries. Revenues from BioGlue represented 43%, 41%, and 40%, of total Company revenues in each of 2014, 2013, and 2012, respectively.

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The Company s BioGlue products compete primarily with sealants from Baxter International, Inc., Ethicon, Inc. (a Johnson & Johnson Company), Integra LifeSciences Holdings Corporation, C.R. Bard, Inc. (Bard), and The Medicines Company. The Company s BioGlue competes with these products based on its benefits and features, such as strength and ease of use.

BioFoam

CryoLife s proprietary product, BioFoam, is a protein hydrogel biomaterial with an expansion agent, which generates a mixed-cell foam. The foam creates a mechanical barrier to decrease blood flow and develops pores for the blood to enter, leading to cellular aggregation and enhanced hemostasis. BioFoam was developed to rapidly seal organs, such as the liver, and for use in cardiovascular surgeries, and may provide hemostasis in penetrating wounds and trauma. It is easily applied and could potentially be used intra-operatively to control internal organ hemorrhage, limit blood loss, and reduce the need for future re-operations in liver resections.

CryoLife distributes BioFoam in Europe under a CE Mark for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) and as an adjunct to hemostasis in cardiovascular surgery when cessation of bleeding by ligature or other conventional methods is ineffective or impractical.

CryoLife distributes BioFoam in approximately 35 countries, primarily in Europe. Revenues from BioFoam represented less than 1% of total Company revenues in each of 2014, 2013, and 2012.

The Company s BioFoam product competes with sealants from Pfizer, Inc., Baxter International, Inc., Ethicon, Inc., Bard, and Orthovita, Inc. The Company s BioFoam product competes on the basis of its clinical efficacy and ease of use.

Hemostats

Hemostatic agents are frequently utilized as an adjunct to sutures and staples to control inter-operative 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. CryoLife currently markets the 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. The purified plant source material helps to minimize the risks of infection and bleeding-related complications during surgery. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier to further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) at the site of application. This gelled adhesive matrix promotes the normal physiological clotting cascade. PerClot does not require additional operating room preparation or special storage conditions and is easy to apply. PerClot is readily dissolved by saline irrigation and is totally absorbed by the body within several days. PerClot is currently available in 1 gram, 3 gram, and 5 gram configurations with a 100mm or 200mm applicator tip for certain sizes. PerClot Laparoscopic is available in a 3 gram configuration with a 380mm applicator tip. In September 2010 CryoLife entered into a distribution agreement and a license and manufacturing agreement with SMI, which allows CryoLife to distribute PerClot worldwide, except in China, Hong Kong, Macau, Taiwan, North Korea, Iran, and Syria.

PerClot has a CE Mark allowing commercial distribution into the EEA and other markets. PerClot is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venular, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. CryoLife distributes PerClot in Europe and other international countries. CryoLife plans to begin distribution of PerClot in additional international markets as required regulatory approvals are obtained.

In April 2014 the FDA cleared PerClot Topical for distribution in the U.S., and CryoLife began distributing PerClot Topical in the second half of 2014 primarily for ENT applications. PerClot Topical is intended for use as a topical dressing for the temporary treatment of mildly bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological, etc.), cuts, and lacerations and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access, and percutaneous catheter

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access sites. CryoLife has received approval to begin clinical trials for the purpose of obtaining Premarket Approval (PMA) to distribute PerClot in the U.S., as discussed further in Research and Development and Clinical Research below.

CryoLife distributes PerClot Topical in the U.S and PerClot in approximately 50 other countries. Revenues from PerClot represented 3%, 3%, and 2% of total Company revenues in 2014, 2013, and 2012, respectively.

The Company s PerClot product competes with various hemostats including thrombin products from Pfizer, Inc., The Medicines Company, and Ethicon, Inc., and surgical hemostats from Pfizer, Inc., Bard, Baxter International, Inc., 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. The Company s PerClot Topical product competes with many of the same products listed above, but also competes with products from Medtronic, Inc., Polyganics B.V., and Hemostasis, LLC, as well as gauze and chemical cauterization. The Company s PerClot and PerClot Topical products compete on the basis of safety, clinical efficacy, absorption rates, and ease of use.

Angina Treatment

Angina consists of pressure, discomfort, and/or pain in the chest typically due to narrowed or blocked arteries, resulting 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. Published research provides evidence that these channels promote the growth of new blood vessels or angiogenesis over time. That, in turn, provides the damaged heart tissue a better supply of blood and oxygen. Angina usually subsides with improved oxygen supply to the targeted areas of the damaged heart muscle. CryoLife currently markets the CardioGenesis cardiac laser therapy product line to perform TMR.

CardioGenesis Cardiac Laser Therapy

CryoLife s 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. CryoLife s 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. The Company also provides service plan options to ensure that the Console is operating within the critical factory specifications. CryoLife distributes the SoloGrip® III, and the Port Enabled Angina Relief with Laser (PEARL) 5.0 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 PEARL 5.0 handpiece is compatible for use with Intuitive Surgical s da Vinci Surgical System for use in minimally invasive surgeries. The Company was previously conducting an FDA required post-approval study for the PEARL 8.0 handpiece. The Company ceased distributing the PEARL 8.0 in August 2014 for business reasons, and the PEARL 8.0 post-approval study was terminated at that time.

The CardioGenesis cardiac laser therapy product line is FDA approved for treating patients with severe angina that is not responsive to conventional therapy. CryoLife began distributing the CardioGenesis cardiac laser therapy product line, primarily in the U.S., in May 2011 when it completed the acquisition of Cardiogenesis Corporation. Although the CardioGenesis cardiac laser therapy product line has a CE Mark allowing commercial distribution into the EEA, CryoLife does not actively market the product line internationally.

CryoLife distributes handpieces and laser consoles primarily in the U.S. Revenues from CardioGenesis cardiac laser therapy represented 6% of total Company revenues in each of 2014, 2013, and 2012.

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The Company s CardioGenesis cardiac laser therapy competes with other methods for the treatment of coronary artery disease, including drug therapy, percutaneous coronary intervention, coronary artery bypass surgery, and enhanced external counterpulsation. Currently, the only directly competitive laser technology for the performance of TMR is the CO_2 Heart Laser System manufactured by Novadaq Technologies, Inc. The Company s 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.

Vascular Access

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. This can result in severe electrolyte disturbance and toxic levels of waste products in the blood which are normally filtered and eliminated by the kidneys. Patients with ESRD often undergo hemodialysis to remove waste products and fluid from the blood, which can take several hours per treatment and often must be performed multiple times each week. Individuals may seek a kidney transplant for a more permanent solution to ESRD, but may wait for months or years before a donor organ is available. In order to perform hemodialysis, blood must be taken from the body, cleaned, and returned to the body through an access site. Typical access sites used to perform hemodialysis include arteriovenous (AV) fistulas, synthetic or biologic vascular access grafts, or catheters. AV fistulas and vascular access grafts may take weeks or months to mature before they can be used as an access site. Catheters are often the last option for vascular access as they tend to have a higher risk of becoming occluded or infected. CryoLife currently markets the HeRO Graft and ProCol for vascular access.

HeRO Graft

CryoLife s HeRO Graft is a proprietary graft-based solution for ESRD hemodialysis patients with limited access options and central venous stenosis (narrowing of the venous system). The HeRO Graft is the only fully subcutaneous AV access solution clinically proven to maintain long-term access for hemodialysis patients with central venous stenosis. Prior to the introduction of the HeRO Graft, the only option for these patients was access through percutaneous tunneled dialysis catheters, which cost more and have higher infection rates than the HeRO Graft, limit a patient s lifestyle, and foster central venous stenosis. The HeRO Graft overcomes the limitations of catheters by providing a completely subcutaneous graft that functions like a regular access graft during dialysis, providing superior blood flow, and achieving a 69% reduction in bacteremia (bacteria in the blood) compared with catheters.

The HeRO Graft has a 510(k) clearance from the FDA for ESRD patients who are either catheter dependent or approaching catheter dependency, on long-term hemodialysis, and have exhausted all other access options, as well as for patients with failing fistulas and grafts due to central venous stenosis. CryoLife began distributing the HeRO Graft in the U.S. in May 2012 when it acquired Hemosphere. The HeRO Graft received a CE Mark in 2013. The Company completed a controlled European market introduction of the product during the second half of 2013 and a broader European launch in 2014. In March 2013 the Company received a 510(k) clearance for the HeRO Graft Adapter, which the Company plans to launch in 2015 following scale up and validation of the manufacturing process. The Adapter allows the HeRO Graft to be used with specific alternative synthetic vascular grafts, based on the needs of the patient and the implanting physician.

CryoLife distributes the HeRO Graft in the U.S. and approximately 35 other countries. Revenues from the HeRO Graft represented 5%, 4%, and 2% of total Company revenues in 2014, 2013, and 2012, respectively.

The Company s HeRO Graft competes with products including balloon angioplasty products from Bard and Boston Scientific Corp., bare metal stents from Boston Scientific Corp., and covered stents from W.L. Gore & Associates (Gore). These products treat central venous stenosis and may preclude the future use of the HeRO Graft due to total occlusion of the central venous system. No product currently on the market serves as a fully subcutaneous AV access graft for patients while treating central venous stenosis. Other companies either have a fully subcutaneous graft for maintaining AV access, or they have a chronic dialysis catheter for maintaining access in patients with central venous stenosis. Vascular graft products from Artegraft, Inc. and Maquet, Inc. and synthetic ePTFE grafts from Bard, and Gore compete with the HeRO Graft. The Company s HeRO Graft competes on the basis of reducing catheter dependency in ESRD patients with central venous stenosis and benefiting patients through fewer infections, superior dialysis adequacy, higher patency rates, and reduced costs as compared to catheters.

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ProCol

ProCol is a biological graft derived from a bovine mesenteric vein that provides vascular access for ESRD hemodialysis patients. ProCol provides vascular access for ESRD patients in an earlier stage of the treatment protocol than the HeRO Graft. In March 2014 CryoLife entered into a distribution agreement with Hancock Jaffe Laboratories, Inc. (Hancock Jaffe), which grants CryoLife the exclusive right to distribute ProCol worldwide. Clinical data shows that ProCol provides excellent patency for patients who have had repeated failures of other grafts. ProCol is FDA approved for sale in the U.S. as a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft.

CryoLife distributes ProCol in the U.S. Revenues from ProCol represented less than 1% of total Company revenues in 2014.

ProCol competes with the same vascular graft products discussed under HeRO Graft above. ProCol competes on the basis of its superior handling characteristics, long-term patency, and lower rates of infection, thrombosis, and interventions compared to synthetic grafts.

Cardiac and Vascular Repair and Reconstruction

Patients with congenital cardiac defects such as Tetralogy of Fallot, Truncus Arteriosis, and Pulmonary Atresia can require complex cardiac reconstructive surgery to repair the defect. Patients with heart disease can experience valve insufficiency, regurgitation, or stenosis that may require heart valve repair or replacement surgery. Cardiac surgery can include the implantation of biological tissues, such as donated human tissues or animal-derived (xenograft) tissues, synthetic tissues, or mechanical valves. Human heart valves allow for more normal blood flow and provide higher cardiac output than animal-derived and mechanical heart valves. Human heart valves are not as susceptible to progressive calcification, or hardening, as are traditional glutaraldehyde-fixed, animal-derived heart valves, and do not require anti-coagulation drug therapy, as do mechanical valves. The synthetic sewing rings contained in many animal based or mechanical valves may harbor bacteria and lead to endocarditis, which can be difficult to treat with antibiotics, and this usually necessitates the surgical removal of these valves at considerable cost, morbidity, and risk of mortality. 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.

The 2013 Society of Thoracic Surgeons Guidelines, as published in the Annals of Thoracic Surgery, have increased the indication (from Class II to Class I) and broadened the scope for using an aortic homograft during aortic valve replacement surgery due to endocarditis. This means that when endocarditis has functionally destroyed the aortic valve annulus, an aortic homograft is the recommended course of treatment. Previously, the Guidelines indication for aortic homograft use was Class II, which meant only that it was an acceptable course of treatment.

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 the patient s own tissue (autograft). However, in cases of advanced vascular disease, patients may not have suitable vascular tissue for transplantation, and the surgeon must consider using synthetic grafts or donated human vascular tissue. Synthetic vascular grafts are generally not optimal for below-the-knee surgeries because they have a tendency to obstruct over time. Human vascular tissues tend to remain open longer and, as such, are used in indications where synthetic grafts typically fail. In addition, synthetic grafts are not suitable for use in infected areas since they may harbor bacteria and are difficult to treat with antibiotics. Therefore, human vascular tissues have advantages for patients with previously infected graft sites. Human vascular and arterial tissues are used in a variety of other reconstruction procedures such as cardiac bypass surgery and as vascular access grafts for hemodialysis. However, for each procedure that may utilize vascular human tissue, there are alternative treatments including the repair, partial removal, or complete removal of the damaged tissue.

Tissue procured from deceased human donors can be used in a variety of medical procedures to treat both congenital and acquired conditions as discussed above. The transplant of human tissue that has not been preserved 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.

CryoLife currently markets its cardiac preservation services, including its CryoValve and CryoValve SG tissues for heart valve replacement surgeries and its CryoPatch and CryoPatch SG tissues for cardiac repair procedures. CryoLife currently

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markets its vascular preservation services, including its CryoVein® and CryoArtery® tissues for vascular reconstruction surgeries. CryoLife began distribution of PhotoFix in 2015 for cardiac and vascular repair.

PhotoFix

In 2014 CryoLife entered into an exclusive supply and distribution agreement with Genesee Biomedical, Inc. to acquire the distribution rights to PhotoFix, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix, which was last commercially available in 2010, has received FDA 510(k) clearance and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure. In January 2015 the Company received its initial shipments and launched its distribution of PhotoFix.

Cardiac and Vascular Preservation Services

The Company s proprietary preservation process involves dissection, processing, preservation, and storage of tissues by the Company, until they are shipped to an implanting physician. The tissues currently preserved by the Company include aortic and pulmonary heart valves; cardiac patches in three primary anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch; and vascular tissues including, 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. The Company s cardiac tissues have been used in a variety of valve replacement and cardiac reconstruction surgeries. The Company s vascular tissues have been 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. Management believes the human tissues it distributes offer specific advantages over mechanical, synthetic, and animal-derived alternatives. Depending on the alternative, the advantages of the Company s 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.

The Company s cardiac tissues include the CryoValve SGPV and the CryoPatch SG, both processed with the Company s proprietary SynerGraft decellularization technology. CryoLife uses the SynerGraft technology for a significant portion of its pulmonary valve and pulmonary cardiac patch tissue processing.

CryoLife distributes human cardiac and vascular tissues to implanting institutions throughout the U.S. CryoLife also distributes tissues in Canada and has limited distribution through a special access program in Germany. The Company s CryoValve SGPV and CryoPatch SG are distributed under 510(k) clearance from the FDA.

Revenues from cardiac tissue preservation services accounted for 20%, 21%, and 23% of total Company revenues in 2014, 2013, and 2012, respectively. Revenues from vascular preservation services accounted for 23%, 25%, and 26% of total Company revenues in 2014, 2013, and 2012, respectively.

Management believes that at least one domestic tissue bank, LifeNet Health, Inc. (LifeNet), offers preserved human heart valves and patches in competition with the Company. Alternatives to human heart valves processed by the Company include valve repair and valve replacement with xenograft valves or mechanical valves. The Company competes with xenograft or mechanical valves from companies including Medtronic, Inc., Edwards Life Sciences, Inc., and St. Jude Medical, Inc. Alternatives to the Company s human cardiac patches include xenograft small intestine submucosa (SIS) and xenograft patches. The Company competes with xenograft and SIS products from companies including CorMatrix Cardiovascular, Inc., Edwards Life Sciences, Inc., Admedus, Inc., St. Jude Medical, Inc., and Synovis Surgical Innovations.

Management believes that the human heart valves preserved by the Company compare favorably with xenograft and mechanical valves and that the human cardiac patches preserved by the Company compare favorably with xenograft SIS and xenograft patches, due to the benefits of human tissue discussed above. In addition, 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 the 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. The Company believes that this may provide a competitive advantage for CryoValve SGPV and CryoPatch SG for potential whole organ transplant recipients, as 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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Management believes that at least one domestic tissue bank, LifeNet, offers vascular tissue in competition with the Company. There are also a number of providers of synthetic alternatives to veins preserved by the Company and those alternatives are available primarily in medium and large diameters. The Company s vascular tissues compete with products from Gore, Bard, Artegraft, Inc., and Maquet, Inc.

Management believes that it competes with other entities that preserve human tissue on the basis of the preference of surgeons and based on CryoLife s documented clinical data, technology, customer service, and quality assurance. Management believes the Company offers advantages in the areas of clinical data and field representatives as compared to other human tissue processors.

Marketing and Distribution

In the U.S. the Company markets its products and preservation services primarily to physicians, and distributes its products through its direct sales team to hospitals or other healthcare facilities. In the U.S., the Company s cardiac specialists focus primarily on marketing the Company s products and services to cardiac surgeons, and cardiovascular field service representatives focus primarily on vascular surgeons. The Company also has a team of region managers, national accounts managers, and sales and marketing management. Through its field representatives, the Company conducts field training for implanting surgeons regarding the application of its products and tissues.

CryoLife s physician relations and education staff, clinical research staff, and field representatives assist physicians by providing educational materials, seminars, and clinics on methods for using Company products and implanting tissue preserved by the Company. The Company sponsors programs where surgeons train other surgeons in best-demonstrated techniques. In addition, the Company hosts several workshops throughout the year including the Central Venous Pathology Summit, Aortic Root Bootcamp, Aortic Allograft Workshops, and TMR Workshops. These workshops aim to provide didactic and hands-on training to surgeons. The Company also produces educational videos for physicians and coordinates peer-to-peer training at various medical institutions. Management believes that these activities enhance the medical community s acceptance of the products and tissues offered by the Company and help to differentiate the Company from other medical device companies and tissue processors. To assist organ and tissue procurement organizations (OTPOs), the Company provides educational materials and training on procurement, dissection, packaging, and shipping techniques. The Company produces educational videos and coordinates laboratory sessions for OTPO personnel to improve their recovery techniques and increase the yield of usable tissue. The Company also maintains a staff 24 hours per day, 365 days per year for OTPO support.

The Company markets its products in the EMEA region through its European subsidiary, Europa, based in Guildford, England. Europa employs direct field service representatives in the U.K., Germany, Austria, Switzerland, and Ireland and manages relationships with other independent distributors in the EMEA region. Europa provides customer service, logistics, marketing, and clinical support to cardiac, vascular, thoracic, and general surgeons throughout the EMEA region.

The Company markets and distributes its products in other international markets through independent distributors in Canada, Asia Pacific, and the Americas. The Company s Singapore subsidiary, CryoLife Asia Pacific, provides sales and marketing support for the Asia Pacific region beginning in 2014.

Suppliers, Sources, and Availability of Raw Materials and Tissues

The Company obtains many of its raw materials and supplies from a small group of suppliers or a single-source supplier. CryoLife also distributes various products through distribution agreements with the manufacturers. Certain raw materials and components used in the Company s products and tissue processing have stringent specifications. Supply interruptions or supplier quality, financial, or operational issues could cause the Company to have to temporarily reduce, temporarily halt, or permanently halt manufacturing, processing, or distribution activities. 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 the Company s revenues or profitability. Supplies of materials are discussed for each of the Company s main products and services below. See also Part I, Item 1A, Risk Factors.

The Company s BioGlue and BioFoam products have 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 resin supplier. The Company maintains a significant inventory of finished delivery devices to help mitigate the effects of a potential supply interruption.

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The Company purchases PerClot from SMI pursuant to a distribution agreement, and the Company manufactures PerClot Topical exclusively for domestic distribution. The Company maintains an inventory of PerClot purchased from SMI to satisfy its distribution needs and places regular orders for additional product. CryoLife s business is subject to interruption if SMI were unable or became unwilling to supply PerClot to CryoLife.

The Company purchases laser consoles and handpieces for its 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 certain of this manufacturer s patent rights. In addition, these manufacturers obtain certain laser and fiber-optic components and subassemblies from single sources. CryoLife s business is subject to interruption if either of these contract manufacturers or their suppliers became unable or unwilling to do business with CryoLife.

Several HeRO Graft components are purchased from single sources, including key components such as the ePTFE arterial graft and nitinol braid. Some of these components are stock items, while others are custom manufactured to CryoLife s specifications. Using a secondary supplier for ePTFE arterial grafts may be difficult because of certain of the manufacturer s patent rights. CryoLife maintains an inventory of ePTFE arterial grafts to help mitigate the effect of a potential supply interruption; however, CryoLife s business is subject to interruption if any of these sole source suppliers became unable or unwilling to do business with CryoLife.

The Company s preservation services business and its 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. The Company must rely on the OTPOs that it works with to educate the public on the need for donation, to foster a willingness to donate tissue, to follow CryoLife s donor screening and procurement procedures, and to send donated tissue to CryoLife. Since 1984 the Company has received tissue from over 132,000 donors. The Company has active relationships with approximately 35 OTPOs throughout the U.S. Management believes these relationships are critical in the preservation services industry and that the breadth of these existing relationships provides the Company with a significant advantage over potential new entrants to this market. The Company also uses various raw materials, including medicines and solutions in its processing. Some of these raw materials are manufactured by single suppliers or by a small group of suppliers. All of these factors subject CryoLife to risk of supply interruption.

Operations, Manufacturing, and Tissue Preservation

The Company maintains a corporate headquarters and laboratory and an additional off-site warehouse both located in Kennesaw, Georgia. The Company manufactures BioGlue, BioFoam, and PerClot, and processes tissues at the Company s headquarters facility. The Company s corporate headquarters also includes a CardioGenesis cardiac laser therapy maintenance and evaluation laboratory space. The Company maintains a secondary facility consisting of manufacturing and office space in Atlanta, Georgia. The Company currently manufactures HeRO Grafts and is planning to expand PerClot manufacturing at the Atlanta, Georgia facility. The Company s European subsidiary, Europa, leases office space in Guildford, England, and shared warehousing space through its third-party shipper. See also Part I, Item 2, Properties.

In all of the Company s facilities, the Company is 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. The Company also operates 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. The Company maintains a Certification of Approval to the ISO 13485. Lloyd s Register Quality Assurance Limited (LRQA) issues this approval. LRQA is a Notified Body officially recognized by the EU to perform assessments of compliance with ISO 13485 and the Medical Device Directive. The Medical Device Directive is the governing document for the EEA that details requirements for safety and risk.

The Company employs a comprehensive quality assurance program in all of its product manufacturing and tissue preservation activities. All materials, solutions, and components utilized in the Company s manufacturing and tissue processing are received and inspected by trained quality control personnel according to written specifications and standard operating procedures, and only items found to comply with Company standards are utilized in the Company s operations. Materials, components, sub-assemblies, and tissues are documented throughout manufacturing or processing to assure traceability.

The Company evaluates and inspects both its manufactured and distributed products to ensure conformity to product specifications. Processes are validated to produce products meeting the Company s specifications. Each process is documented along with all inspection results, including final finished product inspection and acceptance. Records are

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maintained as to the consignees of products to track product performance and to facilitate product removals or corrections, if necessary.

The Company maintains controls over its tissue processing to ensure conformity with Company procedures. OTPOs must follow the Company s 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 which 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 the Company 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 regulatory bodies internationally. 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 the Company. See also Part I, Item 1A, Risk Factors.

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 such approval or clearance through either a 510(k) process or an investigational device exemption (IDE) and PMA process.

Under a Section 510(k) process, a medical device manufacturer provides a 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. Devices subject to an IDE are subject to various restrictions imposed by the FDA, including restrictions on the number of patients to be treated and the number of institutions at which the device may be used. Patients must give informed consent to be treated with an investigational device and review by an Institutional Review Board is needed. The device must be labeled that it is for investigational use and may not be advertised or promoted. The price charged for the device may be limited. Unexpected adverse events for devices sold under an IDE must be reported to the FDA. After a product is subjected to clinical testing under an IDE, the Company may file a PMA application. PMA applications must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device for its intended use. A PMA application is typically a complex submission, usually including the results of human clinical studies, and preparing an application is a detailed and time-consuming process. Once a PMA application has been submitted, the FDA s review may be lengthy and may include requests for additional data, which may require the Company to undertake additional human clinical studies. Marketing of the device may begin when the FDA has approved the PMA.

FDCA requires all medical device manufacturers and distributors to register with the FDA annually and to provide the FDA with a list of those medical devices they distribute commercially. FDCA also requires manufacturers of medical devices to comply with labeling requirements and to manufacture devices in accordance with Quality System Regulations, which require that companies manufacture their products and maintain their documents in a prescribed manner with respect to good manufacturing practices, including: design, document production, process, labeling and packaging controls, process validation, and other 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 Company facilities to review Company compliance with

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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 Company products are, or would, upon approval, be classified as Class III medical devices: BioGlue, BioFoam, PerClot, ProCol, and CardioGenesis cardiac laser therapy. CryoPatch SG and HeRO Graft are classified as Class II medical devices. CryoLife obtained 510(k) clearance from the FDA to market the CryoValve SGPV and PerClot Topical; however, they are not officially classified as Class II or III medical devices. See also Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations Regulatory Status of 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 the Company s 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

The Company s 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. The Company believes that to the extent its activities are subject to NOTA, it meets this statutory provision relating to the reasonableness of its charges. There can be no assurance, however, that restrictive interpretations of NOTA will not be adopted in the future that would call into question one or more aspects of the Company s methods of charging for its preservation services.

State Licensing Requirements

Some states have enacted statutes and regulations governing the preservation, transportation, and storage of human organs and tissues. The activities the Company engages in require it to be either licensed or registered as a clinical laboratory or tissue bank under California, Delaware, Florida, Georgia, Illinois, Maryland, New York, Oregon, and Pennsylvania law. The Company has such licenses or registrations, and the Company believes it is 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. There can be no assurance, however, that more restrictive state laws or regulations will not be adopted in the future that could materially, adversely affect the Company s operations. Certain employees of the Company have obtained other required state licenses. The regulatory bodies of the above states may perform inspections of the Company s 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 CryoLife distributes products and tissue may perform inspections of the Company facilities to ensure compliance with local country regulations.

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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. However, individual EEA members 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. The Company s Notified Body, LRQA, performs periodic on-site inspections, generally at least annually, to independently review the Company s compliance with its 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. The Company has been issued CE Marks for BioGlue, BioFoam, CardioGenesis cardiac laser therapy consoles and handpieces, and the HeRO Graft. Additionally, PerClot, which the Company distributes, has a CE Mark.

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

CryoLife currently distributes tissues through a special access program in Germany. Germany s regulatory authorities and Europa have been in discussions regarding requirements to allow Europa to market tissue in Germany. If Europa is able to reach a satisfactory agreement with the German authorities regarding those requirements, Europa could begin to ship tissues into Germany under that authorization in the second half of 2015. Although these discussions are ongoing, Europa may choose to end these discussions at any time, which would likely result in the cessation of all tissue shipments into Germany.

Recent Regulatory Approvals

March 2014 IDE approval was received for the PerClot Polysaccharide Hemostatic System.

April 2014 510(k) clearance was received for PerClot Topical.

April 2014 Health Canada License Approval was received for HeRO Graft.

May 2014 PMA supplement approval was received for labeling changes to fiberoptic handpieces.

Certifications, Accreditations, and Inspections

February 2014 The FDA conducted an inspection of Hemosphere. A Form 483, Notice of Inspectional Observations, was issued. A response was submitted to the FDA on March 14, 2014. To date, no follow-up regulatory communications from the FDA have been received.

February 2014 LRQA conducted a one-day follow-up assessment of the four minor nonconformances noted during their fall 2013 assessment. No additional findings were noted.

February - March 2014 The FDA conducted an inspection of CryoLife, Inc. A Form 483, Notice of Inspectional Observations, was issued. A response was submitted to the FDA on April 10, 2014. There has been on-going communication with the FDA regarding the progress of corrective actions and commitments.

September - October 2014 LRQA conducted a routine surveillance assessment to ISO 13485 and Canadian CMDCAS requirements. The corrective actions for the four nonconformances from the previous assessment were verified and closed. Four minor observations were noted.

December 2014 State of Georgia Clinical License and CLIA Certification assessment was conducted. No observations were noted and continued certification was granted.

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All registrations, licensures, certifications, and accreditations were renewed or continued and no regulatory actions are pending from state inspections.

Regulatory Activity

See discussion of current regulatory activity in Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations Regulatory Activity and Regulatory Status of the CryoValve SGPV.

Backlog

The Company currently does not have a backlog of orders related to BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Grafts, or ProCol. 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. The Company s backlog is generally not considered firm and must be confirmed with the customer before shipment.

Research and Development and Clinical Research

The Company uses its technical and scientific expertise to identify market opportunities for new products or services or to expand the use of its current products and services, through expanded indications or product or tissue enhancements. The Company s research and development strategy is to allocate available resources among the Company s 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 the Company identifies additional applications for its products, the Company may attempt to license these products to corporate partners for further development or seek funding from outside sources to continue commercial development. The Company may also attempt to acquire or license additional technologies from third-parties to supplement its product lines.

Research on these and other projects is conducted in the Company s research and development laboratory or at universities or clinics where the Company sponsors research projects, under the supervision of the Company s medical and scientific advisory board. The Company also conducts preclinical and clinical studies at universities and other third-party locations under contract with the Company. Research is inherently risky, and any potential products or tissues under development may not ultimately be deemed safe and effective and, therefore, may not generate any revenues for the Company. The Company s clinical research department also collects and maintains clinical data on the use and effectiveness of its products and services. The Company uses this data to provide feedback to physicians on the benefits of the Company s products and services and to help direct its continuing improvement efforts.

The Company s research and development and clinical research staff includes individuals with advanced degrees, including Ph.Ds., with specialties in the fields of chemistry (protein, material, organic, and bio); biomaterials; molecular biology; and engineering. In 2014, 2013, and 2012 the Company spent approximately $8.7 million, $8.5 million, and $7.3 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 6% of the Company s revenues for each of 2014, 2013, and 2012.

CryoLife is in the process of developing or investigating several new products and technologies, as well as changes and enhancements to its existing products and services. The Company s major ongoing research and development or clinical research projects are discussed below.

In March 2014 CryoLife received approval of its IDE for PerClot from the FDA. IDE approval allows the Company to begin clinical trials for the purpose of obtaining a PMA to distribute PerClot in the U.S. As part of the approval for the PerClot IDE, the FDA recommended several study design considerations. The Company made revisions to the investigational study protocol and most recently refiled the IDE submission on December 2, 2014. In December 2014 CryoLife received approval of the supplement to its IDE for PerClot from the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company is now actively initiating the clinical trial and plans to begin enrollment in the first half of 2015. CryoLife currently expects to receive PMA from the FDA during 2017.

In November 2012 CryoLife received an additional indication in Europe to market its BioFoam as an adjunct to hemostasis in cardiovascular surgery when cessation of bleeding by ligature or other conventional methods is ineffective or impractical. The Company is conducting a 100 patient post-market study at two centers in Europe on BioFoam used in cardiovascular applications. This study is expected to be completed in 2015.

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At the FDA s request, the Company has been conducting a post-clearance study to collect long-term clinical data for the CryoValve SGPV. Data collected in this study will be compared to data from a defined control group implanted with a standard processed human pulmonary heart valve. The Company believes the information obtained from this study may help ascertain whether the SynerGraft process extends the long-term durability of pulmonary valves. Additionally, explant analyses may help determine if the heart valve s collagen matrix recellularizes with the recipient s own cells. The study was completed in December 2014, and the results were submitted to the FDA.

The Company s strategies for driving growth include new product indications and global expansion. These activities will likely require additional research, new clinical studies, and/or compilation of clinical data. The Company is currently seeking expanded indications for BioGlue in Japan and seeking regulatory approval for BioGlue in China. In addition, the Company may decide to pursue expanded U.S. indications for BioGlue and approvals for the Company s products in new international markets.

Patents, Licenses, and Other Proprietary Rights

The Company relies on a combination of patents, trademarks, confidentiality agreements, and security procedures to protect its proprietary products, preservation technology, trade secrets, and know-how. The Company believes that its patents, trade secrets, trademarks, and technology licensing rights provide it with important competitive advantages. The Company has also obtained additional rights through license and distribution agreements for additional products and technologies, including PerClot, ProCol, and PhotoFix. The Company owns or has licensed rights to 59 U.S. patents and 20 foreign patents, including patents that relate to its technology for BioGlue and BioFoam, PHT, PerClot, CardioGenesis cardiac laser therapy, HeRO Graft, cardiac and vascular tissue preservation, and decellularization of tissue. The Company has 14 pending U.S. patent applications and 28 pending foreign applications that relate to the Company s products and services. There can be no assurance that any patents pending will ultimately be issued.

The remaining duration of the Company s issued patents range from 2 months to 16 years. The main patent for BioGlue expired in mid-2012 in the U.S. and expired in mid-2013 in the majority of the rest of the world. Although the patent for BioGlue has expired, this technology is still protected by trade secrets and manufacturing know-how, as well as the time and expense to obtain regulatory approvals. See also Part II, Item 8, Note 4 and Note 13 of the Notes to Consolidated Financial Statements for additional discussion of the Company s contractual rights related to PerClot, ProCol, and PhotoFix.

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

The Company is currently engaged in patent litigation with Bard and certain of its subsidiaries. See Part I, Item 3, Legal Proceedings for discussion of this litigation. See also Part I, Item 1A, Risk Factors for a discussion of risks related to the Company s 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 the Company s products and services.

Employees

As of December 31, 2014 CryoLife and its subsidiaries had approximately 535 employees. None of the Company s employees are represented by a labor organization or covered by a collective bargaining agreement, and the Company has never experienced a work stoppage or interruption due to labor disputes. Management believes its relations with its employees are good.

Environmental Matters

The Company s 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 the Company are placed in appropriately constructed and labeled containers

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and are segregated from other wastes generated by the Company. The Company contracts with third-parties for transport, treatment, and disposal of biomedical waste. Although the Company believes it is in compliance in the disposal of its waste with applicable laws and regulations promulgated by the U.S. Environmental Protection Agency and the Georgia Department of Natural Resources, Environmental Protection Division, the failure by the Company, or the companies with which it contracts, to comply fully with any such regulations could result in an imposition of penalties, fines, or sanctions, which could materially, adversely affect the Company s business.

Risk Factors

CryoLife s 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 the Company s policy to make all of its filings with the Securities and Exchange Commission, including, without limitation, its 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 the Company s 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.

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Item 1A. Risk Factors.

Risks Relating To Our Business

We Are Significantly Dependent On Our Revenues From BioGlue And Are Subject To A Variety Of Risks Affecting This Product.

BioGlue® Surgical Adhesive (BioGlue) is a significant source of our revenues. Any of the following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- If BioGlue is the subject of adverse developments with regard to its safety, efficacy, or reimbursement practices, or if our rights to manufacture and market this product are challenged;
- 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. Competitors may utilize the inventions disclosed in the expired patents in competing products, although any competing product will have to be approved by the appropriate regulatory authority, such as the U.S. Food and Drug Administration (FDA), and portions of BioGlue s manufacturing process are protected by trade secrets; or
- Competitors have obtained FDA approval for indications in which BioGlue has been used off-label and for which we cannot market BioGlue, which has reduced addressable procedures for BioGlue, and such actions could continue to reduce addressable procedures.

Our Products And Tissues Are Subject To Many Significant Risks.

The manufacture and sale of medical devices and processing, preservation, and distribution of human tissues have inherent risks. Any of the following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our products and tissues may be recalled or placed on hold by us, the FDA, or other regulatory bodies. For example, in 2002 the FDA issued an order related to our cardiac patch, vascular, and orthopaedic tissues processed from October of 2001 until August of 2002, and pursuant to that order, we recalled these tissues or placed them on quarantine hold (we no longer process orthopaedic tissues);
- Our medical devices and our tissues, which are not sterile when processed, 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 operations and tissue processing are subject to regulatory scrutiny and inspections, including by the FDA and foreign regulatory agencies, and these agencies could require us to change or modify our manufacturing operations, processes, and procedures;
- Regulatory agencies could reclassify or reevaluate our clearances and approvals to sell our medical devices and tissue services; and
- Adverse publicity associated with our medical devices or processed tissues or the industries as a whole that our medical devices and processed tissues are a part of could lead to a decreased use of our medical devices or processed tissues and additional regulatory scrutiny or product or tissue processing liability lawsuits.

As an example of the inherent risks of our manufacturing of medical devices and tissue processing, in January 2013 we received a warning letter (Warning Letter) from the FDA. The Warning Letter followed a Form 483 related to the manufacture of our medical devices and our processing, preservation, and distribution of human tissue (2012 Form 483). The 2012 Form 483 followed a routine quality system inspection of our

facilities by the FDA in September and October 2012.

In February and March 2014 the FDA conducted a re-inspection to review our actions and responses to the Warning Letter and to conduct a quality system inspection. Following this re-inspection, on March 20, 2014 we received a Form 483 from the FDA (2014 Form 483). The 2014 Form 483 included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training.

We responded to the 2014 Form 483 in April 2014 and provided periodic updates to the FDA throughout the remainder of 2014. Communications with the FDA related to these observations have continued, and we have continued to evaluate and

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modify our procedures as part of our ongoing compliance efforts. The FDA has indicated its intent to conduct a re-inspection of our operations in the first quarter of 2015.

We believe that the changes we have implemented, and will implement, will adequately address the FDA s observations; however, it is possible that such changes will not be satisfactory to the FDA. If the FDA is not satisfied with our changes and progress, it could institute a wide variety of enforcement actions, ranging from making additional public statements to more severe sanctions such as fines; injunctions; civil penalties; recalls of our tissues and/or products; operating restrictions; suspension of production; non-approval or withdrawal of approvals or clearances for new products or existing products; and criminal prosecution. The Warning Letter and any further warning letters, recalls, holds, or other negative publicity from the FDA resulting from its inspections, Forms 483, or otherwise may decrease demand for our tissues or products or cause us to write down our inventories or deferred preservation costs and could materially, adversely affect our revenues, financial condition, profitability, and cash flows. In addition, any adverse publicity resulting from an FDA action or a recall or hold could encourage recipients of our medical devices or our tissues to bring lawsuits against us.

Our Investment In Our Distribution And License And Manufacturing Agreements With Starch Medical, Inc. Is Subject To Significant Risks, And Our Ability To Fully Realize Our Investment Is Dependent On Our Ability To Sell PerClot® In The U.S.

On September 28, 2010 we entered into a worldwide distribution agreement and a license and manufacturing agreement with Starch Medical, Inc. (SMI) pursuant to which we distribute and expect to manufacture PerClot. We were also authorized to pursue, obtain, and maintain regulatory approval for PerClot in the U.S. Pursuant to distribution and license agreements, we made additional payments to SMI of $250,000 in 2011, $1.0 million in 2014, and $500,000 in 2015 and will pay contingent amounts of up to $1.0 million to SMI if certain U.S. regulatory and other commercial milestones are achieved. We will also pay royalties on any sales of PerClot we manufacture. In September 2011 we entered into an agreement with SMI for an additional $1.0 million to acquire the technology used to produce the key component in the manufacture of PerClot. We anticipate that we will spend between $5.0 million and $6.0 million in the next several years to obtain U.S. regulatory approval, most of which we expect to be incurred in 2015 and 2016. We will incur additional costs to begin manufacturing PerClot and to begin marketing PerClot in the U.S. Our costs may be greater than anticipated, as the costs to obtain FDA approval, begin manufacturing PerClot, and begin marketing PerClot are estimates, and these costs may ultimately be greater than anticipated.

In April 2014 we received 510(k) clearance for a topical version of PerClot (PerClot Topical) from the FDA, which allowed us to begin commercialization of PerClot Topical in the U.S. We began shipping PerClot Topical in August 2014, and we are in the initial stages of this product launch.

We will not be able to fully realize the benefit of our investment with SMI in future years unless we are able to obtain the necessary regulatory approvals in the U.S. to distribute the surgical version of PerClot within the timetable anticipated. In March 2014 we received approval of our investigational device exemption (IDE) for PerClot from the FDA. This approval allows us to begin the pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Following multiple discussions with the FDA in 2013 and 2014 regarding our investigational study protocol and clinical product labeling, we plan to begin enrollment in the trial in the first half of 2015, and we currently expect to receive a Premarket Approval (PMA) from the FDA during 2017; however, there can be no guarantee that these events will occur as, and when, we expect.

We will not be able to sell the surgical version of PerClot in the U.S. in future years unless, and until, we obtain FDA approval. Failure to obtain FDA approval would materially, adversely affect our financial condition, anticipated future revenues, and profitability. There is no guarantee that we will obtain this approval when anticipated, or at all. Estimates regarding the timing of regulatory approval for PerClot are subject to factors beyond our control, and the approval process may be delayed because of unforeseen scheduling difficulties and unfavorable results at various stages in the process. Our approval efforts for PerClot in the U.S. are subject to delays and cost overages, and management may decide to terminate or delay its pursuit of U.S. regulatory approval for PerClot at any time due to changing conditions in our company, in the marketplace, or in the economy in general. If we are unable to obtain FDA approval by October 1, 2017, SMI may terminate our license to apply for FDA approval, and the parties will have to, in good faith, renegotiate our rights to attempt to obtain FDA approval.

In addition, once we receive approval, we may be unsuccessful in our attempts to sell PerClot in the U.S., as other competing products may have penetrated the market by that time and have substantial market share or significant market protections due to contracts. Any of these occurrences could materially, adversely affect our future revenues, financial condition, profitability, and cash flows.

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Finally, we are currently engaged in litigation with Medafor, Inc. (Medafor) and its parent entity, C. R. Bard, Inc. (Bard), regarding whether our anticipated sales of PerClot and sales of certain of its derivative products, such as PerClot Topical, in the U.S. violate a Medafor/Bard patent. See also Our Patent Lawsuit Against Bard et al Will Be Expensive, And If We Lose, We May Be Prohibited From Selling PerClot Or May Have To Pay Substantial Royalties Or Damages When We Sell PerClot below.

Our Patent Lawsuit Against Bard et al Will Be Expensive, And If We Lose, We May Be Prohibited From Selling PerClot Or May Have To Pay Substantial Royalties Or Damages When We Sell PerClot.

As discussed in Part I, Item 3, Legal Proceedings, of this Form 10-K we are engaged in litigation with Bard and certain of its subsidiaries related to PerClot and Bard s U.S. Patent No. 6,060,461 (the 461 Patent). We expect that this litigation will be protracted and will result in significant costs during 2015. We do not believe that PerClot infringes the 461 Patent.

If we obtain FDA approval, but are found by a court to have infringed Bard s or another third-party s patent rights, we may ultimately not be able to sell PerClot in the U.S., or we may have to pay a material license fee that may not allow us to fully realize the benefit of our investment in PerClot.

In 2013 we entered into an indemnification agreement with SMI (Indemnification Agreement) whereby certain of the royalties and a portion of the milestone payments that we would otherwise be required to pay to SMI under our license agreement can be offset by legal fees and certain types of damages we might pay associated with this patent litigation. However, the availability of these monies and the timing of these offsets will not match the timing of the related legal expenses and damages we have incurred and may incur in the future. Even with the benefits of the Indemnification Agreement, any of the occurrences discussed above could materially, adversely affect our future revenues, financial condition, profitability, and cash flows.

Our Investments In Our Distribution Agreements With Hancock Jaffe Laboratories, Inc. And Genesee Biomedical, Inc. Are Subject To Significant Risks, And Our Ability To Fully Realize Our Investments Is Dependent On Our Ability To Sell ProCol® and PhotoFix™ In The U.S.

In March 2014 we acquired the exclusive worldwide distribution rights for ProCol Vascular Bioprosthesis (ProCol) from Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). We also acquired the option to purchase the ProCol product line from Hancock Jaffe beginning in March 2016. We began limited distribution of ProCol in the second quarter of 2014.

In August 2014 we acquired the exclusive worldwide distribution rights for PhotoFix from Genesee BioMedical, Inc. (Genesee). We also acquired the option to purchase the PhotoFix product line from Genesee beginning in March 2015. We anticipate beginning distribution of PhotoFix in the first quarter of 2015.

Both ProCol and PhotoFix are new products in our portfolio, and we may be unsuccessful in our attempts to distribute one or both of them in the U.S. due to our inability to effectively penetrate the market for these products or competing products penetrating the market and gaining substantial market share or securing significant market protections due to contracts. With respect to both ProCol and PhotoFix, we will be reliant, at least initially, on Hancock Jaffe and Genesee to produce quality products in the quantities we and our customers require. If Hancock Jaffe and/or Genesee experience supply or production challenges, their products are subject to recall or other quality action, their business operations and/or their facilities that make the products are shut down temporarily or permanently, whether by government order, natural disaster, or otherwise, there may not be sufficient product to enable us to meet demand. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, cash flows, and the value of our options to acquire the respective product lines.

Reclassification By The FDA Of CryoValve® SGPV Would Result In Significant Risks And 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 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 SG pulmonary heart valve (CryoValve SGPV.) At the meeting, a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves should be classified as a Class III product. We expect that the FDA will issue a proposal for classification 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 a PMA, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers.

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We currently plan to continue to process and ship our CryoValve SGPV tissues. However, 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 or if we are unsuccessful in obtaining the PMA, the costs associated with obtaining such a PMA and/or the potential impact upon our tissue revenues, could materially, adversely affect our revenues, financial condition, profitability, and/or cash flows in future periods. In addition, we could decide that the requirements for obtaining a PMA make continued processing of the CryoValve SGPV infeasible, necessitating that we discontinue it.

We Continue To Evaluate Expansion Through Acquisitions, Licenses, Investments, And Other Distribution Arrangements In Other Companies Or Technologies, Which Contain Significant Risks.

One of our business strategies is to acquire companies, divisions, technologies, products, and rights through licenses, distribution agreements, investments, and outright acquisitions to grow our business. In connection with one or more of those transactions, we may:

Issue additional equity securities that would dilute our stockholders value;

Use cash that we may need in the future to operate our business;

Incur debt that could have terms unfavorable to us or 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 of the acquisition;

Be unable to secure the services of key employees related to the acquisition; or

Be unable to succeed in the marketplace with the acquisition.

Any of these items could materially, adversely affect our revenues, financial condition, and profitability. Business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Incurring unknown liabilities or the failure to realize the anticipated benefits of an acquisition could materially, adversely affect our business if we are unable to recover our initial investment, which could include the cost of acquiring licenses or distribution rights, acquiring products, purchasing initial inventory, or investments in early stage companies. Inability to recover our investment, or any write off of such investment, associated goodwill, or assets, may materially, adversely affect our financial condition and profitability.

Although We May Receive Additional Cash In The Future Related To Medafor s Earnout And Release Of Escrow Funds Related To Bard s Acquisition of Medafor, It Is Possible That We May Not Receive Any Additional Monies, Or That The Amount Of Additional Monies Received Could Be Significantly Less Than We Anticipate.

As discussed elsewhere in this Form 10-K, we received an initial payment of approximately $15.4 million in the fourth quarter of 2013 for our shares of Medafor common stock due to Bard s acquisition of Medafor and received an additional payment of $530,000 in the fourth quarter of 2014 related to the release of funds in escrow. Based on information provided by Medafor as part of its September 24, 2013 Proxy Statement (Medafor Proxy), we believe that we could receive additional payments totaling up to an additional $7.9 million upon the final release of funds

held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015.

We estimate that we could receive additional payments of up to $987,000 in the second quarter of 2015, and up to $168,000 in 2017 related to escrow releases, and that additional amounts of up to $6.7 million could be paid to us in either the second or third quarter of 2015 based on an earnout of net sales of Medafor. We estimate that the amount we could receive under this earnout could range from zero to $7.9 million, depending on Medafor net sales during the period from July 1, 2014 to June 30, 2015.

However, we do not have any control over, or visibility regarding, any claims that may have been or will be made against the escrow, whether these escrow amounts will be released, whether Medafor products will meet the sales requirements that would generate the earnout amounts, or whether any setoffs will occur. Additionally, we may not be aware of any of these issues until we are scheduled to receive payments, if any, because of our lack of visibility into what may have

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occurred. As a result, the amount of additional monies that could be paid to us may be significantly less than the amounts we have estimated we may receive based on information provided in the Medafor Proxy.

The Receipt Of Impaired Materials Or Supplies That Do Not Meet Our Standards, The Recall Of Materials Or Supplies By Our Vendors Or Suppliers, Supplier Financial Or Operational Challenges, Lack Of Alternative Suppliers, Or Our Inability To Obtain Materials And Supplies Could Materially, Adversely Affect Our Business.

The materials and supplies used in our medical device manufacturing and our processing of tissue are subject to stringent quality standards and requirements, and many of these materials and supplies are subject to 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, the likely outcome would be the rejection or recall of our processed tissue or devices and/or the immediate expense of the costs of the manufacturing or preservation. In addition, if these materials and supplies are recalled or the suppliers and/or their facilities that make them 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 our tissues. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

Not Having Alternative Or Multiple Vendors For Key Materials, Supplies, Or Services Could Materially, Adversely Affect Our Business.

Certain of the materials, supplies, and services that are crucial to our medical device manufacturing or our processing of tissue are sourced from a single vendor. As a result, our ability to negotiate favorable terms with those vendors is limited, and if those vendors experience operational, financial, or regulatory difficulties, or those vendors and/or their facilities cease operations temporarily or permanently, we could be forced to cease production of devices or processing of tissue until the vendor resumes operations or an alternative vendor could be identified and qualified, or we could be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

Healthcare Policy Changes, Including Recent Federal Legislation To Reform The U.S. Healthcare System, May Materially, Adversely Affect Our Business.

In response to perceived increases in health care 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. Certain of these proposals could limit the fees we are able to charge for our services, prices we are able to charge for our products, and/or the amounts of reimbursement available for our products or services and could limit the acceptance and availability of our products and services.

Our Sales Are Affected By Challenging Domestic And International Economic Conditions And Their Constraining Effect On Hospital Budgets, And Demand For Our Products And Tissues Could Decrease In The Future, Which Could Materially, Adversely Affect Our Business.

The demand for certain of our products and tissues has fluctuated recently and may continue to fluctuate. In challenging economic environments, hospitals attempt to control costs by reducing spending on consumable and capital items, which can result in reduced demand for some of our products and services. If economic conditions worsen, if changes occur in healthcare policies that force or encourage our customers to limit their use of our products and tissues, or if new competitive products or tissues are introduced, demand for our products or tissues could decrease in the future. If demand for our products or tissues decreases significantly in the future, our revenues, profitability, and cash flows would likely decrease, possibly materially. In addition, the manufacturing throughput of our products and the processing throughput of our tissues would necessarily decrease, which would likely adversely impact our margins and, therefore, our profitability, possibly materially. Further, if demand for our products and/or tissues materially decreases in the future, we may not be able to ship our products and/or tissues before they expire, which would cause us to write down our inventories and/or deferred preservation costs.

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

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Key Growth Vectors May Not Generate The Anticipated Benefits.

Our strategic plan is focused on four growth vectors which are expected to drive our business expansion in the near term. These growth vectors and their key elements are described below:

New Products Drive growth through the rollout of the Company s new products including ProCol, PerClot, and PhotoFix™

New Indications Broaden the reach of the Company s flagship products, including BioGlue and PerClot, with new and expanded approvals and indications.

Global Expansion Expand the Company s current products and services into new markets, including emerging markets, and accelerate growth by developing new direct sales territories overseas.

Business Development Selectively pursue potential acquisition, licensing, or distribution rights of companies or technologies that complement CryoLife s existing products, services, and infrastructure.

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

Uncertainties Related To Patents And Protection Of Proprietary Technology May Adversely Impact The Value Of Our Intellectual Property Or May Result In Our Payment Of Significant Monetary Damages And/Or Royalty Payments, Negatively Impacting Our Ability To Sell Current Or Future Products, Or Prohibit Us From Enforcing Our Patent And Other Proprietary Technology Rights Against Others.

We own several 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 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. We also cannot be certain that if anyone does make such a challenge, we will be able to successfully defend that challenge. We may have to incur substantial litigation costs to uphold the validity and prevent infringement of a patent or to protect our proprietary technologies and methods. Furthermore, competitors may independently develop similar technologies or duplicate our technologies or design around the patented aspects of such technologies. In addition, our technologies or products or services could infringe patents or other rights owned by others, or others could infringe our patents. If we are forced to defend ourselves in a patent infringement case, the costs of such defense could be expensive, and if we were to lose or decide to settle the lawsuit, the costs of the settlement or amount awarded by a court could be expensive. For example, in 2012 we settled a patent infringement case with CardioFocus, Inc. (CardioFocus) related to technology we acquired from Cardiogenesis. The settlement of that patent infringement action required a payment to CardioFocus of $4.5 million. 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. See also, Our Patent Lawsuit Against Bard et al Will Be Expensive, And If We Lose, We May Be Prohibited From Selling PerClot Or May Have To Pay Substantial Royalties Or Damages When We Sell PerClot.

Intense Competition May Impact Our Ability To Operate Profitably.

We face competition from other companies engaged in the following lines of business:

The marketing of mechanical, synthetic, and animal-based tissue valves for implantation;

The marketing of surgical adhesives, surgical sealants, and hemostatic agents;

The marketing of CardioGenesis cardiac laser therapy;

The marketing of products addressing dialysis therapies; and

The processing and preservation of human tissue.

Many of our competitors have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets.

We cannot give assurance that our products and tissues will be able to compete successfully. In addition, our competitors may gain competitive advantages that may be difficult to overcome. If we fail to compete effectively, this could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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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; however, we cannot guarantee that we will develop commercially acceptable new products and services. We must also expend significant time and resources to obtain the required regulatory approvals. Although we have conducted preclinical 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 the results we obtain from expanded clinical studies will be consistent with earlier trial results or be sufficient for us to obtain any required regulatory approvals or clearances. We cannot give assurance that we will not experience difficulties that could delay or prevent us from successfully developing, introducing, and marketing new products and services. We also cannot give assurance that the relevant regulatory agencies will clear or approve these or any new products and services on a timely basis, if ever, or that the new products and services will adequately meet the requirements of the applicable market or achieve market acceptance. We may encounter delays or rejections during any stage of the regulatory approval process if clinical or other data fails to satisfactorily demonstrate compliance with, or if the service or product fails to meet, the regulatory agency s requirements for safety, efficacy, and quality. Those requirements 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 due to the following:

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 product, particular tissue, or any other components required for clinical trials;

Changes in development focus; and

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 which are under development, 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, 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 services or products. 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.

Even if we are able to obtain regulatory approval for any products or services offered, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. The unapproved use of our products or tissues could adversely impact the reputation of our company and our products and services. Products or services marketed pursuant to FDA or foreign oversight or foreign approvals are subject to continuing regulation and periodic inspections. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of devices and biologics is also subject to regulation and may require FDA approval. From time to time, the FDA may modify such regulations, imposing additional or different requirements. If we fail to comply with applicable FDA requirements, which may be ambiguous, we could face civil and criminal enforcement actions, warnings, citations, product recalls or detentions, and other penalties. This could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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In addition, U.S. and foreign governments and regulatory agencies have adopted restrictive laws, regulations, and rules. These include:

- The National Organ Transplant Act of 1984 or NOTA , which prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation, but allows for the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs;

- U.S. Department of Labor, Occupational Safety and Health Administration and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment, all of which affect our manufacturing operations and tissue processing ; and

- European Union directives, called the EUCTD, which require that countries in the European Economic Area take responsibility for regulating tissues and cells through a Competent Authority.

Any of these laws, regulations, and rules could change, or the U.S. or foreign governments and regulatory agencies could adopt more restrictive laws or regulations in the future that could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

The Success Of Many Of Our Products And Tissues Depends Upon Strong Relationships With Physicians.

If we fail to maintain our working relationships with physicians, many of our products and tissues may not be developed and marketed to appropriately meet the needs and expectations of the professionals who use and support our products and tissues. The research, development, marketing, and sales of many of our new and improved products and tissues are dependent upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding our products and tissues and their marketing. Physicians assist us as researchers, marketing consultants, product consultants, and public speakers.

Certain states have begun to regulate interactions with physicians and other healthcare professionals. There are existing laws and regulations that govern interactions with physicians and other healthcare professionals. For example, in 2014 we began disclosing payments made to physicians for meals or other services to the Department of Health and Human Services. These existing laws and regulations currently impact our ability to maintain strong relationships with physicians and may, in the future, further impact our relationships with physicians. If we are unable to maintain our strong relationships with these professionals and do not continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Our Existing Insurance Policies May Not Be Sufficient, And We May Be Unable To Obtain Insurance In The Future.

Although we have significant insurance for products, tissues, securities, and property, it is possible that:

- We could be exposed to product liability, tissue processing, and security claims greater than the amount that we have insured;

- Because our insurance is a claims-made policy, 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, national disasters or other catastrophes could adversely impact our business.

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

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

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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. In addition, insurance rates could be significantly higher than in the past, and insurers may provide less coverage than we have estimated or expected. 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 operational capacity, along with a potential adverse impact on our customers and opportunity costs for which our insurance would not compensate us.

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

If We Are Not Successful In Expanding Our Business Activities In International Markets, It Could Have a Material, Adverse Impact On Our Revenues, Financial Condition, Profitability, and Cash Flows.

Our international operations are subject to a number of risks which may vary from the risks we face in the U.S., including:

- Difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships and developing direct sales operations in selected territories;
- Unexpected changes in regulatory requirements;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;
- More limited protection for intellectual property in some countries;
- Changes in currency exchange rates, particularly fluctuations in the British Pound and Euro as compared to the U.S. Dollar;
- Adverse economic or political changes;
- Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs; and
- Potentially adverse tax consequences of overlapping tax structures.

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

Consolidation In The Healthcare Industry Could Continue To Result In Demands For Price Concessions, Limits On The Use Of Our Products And Tissues, And Limitations On Our Ability To Sell To Certain Of Our Significant Market Segments.

The cost of healthcare has risen significantly over the past decade, and numerous initiatives and reforms initiated by legislators, regulators, and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry as well as among our customers, including healthcare providers. This in turn has resulted in greater pricing pressures and limitations on our ability to sell to important market segments, as group purchasing organizations, independent delivery networks, and large single accounts continue to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the prices for our products and fees charged for our tissues, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

Our Current Plans To Continue To Pay A Quarterly Cash Dividend May Change.

We initiated the payment of a quarterly cash dividend during the third quarter of 2012 and increased the amount of this dividend in 2013 and again in 2014. Although we anticipate the continued payment of a cash dividend to our shareholders in future quarters, the projected timing and amount of any future dividend payments are subject to change based on a variety of factors, including: management s assessment of our overall needs at the time; our ability to generate current and sustained future earnings and cash flows; and financial requirements, including the requirements of our credit agreement.

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Management must determine the proper allocation of available resources among operating needs, capital expenditures, research and development spending, acquisitions or other investments in our business, stock repurchases, dividends, and other needs. Our credit agreement imposes limits on our ability to declare cash dividends, including that we may only make dividend payments if, on the date of the dividend payment, no default or event of default under the agreement has occurred and is continuing, and that we are in compliance with certain financial covenants contained in the agreement, including maintenance of certain liquidity requirements. Our total annual dividend may vary from current expectations based on management decisions regarding the timing and per share value of any future cash dividends, or may be discontinued at any time, due to any of the factors described above, or other factors, as well as due to changes to the number of shares outstanding.

We Are Dependent On The Availability Of Sufficient Quantities Of Tissue From Human Donors.

The success of our tissue preservation services depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. 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. If the supply of donated human tissue is materially reduced, this would restrict our growth and could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Continued Fluctuation Of Foreign Currencies Relative To The U.S. Dollar Could Materially, Adversely Affect Our Business.

The majority of our foreign product and tissue processing revenues are denominated in British Pounds and 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 British Pounds and 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 Credit Facility Limits Our Ability To Pursue Significant Acquisitions And Also May Limit Our Ability To Borrow.

Our credit facility, which was extended in 2014 to September 26, 2019, prohibits mergers and acquisitions other than certain permitted acquisitions along with certain affirmative covenants that we must satisfy before we can borrow or enter into a permitted acquisition. Permitted acquisitions include certain stock acquisitions and non-hostile acquisitions that have been approved by the Board of Directors and/or the stockholders of the target company if, after giving effect to the acquisition, there is no event of default under the credit facility and there is still at least $1.5 million available to be borrowed under the credit facility. The total consideration that we pay, or are obligated to pay, for all acquisitions consummated during the term of the credit facility, less the portion of any such consideration funded by the issuance of common or preferred stock, may not exceed an aggregate of $35.0 million. Although our lender has modified the credit facility in the past to allow us to make acquisitions that would not affect this aggregate of $35.0 million, this is no guarantee that they will do so in the future. In addition, we must satisfy specified leverage ratios, and there are also varying levels of adjusted earnings before interest, taxes, depreciation, and amortization under the credit facility that we have covenanted to maintain during the term of the credit facility. Failure to satisfy any of these requirements could limit our borrowing ability and materially, adversely affect our liquidity.

Therefore, as a result, our ability to consummate acquisitions and fully realize our growth strategy may be materially, adversely affected while this credit facility remains in effect. Any credit facility we subsequently enter into may have similar or more stringent restrictions on our ability to pursue significant acquisitions.

We Are Dependent On Our Key Personnel.

Our business and future operating results depend in significant part upon the continued contributions of our key field personnel and senior management, many of whom would be difficult to replace. Our business and future operating results also depend in significant part upon our ability to attract and retain qualified management, processing, marketing, sales, and support personnel for our operations. 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

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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.

Rapid Technological Change Could Cause Our Products And Services To Become Obsolete.

The technologies underlying our products and services are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products, or processes with significant advantages over the products, services, and processes that we offer or are seeking to develop. Any such occurrence could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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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. Forward-looking statements give the Company s current expectations or forecasts of future events. The words could, may, might, will, would, shall, should, pro forma, potential, pending, intend, believe, expect, anticipate, e similar expressions generally identify forwarding-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, other than statements of historical facts, included herein that address activities, events or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

The Company s beliefs regarding the advantages of the human tissues it distributes;

The Company s plans, costs, and expected timeline regarding regulatory approval for PerClot; the distribution of PerClot in certain markets after the requisite regulatory approvals are obtained; and the Company s expectation that it will terminate its minimum purchase requirements after regulatory approval of PerClot;

The Company s expectations regarding the clinical trials necessary to obtain PMA to distribute PerClot in the U.S.;

The Company s beliefs regarding the potential impact of the patent infringement litigation between CryoLife and C.R. Bard, Inc. and certain of its subsidiaries, that PerClot does not and will not infringe Medafor s patent, and that the costs associated with the litigation will be significant in 2015;

The Company s beliefs regarding the potential benefits and additional applications of the Company s surgical adhesives, sealants, hemostats, revascularization technologies, HeRO Graft, and ProCol products;

The Company s belief regarding the sufficiency of its response to the 2014 CryoLife Form 483 and the Warning Letter, and that any issues related to the FDA s observations in the 2014 CryoLife Form 483 and the Warning Letter will not have a continuing material effect on the Company;

The Company s expectations regarding continued review and modification of its tissue processing and quality procedures during 2015;

The Company s plans related to regulatory approval for, and the subsequent distribution of, BioGlue in Europe;

The Company s plans related to regulatory approval in certain markets for BioFoam, and the subsequent distribution of BioFoam in those markets;

The Company s beliefs regarding the anticipated benefits of conducting a post-clearance study at the FDA s request to collect long-term clinical data for the CryoValve SGPV;

The potential impact of the FDA s review of the classification of CryoValve SGPV and the FDA advisory committee s vote in favor of classifying such tissue as a class III device;

The Company s expectations regarding commencement of distribution of PhotoFix;

The Company s plans regarding HeRO Graft product enhancements;

The Company s beliefs that HeRO Graft revenues will expand in 2015, and that HeRO revenue volatility will decrease;

The Company s beliefs regarding the possibility of shipping tissues to Germany in the second half of 2015;

The Company s expectations about whether it may receive any additional payments, and if so, the timing and amount of such payments, related to its sale of Medafor stock;

The Company s expectation that general, administrative, and marketing expenses will increase in 2015 as compared to 2014, and that litigation and business development expenses could further increase these expenses;

The Company s beliefs regarding the international growth opportunities that would be provided by obtaining expanded indications for BioGlue in Japan and regulatory approval for BioGlue in China;

The Company s expectations that research and development spending will increase materially in 2015;

The Company s expectations regarding the possible bankruptcy of ValveXchange;

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The Company s anticipated payment of quarterly dividends each year;

The Company s expectations regarding the recoverability and realizability of deferred tax assets and net operating loss carryforwards;

The Company s estimates of unreported loss liabilities, including unreported product and tissue processing liability claims, the assumptions used to establish those estimates, and the Company s belief that those assumptions provide a reasonable basis for the estimates;

The Company s expectations regarding the source of any future payments related to any unreported product or tissue processing liability claims;

The Company s estimates of fair value of acquired assets, and its belief that the estimates are reasonable;

The Company s expectation that it will continue to renew certain acquired contracts and procurement agreements for the foreseeable future;

The Company s beliefs regarding the importance of, and competitive advantages associated with, its relationships with tissue procurement organizations;

The Company s belief regarding its compliance with NOTA, state licensing requirements, and environmental laws and regulations;

The Company s expectations regarding the recognition of stock compensation expense;

The Company s assessment of the effect of adopting new accounting standards regarding the recognition of revenue from contracts with customers;

The Company s plans and expectations regarding research and development of new technologies and products;

The Company s expectations regarding business consolidations in the healthcare industry that could exert downward pressure on fees charged by the Company;

The Company s belief that healthcare policy and law changes may have a material adverse effect on the business;

The Company s beliefs regarding the seasonal nature of the demand for some of its products and services;

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

The Company s estimates of contingent payments and royalties that may be paid by the Company and the timing of such payments;

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

The anticipated impact of changes in prevailing economic conditions, interest rates, and foreign currency exchange rates;

The Company s estimates regarding specific country and worldwide market opportunities for certain types of procedures, certain types of products, and the Company s products and tissues;

The Company s beliefs and estimates regarding its competitors in various geographic, procedure, and product markets;

The Company s expectations about not triggering certain contingent payment obligations;

The Company s beliefs regarding probability of achievement of certain performance components under performance share awards granted pursuant to its stock incentive plan;

The Company s beliefs regarding the factors upon which customers base purchasing decisions and any competitive advantages or disadvantages of the Company s products or tissues relative to those of competitors;

The constraints imposed on the Company by its lender under the existing credit facility;

The Company s plans regarding acquisition and investment opportunities of complementary product lines and companies;

The Company s beliefs regarding the state of relations with its employees;

The Company s plans regarding the licensing of the Company s technology to third parties for non-competing uses;

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

The Company s revenue and cost trend estimates, and the underlying reasons for those trends, for its products and services for 2015;

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The Company s beliefs regarding the enhanced efficacy of certain procedures provided by using its surgical sealants;

The Company s beliefs regarding the adequacy of, and competitive advantages conferred by, its intellectual property protections;

The Company s beliefs regarding the potential for competitive products and services to affect the market for the Company s products and services;

The Company s expectations regarding the benefits of the Company s marketing, educational and technical support efforts;

The expected impacts of the Company s issuance of additional shares and share repurchases on financial results calculated on a per-share basis;

The Company s beliefs regarding the anticipated benefits of providing on-site freezers;

Issues that may affect the Company s future financial performance and cash flows; and

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

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company s expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company s 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 the control of CryoLife. 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 the Company will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, the Company or its business or operations. The Company assumes 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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Item 1B. Unresolved Staff Comments.

The Company has no unresolved written comments received from the staff of the Securities and Exchange Commission regarding its periodic or current reports under the Securities Exchange Act of 1934 not less than 180 days before December 31, 2014 (the end of the fiscal year to which this Form 10-K relates).

Item 2. Properties.

The Company s 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 Company manufacturing operations and liquid nitrogen freezers maintain preserved tissue at or below 135°C. The Company manufactures products from its Medical Devices segment, including: BioGlue, BioFoam, and PerClot, and processes and preserves tissues from its Preservation Services segment at the Company s headquarters facility. The Company s corporate headquarters also includes a CardioGenesis cardiac laser therapy maintenance and evaluation laboratory space.

The Company s 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 Elkins Learning Center provides visiting surgeons with a hands-on training environment for surgical and implantation techniques for the Company s technology platforms.

The Company maintains a secondary facility which consists of 15,600 square feet of combined manufacturing and office space in Atlanta, Georgia. The Company currently manufactures HeRO Grafts and is planning to expand PerClot manufacturing from its Medical Devices segment at this Atlanta, Georgia manufacturing facility.

In October 2014 the Company entered into a lease for approximately 24,980 square feet of additional office space in Kennesaw, GA. The Company expects to take possession of the facility in February 2015 and may use the premises for general office purposes, research and development, light manufacturing, storage of medical devices, tissues, and materials, or other uses permitted by the lease.

The Company s European subsidiary, Europa, maintains a leased facility located in Guildford, England, which contains approximately 3,400 square feet of office space. In addition, Europa leases shared warehousing space through its third-party shipper.

Item 3. Legal Proceedings.

On April 28, 2014 CryoLife filed a declaratory judgment lawsuit (the Original Complaint) against C.R. Bard, Inc. (Bard), and its subsidiaries Davol, Inc. and Medafor, Inc. (Medafor) (collectively, Defendants), in the U.S. District Court for the District of Delaware (the Court). CryoLife requested that the Court declare that CryoLife s manufacture, use, offer for sale, and sale of PerClot in the U.S. does not and would not infringe Bard s U.S. Patent No. 6,060,461 (the 461 Patent). In addition CryoLife requested that the Court declare that the claims of the 461 Patent are invalid. As part of the relief requested, CryoLife requested injunctive relief and an award of attorneys fees.

The lawsuit against the Defendants follows the receipt by CryoLife of a letter from Medafor in September 2012 stating that PerClot, when introduced in the U.S., will infringe the 461 Patent when used in accordance with the method published in CryoLife s literature and with the instructions for use. CryoLife received FDA 510(k) clearance for the sale of PerClot Topical in April 2014, began distributing PerClot Topical in September 2014, and received IDE approval in March 2014 to begin clinical trials for PerClot in certain surgical indications.

In June 2014 CryoLife filed an amended complaint, and the Defendants filed a counterclaim for infringement in August 2014. The Defendants filed various motions to dismiss; the Court has not yet ruled on those motions. On September 19, 2014 the Defendants filed a motion for a preliminary injunction, asking the Court to enjoin CryoLife s marketing and sale of

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PerClot in the U.S. The hearing with respect to the preliminary injunction motion was held on January 23, 2015; the Court is expected to issue a ruling on the motion imminently.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 4A. Executive Officers of the Registrant.

The following table lists the executive officers of CryoLife and their ages, positions with CryoLife, and the dates from which they have continually served as executive officers with CryoLife. Each of the executive officers of CryoLife was elected by the Board of Directors to serve until the Board of Directors meeting immediately following the next annual meeting of shareholders or until his earlier removal by the Board of Directors or his resignation.

Name	Service as Executive	Age	Position
James P. Mackin	Since 2014	48	President and Chief Executive Officer
Steven G. Anderson	Since 1984	76	Executive Chairman
Bruce G. Anderson	Since 2012	48	Vice President, U.S. Sales and Marketing
Scott B. Capps	Since 2007	48	Vice President, Clinical Research
David M. Fronk	Since 1998	51	Vice President, Regulatory Affairs and Quality Assurance
David C. Gale, Ph.D.	Since 2012	47	Vice President, Research and Development
David P. Lang	Since 2012	68	Senior Vice President, International Sales and Global Marketing
D. Ashley Lee, CPA	Since 2000	50	Executive Vice President, Chief Operating Officer, and Chief Financial Officer

James P. Mackin assumed the position of President and Chief Executive Officer in September 2014 and was appointed to the Board of Directors in October 2014. Mr. Mackin has more than 20 years of experience in the medical device industry. Prior to joining CryoLife, Mr. Mackin served as President of Cardiac Rhythm Disease Management, the largest operating division of Medtronic, Inc. At Medtronic, he previously held the positions of Vice President, Vascular, Western Europe and Vice President and General Manager, Endovascular Business Unit. Prior to joining Medtronic in 2002, Mr. Mackin worked for six years at Genzyme, Inc. serving as Senior Vice President and General Manager for the Cardiovascular Surgery Business Unit and as Director of Sales, Surgical Products division. Before joining Genzyme, Mr. Mackin spent four years at Deknatel/Snowden-Pencer, Inc. in various roles and three years as a First Lieutenant in the U.S. Army. Mr. Mackin received an MBA from Northwestern University s Kellogg Graduate School of Management and is a graduate of the U.S. Military Academy at West Point.

Steven G. Anderson, a founder of CryoLife, served as CryoLife s President, Chief Executive Officer, and Chairman of the Board of Directors from its inception until 2014, when he was appointed to the position of Executive Chairman. Mr. Anderson has more than 40 years of experience in the implantable medical device industry. Prior to founding CryoLife, Mr. Anderson was Senior Executive Vice President and Vice President, Marketing, from 1976 until 1983 of Intermedics, Inc. (now Boston Scientific Corp.), a manufacturer and distributor of pacemakers and other medical devices. Mr. Anderson is a graduate of the University of Minnesota.

Bruce G. Anderson was appointed to the position of Vice President, U.S. Sales and Marketing in July 2008. Mr. Anderson joined the Company in May 1994 as a field technical representative in Tennessee. During his time at the Company he has served as a Director and then Senior Director of U.S. Sales and Marketing from November 2002 until July 2008, Director of Global Cardiovascular Marketing from April 2001 until November 2002, and Product Manager and then Senior Product Manager for Cardiac Technologies from January 1997 until April 2001. Mr. Anderson is responsible for developing and implementing the Company s domestic sales and marketing plans and supervising all tissue procurement activities. Prior to joining the Company, Mr. Anderson was an Account Executive at Dun & Bradstreet for four years. Mr. Anderson received his B.A. in History from the University of South Florida.

Scott B. Capps was appointed to the position of Vice President of Clinical Research in November 2007. Prior to this position, Mr. Capps served as Vice President, General Manager of CryoLife Europa, Ltd. in the U.K. from February 2005 to

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

David M. Fronk was appointed to the position of Vice President of Regulatory Affairs and Quality Assurance in April 2005 and has been with the Company since 1992, serving as Vice President of Clinical Research from December 1998 to April 2005 and Director of Clinical Research from December 1997 until December 1998. Mr. Fronk is responsible for developing and implementing improved safety processes and procedures for new and existing medical products. Prior to joining the Company, Mr. Fronk held engineering positions with Zimmer, Inc. from 1986 until 1988 and Baxter Healthcare Corporation from 1988 until 1991. Mr. Fronk served as a market manager with Baxter Healthcare Corporation from 1991 until 1992. Mr. Fronk received his B.S. in Mechanical Engineering from the Ohio State University and his M.S. in Biomedical Engineering from the Ohio State University.

David C. Gale, Ph.D. has served as Vice President, Research and Development since January 2012. Dr. Gale joined the Company in August 2009 as the Director, Biomaterials and Product Development. He was promoted to Senior Director, Biomaterials and Device Engineering in April 2011. Prior to joining CryoLife, Dr. Gale was with Sinexus, Inc., a start-up medical device company, from January 2007 to August 2009. He joined Sinexus as their Vice President of Research and was promoted to the position of Vice President, Research and Development in July 2007. Dr. Gale has 17 years of experience in biomaterials and medical device product research and development including roles at Abbott Vascular and Guidant Corporation. Dr. Gale is the inventor or co-inventor on over 70 issued U.S. patents related to the design and manufacture of medical devices. He received his Ph.D. in Materials Science from the University of Alabama at Birmingham, his M.S. in Chemical Engineering from Auburn University and has received both an M.Sc. in Instrumentation and Analysis and a B.Sc. in Chemistry from Manchester University in the U.K.

David P. Lang has served as Senior Vice President, International Sales and Marketing since December 2012 and has been with the Company since October 2010 as Vice President, Market Development. Mr. Lang is responsible for developing and implementing the Company s international sales and marketing plans. Prior to joining the Company, Mr. Lang was President and then consultant to Starch Medical, Inc. from 2008 to 2010. From July 2007 until February 2008 he was Director, International Sales of Medafor, Inc. From July 2001 until June 2007 he was Vice President, International Sales of Medafor, Inc. He has over 40 years of experience in international medical device sales and marketing, principally beginning as Director of Marketing for Medtronic Europe. His senior management positions included four resident assignments in Paris, Munich, and Shanghai. He was founder of the first Sino-American medical electronics joint venture in China in 1985. Mr. Lang received a B.A. in Economics from Harvard University.

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

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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

The Company s 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.

2014	High	Low
First quarter	$ 12.14	$ 8.64
Second quarter	10.80	8.40
Third quarter	10.69	8.55
Fourth quarter	12.00	9.16

2013	High	Low
First quarter	$ 6.78	$ 5.81
Second quarter	6.65	5.52
Third quarter	7.80	6.01
Fourth quarter	11.15	6.69

As of February 13, 2015 the Company had 322 shareholders of record.

Dividends

The Company s Board of Directors approved the initiation of a quarterly cash dividend of $0.025 per share of common stock outstanding in the third quarter of 2012. The Board of Directors increased this dividend to $0.0275 per share in the second quarter of 2013, and to $0.03 per share in the second quarter of 2014. Cash dividends have been paid every three months since their initiation in September 2012. In February 2015 the Company announced a quarterly cash dividend for the first quarter of 2015 of $0.03 per share, which will be paid on March 20, 2015 to all common stockholders of record as of March 13, 2015. The Company currently anticipates paying the quarterly dividends in March, June, September, and December of each year; however, this may change. See also Part I, Item 1A, Risk Factors Our Current Plans To Continue To Pay A Quarterly Cash Dividend May Change.

The Company s amended and restated credit agreement with General Electric Capital Corporation (GE Capital) limits the payment of cash dividends, up to specified maximums and subject to satisfaction of specified conditions. If the Company chooses to issue preferred stock, the holders of shares of that preferred stock could have a preference as to the payment of dividends over the holders of common stock. See also Part II, Item 8, Note 12 of the Notes to Consolidated Financial Statements for further discussion of the Company s credit agreement.

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Issuer Purchases of Equity Securities

The following table provides information about purchases by the Company during the quarter ended December 31, 2014 of equity securities that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934.

Issuer Purchases of Equity Securities

Common Stock

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
10/01/14 10/31/14	97,103	$ 10.34	97,103	$ 7,889,118
11/01/14 11/30/14	18,355	10.06		
12/01/14 12/31/14	12,881	10.62		
Total	128,339	10.33	97,103	

In February 2013 the Company announced that its Board of Directors had authorized the purchase of up to $15.0 million of its common stock. This program expired on October 31, 2014. The purchase of shares were made from time-to-time in the open market or through privately negotiated transactions, on such terms as management deemed appropriate, and was dependent upon various factors, including: price, regulatory requirements, and other market conditions. For the year ended December 31, 2014 the Company purchased 585,000 shares of its common stock through this authorization for an aggregate purchase price of $5.6 million.

Under the Company s amended and restated credit agreement with GE Capital, the Company is required, after giving effect to stock repurchases, to maintain liquidity, as defined within the agreement, of at least $20.0 million. The Company is also entitled to repurchase up to approximately $14.0 million of common stock under an authorized stock repurchase plan without obtaining its lender s consent.

The Company purchased 31,000 common shares during the quarter ended December 31, 2014 that were tendered to the Company in payment of the exercise price of outstanding options and taxes on stock compensation and were not part of a publicly announced plan or program.

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Item 6. Selected Financial Data.

The following Selected Financial Data should be read in conjunction with the Company s 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,				
	2014	**2013**	**2012**	**2011**	**2010**
Operations					
Revenues	$ 144,641	$ 140,763	$ 131,718	$ 119,626	$ 116,645
Operating income	8,838	13,820	12,612	11,643	9,868
Net income[1]	7,322	16,172	7,946	7,371	3,944
Net income applicable to common shareholders - diluted	7,164	15,813	7,768	7,224	3,894
Research and development expense as a percentage of revenues	6.0%	6.0%	5.5%	5.8%	5.1%
Income Per Common Share					
Basic	$ 0.26	$ 0.59	$ 0.29	$ 0.26	$ 0.14
Diluted	$ 0.25	$ 0.57	$ 0.28	$ 0.26	$ 0.14
Dividend Declared Per Common Share	$ 0.118	$ 0.108	$ 0.050	$	$
Year-End Financial Position					
Total assets	$ 176,157	$ 174,683	$ 157,156	$ 147,864	$ 137,438
Working capital	85,401	85,605	56,073	62,413	82,162
Long-term liabilities	6,845	9,214	7,614	4,869	4,168
Shareholders equity	148,685	144,747	128,112	121,538	113,942
Current ratio[2]	5:1	5:1	4:1	4:1	5:1

1 The fourth quarter 2013 net income and income per common share-diluted includes the favorable effect of a $12.7 million pre-tax gain on the sale of an investment in the common stock of Medafor, Inc. as a result of C.R. Bard, Inc. completing its acquisition of the outstanding common shares of Medafor, Inc.

2 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 medical device manufacturing and distributio and in the processing and distribution of implantable human tissues for use in cardiac and vascular surgeries. CryoLife s surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot®, an absorbable powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI), and PerClot Topical, which is being marketed in the U.S. primarily for use in ENT applications. CryoLife s CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used for the treatment of coronary artery disease in patients with severe angina. CryoLife markets the Hemodialysis Reliable Outflow Graft (HeRO® Graft) and exclusively distributes ProCol® Vascular Bioprosthesis (ProCol), both of which are solutions for end-stage renal disease (ESRD) in certain hemodialysis patients. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both of which are processed using CryoLife s proprietary SynerGraft® technology.

For the year ended December 31, 2014 CryoLife had record annual revenues of $144.6 million, increasing 3% over the prior year. The Company s cash position was strong, as the Company generated $8.1 million in cash flows from operations during 2014. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2014 results. See Part I, Item 1, Business, for further discussion of the Company s business and activities during 2014.

Recent Events

Appointment of Mr. James P. Mackin as President and CEO

On September 2, 2014 Mr. James P. Mackin became the President and Chief Executive Officer (CEO) of CryoLife, and Mr. Steven G. Anderson, the former President and CEO, continued employment with the Company and assumed the role of Executive Chairman. Mr. Mackin previously worked at Medtronic, Inc. (Medtronic), where he most recently served as President of Cardiac Rhythm Disease Management, Medtronic s largest operating division. Mr. Mackin is a highly respected professional with more than 20 years of medical device industry experience. Mr. Mackin was appointed to the Company s Board of Directors in October 2014.

Regulatory Activity

In January 2013 CryoLife received a warning letter (Warning Letter) from the U.S. Food and Drug Administration (FDA). The Warning Letter followed a Form 483, Notice of Inspectional Observations, from the FDA (2012 CryoLife Form 483), related to a routine quality system inspection of the Company s facilities by the FDA in September and October 2012.

In February and March 2014 the FDA re-inspected the Company to review the Company s actions and responses to the Warning Letter and to conduct a quality system inspection. Following this re-inspection, on March 20, 2014 CryoLife received a Form 483, Notice of Inspectional Observations, from the FDA (2014 CryoLife Form 483). The 2014 CryoLife Form 483 included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training.

The Company responded timely to the 2014 CryoLife Form 483 on April 10, 2014 and provided periodic updates through the fourth quarter of 2014. Communications with the FDA related to these observations are ongoing, and the FDA could choose to re-inspect the Company at any time. As part of the Company s response to the 2014 CryoLife Form 483, the Company voluntarily restricted the distribution of certain cardiac and vascular tissues during the second quarter of 2014 while it performed a review of its internal training programs. The Company gradually resumed shipments of tissues during the second quarter of 2014, in accordance with its procedures. The Company continues to review and modify its procedures as part of its ongoing compliance efforts. Preservation services revenues were negatively impacted during the second through fourth quarters of 2014 as a result of reduced tissue availability due to these efforts. Some of these procedural modifications resulted in additional costs to the Company during this period. These efforts and additional costs are ongoing and are expected to continue into 2015. See the Results of Operations section below for additional discussion of preservation services revenues for the three and twelve months ended December 31, 2014.

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The Company believes that the changes it has implemented, and will implement, will adequately address the FDA s observations; however, it is possible that the Company may not be able to do so in a manner satisfactory to the FDA, and the FDA could issue a warning letter or take other enforcement or regulatory actions, including requiring a recall or manufacturing hold. In addition to the efforts discussed above, it is possible that actions the FDA may take, or the Company may be required to take, in response to the 2014 CryoLife Form 483 could materially, adversely affect the Company s revenues, financial condition, profitability, and/or cash flows in future periods.

Regulatory Status of the CryoValve SGPV

In February 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company s decellularized CryoValve SGPV. In November 2003 the Company filed a 510(k) premarket notification, which was cleared by the FDA in February 2008. At the time of the clearance, the CryoValve SGPV was categorized by the FDA as an unclassified medical device. At the FDA s request, CryoLife committed to conducting a post-clearance study to collect long-term clinical data for the CryoValve SGPV. The follow-up study included more than 800 cumulative patient years of data. The study was completed in December 2014 and the results were submitted to the FDA.

On October 9, 2014 the FDA convened an advisory committee meeting to consider the FDA s recommendation to 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 CryoLife s CryoValve SGPV. At the meeting a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves should be classified as a class III product. CryoLife expects that the FDA will issue a proposal for classification of MMM allograft heart valves, which would be subject to a public comment period before finalization. After publication of the reclassification rule, CryoLife expects it would have thirty months to submit for a Premarket Approval (PMA), after which the FDA would determine if, and for how long, CryoLife could continue to provide these tissues to customers.

The Company currently plans to continue to process and ship its CryoValve SGPV tissues. However, if the FDA ultimately classifies CryoLife s CryoValve SGPV as a class III medical device, the Company anticipates it will request a meeting with the FDA to determine the specific requirements to file for and obtain a PMA and will determine an appropriate course of action in light of those requirements. The costs associated with obtaining, or attempting to obtain, a PMA could be material. Any delay in or failure to obtain a PMA, could materially, adversely affect the Company s preservation services revenues, financial condition, profitability, and/or cash flows in future periods.

See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Reclassification By The FDA Of CryoValve SGPV Would Result In Significant Risks And May Make It Commercially Infeasible To Continue Processing The CryoValve SGPV.

Critical Accounting Policies

A summary of the Company s significant accounting policies is included in Part II, Item 8, Note 1 of the Notes to Consolidated Financial Statements. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company s operating results and financial condition. The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. which require the Company to make estimates and assumptions. The following are accounting policies that management believes are most important to the portrayal of the Company s financial condition and results of operations and may involve a higher degree of judgment and complexity.

Fair Value Measurements

The Company records certain financial instruments at fair value, including: cash equivalents, certain marketable securities, certain restricted securities, contingent consideration, and derivative instruments. The Company may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis; although as of December 31, 2014 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

The Company also measures 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; and applying accounting for business combinations.

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The Company uses the fair value measurement framework to value these assets and reports these fair values in the periods in which they are recorded or written down.

The fair value measurement framework includes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data; and

Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available.

The determination of fair value and the assessment of a measurement s placement within the hierarchy requires judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Level 3 valuations may require the use of various cost, market, or income valuation methodologies applied to unobservable management estimates and assumptions. Management s 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. The Company may also engage external advisors to assist in determining fair value, as appropriate.

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

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations (OTPOs), which consign the tissue to the Company 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. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management estimates quarantine yields based on its experience and reevaluates these estimates periodically. Actual yields could differ significantly from the Company s 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.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company also evaluates its 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

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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 the Company s estimates change.

The Company recorded write-downs to its deferred preservation costs totaling $540,000, $448,000, and $195,000 for the years ended December 31, 2014, 2013, and 2012, respectively.

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. The Company periodically assesses the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance against its deferred tax assets when, as a result of this analysis, management believes it is more likely than not that some portion or all of its deferred tax assets will not be realized.

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

Projected future operating results;

Anticipated future state tax apportionment;

Timing and amounts of anticipated future taxable income;

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

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

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

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

The Company believes that the realizability of its acquired net operating loss carryforwards will be limited in future periods due to a change in control of its former subsidiaries Hemosphere, Inc. (Hemosphere) and Cardiogenesis Corporation (Cardiogenesis), as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisitions of these companies each constituted a change in control, and that prior to the Company s acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. The deferred tax assets recorded on the Company s Consolidated Balance Sheets do not include amounts that it expects 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 management believes it is more likely than not that these deferred tax assets will not be realized. Therefore, the Company recorded a valuation allowance against these state net operating loss carryforwards.

Valuation of Acquired Assets or Businesses

As part of its corporate strategy, the Company is seeking to identify and capitalize upon acquisition opportunities of complementary product lines and companies. The Company evaluates and accounts 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 significant judgment based on the weight of available evidence.

For the purchase of an asset group, the Company allocates 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. The Company accounts for business combinations by allocating the purchase price to the assets and liabilities acquired at their estimated fair value. 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.

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The Company typically engages external advisors to assist it 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. Management, in consultation with its advisor(s), makes these estimates based on its prior experiences and industry knowledge. Management believes that its estimates are reasonable, but actual results could differ significantly from the Company s estimates. A significant change in management s estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by the Company and, therefore, could materially impact the Company s financial position and profitability. If the value of the liabilities assumed by the Company, including contingent liabilities, is determined to be significantly different from the amounts previously recorded in purchase accounting, the Company may need to record additional expenses or write-downs in future periods, which could materially impact the Company s financial position and profitability.

New Accounting Pronouncements

In May 2014 the Financial Accounting Standards Board issued ASU No. 2014-09, *Revenue from Contracts with Customers,* which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard is effective for annual and interim reporting periods beginning after December 15, 2016, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2014-09 to have a material impact on its financial position, results of operations, or cash flows.

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Results of Operations

(In thousands)

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2014	**2013**	**2014**	**2013**
Products:				
BioGlue and BioFoam	$ 16,346	$ 14,766	44%	42%
PerClot	1,232	808	3%	2%
CardioGenesis cardiac laser therapy	2,151	2,128	6%	6%
HeRO Graft	1,827	1,668	5%	5%
ProCol	117		%	%
Total products	21,673	19,370	58%	55%
Preservation services:				
Cardiac tissue	7,456	7,488	20%	21%
Vascular tissue	8,022	8,599	22%	24%
Total preservation services	15,478	16,087	42%	45%
Total	$ 37,151	$ 35,457	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2014	**2013**	**2014**	**2013**
Products:				
BioGlue and BioFoam	$ 62,091	$ 58,004	43%	41%
PerClot	4,289	3,494	3%	3%
CardioGenesis cardiac laser therapy	8,225	8,965	6%	6%
HeRO Graft	7,131	5,731	5%	4%
ProCol	147		%	%
Total products	81,883	76,194	57%	54%
Preservation services:				
Cardiac tissue	29,437	29,523	20%	21%
Vascular tissue	33,321	34,975	23%	25%
Total preservation services	62,758	64,498	43%	46%
Other		71	%	%
Total	$ 144,641	$ 140,763	100%	100%

Revenues increased 5% and 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2014 is presented below.

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Products

Revenues from products increased 12% and 7% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. These increases were primarily due to an increase in BioGlue revenues and, to a lesser extent, an increase in PerClot and HeRO Graft revenues. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot; CardioGenesis cardiac laser therapy; and HeRO Graft is presented below.

The Company s sales of products through its direct sales force to U.K. hospitals are denominated in British Pounds, and its sales to German, Austrian, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. If the exchange rates between the U.S. Dollar and the British Pound and/or Euro decline materially in the future, this would have a material, adverse effect on the Company s revenues denominated in these currencies.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 11% for the three months ended December 31, 2014, as compared to the three months ended December 31, 2013. This increase was primarily due to a 12% increase in the volume of milliliters sold, which increased revenues by 10%, and an increase in average sales prices, which increased revenues by 2%, partially offset by the unfavorable impact of foreign exchange rates, which decreased revenues by 1%.

Revenues from the sale of surgical sealants increased 7% for the twelve months ended December 31, 2014, as compared to the twelve months ended December 31, 2013. This increase was primarily due to a 6% increase in the volume of milliliters sold, which increased revenues by 5%, and by an increase in average sales prices, which increased revenues by 2%.

The increase in sales volume of surgical sealants for the three and twelve months ended December 31, 2014 was primarily due to an increase in shipments of BioGlue in international markets and, to a lesser extent, an increase in the Company s domestic markets. International sales of BioGlue increased in all major market areas including Latin America, Asia Pacific, including Japan, and the Company s direct and indirect markets in Europe, which includes sales for neurosurgical indications.

The increase in average sales prices for the three and twelve months ended December 31, 2014 was primarily due to list price increases in domestic markets and due to the routine negotiation of pricing contracts with certain customers.

Revenues from shipments to Japan were $1.1 million and $5.0 million for the three and twelve months ended December 31, 2014, respectively, and $801,000 and $4.8 million for the three and twelve months ended December 31, 2013, respectively. The Company is currently seeking expanded indications for BioGlue in Japan and regulatory approval for BioGlue in China and, if these efforts are successful, management believes this will provide additional international growth opportunities for BioGlue in future years.

Domestic revenues accounted for 55% and 56% of total BioGlue revenues for the three and twelve months ended December 31, 2014, respectively, and 58% and 57% of total BioGlue revenues for the three and twelve months ended December 31, 2013, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2014 and 2013. BioFoam is currently approved for sale in certain international markets.

PerClot

Revenues from the sale of PerClot, including PerClot and PerClot Topical, increased 52% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. This increase was primarily due to an increase in the volume of grams sold, which increased revenues by 64%, partially offset by a decrease in average selling prices, which decreased revenues by 8%, and the unfavorable effect of foreign currency exchange, which decreased revenues by 4%.

Revenues from the sale of PerClot increased 23% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This increase was primarily due to an increase in the volume of grams sold, which increased revenues by 27%, and the favorable effect of foreign currency exchange, which increased revenues by less than 1%, partially offset by a decrease in average selling prices, which decreased revenues by 5%.

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Revenues during these three and twelve month periods were largely for sales in certain international markets, as PerClot Topical was only recently approved for domestic distribution, as discussed below. The increase in revenues for the three and twelve months ended December 31, 2014 was primarily due to increased sales in the Company s markets in Europe, Asia Pacific, and Latin America, partially due to growth in both new geographies and new surgical indications. The Company expects that overall PerClot revenues will increase in 2015 as compared to 2014; however, revenues may show some variability from quarter to quarter.

In April 2014 CryoLife received 510(k) clearance for PerClot Topical from the FDA, which allowed CryoLife to begin commercialization of PerClot Topical in the U.S. The Company began shipping PerClot Topical in August 2014 and is currently in the early stages of this product launch.

In December 2014 CryoLife received approval of the supplement to its investigational device exemption (IDE) for PerClot from the FDA that addressed several study design considerations previously raised by the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company plans to begin enrollment in the trial in the first half of 2015 and currently expects to receive PMA from the FDA during 2017.

CardioGenesis Cardiac Laser Therapy

Revenues from the Company s 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 increased 1% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. Revenues from the sale of laser consoles were $240,000 and $470,000 for the three months ended December 31, 2014 and 2013, respectively. Revenues from the sale of handpieces increased 17% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013, primarily due to a 19% increase in unit shipments of handpieces.

Revenues from cardiac laser therapy decreased 8% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. Revenues from the sale of laser consoles were $384,000 and $932,000 for the twelve months ended December 31, 2014 and 2013, respectively. Revenues from the sale of handpieces decreased 3% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This decrease was primarily due to a 4% decrease in unit shipments of handpieces, which decreased revenues by 5%, partially offset by an increase in average sales prices, which increased revenues by 2%.

Revenues from laser console sales decreased for both the three and twelve months ended December 31, 2014 due to both fewer laser console sales and a reduction in the average price paid per laser console as hospitals are increasingly reluctant to make large capital equipment purchases.

In June 2013 the FDA approved the Company s new handpiece design, and the Company made the decision to exclusively distribute the new handpiece beginning late in the second quarter of 2013. The Company s handpiece revenues were negatively impacted in the second half of 2013 and the first half of 2014, due to the slower than anticipated adoption of the new handpiece design. The decrease in handpiece revenues for the twelve months ended December 31, 2014 is a result of a decrease in revenues in the first half of 2014 as compared to the first half of 2013.

The Company expects that overall cardiac laser therapy revenues will increase slightly in 2015 as compared to 2014; however, revenues from laser console sales can vary significantly from quarter to quarter due to the long lead time required to generate sales of capital equipment.

HeRO Graft

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. HeRO Grafts are primarily distributed in domestic markets as a solution for ESRD in certain hemodialysis patients. HeRO Graft revenues increased 10% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. HeRO Grafts revenues increased 24% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013.

The increase in sales of HeRO Grafts for the three months ended December 31, 2014 was primarily due to an increase in shipments in direct markets in Europe. The increase in sales of HeRO Grafts for the twelve months ended December 31, 2014 was primarily due to an increase in shipments in domestic markets, as a result of increased procedure volume and an

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increase in the number of implanting physicians, and to a lesser extent, due to shipments to direct markets in Europe. Sales of the HeRO Graft have increased significantly in Europe since the Company launched the product in September 2013.

The Company expects that HeRO Graft revenues will increase in 2015 as compared to 2014. Although HeRO Graft revenues are subject to variability quarter to quarter due to the timing of surgical cases, the Company believes that this variability will continue to decrease as the Company broadens its base of implanting physicians.

Preservation Services

Revenues from preservation services decreased 4% and 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. The decrease in revenues for the three and twelve month periods was primarily due to a decrease in vascular tissue services revenues. See further discussion of cardiac and vascular preservation services revenues below.

During the second quarter of 2014 the Company voluntarily restricted the distribution of certain cardiac and vascular tissues while it performed a review of its internal training programs. The Company gradually resumed shipments of tissues during the second quarter of 2014, in accordance with its procedures.

The Company is making significant changes to various tissue processing and quality procedures in an effort to address the Warning Letter, 2012 CryoLife Form 483, and 2014 CryoLife Form 483 discussed in Regulatory Activities above. These efforts have resulted in a decrease in tissue processing throughput and an increase in the Company s cost of processing tissues. The Company continues to review and modify its procedures as part of these ongoing compliance efforts, and these efforts are expected to continue into 2015. Preservation services revenues were negatively impacted during the second, third, and fourth quarters of 2014 due to these efforts, as well as the internal training program review discussed above.

Preservation services revenues, particularly revenues for certain high-demand 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 of any specific items affecting cardiac and vascular preservation services revenues for the three and twelve months ended December 31, 2014 below.

Cardiac Preservation Services

Revenues from cardiac preservation services (consisting of revenues from the distribution of heart valves and cardiac patch tissues) decreased slightly for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. This decrease was primarily due to a 2% decrease in unit shipments of cardiac tissues, which decreased revenues by 5%, largely offset by an increase in average service fees, which increased revenues by 5%.

Revenues from cardiac preservation services decreased slightly for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This decrease was primarily due to a 4% decrease in unit shipments of cardiac tissues, which decreased revenues by 6%, largely offset by an increase in average service fees, which increased revenues by 6%.

The decrease in volume for the three and twelve months ended December 31, 2014 was primarily due to a decrease in volume of cardiac valve shipments in domestic markets and due to a significant decrease in cardiac shipments in Europe, as discussed further below, partially offset by an increase in shipments of cardiac patches in domestic markets. The decrease in cardiac valve shipments in domestic markets was due to the timing of tissue releases, which were unfavorably impacted by reduced tissue availability as discussed above, as compared to the prior year periods. The Company ceased the routine distribution of tissues into Europe as of March 31, 2014, although a limited number of tissues have shipped and may continue to be shipped through a special regulatory process. During the twelve months ended December 31, 2014 the Company s revenues from shipments of cardiac tissues into Europe were $253,000, as compared to $1.1 million in the corresponding period in 2013.

The increase in average service fees for the three and twelve months ended December 31, 2014 was primarily due to list fee increases in domestic markets in July 2014 and 2013 and due to the routine negotiation of pricing contracts with certain customers.

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Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 66% and 64% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2014, respectively, and 53% and 52% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2013, respectively. Domestic revenues accounted for 96% of total cardiac preservation services revenues for both the three and twelve months ended December 31, 2014, and 93% of total cardiac preservation services revenues for both the three and twelve months ended December 31, 2013.

The Company s cardiac valves are primarily used in cardiac replacement and reconstruction surgeries, including the Ross procedure, for patients with endocarditis or congenital heart defects.

The Company expects that overall cardiac preservation services revenues will increase slightly for the full year 2015 as compared to 2014; however, cardiac preservation services revenues will likely decrease in the first quarter of 2015 as compared to the first quarter of 2014 and then improve later in the year.

Vascular Preservation Services

Revenues from vascular preservation services decreased 7% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. This decrease was primarily due to a 12% decrease in unit shipments of vascular tissues, which decreased revenues by 12%, partially offset by an increase in average service fees, which increased revenues by 5%.

Revenues from vascular preservation services decreased 5% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This decrease was primarily due to a 10% decrease in unit shipments of vascular tissues, which decreased revenues by 11%, partially offset by an increase in average service fees, which increased revenues by 6%.

The decrease in vascular volume for the three and twelve months ended December 31, 2014 was primarily due to decreases in shipments of saphenous veins, which was impacted by reduced tissue availability as discussed above.

The increase in average service fees for the three and twelve months ended December 31, 2014 was primarily due to list fee increases in domestic markets in July 2014 and 2013, fee differences due to physical characteristics of vascular tissues, and the routine negotiation of pricing contracts with certain customers.

The majority of the Company s vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. These tissues are primarily distributed in domestic markets.

The Company expects that overall vascular preservation services revenues will increase slightly in 2015 as compared to 2014; however, vascular preservation services revenues will likely decrease in the first quarter of 2015 and then improve later in the year.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Cost of products	$ 5,068	$ 4,417	$ 17,167	$ 15,147

Cost of products increased 15% and 13% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Cost of products in 2014 and 2013 includes costs related to BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Grafts, and ProCol.

The increase in cost of products was primarily due to an increase in the volume of products sold, an increase in the per unit cost of manufacturing HeRO Grafts, as a result of the transfer of manufacturing to a new location and lower

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manufacturing throughput, and an increase in the cost of manufacturing BioGlue, partially offset by a decrease in inventory impairment charges and write-downs.

Cost of products for the twelve months ended December 31, 2013 included $483,000 in additional costs for CardioGenesis cardiac laser therapy handpieces that were made obsolete by the Company s decision to exclusively distribute the new handpiece design, which was approved by the FDA in June 2013. Cost of products for the three and twelve months ended December 31, 2013 included $684,000 in additional contractual costs and inventory impairment costs primarily related to a BioGlue accessory product.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Cost of preservation services	$ 9,448	$ 8,758	$ 36,183	$ 35,230

Cost of preservation services increased 8% and 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The increase in cost of preservation services was primarily due to an increase in the per unit cost of processing tissues, as a result of lower processing throughput of tissues, increased compliance and personnel costs, and an increase in the cost of materials, partially offset by a decrease in volume of tissues shipped during the period. The higher per unit cost of processing tissues is expected to continue into 2015.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Gross margin	$ 22,635	$ 22,282	$ 91,291	$ 90,386
Gross margin as a percentage of total revenues	61%	63%	63%	64%

Gross margin increased 2% and 1% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Gross margin as a percentage of total revenues decreased in the three and twelve months ended December 31, 2014 as compared to the three and twelve months ended December 31, 2013, respectively, primarily due to an increase in the per unit cost of processing tissues, partially offset by a mix shift as a higher percentage of the Company s revenues were related to products, which generate higher margins.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
General, administrative, and marketing expenses	$ 18,638	$ 16,671	$ 73,754	$ 68,112
General, administrative, and marketing expenses as a percentage of total revenues	50%	47%	51%	48%

General, administrative, and marketing expenses increased 12% and 8% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively.

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The increase in general, administrative, and marketing expenses in the current year periods was due to $565,000 and $2.0 million for the three and twelve months ended December 31, 2014, respectively, in compensation charges related to personnel changes, including the appointment of Mr. Mackin as President and CEO in the third quarter of 2014 and one-time expenses associated with certain employee departures. In addition, the increase was due to higher legal fees related to the litigation with C.R. Bard, Inc. (Bard) and certain of its subsidiaries, higher professional fees related to FDA compliance, and higher expenses to support the Company s increasing revenue base, international expansion, new product offerings, and increasing employee headcount.

The Company expects that its general, administrative, and marketing expenses will increase for the full year 2015, as compared to 2014 due to the factors discussed above. In addition, the effects of business development expenses and/or legal fees could further increase expenses. See Part I, Item 3, Legal Proceedings, for discussion of the Company s litigation with Bard. Management expects that this litigation will be protracted and will result in significant costs during 2015.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Research and development expenses	$ 2,092	$ 2,478	$ 8,699	$ 8,454
Research and development expenses as a percentage of total revenues	6%	7%	6%	6%

Research and development expenses decreased 16% and increased 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Research and development spending in these periods was primarily focused on clinical and pre-clinical work with respect to PerClot, the Company s tissue processing, and BioGlue and BioFoam.

The Company expects that research and development spending will increase materially in 2015 due to planned increases in spending on the PerClot clinical study.

Gain on Sale of Medafor Investment

The gain on sale of Medafor, Inc. (Medafor) investment was $530,000 for the three and twelve months ended December 31, 2014 as compared to $12.7 million for the three and twelve months ended December 31, 2013. This gain was recorded upon the sale of the Company s 2.4 million shares of Medafor common stock to Bard in connection with its October 2013 acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately $15.4 million in the fourth quarter of 2013, and it received an additional payment of $530,000 in the fourth quarter of 2014 related to the release of funds in escrow. The Company could receive additional payments totaling up to an additional $7.9 million upon the final release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. Subsequent payments will be recorded as an additional gain if and when received by the Company. See also Part I, Item 1A, Risk Factors Risks Relating to Our Business Although We May Receive Additional Cash In The Future Related To Medafor s Earnout And Release Of Escrow Funds Related To Bard s Acquisition of Medafor, It Is Possible We May Not Receive Any Additional Monies, Or The Amount Of The Additional Monies Received Could Be Significantly Less Than We Anticipate.

Other Than Temporary Investment Impairment

Based on available information, the Company determined that the fair value of its investment in ValveXchange, Inc. (ValveXchange) preferred stock had declined significantly in the fourth quarter of 2013 and that any of that remaining value was nominal. Therefore, the Company recorded an other than temporary investment impairment of $3.2 million for the three and twelve months ended December 31, 2013 to fully impair the value of its investment. The carrying value of the Company s investment in ValveXchange preferred stock after this write-down was zero as of December 31, 2013.

Other Expense (Income)

Other expense (income) for the three and twelve months ended December 31, 2014 includes $2.0 million in expense to write-down the Company s long-term note receivable from ValveXchange, as this loan became fully impaired during the

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fourth quarter of 2014. This expense was largely offset by a gain of $1.4 million and $1.9 million for the three and twelve months ended December 31, 2014, respectively, on the remeasurement of contingent consideration related to the Company s acquisition of Hemosphere. During the fourth quarter of 2014 the Company s estimate of the likelihood of achieving the minimum revenue target to trigger this payment became remote.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Income before income taxes	$ 1,625	$ 12,881	$ 8,703	$ 23,292
Income tax (benefit) expense	(151)	3,855	1,381	7,120
Net income	$ 1,776	$ 9,026	$ 7,322	$ 16,172
Diluted income per common share	$ 0.06	$ 0.31	$ 0.25	$ 0.57
Diluted weighted-average common shares outstanding	28,238	28,208	28,313	27,698

Income before income taxes decreased significantly for the three and twelve months ended December 31, 2014 as compared to the three and twelve months ended December 31, 2013, respectively. This decrease was primarily due to the gain on sale of Medafor investment recorded in the fourth quarter of 2013 and an increase in operating expenses, as discussed above, partially offset by an increase in product revenues, which increased margins.

The Company s effective income tax rate was a benefit of 9% and expense of 16% for the three and twelve months ended December 31, 2014, respectively, as compared to expense of 30% and 31% for the three and twelve months ended December 31, 2013, respectively. The Company s income tax rate for the three and twelve months ended December 31, 2014 was favorably affected by the reduction in uncertain tax positions, nontaxable gains recorded as change in stock basis of subsidiary, and favorable deductions taken on the Company s 2013 federal tax return, which was filed in 2014. The Company s income tax rate for the twelve months ended December 31, 2013 was favorably affected by the full year 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company s tax expense during 2013 and adjustments to valuation allowances on certain of the Company s state net operating loss carryforwards, based on revised estimates of utilization of these carryforwards.

Net income and diluted income per common share decreased for the three and twelve months ended December 31, 2014 as compared to the three and twelve months ended December 31, 2013, primarily due to the decrease in income before income taxes, partially offset by a reduction in income tax expense, as discussed above.

Diluted income per common share could be unfavorably affected in future periods by the issuance of additional shares of common stock and favorably affected by the Company s repurchase of its common stock. Stock repurchases are influenced by many factors, including: stock price, available funds, and competing demands for such funds, and as a result, may be suspended or discontinued at any time. The Company s most recent repurchase authorization expired October 31, 2014.

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Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2013	2012	2013	2012
Products:				
BioGlue and BioFoam	$ 14,766	$ 13,353	42%	41%
PerClot	808	1,009	2%	3%
CardioGenesis cardiac laser therapy	2,128	1,985	6%	6%
HeRO Graft	1,668	1,106	5%	3%
Total products	19,370	17,453	55%	53%
Preservation services:				
Cardiac tissue	7,488	7,094	21%	22%
Vascular tissue	8,599	8,138	24%	25%
Total preservation services	16,087	15,232	45%	47%
Other		115	%	%
Total	$ 35,457	$ 32,800	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2013	2012	2013	2012
Products:				
BioGlue and BioFoam	$ 58,004	$ 53,211	41%	41%
PerClot	3,494	3,078	3%	2%
CardioGenesis cardiac laser therapy	8,965	8,092	6%	6%
HeRO Graft	5,731	3,115	4%	2%
Total products	76,194	67,496	54%	51%
Preservation services:				
Cardiac tissue	29,523	29,756	21%	23%
Vascular tissue	34,975	33,847	25%	26%
Total preservation services	64,498	63,603	46%	49%
Other	71	619	%	%
Total	$ 140,763	$ 131,718	100%	100%

Revenues increased 8% and 7% for the three and twelve months ended December 31, 2013, respectively, as compared to the three and twelve months ended December 31, 2012, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2013 is presented below.

Products

Revenues from products increased 11% and 13% for the three and twelve months ended December 31, 2013, respectively, as compared to the three and twelve months ended December 31, 2012, respectively. These increases were primarily due to an increase in BioGlue revenues, and to a lesser extent due to the addition of HeRO Graft revenues as a result of the Company s acquisition of Hemosphere in the second quarter of 2012. A detailed discussion of the changes in

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product revenues for BioGlue and BioFoam; PerClot; CardioGenesis cardiac laser therapy; and HeRO Graft is presented below.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 11% for the three months ended December 31, 2013, as compared to the three months ended December 31, 2012. This increase was primarily due to a 12% increase in the volume of milliliters sold, which increased revenues by 8%, an increase in average sales prices, which increased revenues by 2%, and the favorable impact of foreign exchange rates, which increased revenues by 1%.

Revenues from the sale of surgical sealants increased 9% for the twelve months ended December 31, 2013, as compared to the twelve months ended December 31, 2012. This increase was primarily due to a 9% increase in the volume of milliliters sold, which increased revenues by 7%, and by an increase in average sales prices, which increased revenues by 2%.

The increase in sales volume of surgical sealants for the three months ended December 31, 2013 was primarily due to an increase in shipments of BioGlue in certain international markets and, to a lesser extent, an increase in the Company s domestic markets. The increase in sales volume of surgical sealants for the twelve months ended December 31, 2013 was due to an increase in shipments of BioGlue in certain international markets, partially offset by a volume decrease in the Company s domestic markets. The increase in international sales of BioGlue was primarily due to increased sales to Japan, to direct markets in Europe, including sales for neurological indications, and to Latin America.

The increase in average sales prices for the three and twelve months ended December 31, 2013 was primarily due to list price increases in domestic markets and due to the routine negotiation of pricing contracts with certain customers.

Revenues from shipments to Japan were $801,000 and $697,000 for the three months ended December 31, 2013 and 2012, respectively, and $4.8 million and $4.1 million for the twelve months ended December 31, 2013 and 2012, respectively.

Management believes that the decrease in BioGlue shipments in its domestic markets for the twelve months ended December 31, 2013 was a result of various factors, including: continued economic pressures on hospitals and the resulting attempts by hospitals to control costs by reducing spending on consumable items such as BioGlue, the efforts of some large competitors in imposing and enforcing contract purchasing requirements for competing non-CryoLife products, and the U.S. market introduction of sealant products with approved indications for use in clinical applications in which BioGlue has been used off-label previously. However, the Company saw the effect of these factors on its domestic BioGlue shipments slow in both the third and fourth quarters of 2013 as domestic shipments showed a 2% increase in the volume of milliliters sold over the same quarters in 2012.

Domestic revenues accounted for 58% and 57% of total BioGlue revenues for the three and twelve months ended December 31, 2013, respectively, and 61% and 60% of total BioGlue revenues for the three and twelve months ended December 31, 2012, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2013. BioFoam is approved for sale in certain international markets.

PerClot

Revenues from the sale of PerClot decreased 20% for the three months ended December 31, 2013 as compared to the three months ended December 31, 2012. This decrease was primarily due to a 28% decrease in the volume of grams sold, which decreased revenues by 23%, partially offset by the favorable effect of foreign currency exchange, which increased revenues by 2%, and an increase in average selling prices, which increased revenues by 1%.

Revenues from the sale of PerClot increased 14% for the twelve months ended December 31, 2013 as compared to the twelve months ended December 31, 2012. This increase was primarily due to an increase in the volume of grams sold, which increased revenues by 14%.

Revenues during these three and twelve month periods were for sales in certain international markets, as PerClot was not yet approved for domestic distribution or widespread international distribution. The decrease in revenues for the three months ended December 31, 2013 was primarily due to fluctuating ordering patterns in certain countries, which can result in some variability in sales from quarter to quarter. The increase in revenues for the twelve months ended December 31, 2013 was primarily due to increased sales in the Company s markets in Europe, partially due to growth in both new geographies and new surgical indications.

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CardioGenesis Cardiac Laser Therapy

Revenues from CardioGenesis cardiac laser therapy includes revenues related primarily to the sale of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from cardiac laser therapy increased 7% for the three months ended December 31, 2013 as compared to the three months ended December 31, 2012. Revenues from the sale of laser consoles were $470,000 and zero for the three months ended December 31, 2013 and 2012, respectively. Revenues from the sale of handpieces decreased 18% for the three months ended December 31, 2013 as compared to the three months ended December 31, 2012. This decrease was primarily due to a 25% decrease in unit shipments of handpieces, which decreased revenues by 26%, partially offset by an increase in average sales prices, which increased revenues by 8%.

Revenues from cardiac laser therapy increased 11% for the twelve months ended December 31, 2013 as compared to the twelve months ended December 31, 2012. Revenues from the sale of laser consoles were $932,000 and $279,000 for the twelve months ended December 31, 2013 and 2012, respectively. Revenues from the sale of handpieces increased 5% for the twelve months ended December 31, 2013 as compared to the twelve months ended December 31, 2012. This increase was primarily due to an increase in average sales prices, which increased revenues by 8%, partially offset by a 3% decrease in unit shipments of handpieces, which decreased revenues by 3%.

In June 2013 the FDA approved the Company s new handpiece design, and the Company made the decision to exclusively distribute the new handpiece beginning late in the second quarter of 2013. The decrease in handpiece volume for the three and twelve months ended December 31, 2013 was primarily due to the slower than anticipated rollout and adoption of the new handpiece design.

HeRO Graft

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. HeRO Grafts are primarily distributed in domestic markets as a solution for ESRD in certain hemodialysis patients. HeRO Graft revenues for the three months ended December 31, 2013 increased 51% when compared to the three months ended December 31, 2012. Revenues from HeRO Grafts for the twelve months ended December 31, 2013 increased significantly over the corresponding period in 2012 as HeRO Grafts were not marketed by the Company for the full prior year period. The Company began marketing HeRO Grafts following its acquisition of Hemosphere in May 2012. HeRO Graft revenues for the twelve months ended December 31, 2013 increased 12% when compared to the combined pre- and post-acquisition revenues for the twelve months ended December 31, 2012.

This increase was primarily due to an increase in procedure volume and an increase in the number of implanting physicians.

Preservation Services

Revenues from preservation services increased 6% and 1% for the three and twelve months ended December 31, 2013, respectively, as compared to the three and twelve months ended December 31, 2012, respectively. The increase in revenues for the three month period was due to an increase in both cardiac and vascular tissue services revenues. The increase in revenues for the twelve month period was due to an increase in vascular tissue services revenues, partially offset by a decrease in cardiac tissue services revenues. See further discussion of cardiac and vascular preservation services revenues below.

Cardiac Preservation Services

Revenues from cardiac preservation services (consisting of revenues from the distribution of heart valves and cardiac patch tissues) increased 6% for the three months ended December 31, 2013 as compared to the three months ended December 31, 2012. This increase was primarily due to an increase in average service fees, which increased revenues by 5%.

Revenues from cardiac preservation services decreased 1% for the twelve months ended December 31, 2013 as compared to the twelve months ended December 31, 2012. This decrease was primarily due to a 7% decrease in unit shipments of cardiac tissues, which decreased revenues by 4%, partially offset by an increase in average service fees, which increased revenues by 3%.

The increase in average service fees for the three and twelve months ended December 31, 2013 was primarily due to list fee increases in domestic markets in November 2012 and July 2013, and due to the routine negotiation of pricing contracts with certain customers.

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Unit shipments of cardiac tissues into Europe decreased for the twelve months ended December 31, 2013 as a result of the U.K. s Human Tissue Authority (HTA s) letter suspending CryoLife s license to distribute tissue in Europe. As tissues distributed in Europe generate lower average fees than tissues distributed in the U.S., the decrease in unit shipments did not result in a proportional decrease in cardiac preservation services revenues. For the three months ended December 31, 2013 the decrease in shipments to Europe was offset by increased shipments in the U.S. The Company s revenues from shipments of cardiac tissues into Europe under the special access variance allowed by the HTA were $249,000 and $1.1 million for the three and twelve months ended December 31, 2013, respectively, as compared to revenues of $409,000 and $1.8 million for the three and twelve months ended December 31, 2012, respectively. The Company ceased the distribution of tissue into Europe as of March 31, 2014.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 53% and 52% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2013, respectively, and 50% and 47% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2012, respectively. Domestic revenues accounted for 93% of total cardiac preservation services revenues for both the three and twelve months ended December 31, 2013, and 90% of total cardiac preservation services revenues for both the three and twelve months ended December 31, 2012.

The Company s cardiac valves are primarily used in cardiac replacement and reconstruction surgeries, including the Ross procedure, for patients with endocarditis or congenital heart defects.

Vascular Preservation Services

Revenues from vascular preservation services increased 6% for the three months ended December 31, 2013 as compared to the three months ended December 31, 2012. This increase was primarily due to an increase in average service fees, which increased revenues by 9%, partially offset by a 4% decrease in unit shipments of vascular tissues, which decreased revenues by 3%.

Revenues from vascular preservation services increased 3% for the twelve months ended December 31, 2013 as compared to revenues for the twelve months ended December 31, 2012. This increase was primarily due to an increase in average service fees, which increased revenues by 7%, partially offset by a 5% decrease in unit shipments of vascular tissues, which decreased revenues by 4%.

The increase in average service fees for the three and twelve months ended December 31, 2013 was primarily due to list fee increases in domestic markets in November 2012 and July 2013, fee differences due to physical characteristics of vascular tissues, and the routine negotiation of pricing contracts with certain customers.

The decrease in vascular volume for the three and twelve months ended December 31, 2013 was primarily due to decreases in shipments of saphenous veins. The Company believes that the decrease in unit shipments of veins was primarily due to the timing of tissue releases for shipments to domestic markets as compared to the prior year periods, which can vary as discussed above.

The majority of the Company s vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. These tissues are primarily distributed in domestic markets.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Cost of products	$ 4,417	$ 3,080	$ 15,147	$ 11,380

Cost of products increased 43% and 33% for the three and twelve months ended December 31, 2013, respectively, as compared to the three and twelve months ended December 31, 2012, respectively. Cost of products in 2013 and 2012 included costs related to BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, and HeRO Grafts.

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Cost of products for the twelve months ended December 31, 2013 included $483,000 in additional costs for CardioGenesis cardiac laser therapy handpieces that were made obsolete by the Company s decision to exclusively distribute the new handpiece design, which was approved by the FDA in June 2013. Cost of products for the three and twelve months ended December 31, 2013 included $684,000 in additional contractual costs and inventory impairment costs primarily related to a BioGlue accessory product.

The increase in cost of products in the three and twelve months ended December 31, 2013 was primarily due to the write-offs discussed above and due to an increase in sales volume of BioGlue and HeRO Grafts.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Cost of preservation services	$ 8,758	$ 8,675	$ 35,230	$ 35,320

Cost of preservation services increased 1% for the three months ended December 31, 2013 as compared to the three months ended December 31, 2012. Cost of preservation services for the twelve months ended December 31, 2013 was consistent with costs for the twelve months ended December 31, 2012. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services in 2013 was affected by an increase in the per-unit cost of processing tissues and by a decrease in volume of tissues shipped during the period. These largely offset during the three and twelve months ended December 31, 2013. The increase in tissue processing costs includes the write-down of certain cardiac tissues designated for distribution in international markets in the first half of 2013 and the write-down of certain vascular tissues in the fourth quarter of 2013, as these tissues were not expected to ship prior to the expiration date of their packaging.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Gross margin	$ 22,282	$ 21,045	$ 90,386	$ 85,018
Gross margin as a percentage of total revenues	63%	64%	64%	65%

Gross margin increased 6% for both the three and twelve months ended December 31, 2013 as compared to the three and twelve months ended December 31, 2012, respectively. Gross margin increased primarily due to an increase in product revenues during the 2013 periods. To a lesser extent, gross margins for the three months ended December 31, 2013 were favorably affected by increases in fees on preservation services and unfavorably affected by additional product costs and write-downs discussed above. Gross margin as a percentage of total revenues in the three and twelve months ended December 31, 2013 was comparable to the three and twelve months ended December 31, 2012, respectively.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
General, administrative, and marketing expenses	$ 16,671	$ 16,775	$ 68,112	$ 65,149
General, administrative, and marketing expenses as a percentage of total revenues	47%	51%	48%	49%

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General, administrative, and marketing expenses decreased 1% for the three months ended December 31, 2013 as compared to the three months ended December 31, 2012. General, administrative, and marketing expenses increased 5% for the twelve months ended December 31, 2013, as compared to the twelve months ended December 31, 2012.

General, administrative, and marketing expenses for the twelve months ended December 31, 2013 included marketing expenses of the expanded sales staff and costs related to the transfer of HeRO Graft manufacturing operations, which were not present in the full corresponding prior year period, due to the acquisition of Hemosphere in May 2012. Medical device excise taxes were $264,000 and $1.0 million for the three and twelve months ended December 31, 2013, respectively, and zero for both the three and twelve months ended December 31, 2012.

General, administrative, and marketing expenses for the twelve months ended December 31, 2012 included a $4.7 million gain on the settlement of the Medafor lawsuit and a $4.1 million loss for the settlement of the lawsuit with CardioFocus, Inc. (CardioFocus) related to patent infringement by the Company s Cardiogenesis laser products. Both of these lawsuits were settled in the second quarter of 2012. Legal fees related to lawsuits, primarily the Medafor and CardioFocus lawsuits, were $3.9 million for the twelve months ended December 31, 2012, and reductions to legal fees for insurance reimbursements for certain litigation expenses were $3.4 million for the twelve months ended December 31, 2012. Business development costs, primarily related to the acquisition and integration of Hemosphere, were $790,000 and $2.7 million for the three and twelve months ended December 31, 2012, respectively.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Research and development expenses	$ 2,478	$ 2,065	$ 8,454	$ 7,257
Research and development expenses as a percentage of total revenues	7%	6%	6%	6%

Research and development expenses increased 20% for the three months and 16% for the twelve months ended December 31, 2013 as compared to the three and twelve months ended December 31, 2012, respectively. Research and development spending in these periods was primarily focused on PerClot, the Company s tissue processing, CardioGenesis cardiac laser therapy, and BioGlue and BioFoam. The increase in research and development expenses for the three and twelve months ended December 31, 2013 was primarily due to planned increases in spending related to PerClot clinical trial development efforts, clinical trial start-up, and non-clinical evaluations.

Gain on Sale of Medafor Investment

The gain on sale of Medafor investment was $12.7 million for the three and twelve months ended December 31, 2013. This gain was recorded upon the sale of the Company s 2.4 million shares of Medafor common stock to Bard in connection with its October 2013 acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately $15.4 million in the fourth quarter of 2013.

Other Than Temporary Investment Impairment

Based on available information the Company determined that the fair value of its investment in ValveXchange preferred stock had declined significantly in the fourth quarter of 2013 and that any of that remaining value was nominal. Therefore, the Company recorded an other than temporary investment impairment of $3.2 million for the three and twelve months ended December 31, 2013 to fully impair the value of its investment. The carrying value of the Company s investment in ValveXchange preferred stock after this write-down was zero as of December 31, 2013.

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Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Income before income taxes	$ 12,881	$ 2,242	$ 23,292	$ 12,052
Income tax expense	3,855	159	7,120	4,106
Net income	$ 9,026	$ 2,083	$ 16,172	$ 7,946
Diluted income per common share	$ 0.31	$ 0.07	$ 0.57	$ 0.28
Diluted weighted-average common shares outstanding	28,208	27,357	27,698	27,411

Income before income taxes increased significantly for the three and twelve months ended December 31, 2013 as compared to the three and twelve months ended December 31, 2012, respectively. This increase was primarily due to the gain on sale of Medafor investment as discussed above and to a lesser extent due to an increase in product revenues, which increased margins, partially offset by an increase in operating expenses, as discussed above.

The Company s effective income tax rate was approximately 30% and 31% for the three and twelve months ended December 31, 2013, respectively, as compared to 7% and 34% for the three and twelve months ended December 31, 2012, respectively. The Company s income tax rate for the twelve months ended December 31, 2013 was favorably affected by the full year 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company s tax expense during the first quarter of 2013 and adjustments to valuation allowances on certain of the Company s state net operating loss carryforwards, based on revised estimates of utilization of these carryforwards. The Company s income tax rates for the three and twelve months ended December 31, 2012 were favorably affected by $427,000 in adjustments to valuation allowances on certain of the Company s state net operating loss carryforwards, based on revised estimates of utilization of these carryforwards, and unfavorably affected by the tax treatment of certain acquisition related expenses due to the acquisition of Hemosphere and by the research and development tax credit, which had not been enacted for the 2012 tax year.

Net income and diluted income per common share increased for the three and twelve months ended December 31, 2013 as compared to the three and twelve months ended December 31, 2012, primarily due to the increase in income before income taxes, as discussed above.

Seasonality

The Company believes the demand for BioGlue is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to the summer holiday season in Europe and in the U.S. The Company believes 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.

The Company is uncertain whether the demand for its PerClot products will be seasonal, as these are a newer product that have not fully penetrated most markets and, therefore, the nature of any seasonal trends in PerClot sales may be obscured.

The Company does not believe the demand for CardioGenesis cardiac laser therapy and HeRO Grafts is seasonal, as the Company s data does not indicate a significant trend.

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

The Company s demand for its vascular preservation services is seasonal, with lowest demand generally occurring in the fourth quarter. Management believes this trend for vascular preservation services is primarily due to fewer vascular surgeries being scheduled during the winter holiday months.

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Liquidity and Capital Resources

Net Working Capital

At December 31, 2014 net working capital (current assets of $106.0 million less current liabilities of $20.6 million) was $85.4 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $85.6 million and a current ratio of 5 to 1 at December 31, 2013.

Overall Liquidity and Capital Resources

The Company s largest cash requirement for the twelve months ended December 31, 2014 was cash for general working capital needs, as certain of the Company s current asset balances increased significantly from December 31, 2013. These increases are primarily due to increases in purchased finished goods and raw materials inventory, increases in receivable balances, and cash advances related to the Company s new ProCol product line. In addition, the Company s other cash requirements included common stock repurchases, capital expenditures, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves and its operating activities, which generated cash during the period.

The Company believes that its cash from operations and existing cash and cash equivalents will enable the Company to meet its current operational liquidity needs for at least the next twelve months. The Company s future cash requirements are expected to include cash to fund the startup of the PerClot clinical trials, to fund the litigation against Bard, to fund the cash dividend to common shareholders, to fund additional research and development expenditures, for general working capital needs, for capital expenditures, to fund business development activities, and for other corporate purposes. These items may have a significant effect on the Company s cash flows during 2015. The Company may seek additional borrowing capacity or financing, pursuant to its current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If the Company undertakes further significant business development activity in 2015, it may need to finance such activities by drawing down monies under its credit agreement, discussed below, obtaining additional debt financing, or using a shelf registration statement to sell equities.

Significant Sources and Uses of Liquidity

On September 26, 2014 CryoLife amended and restated its credit agreement with General Electric Capital Corporation (GE Capital), extending the expiration date and amending other terms, which are discussed further below. CryoLife s amended and restated credit agreement with GE Capital (the GE Credit Agreement) provides revolving credit for working capital, acquisitions, and general corporate purposes. The GE Credit Agreement has a borrowing capacity of $20.0 million (including a letter of credit subfacility and a swingline subfacility) and expires on September 26, 2019. The commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. The GE Credit Agreement also permits CryoLife to request a term loan in an aggregate amount of up to $25.0 million to finance or refinance the purchase price of a permitted acquisition. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least $5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company s liquidity needs during the term of the GE Credit Agreement and, as such, have been recorded as long-term restricted cash on the Company s Consolidated Balance Sheets. Also, the GE Credit Agreement requires that, after giving effect to stock repurchases, the Company maintain liquidity, as defined in the agreement, of at least $20.0 million. As of December 31, 2014 the outstanding balance under the GE Credit Agreement was zero, and $20.0 million was available for borrowing.

On October 1, 2013 Bard completed its previously announced acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately $15.4 million in the fourth quarter of 2013 for its shares of Medafor common stock due to Bard s acquisition of Medafor, and received an additional payment of $530,000 in the fourth quarter of 2014 related to the release of funds in escrow. Based on information provided by Medafor as part of its September 24, 2013 Proxy Statement, the Company could receive additional payments totaling up to an additional $7.9 million upon the final release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. Subsequent payments will be recorded as an additional gain if, and when, received by the Company.

As discussed in Part I, Item 3, Legal Proceedings, of this Form 10-K, the Company is engaged in litigation with Bard and certain of its subsidiaries. Management expects that this litigation will be protracted and will result in significant costs during 2015.

In April 2014 CryoLife received 510(k) clearance for PerClot Topical from the FDA, which allowed CryoLife to begin commercialization of PerClot Topical in the U.S. The Company began shipping PerClot Topical in August 2014 and is

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currently in the early stages of this product launch. As a result of this recent approval and clearance, CryoLife paid $1.0 million to SMI in the second quarter of 2014 pursuant to the terms of the agreements between CryoLife and SMI.

In December 2014 CryoLife received approval of the supplement to its IDE for PerClot from the FDA that addressed several study design considerations previously raised by the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company plans to begin enrollment in the trial in the first half of 2015 and currently expects to receive PMA from the FDA during 2017. Management believes that the costs of this clinical trial will be significant in 2015.

In March 2014 CryoLife acquired the exclusive worldwide distribution rights for ProCol from Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). CryoLife made payments to Hancock Jaffe under the distribution arrangement of $1.7 million during 2014 and $576,000 in January 2015. The Company began limited distribution of ProCol in the second quarter of 2014, and began to distribute newly manufactured product in the fourth quarter of 2014.

During 2012 the Company advanced a total of $2.0 million in debt financing to ValveXchange through a revolving credit facility (the Loan). The Loan is secured by substantially all of the tangible and intangible assets of ValveXchange. In December 2014 CryoLife notified ValveXchange that it was in breach of the terms of the Loan, and in January 2015, after ValveXchange failed to cure this breach, CryoLife accelerated all the amounts due under the Loan. In January 2015 ValveXchange informed CryoLife management of its intent to file for bankruptcy. If ValveXchange does file for bankruptcy, the bankruptcy process is expected to be lengthy, and the ultimate disposition of CryoLife s claim for amounts it is owed under the Loan is uncertain. Given this fact pattern, CryoLife believes that its Loan became fully impaired in the fourth quarter of 2014. As a result, during the three months ended December 31, 2014 the Company recorded other non-operating expense of $2.0 million to write-down its long-term note receivable from ValveXchange.

In the twelve months ended December 31, 2014 the Company purchased approximately 585,000 shares of its common stock for an aggregate purchase price of $5.6 million. The Company s common stock repurchase program authorized by the Company s Board of Directors expired on October 31, 2014.

The Company acquired net operating loss carryforwards from its acquisitions of Hemosphere, Inc. and Cardiogenesis Corporation that the Company believes will reduce required cash payments for federal income taxes by approximately $1.5 million for the 2014 tax year.

As of December 31, 2014 approximately 10% of the Company s cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $8.1 million for the twelve months ended December 31, 2014 as compared to $16.8 million for the twelve months ended December 31, 2013. The decrease in net cash provided is primarily due to a reduction in net income due to the $12.7 million gain on the sale of Medafor common stock recorded in 2013, as discussed in Results of Operations above, and an increase in working capital needs, as discussed further below.

The Company uses the indirect method to prepare its cash flow statement, and, accordingly, the operating cash flows are based on the Company s 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, 2014 these items included a favorable $6.0 million in depreciation and amortization expense and $3.4 million in non-cash compensation.

The Company s working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the twelve months ended December 31, 2014 the increase in working capital needs of $8.5 million was primarily due to the timing difference between recording receivables and the receipt of cash and $2.8 million in prepaid expenses and other assets, for which payments have already been made.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $5.4 million for the twelve months ended December 31, 2014 as compared to cash provided of $10.9 million for the twelve months ended December 31, 2013. The current year cash used was primarily due to $4.3 million in capital expenditures. The prior year cash provided was primarily due to $15.4 million in proceeds from the sale of the Company s Medafor common stock.

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Net Cash Flows from Financing Activities

Net cash used in financing activities was $7.0 million for the twelve months ended December 31, 2014 as compared to $3.1 million for the twelve months ended December 31, 2013. The current year cash used was primarily due to $5.6 million in purchases of treasury stock related to the Company s publicly announced stock repurchase plan and $3.3 million in cash dividends paid on the Company s common stock, and, partially offset by $2.7 million in proceeds from the exercise of stock options and the issuance of common stock under the Company s employee stock purchase plan. The prior year cash used was primarily due to $3.0 million in dividends paid on the Company s common stock.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of December 31, 2014 are as follows (in thousands):

	Total	2015	2016	2017	2018	2019	Thereafter
Operating leases	$ 27,319	$ 3,073	$ 3,364	$ 3,431	$ 3,486	$ 3,460	$ 10,505
Purchase commitments	4,466	2,085	1,661				
Contingent payments	1,000			1,000			
Compensation payments	1,985			1,985			
Research obligations	2,318	2,074	244				
Total contractual obligations	$ 37,088	$ 7,952	$ 5,269	$ 6,416	$ 3,486	$ 3,460	$ 10,505

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

The Company s purchase commitments include minimum purchase requirements for PerClot related to the Company s transaction with SMI. These minimum purchases are included through 2016, which assumes that the Company receives FDA approval for PerClot during 2017. Upon FDA approval, the Company may terminate its minimum purchase requirements, per the terms of its agreements with SMI, which the Company expects to do. However, if the Company does not terminate this provision, it will have minimum purchase obligations of up to $1.75 million per year through the end of the contract term in 2025. The Company s purchase commitments includes obligations from agreements with suppliers.

The contingent payments obligation include payments that the Company will make if certain FDA regulatory approvals and other commercial milestones are achieved related to the Company s transaction with SMI for PerClot.

The Company s compensation payment obligations represent estimated payments for post-employment benefits for Mr. Steven G. Anderson, the Company s former President and CEO and current Executive Chairman. The timing of Mr. Anderson s post-employment benefits, for purposes of the schedule above, is based on the December 2016 expiration date of his current employment agreement; however, payment of these benefits may be accelerated upon the occurrence of certain events, including Mr. Anderson s voluntary retirement, for which he is currently eligible, or his termination in conjunction with certain change in control events or without cause.

The Company s research obligations represent commitments for ongoing studies and payments to support research and development activities and largely represent commitments related to the PerClot pivotal clinical trial.

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, (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $1.8 million, as no specific assessments by any taxing authorities, and (iii) contingent payment obligations of up to $4.5 million related to the Company s acquisition of Hemosphere, Inc. as the Company does not currently anticipate triggering these contingent payments.

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Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2014 and 2013 were $4.3 million. Capital expenditures in the twelve months ended December 31, 2014 were primarily related to the routine purchases of manufacturing and tissue processing equipment, including support for the Company s HeRO Graft and PerClot product lines; leasehold improvements needed to support the Company s business; CardioGenesis cardiac laser therapy laser consoles; computer software; and computer and office equipment.

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

Interest Rate Risk

The Company s 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 the Company s cash and cash equivalents of $33.4 million, restricted cash and securities of $5.0 million, and interest paid on the Company s variable rate line of credit as of December 31, 2014. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the twelve months ended December 31, 2014, affecting the Company s cash and cash equivalents, restricted cash, and line of credit would not have had a material impact on the Company s financial position, profitability, or cash flows.

Foreign Currency Exchange Rate Risk

The Company has 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 the Company will receive in payment for assets or that the Company would have to pay to settle liabilities. As a result, the Company could be required to record these changes as gains or losses on foreign currency translation.

The Company has revenues and expenses that are denominated in foreign currencies. Specifically, a significant portion of the Company s international BioGlue and PerClot revenues are denominated in British Pounds and Euros, and a portion of the Company s general, administrative, and marketing expenses are denominated in British Pounds, Euros, Swiss Francs, 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, the Company 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, 2014 affecting the Company s balances denominated in foreign currencies would not have had a material impact on the Company s financial position or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by the Company for the twelve months ended December 31, 2014 affecting the Company s revenue and expense transactions denominated in foreign currencies, would not have had a material impact on the Company s financial position, profitability, or cash flows.

Item 8. Financial Statements and Supplementary Data.

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

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

As previously disclosed in the Company s Current Report on Form 8-K filed on February 22, 2013, our Audit Committee approved the engagement of Ernst & Young LLP as our independent registered public accounting firm effective February 18, 2013. There were no disagreements or reportable events related to the change in accountants requiring disclosure under Item 304(b) of Regulation S-K.

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Item 9A. Controls and Procedures.

The Company maintains disclosure controls and procedures (Disclosure Controls) as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934. These Disclosure Controls are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Commission s rules and forms, and that such information is accumulated and communicated to management, including the Chief Executive Officer (CEO) and Chief Financial Officer (CFO), as appropriate, to allow timely decisions regarding required disclosures.

The Company s management, including the Company s President and CEO and the Company s Executive Vice President of Finance, Chief Operating Officer, and CFO, does not expect that its Disclosure Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake. The Company s Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

The Company s management utilizes the criteria set forth in Internal Control-Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of December 31, 2014, the CEO and CFO have concluded that the Company s Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission s rules and forms.

During the quarter ended December 31, 2014 there were no changes in the Company s internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company s internal control over financial reporting.

The report called for by Item 308(a) of Regulation S-K is incorporated herein by reference to Management s Report on Internal Control over Financial Reporting under Sarbanes-Oxley Section 404 on page F-1 of this report.

The attestation report called for by Item 308(b) of Regulation S-K is incorporated herein by reference to Report of Independent Registered Public Accounting Firm on page F-2 of this report.

Item 9B. Other Information.

None.

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PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The response to Item 10 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2014, with the exception of information concerning executive officers, which is included in Part I, Item 4A, Executive Officers of the Registrant of this Form 10-K.

Item 11. Executive Compensation.

The response to Item 11 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2014.

Item 12. Security Ownership of Certain Beneficial Owners and Management, and Related Stockholder Matters.

The response to Item 12 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2014.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The response to Item 13 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2014.

Item 14. Principal Accounting Fees and Services.

The response to Item 14 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2014.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following are filed as part of this report:

(a) 1. Consolidated Financial Statements begin on page F-1.

All financial statement schedules are omitted, as the required information is immaterial, not applicable, or the information is presented in the consolidated financial statements or related notes.

(b) Exhibits

The following exhibits are filed herewith or incorporated herein by reference:

Exhibit Number	Description
2.1+	Series A Preferred Stock Purchase Agreement Among CryoLife, Inc., The Cleveland Clinic Foundation, and ValveXchange, Inc. dated July 6, 2011. (Incorporated herein by reference to Exhibit 2.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.)
2.2	Agreement and Plan of Merger, dated May 14, 2012, by and among CryoLife, Inc., CL Crown, Inc., Hemosphere, Inc. and a Stockholder Representative. (Incorporated herein by reference to Exhibit 2.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.)
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.)
3.2	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed July 27, 2011.) (File No. 001-13165)
4.1	Form of Certificate for the Company s Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1997.) (File No. 001-13165)
4.2	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant s Current Report on Form 8-K filed November 3, 2005.) (File No. 001-13165)
10.1++	Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc. as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.)
10.1(a)	First Amendment, dated May 7, 2009, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc. as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.9(a) to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009.)
10.1(b)+	Second Amendment, dated November 9, 2009, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc. as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.9(a) to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009.)

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Exhibit Number	Description
10.1(c)+	Third Amendment, dated January 12, 2010, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)
10.1(d)	Fourth Amendment, dated May 28, 2010, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.)
10.1(e)	Fifth Amendment, dated March 2, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)
10.1(f)	Sixth Amendment, dated June 30, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)
10.1(g)	Seventh Amendment, dated August 30, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.)
10.1(h)+	Amended and Restated Credit Agreement, dated October 28, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.2(h) to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2011.)
10.1(i)	First Amendment, dated August 20, 2012, to the Amended and Restated Credit Agreement, dated October 28, 2011, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.1(j)	Second Amendment, dated May 23, 2013, to the Amended and Restated Credit Agreement, dated October 28, 2011, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013.)
10.1(k)	Third Amendment, dated September 20, 2013, to the Amended and Restated Credit Agreement, dated October 28, 2011, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2013.)

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Exhibit Number	Description
10.1(l)	Fourth Amendment, dated April 2, 2014, to the Amended and Restated Credit Agreement, dated October 28, 2011, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)
10.1(m)	Second Amended and Restated Credit Agreement, dated September 26, 2014, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.)
10.2	CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.2(a)	First Amendment, dated July 24, 2012, to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.3	CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Appendix 1 to the Registrant s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.4	Form of 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.7 to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.4(a)	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2002 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed August 7, 2006.)
10.4(b)	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.5	Form of Incentive Stock Option Grant Agreement under the 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.6	Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.9 to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.6(a)	First Amendment, dated as of May 28, 2014, to the Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)
10.6(b)	Second Amendment, dated as of September 3, 2014, to the Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed September 9, 2014.)
10.6(c)	Form of Change of Control Agreement (entered into with respect to Jeffrey W. Burris, David M. Fronk, and Scott B. Capps). (Incorporated herein by reference to Exhibit 10.9(a) to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.6(d)	Change of Control Agreement, by and between the Company and D. Ashley Lee, dated October 24, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed October 28, 2008.)

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Exhibit Number	Description
10.7	Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated herein by reference to Exhibit 10.9 to the Registrant s Registration Statement on Form S-1 (No. 33-56388).)
10.8	Form of Key Employee Secrecy and Noncompete Agreement, by and between the Company and its Officers and Key Employees (Incorporated herein by reference to Exhibit 10.11 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.).
10.9*	Summary of Salaries for Named Executive Officers.
10.10	Separation and Release Agreement, by and between the Company and Jeffrey W. Burris. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)
10.11	CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated herein by reference to Appendix 2 to the Registrant s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.12	Lease Agreement between the Company and Amli Land Development I Limited Partnership, dated April 18, 1995. (Incorporated herein by reference to Exhibit 10.16 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007.)
10.12(a)	First Amendment to Lease Agreement, dated April 18, 1995, between the Company and Amli Land Development I Limited Partnership dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)
10.12(b)	Restatement and Amendment to Funding Agreement between the Company and Amli Land Development I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(b) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.12(c)	Amended and Restated Lease Agreement between the Company and Amli Land Development I Limited Partnership, dated May 10, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.)
10.12(d)	Lease, dated October 23, 2014, by and between Roberts Boulevard, LLC, as Landlord, and CryoLife, Inc., as Tenant. (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed October 27, 2014.)
10.13	CryoLife, Inc. 2004 Employee Stock Incentive Plan, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.13(a)	First Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated October 27, 2009. (Incorporated herein by reference to Exhibit 10.46 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009.)
10.13(b)	Second Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated May 24, 2011. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)
10.14	Form of Incentive Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)
10.15	Form of Non-Qualified Employee Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)
10.16	Technology License Agreement between the Company and Colorado State University Research Foundation dated March 28, 1996. (Incorporated herein by reference to Exhibit 10.22 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007.)

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Exhibit Number	Description
10.17	Form of Section 16 Officer Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)
10.18	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)
10.19	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.20	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.33 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.21	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.35 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.22	International Distribution Agreement, dated September 17, 1998, between the Company and Century Medical, Inc. (Incorporated by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.23	CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.)
10.24	Settlement and Release Agreement, dated August 2, 2002, by and between Colorado State University Research Foundation, the Company, and Dr. E. Christopher Orton. (Incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.25	Settlement Agreement and Release, dated September 25, 2006, by and between CryoLife, Inc. and St. Paul Mercury Insurance Company. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.)
10.26*	Summary of Compensation Arrangements with Non-Employee Directors.
10.27	CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.)
10.28	Form of 2013 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on 10-Q for the quarter ended March 31, 2013.)
10.29	Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)
10.30+	Distribution Agreement between the Company and Starch Medical, Inc., dated September 28, 2010. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed December 30, 2014.)
10.30(a)	First Amendment to the Distribution Agreement between the Company and Starch Medical, Inc., dated May 18, 2011. (Incorporated herein by reference to Exhibit 10.7 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.)
10.30(b)	Second Amendment to the Distribution Agreement between the Company and Starch Medical, Inc., dated September 20, 2013. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2013.)

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Exhibit Number	Description
10.31+	License Agreement between the Company and Starch Medical, Inc., dated September 28, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed December 30, 2014.)
10.31(a)	Indemnification Agreement between the Company and Starch Medical, Inc., dated May 21, 2013. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013.)
10.32	CryoLife, Inc. Executive Deferred Compensation Plan. (Incorporated herein by reference to Exhibit 10.52 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2010.)
10.33	Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)
10.34	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)
10.35++	Loan and Security Agreement by and between ValveXchange, Inc., and CryoLife, Inc. dated July 6, 2011. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.)
10.35(a)	First Amendment to Loan and Security Agreement by and between ValveXchange, Inc., and CryoLife, Inc. dated September 6, 2011. (Incorporated herein by reference to Exhibit 10.56(a) to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2011.)
10.35(b)	Second Amendment, dated July 18, 2012, to the Loan and Security Agreement by and between ValveXchange, Inc. and CryoLife, Inc. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.36	Form of Indemnification Agreement entered into with each of the Registrant s directors, except Harvey Morgan, and its Executive Vice President, Chief Operating Officer and Chief Financial Officer. (Incorporated herein by reference to Exhibit 99.1 to the Form S-3/A filed by Registrant on January 4, 2005.)
10.37	Form of Indemnification Agreement entered into with Harvey Morgan. (Incorporated herein by reference to Exhibit 99.2 to the Form S-3 filed by Registrant on November 21, 2008.)
10.38	Form of Performance Share Agreement with Named Executive Officers. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed March 22, 2012.)
10.38(a)	First Amendment, dated July 23, 2012, to the 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.38(b)	Stock Option Grant Agreement, dated September 2, 2014, by and between CryoLife, Inc. and James P. Mackin. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)
10.38(c)	Restricted Stock Award Agreement, dated September 2, 2014, by and between CryoLife, Inc. and James P. Mackin. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)
10.39	Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 99.1 to the Registrant s Form S-8 filed June 22, 2012.)
10.39(a)	First Amendment, dated July 24, 2012, to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)

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Exhibit Number	Description
10.39(b)	Second Amended and Restated CryoLife Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Appendix B to the Company s Definitive Proxy Statement filed April 8, 2014.)
10.40	Waiver Agreement, dated May 14, 2012, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, and General Electric Capital Corporation, as lender and administrative agent for all lenders, under the Amended and Restated Credit Agreement between the parties, dated October 28, 2011. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.)
10.41	Final Settlement Agreement, dated June 28, 2012, by and among CryoLife, Inc. and Medafor, Inc. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.)
10.42	Settlement Agreement, dated June 14, 2012, by and among CryoLife, Inc. and CardioFocus, Inc. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.)
10.43	Exclusive Supply and Distribution Agreement, dated as of March 26, 2014, by and between CryoLife, Inc. and Hancock Jaffe Laboratories, Inc. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.)
10.44	Employment Agreement dated as of July 7, 2014, between CryoLife, Inc. and James P. Mackin. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed July 11, 2014.)
10.45*	Form of Non-Employee Directors Restricted Stock Award Agreement pursuant to the Second Amended and Restated CryoLife, Inc. 2009 Employee Stock Incentive Plan.
21.1*	Subsidiaries of CryoLife, Inc.
23.1*	Consent of Ernst & Young LLP.
23.2*	Consent of Deloitte & Touche LLP.
31.1*	Certification by James P. Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

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

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3. B. Executive Compensation Plans and Arrangements.

1. Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2002 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed August 7, 2006.)

2. Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.9 to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)

3. First Amendment, dated as of May 28, 2014, to the Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)

4. Second Amendment, dated as of September 3, 2014, to the Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed September 9, 2014.)

5. Form of Change of Control Agreement (entered into with respect to Jeffrey W. Burris, David M. Fronk, and Scott B. Capps). (Incorporated herein by reference to Exhibit 10.9(a) to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)

6. Change of Control Agreement, by and between the Company and D. Ashley Lee, dated October 24, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed October 28, 2008.)

7. Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated herein by reference to Exhibit 10.9 to the Registrant s Registration Statement on Form S-1 (No. 33-56388).)

8. Form of Key Employee Secrecy and Noncompete Agreement, by and between the Company and its Officers and Key Employees. (Incorporated herein by reference to Exhibit 10.11 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

9. CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Appendix 1 to the Registrant s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)

10. CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.)

11. CryoLife, Inc. 2004 Employee Stock Incentive Plan, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)

12. CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)

13. Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)

14. Form of Incentive Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)

15. Form of Section 16 Officer Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)

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16. Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)

17. *Summary of Salaries for Named Executive Officers.

18. Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.29 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

19. Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

20. Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.33 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

21. Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.34 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

22. Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.35 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

23. Form of 2013 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on 10-Q for the quarter ended March 31, 2013.)

24. Form of Incentive Stock Option Grant Agreement under the 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)

25. *Summary of Compensation Arrangements with Non-Employee Directors.

26. Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)

27. CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.)

28. Form of Incentive Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)

29. CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.)

30. First Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated October 27, 2009. (Incorporated herein by reference to Exhibit 10.46 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009.)

31. Form of 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.7 to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)

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32. First Amendment, dated July 24, 2012, to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)

33. Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)

34. CryoLife, Inc. Executive Deferred Compensation Plan. (Incorporated herein by reference to Exhibit 10.52 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2010.)

35. Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)

36. Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)

37. Second Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated May 24, 2011. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)

38. Form of Non-Qualified Employee Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)

39. Form of Indemnification Agreement entered into with each of the Registrant s directors, except Harvey Morgan, and its Executive Vice President, Chief Operating Officer and Chief Financial Officer. (Incorporated herein by reference to Exhibit 99.1 to the Form S-3/A filed by Registrant on January 4, 2005.)

40. Form of Indemnification Agreement entered into with Harvey Morgan. (Incorporated herein by reference to Exhibit 99.2 to the Form S-3 filed by Registrant on November 21, 2008.)

41. Form of Performance Share Agreement with Named Executive Officers. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed March 22, 2012.)

42. First Amendment, dated July 23, 2012, to the 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)

43. Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 99.1 to the Registrant s Form S-8 filed June 22, 2012.)

44. First Amendment, dated July 24, 2012, to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)

45. Second Amended and Restated CryoLife Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Appendix B to the Company s Definitive Proxy Statement filed April 8, 2014.)

46. *Form of Non-Employee Directors Restricted Stock Award Agreement pursuant to the Second Amended and Restated CryoLife, Inc. 2009 Employee Stock Incentive Plan.

* Filed herewith.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CRYOLIFE, INC.

February 18, 2015 By /s/ JAMES P. MACKIN

James P. Mackin

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JAMES P. MACKIN **James P. Mackin**	President, Chief Executive Officer, and Director (Principal Executive Officer)	February 18, 2015
/s/ D. ASHLEY LEE **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 18, 2015
/s/ AMY D. HORTON **Amy D. Horton**	Chief Accounting Officer (Principal Accounting Officer)	February 18, 2015
/s/ STEVEN G. ANDERSON **Steven G. Anderson**	Executive Chairman and Chairman of the Board of Directors	February 18, 2015
/s/ THOMAS F. ACKERMAN **Thomas F. Ackerman**	Director	February 18, 2015
/s/ JAMES S. BENSON **James S. Benson**	Director	February 18, 2015
/s/ DANIEL J. BEVEVINO **Daniel J. Bevevino**	Director	February 18, 2015

/s/ Ronald C. Elkins, M.D.	Director	February 18, 2015
Ronald C. Elkins, M.D.		
/s/ Ronald D. McCall	Director	February 18, 2015
Ronald D. McCall		
/s/ Harvey Morgan	Director	February 18, 2015
Harvey Morgan		
/s/ Jon W. Salveson	Director	February 18, 2015
Jon W. Salveson		

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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, 2014. 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 (1992 framework). Based on our assessment, we believe that, as of December 31, 2014, the company s 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, 2014.

CryoLife, Inc.

February 18, 2015

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Report of Independent Registered Public Accounting Firm on the Financial Statements

The Board of Directors and Shareholders of CryoLife, Inc.

We have audited the accompanying consolidated balance sheets of CryoLife, Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive income, shareholders equity and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of CryoLife, Inc. and subsidiaries at December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2014, 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), CryoLife, Inc. and subsidiaries internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated February 18, 2015 expressed an unqualified opinion thereon.

Ernst & Young LLP

Atlanta, GA

February 18, 2015

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

The Board of Directors and Shareholders of CryoLife, Inc.

We have audited CryoLife, Inc. and subsidiaries internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (the COSO criteria). CryoLife, Inc. and subsidiaries 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 under Sarbanes-Oxley Section 404. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, CryoLife, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of CryoLife, Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive income, shareholders equity and cash flows for each of the two years in the period ended December 31, 2014 of CryoLife, Inc. and subsidiaries and our report dated February 18, 2015 expressed an unqualified opinion thereon.

Ernst & Young, LLP

Atlanta, Georgia

February 18, 2015

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

CryoLife, Inc.

Kennesaw, Georgia

We have audited the accompanying consolidated statement of operations and comprehensive income, shareholders equity and cash flows of CryoLife, Inc. and subsidiaries (the Company) for the year ended December 31, 2012. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and the significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 15, 2013

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,375	$ 37,643
Restricted cash and securities	884	5,350
Receivables:		
Trade accounts, net	21,064	17,838
Other	1,799	469
Total receivables	**22,863**	**18,307**
Inventories	12,739	9,771
Deferred preservation costs	25,196	27,297
Deferred income taxes	6,210	5,162
Prepaid expenses and other	4,761	2,797
Total current assets	**106,028**	**106,327**
Property and equipment:		
Equipment and software	26,699	26,976
Furniture and fixtures	4,375	4,390
Leasehold improvements	30,660	30,051
Total property and equipment	61,734	61,417
Less accumulated depreciation and amortization	49,732	49,246
Net property and equipment	**12,002**	**12,171**
Other assets:		
Restricted cash	5,000	
Goodwill	11,365	11,365
Patents, less accumulated amortization of $2,497 in 2014 and $2,414 in 2013	1,784	1,934
Trademarks and other intangibles, less accumulated amortization of $6,352 in 2014 and $4,593 in 2013	19,496	19,985
Notes receivable, net		2,000
Deferred income taxes	15,659	16,885
Other	4,823	4,016
Total assets	**$ 176,157**	**$ 174,683**

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31, 2014	2013
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,497	$ 4,137
Taxes payable	46	1,377
Accrued compensation	5,406	4,886
Accrued procurement fees	4,675	5,427
Accrued expenses	2,991	2,411
Other	3,012	2,484
Total current liabilities	**20,627**	**20,722**
Contingent consideration liability		1,884
Deferred compensation liability	1,918	1,533
Deferred rent obligations	1,649	1,686
Other	3,278	4,111
Total liabilities	**27,472**	**29,936**
Commitments and contingencies		
Shareholders equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued:		
Series A Junior Participating Preferred Stock, 2,000 shares auth., no shares issued		
Convertible preferred stock, 460 shares auth., no shares issued		
Common stock $0.01 par value per share, 75,000 shares authorized, 29,229 shares issued in 2014 and 28,244 shares issued in 2013	292	282
Additional paid-in capital	135,227	128,585
Retained earnings	22,768	18,741
Accumulated other comprehensive (loss) income	(121)	7
Treasury stock at cost, 1,101 shares in 2014 and 413 shares in 2013	(9,481)	(2,868)
Total shareholders equity	**148,685**	**144,747**
Total liabilities and shareholders equity	**$ 176,157**	**$ 174,683**

See accompanying Notes to Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

(in thousands, except per share data)

	Year Ended December 31,		
	2014	**2013**	**2012**
Revenues:			
Products	$ 81,883	$ 76,194	$ 67,496
Preservation services	62,758	64,498	63,603
Other		71	619
Total revenues	**144,641**	**140,763**	**131,718**
Cost of products and preservation services:			
Products	17,167	15,147	11,380
Preservation services	36,183	35,230	35,320
Total cost of products and preservation services	**53,350**	**50,377**	**46,700**
Gross margin	**91,291**	**90,386**	**85,018**
Operating expenses:			
General, administrative, and marketing	73,754	68,112	65,149
Research and development	8,699	8,454	7,257
Total operating expenses	**82,453**	**76,566**	**72,406**
Operating income	**8,838**	**13,820**	**12,612**
Interest expense	175	71	179
Interest income	(50)	(4)	(6)
Gain on sale of Medafor investment	(530)	(12,742)	
Other than temporary investment impairment		3,229	340
Other expense (income), net	540	(26)	47
Income before income taxes	**8,703**	**23,292**	**12,052**
Income tax expense	1,381	7,120	4,106
Net income	**$ 7,322**	**$ 16,172**	**$ 7,946**
Income per common share:			
Basic	**$ 0.26**	**$ 0.59**	**$ 0.29**
Diluted	**$ 0.25**	**$ 0.57**	**$ 0.28**
Dividends declared per common share	**$ 0.118**	**$ 0.108**	**$ 0.050**
Weighted-average common shares outstanding:			
Basic	27,379	26,885	26,967
Diluted	28,313	27,698	27,411
Net income	**$ 7,322**	**$ 16,172**	**$ 7,946**

Other comprehensive (loss) income	(128)	46	(33)
Comprehensive income	**$ 7,194**	**$ 16,218**	**$ 7,913**

See accompanying Notes to Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2014	**2013**	**2012**
Net cash flows from operating activities:			
Net income	$ 7,322	$ 16,172	$ 7,946
Adjustments to reconcile net income to net cash from operating activities:			
Gain on sale of Medafor investment	(530)	(12,742)	
Depreciation and amortization	6,028	5,843	5,633
Non-cash compensation	3,436	3,240	3,162
Other than temporary investment impairment		3,229	340
Write-down of inventories and deferred preservation costs	680	1,693	288
Deferred income taxes	178	617	1,227
Other non-cash adjustments to income	(474)	298	683
Changes in operating assets and liabilities:			
Receivables	(4,556)	(1,637)	1,363
Inventories and deferred preservation costs	(1,131)	193	(1,598)
Prepaid expenses and other assets	(2,771)	(706)	(583)
Accounts payable, accrued expenses, and other liabilities	(64)	572	529
Net cash flows provided by operating activities	**8,118**	**16,772**	**18,990**
Net cash flows from investing activities:			
Sales and maturities of restricted securities and investments	639		
Proceeds from sale of Medafor investment	530	15,421	
Capital expenditures	(4,310)	(4,338)	(3,070)
Purchases of restricted securities and investments	(1,208)	(20)	
Acquisition of intangible assets	(1,010)	(196)	(819)
Acquisition of Hemosphere, net of cash acquired			(17,040)
Advances under notes receivable			(2,000)
Other	6	10	9
Net cash flows (used in) provided by investing activities	**(5,353)**	**10,877**	**(22,920)**
Net cash flows from financing activities:			
Proceeds from exercise of stock options and issuance of common stock	2,675	2,207	330
Cash dividends paid	(3,295)	(2,967)	(1,373)
Repurchases of common stock	(5,588)	(1,523)	(3,310)
Redemption and repurchase of stock to cover tax withholdings	(1,483)	(681)	(219)
Other	738	(87)	(143)
Net cash flows used in financing activities	**(6,953)**	**(3,051)**	**(4,715)**
Effect of exchange rate changes on cash	(80)	36	(51)
(Decrease) increase in cash and cash equivalents	**(4,268)**	**24,634**	**(8,696)**
Cash and cash equivalents, beginning of year	37,643	13,009	21,705
Cash and cash equivalents, end of year	**$ 33,375**	**$ 37,643**	**$ 13,009**

See accompanying Notes to Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands)

	Common Stock		Additional Paid In Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Shareholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2011	**30,067**	**$ 301**	**$ 135,003**	**$ (1,037)**	**$ (6)**	**(2,265)**	**$ (12,723)**	**$ 121,538**
Net income				7,946				7,946
Other comprehensive loss					(33)			(33)
Comprehensive income								7,913
Cash dividends paid ($0.050 per share)				(1,373)				(1,373)
Equity compensation	37		2,410			229	966	3,376
Exercise of options	8		37					37
Employee stock purchase plan	72	1	292					293
Excess tax shortfall			(143)					(143)
Repurchase of common stock						(639)	(3,310)	(3,310)
Redemption and repurchase of stock to cover tax withholdings	(11)		(66)			(26)	(153)	(219)
Shares retired	(2,687)	(27)	(15,119)			2,687	15,146	
Balance at December 31, 2012	**27,486**	**$ 275**	**$ 122,414**	**$ 5,536**	**$ (39)**	**(14)**	**$ (74)**	**$ 128,112**
Net income				16,172				16,172
Other comprehensive income					46			46
Comprehensive income								16,218
Cash dividends paid ($0.108 per share)				(2,967)				(2,967)
Equity compensation	352	3	3,465					3,468
Exercise of options	365	4	2,728			(102)	(1,000)	1,732
Employee stock purchase plan	97	1	474					475
Excess tax shortfall			(87)					(87)
Repurchase of common stock						(253)	(1,523)	(1,523)
Redemption and repurchase of stock to cover tax withholdings	(56)	(1)	(409)			(44)	(271)	(681)
Balance at December 31, 2013	**28,244**	**$ 282**	**$ 128,585**	**$ 18,741**	**$ 7**	**(413)**	**$ (2,868)**	**$ 144,747**
Net income				7,322				7,322
Other comprehensive loss					(128)			(128)
Comprehensive income								7,194

Cash dividends paid ($0.118 per share)				(3,295)				(3,295)
Equity compensation	642	6	3,691					3,697
Exercise of options	297	3	2,150			(18)	(191)	1,962
Employee stock purchase plan	111	1	712					713
Excess tax benefit			738					738
Repurchase of common stock						(585)	(5,588)	(5,588)
Redemption and repurchase of stock to cover tax withholdings	(65)		(649)			(85)	(834)	(1,483)
Balance at December 31, 2014	**29,229**	**$ 292**	**$ 135,227**	**$ 22,768**	**$ (121)**	**(1,101)**	**$ (9,481)**	**$ 148,685**

See accompanying Notes to Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Nature of Business

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, is a leader in medical device manufacturing and distributio and in the processing and distribution of implantable human tissues for use in cardiac and vascular surgeries. CryoLife s surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot®, an absorbable powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI), and PerClot Topical, which is being marketed in the U.S. primarily for use in ENT applications. CryoLife s CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used for the treatment of coronary artery disease in patients with severe angina. CryoLife markets the Hemodialysis Reliable Outflow Graft (HeRO® Graft) and exclusively distributes ProCol® Vascular Bioprosthesis (ProCol), both of which are solutions for end-stage renal disease (ESRD) in certain hemodialysis patients. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both of which are processed using CryoLife s proprietary SynerGraft® technology.

Principles of Consolidation

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

Translation of Foreign Currencies

The Company s revenues and expenses transacted in foreign currencies are translated as they occur at exchange rates in effect at the time of each transaction. Realized gains and losses on foreign currency transactions are recorded as a component of other (income) expense, net on the Company s Consolidated Statements of Operations and Comprehensive Income. Assets and liabilities of the Company denominated in foreign currencies are translated at the exchange rate in effect as of the balance sheet date and are recorded as a separate component of accumulated other comprehensive income (loss) in the shareholders equity section of the Company s Consolidated Balance Sheets.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Estimates and assumptions are used when accounting for investments, allowance for doubtful accounts, deferred preservation costs, acquired assets or businesses, long-lived tangible and intangible assets, deferred income taxes, commitments and contingencies (including product and tissue processing liability claims, claims incurred but not reported, and amounts recoverable from insurance companies), stock-based compensation, certain accrued liabilities (including accrued procurement fees, income taxes, and financial instruments), contingent consideration liability, and other items as appropriate.

Revenue Recognition

Revenues for products, including: BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy handpieces and accessories, HeRO Grafts, ProCol, PhotoFix™, and other medical devices, are recognized at the time the product is shipped, at which time title passes to the customer, and there are no further performance obligations. The Company recognizes revenues for preservation services when services are completed and tissue is shipped to the customer. Revenues from research grants are recognized in the period the associated costs are incurred. Revenues from upfront licensing agreements are recognized ratably over the period the Company expects to fulfill its obligations.

Revenues from the sale of laser consoles are considered multiple element arrangements, and such revenues are allocated to the elements of the sale. The Company allocates revenues based primarily on the revenue these individual elements would generate if sold separately. Revenues from domestic laser consoles sales are typically recognized when the laser is installed

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at a customer site and all materials for the laser console s use are delivered. Revenues from the sales of laser consoles to international distributors are evaluated individually based on the terms of the sale and collectability to determine when revenue has been earned and can be recognized.

Shipping and Handling Charges

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

Advertising Costs

The costs to develop, produce, and communicate the Company s advertising are expensed as incurred and are classified as general, administrative, and marketing expenses. The Company records the cost to print or copy certain sales materials as a prepaid expense and amortizes these costs as an advertising expense over the period they are expected to be used, typically six months to one year. The total amount of advertising expense included in the Company s Consolidated Statements of Operations and Comprehensive Income was $821,000, $880,000, and $1.5 million for the years ended December 31, 2014, 2013, and 2012, respectively.

Stock-Based Compensation

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of restricted stock awards (RSA s), performance stock awards (PSA s), restricted stock units (RSU s), performance stock units (PSU s), and options to purchase shares of CryoLife common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP) for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period. The RSAs, PSAs, RSUs, PSUs, and stock options granted by the Company typically vest over a one to three-year period. The stock options granted by the Company typically expire within seven years of the grant date.

The Company values its RSAs, PSAs, RSUs, and PSUs based on the stock price on the date of grant. The Company expenses the related compensation cost of RSAs, PSAs, and RSUs using the straight-line method over the vesting period. The Company expenses the related compensation cost of PSUs based on the number of shares expected to be issued if achievement of the performance component is probable using a straight-line method over each vesting tranche of the award. The amount of compensation costs expensed related to PSUs is adjusted as needed if the Company deems that achievement of the performance component is no longer probable, or if the Company s expectation of the number of shares to be issued changes. The Company uses a Black-Scholes model to value its stock option grants and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company s ESPP options is also determined using a Black-Scholes model and is expensed over the vesting period.

The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, volatility, dividend yield, and the risk-free interest rate. The expected term is primarily based on the contractual term of the option and Company data related to historic exercise and post-vesting forfeiture patterns, which is adjusted based on management s expectations of future results. The Company s anticipated volatility level is primarily based on the historic volatility of the Company s common stock, adjusted to remove the effects of certain periods of unusual volatility not expected to recur, and adjusted based on management s expectations of future volatility, for the life of the option or option group. The Company s model included a zero dividend yield assumption in the periods prior to the Company s initiation of a quarterly dividend in the third quarter of 2012. The risk-free interest rate is based on recent U.S. Treasury note auction results with a similar life to that of the option. The Company s model does not include a discount for post-vesting restrictions, as the Company has not issued awards with such restrictions.

The period expense for the Company s stock compensation is determined based on the valuations discussed above and, at that time, an estimated forfeiture rate is used to reduce the expense recorded. The Company s estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company and is later adjusted to reflect actual forfeitures.

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Income Per Common Share

Income per common share is computed using the two class method, which requires the Company to include unvested RSAs and PSAs that contain non-forfeitable rights to dividends (whether paid or unpaid) as participating securities in the income per common share calculation.

Under the two class method, net income is allocated to the weighted-average number of common shares outstanding during the period and the weighted-average participating securities outstanding during the period. The portion of net income that is allocated to the participating securities is excluded from basic and dilutive net income per common share. Diluted net income per share is computed using the weighted-average number of common shares outstanding plus the dilutive effects of outstanding stock options and awards and other dilutive instruments as appropriate.

Dividends

The Company initiated a quarterly cash dividend of $0.025 per share of common stock outstanding in the third quarter of 2012 and increased the dividend to $0.0275 per share in the second quarter of 2013 and $0.03 per share in the second quarter 2014. The Company currently anticipates paying quarterly dividends in March, June, September, and December of each year from cash on hand. Dividend payments are recorded as a reduction to retained earnings on the Company s Consolidated Balance Sheets.

Financial Instruments

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

Fair Value Measurements

The Company records certain financial instruments at fair value, including: cash equivalents, certain marketable securities, certain restricted securities, contingent consideration, and derivative instruments. The Company may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis; although as of December 31, 2014 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

The Company also measures 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; and applying accounting for business combinations. The Company uses the fair value measurement framework to value these assets and reports these fair values in the periods in which they are recorded or written down.

The fair value measurement framework includes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data; and

Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available.

The determination of fair value and the assessment of a measurement s placement within the hierarchy requires judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Level 3 valuations may require the use of various cost, market, or income valuation methodologies applied to unobservable management estimates and assumptions. Management s 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. The Company may also engage external advisors to assist in determining fair value, as appropriate.

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

Cash and Cash Equivalents

Cash equivalents consist primarily of highly liquid investments with maturity dates of three months or less at the time of acquisition. The carrying value of cash equivalents approximates fair value.

Cash Flow Supplemental Disclosures

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

	2014	2013	2012
Cash paid during the year for:			
Interest	$ 34	$ 3	$ 22
Income taxes	3,450	5,693	1,263

Marketable Securities and Other Investments

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

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

Under the fair value method, the Company adjusts each investment to its market price and records the unrealized gains or losses in other (income) expense, net for trading securities, or accumulated other comprehensive income (loss), for available-for-sale securities. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in other (income) expense, net. Under the cost method, investments are recorded at cost, with subsequent dividends received recognized as income. Cost method investments are reviewed for impairment if factors indicate that a decrease in the value of the investment has occurred.

Accounts and Notes Receivable and Allowance for Doubtful Accounts

The Company s accounts receivable are primarily from hospitals and distributors that either use or distribute the Company s products and tissues. The Company assesses the likelihood of collection based on a number of factors, including past transaction history and the credit worthiness of the customer, as well as the increased risks related to international customers and large distributors. The Company s accounts receivable balances were reported net of allowance for doubtful accounts of $317,000 and $356,000 as of December 31, 2014 and 2013, respectively.

The Company may lend money from time-to-time through a note receivable, which may be made in conjunction with a longer term strategic investment in a medical device company, as approved by the Board of Directors. The Company assesses the likelihood of collection of its notes receivable based on a number of factors, including past transaction history, credit worthiness, and the liquidity position of the recipient as well as the expected value of any collateral. The Company s notes receivable balance was reported net of allowance of $2.0 million and zero as of December 31, 2014 and 2013, respectively. See Note 6 for further discussion of the Company s note receivable from ValveXchange, Inc. (ValveXchange).

Inventories

Inventories are comprised of BioGlue; BioFoam; PerClot; CardioGenesis cardiac laser therapy laser consoles, handpieces, and accessories; HeRO Grafts; ProCol; other medical devices; supplies; and raw materials. Inventories are

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valued at the lower of cost or market on a first-in, first-out basis. Upon shipment revenue is recognized and the related inventory costs are expensed as cost of products. Cost of products also includes, as applicable, lower of cost or market write-downs and impairments for products not deemed to be recoverable and, as incurred, idle facility expense, excessive spoilage, extra freight, and rehandling costs.

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

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

The Company recorded write-downs to its inventory totaling $140,000, $1.2 million, and $77,000 for the years ended December 31, 2014, 2013, and 2012, respectively. The 2013 write-down includes $684,000 in additional contractual costs and inventory impairment costs, primarily related to a BioGlue accessory product, and $483,000 in additional costs for CardioGenesis cardiac laser therapy handpieces that were made obsolete by the Company s decision to exclusively distribute the new handpiece design, which was approved by the U.S. Food and Drug Administration (FDA) in June 2013.

Deferred Preservation Costs

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

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations (OTPOs), which consign the tissue to the Company 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. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management estimates quarantine yields based on its experience and reevaluates these estimates periodically. Actual yields could differ significantly from the Company s 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.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company also evaluates its 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

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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 the Company s estimates change.

The Company recorded write-downs to its deferred preservation costs totaling $540,000, $448,000, and $195,000 for the years ended December 31, 2014, 2013, and 2012, respectively.

Property and Equipment

Property and equipment is stated at cost. Depreciation is provided over the estimated useful lives of the assets, generally three to ten years, on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the remaining lease term at the time the assets are capitalized or the estimated useful lives of the assets, whichever is shorter.

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

	2014	2013	2012
Depreciation expense	$ 4,001	$ 3,837	$ 3,662

Goodwill and Other Intangible Assets

The Company s intangible assets consist of goodwill, patents, trademarks, and other intangible assets, as discussed in Note 10. These assets include intangible assets from the acquisition of Hemosphere, Inc. (Hemosphere) in 2012 and the acquisition of Cardiogenesis Corporation (Cardiogenesis) in 2011.

The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method, which the Company believes approximates the period of economic benefits of the related assets. The Company s indefinite lived intangible assets do not amortize, but are instead subject to periodic impairment testing as discussed in Impairments of Long-Lived Assets and Non-Amortizing Intangible Assets below.

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

The Company assesses the potential impairment of its long-lived assets to be held and used whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include, but are not limited to, the following:

- Significant underperformance relative to expected historical or projected future operating results;
- Significant negative industry or economic trends;
- Significant decline in the Company s stock price for a sustained period; or
- Significant decline in the Company s market capitalization relative to net book value.

If CryoLife determines that an impairment review is necessary, the Company will evaluate its assets or asset groups by comparing their carrying values to the sum of the undiscounted future cash flows expected to result from their use and eventual disposition. If the carrying values exceed the future cash flows, then the asset or asset group is considered impaired, and the Company will write down the value of the asset or asset group. For the years ended December 31, 2014, 2013, and 2012 the Company did not experience any factors that indicated that an impairment review of its long-lived assets was warranted.

CryoLife evaluates its goodwill and other non-amortizing intangible assets for impairment on an annual basis as of October 31 and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of October 31, 2014 the Company s non-amortizing intangible assets consisted of goodwill, acquired procurement contracts and agreements, trademarks, and other acquired technology. The Company performed an analysis of its non-amortizing intangible assets as of October 31, 2014 and 2013, and determined that the fair value of the assets and the fair value of the reporting unit exceeded their associated carrying values and were, therefore, not impaired. Management will continue to evaluate the recoverability of these non-amortizing intangible assets.

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Accrued Procurement Fees

Donated tissue is procured from deceased human donors by OTPOs, which consign the tissue to the Company for processing, preservation, and distribution. The Company reimburses the OTPOs for their costs to recover the tissue and includes these costs as part of deferred preservation costs, discussed above. The Company accrues estimated procurement fees due to the OTPOs at the time tissues are received based on contractual agreements between the Company and the OTPOs.

Leases

The Company has operating lease obligations resulting from the lease of land and buildings that comprise the Company s corporate headquarters and manufacturing facilities, leases related to additional manufacturing, office, and warehouse space, leases on Company vehicles, and leases on a variety of office equipment as discussed in Note 13. Certain of the Company s leases contain escalation clauses, rent concessions, and renewal options for additional periods. Rent expense is computed on the straight-line method over the lease term and the related liability is recorded as deferred rent obligations on the Company s Consolidated Balance Sheets.

Liability Claims

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

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

The Company accrues its estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and records the related recoverable insurance amounts as a component of other long-term assets. The amounts recorded represent management s estimate of the probable losses and anticipated recoveries for unreported claims related to products sold and services performed prior to the balance sheet date.

Legal Contingencies

The Company accrues losses from a legal contingency when the loss is both probable and reasonably estimable. The accuracy of the Company s estimates of losses for legal contingencies is limited by uncertainties surrounding litigation. Therefore, actual results may differ significantly from the amounts accrued, if any. The Company accrues for legal contingencies as a component of accrued expenses and/or other long-term liabilities. Gains from legal contingencies are recorded when the contingency is resolved.

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Legal Fees

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

Uncertain Tax Positions

The Company periodically assesses its uncertain tax positions and recognizes tax benefits if they are more-likely-than-not to be upheld upon review by the appropriate taxing authority. The Company measures the tax benefit by determining the maximum amount that has a greater than 50 percent likelihood of ultimately being realized. The Company reverses previously accrued liabilities for uncertain tax positions when audits are concluded, statutes expire, administrative practices dictate that a liability is no longer warranted, or in other circumstances as deemed necessary. These assessments can be complex and the Company often obtains assistance from external advisors to make these assessments. The Company recognizes interest and penalties related to uncertain tax positions in other (income) expense, net on its Consolidated Statements of Operations and Comprehensive Income. See Note 11 for further discussion of the Company s liabilities for uncertain tax positions.

Deferred Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company periodically assesses the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance against its deferred tax assets when, as a result of this analysis, management believes it is more likely than not that some portion or all of its deferred tax assets will not be realized.

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

Projected future operating results;

Anticipated future state tax apportionment;

Timing and amounts of anticipated future taxable income;

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

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

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

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

The Company believes that the realizability of its acquired net operating loss carryforwards will be limited in future periods due to a change in control of its former subsidiaries Hemosphere and Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisitions of these companies each constituted a change in control, and that prior to the Company s acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. The deferred tax assets

recorded on the Company s Consolidated Balance Sheets do not include amounts that it expects 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 management believes it is more likely than not that these deferred tax assets will not be realized. Therefore, the Company recorded a valuation allowance against these state net operating loss carryforwards.

Valuation of Acquired Assets or Businesses

As part of its corporate strategy, the Company is seeking to identify and capitalize upon acquisition opportunities of complementary product lines and companies. The Company evaluates and accounts for acquired patents, licenses,

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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 significant judgment based on the weight of available evidence.

For the purchase of an asset group, the Company allocates 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. The Company accounts for business combinations by allocating the purchase price to the assets and liabilities acquired at their estimated fair value. Transaction costs related to business combinations are expensed as incurred. In-process research and development acquired as part of a business combination is accounted for as an indefinite-lived intangible asset until the related research and development project gains regulatory approval or is discontinued.

The Company typically engages external advisors to assist it 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. Management, in consultation with its advisor(s), makes these estimates based on its prior experiences and industry knowledge. Management believes that its estimates are reasonable, but actual results could differ significantly from the Company s estimates. A significant change in management s estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by the Company and, therefore, could materially impact the Company s financial position and profitability. If the value of the liabilities assumed by the Company, including contingent liabilities, is determined to be significantly different from the amounts previously recorded in purchase accounting, the Company may need to record additional expenses or write-downs in future periods, which could materially impact the Company s financial position and profitability.

Derivative Instruments

The Company determines the fair value of its stand-alone and embedded derivative instruments at issuance and records any resulting asset or liability on the Company s Consolidated Balance Sheets. Changes in the fair value of the derivative instruments are recognized in other (income) expense on the Company s Consolidated Statements of Operations and Comprehensive Income.

New Accounting Pronouncements

In May 2014 the Financial Accounting Standards Board issued ASU No. 2014-09, *Revenue from Contracts with Customers,* which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard is effective for annual and interim reporting periods beginning after December 15, 2016, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2014-09 to have a material impact on its financial position, results of operations, or cash flows.

2. Financial Instruments

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

December 31, 2014	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 18,213	$	$	$ 18,213
Restricted securities:				
Money market funds	884			884
Total assets	$ 19,097	$	$	$ 19,097

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December 31, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 5,349	$	$	$ 5,349
Certificates of deposit	749			749
Restricted securities:				
Money market funds	350			350
Total assets	$ 6,448	$	$	$ 6,448
Long-term liabilities:				
Contingent consideration	$	$	$ (1,884)	$ (1,884)
Total liabilities	$	$	$ (1,884)	$ (1,884)

The Company used prices quoted from its investment management companies to determine the Level 1 valuation of its investments in money market funds, certificates of deposit, and securities. The Company recorded contingent consideration liability, classified as Level 3, as a result of its acquisition of Hemosphere in May 2012. Refer to Note 5 for further discussion of the Level 3 contingent consideration liability. Changes in fair value of Level 3 liabilities are listed below (in thousands):

	Contingent Consideration
Balance as of December 31, 2013	$ 1,884
Gain on remeasurement of contingent consideration	(1,884)
Balance as of December 31, 2014	$

3. Cash Equivalents and Restricted Cash and Securities

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

December 31, 2014	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value
Cash equivalents:			
Money market funds	$ 18,213	$	$ 18,213
Restricted cash and securities:			
Cash	5,000		5,000
Money market funds	884		884
December 31, 2013			
Cash equivalents:			
Money market funds	$ 5,349	$	$ 5,349
Certificates of deposit	749		749
Restricted cash and securities:			
Cash	5,000		5,000
Money market funds	350		350

As of December 31, 2014 and 2013 $884,000 and $350,000, respectively, of the Company s money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations. As of December 31, 2014 $5.0 million of the Company s cash was designated as long-term restricted cash due to a financial covenant requirement under the Company s credit agreement with General Electric Capital Corporation (GE Capital) as discussed in Note 12. This restriction lapses upon expiration of the credit agreement with GE Capital on September 26, 2019. As of December 31, 2013 $5.0 million of the Company s cash was designated as short-term under the Company s credit agreement with GE Capital prior to the September 26, 2014

amendment.

There were no gross realized gains or losses on cash equivalents or restricted securities for the years ended December 31, 2014, 2013, and 2012. At December 31, 2014 and 2013 $5.0 million of the Company s restricted cash had no maturity date.

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At December 31, 2014 $622,000 of the Company s restricted securities had a maturity date within three months and $262,000 had a maturity date between three months and one year. At December 31, 2013 $328,000 of the Company s restricted securities had a maturity date within three months and $22,000 of the Company s restricted securities had a maturity date between three months and one year.

4. Distribution Agreements

ProCol Distribution Agreement

In 2014 CryoLife acquired the exclusive worldwide distribution rights for ProCol from Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). The agreement between CryoLife and Hancock Jaffe (the HJ Agreement) has an initial three-year term and is renewable for two one-year periods at CryoLife s option. Per the terms of the HJ Agreement, CryoLife has the option to acquire the ProCol product line from Hancock Jaffe beginning in March 2016.

ProCol, which is approved for sale in the U.S., is a biological graft derived from a bovine mesenteric vein that provides vascular access for ESRD hemodialysis patients. It is intended for the creation of a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft. ProCol is complementary to the Company s HeRO Graft, which also serves patients with ESRD; however, ProCol provides vascular access for ESRD patients in an earlier stage of the treatment protocol than the HeRO Graft.

In accordance with the terms of the HJ Agreement, CryoLife made payments to Hancock Jaffe of $1.7 million during 2014 and $576,000 in January 2015. In exchange for these payments, CryoLife obtained the right to receive a designated amount of ProCol inventory for resale, a portion of which the Company received in 2014. Subsequent to this initial inventory purchase, CryoLife can purchase additional units from Hancock Jaffe at an agreed upon transfer price. The Company began limited distribution of ProCol in the second quarter of 2014. On September 29, 2014 Hancock Jaffe received FDA approval of the Premarket Approval (PMA) Supplement associated with its new manufacturing facility, and the Company began shipping product made in this new facility in the fourth quarter of 2014.

PhotoFix Distribution Agreement

In 2014 CryoLife entered into an exclusive supply and distribution agreement with Genesee Biomedical, Inc. to acquire the distribution rights to PhotoFix, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix, which was last commercially available in 2010, has received FDA 510(k) clearance and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure. In January 2015 the Company received its initial shipments and launched its distribution of PhotoFix.

5. Hemosphere Acquisition

Overview

On May 16, 2012 CryoLife completed its acquisition of Hemosphere, a privately held company, and its HeRO Graft product line for a total purchase price of approximately $22.0 million, net of $3.2 million cash acquired. CryoLife used cash on hand to fund the transaction and operated Hemosphere as a wholly owned subsidiary until December 31, 2014, when it was merged into the CryoLife, Inc. parent entity. The HeRO Graft is a proprietary graft-based solution for ESRD hemodialysis patients with limited access options and central venous obstruction.

Contingent Consideration

As of the acquisition date, CryoLife recorded a contingent consideration liability of $1.8 million in long-term liabilities on its Consolidated Balance Sheet, representing the estimated fair value of the contingent consideration expected to be paid to the former shareholders of Hemosphere upon the achievement of certain revenue-based milestones. The acquisition agreement provides for a maximum of $4.5 million in future consideration payments through December 2015 based on specified sales targets.

The fair value of the contingent consideration liability was estimated by discounting to present value the contingent payments expected to be made based on a probability-weighted scenario approach. The Company applied a risk-based

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estimate of the probability of achieving each scenario and then applied a cost of debt based discount rate. This fair value measurement was based on unobservable inputs, including management estimates and assumptions about future revenues, and was, therefore, classified as Level 3 within the fair value hierarchy presented in Note 2. The Company remeasured this liability at each reporting date and recorded changes in the fair value of the contingent consideration in other (income) expense on the Company s Consolidated Statements of Operations and Comprehensive Income. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the timing and amount of Company revenue estimates. As of December 31, 2014 the Company reviewed the full year revenue performance of Hemosphere for 2014 and 2013, and reviewed its 2015 annual budgets, which were updated in the fourth quarter of 2014. As a result of this review, as of December 31, 2014 the Company believed that achievement of the minimum revenue target to trigger payment was remote, and, therefore, estimated the fair value of the contingent consideration to be zero.

The Company recorded gains of $1.9 million and $28,000 for the year ended December 31, 2014 and 2013, respectively, on the remeasurement of the contingent consideration liability. The balance of the contingent consideration liability was zero and $1.9 million as of December 31, 2014 and 2013, respectively.

Accounting for the Transaction

The Company recorded an allocation of the $22.0 million purchase price to Hemosphere s tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of May 16, 2012. Goodwill was recorded based on the amount by which the purchase price exceeds the fair value of the net assets acquired and is not deductible for tax purposes. Goodwill from this transaction has been allocated to the Company s medical devices segment.

The purchase price allocation as of December 31, 2012 is as follows (in thousands):

	Opening Balance Sheet
Cash and cash equivalents	$ 3,155
Receivables	653
Inventories	554
Intangible assets	5,790
Goodwill	7,145
Deferred tax assets, net	5,379
Other assets	331
Liabilities assumed	(972)
Total purchase price	$ 22,035

CryoLife incurred integration costs of $940,000 for the year ended December 31, 2013 and transaction and integration costs related to the acquisition of approximately $2.4 million for the year ended December 31, 2012. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on the Company s Consolidated Statements of Operations and Comprehensive Income.

Pro Forma Results (unaudited)

Hemosphere s revenues of $3.1 million from the date of acquisition through December 31, 2012 are included in the Consolidated Statements of Operations and Comprehensive Income. The Company s pro forma results of operations for the year ended 2012 assuming the Hemosphere acquisition had occurred as of January 1, 2012 are presented for comparative purposes below (in thousands):

	2012
Total revenues	$ 133,722
Net income	8,758

Pro forma disclosures were calculated using a tax rate of approximately 34%.

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6. ValveXchange

Preferred Stock Investment

In July 2011 the Company purchased 2.4 million shares of Series A Preferred Stock of ValveXchange for approximately $3.5 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. The Company s carrying value of this investment included the purchase price and certain transaction costs, and CryoLife s investment represented an approximate 19% equity ownership in ValveXchange. As ValveXchange s stock is not actively traded on any public stock exchange, as the Company does not exert significant influence over ValveXchange, and as the Company s investment is in preferred stock, the Company accounted for this investment using the cost method. The Company recorded its investment as a long-term asset, investment in equity securities, on the Company s Consolidated Balance Sheets.

Loan Agreement

In July 2011 the Company entered into an agreement with ValveXchange, as amended, to make available up to $2.0 million to ValveXchange in debt financing through a revolving credit facility (the Loan). The Loan includes various affirmative and negative covenants, including financial covenant requirements, and expires on July 30, 2018, unless terminated earlier. Amounts under the Loan earn interest at an 8% annual rate and are secured by substantially all of the tangible and intangible assets of ValveXchange. The Company advanced $2.0 million to ValveXchange under the Loan in 2012. The $2.0 million advance was recorded as long-term notes receivable on the Company s Consolidated Balance Sheets as of December 31, 2013.

During 2013 CryoLife repeatedly notified ValveXchange that ValveXchange was in default of certain loan covenants. In April 2014, in conjunction with ValveXchange s series B preferred stock fundraising (the Series B), CryoLife and ValveXchange entered into an amendment to the Loan agreement pursuant to which CryoLife waived ValveXchange s previous Loan defaults in exchange for an agreement that 10% of any amounts raised in the Series B in excess of $1.25 million would be paid to CryoLife. As of December 31, 2014 ValveXchange had raised $1.7 million under the Series B.

Investment and Loan Analysis

During the quarter ended September 30, 2012 the Company determined that available information indicated that the Company should evaluate its investment in ValveXchange preferred stock for impairment. The Company used available information to analyze its investment for impairment. Based on this analysis, the Company believed that its investment in ValveXchange was impaired in the third quarter of 2012, and the impairment was other than temporary. As a result, the Company recorded an other non-operating expense of $340,000 to write down its investment in ValveXchange preferred stock. During the quarter ended December 31, 2013 the Company determined that available information, including ValveXchange s financial condition and cash position, indicated that the Company should reevaluate its investment in ValveXchange preferred stock for impairment. The Company used available information, including new information obtained in the fourth quarter of 2013, to analyze its investment for impairment, and this information indicated that the fair value of the investment had declined significantly, the impairment was other than temporary, and any remaining value was nominal. As a result, the Company recorded an other non-operating expense of $3.2 million to write-down its investment in ValveXchange preferred stock. The carrying value of the Company s investment in ValveXchange preferred stock after this write down was zero as of December 31, 2014 and 2013.

During the quarter ended December 31, 2014 CryoLife became aware of various factors, including ValveXchange s inability to secure additional funding, its lack of capital to continue basic operations, and the likelihood of impending default on the Loan. In December 2014 CryoLife notified ValveXchange that it was in breach of the Loan and in January 2015, after ValveXchange failed to cure this breach, CryoLife accelerated the amounts due under the Loan. In January 2015 ValveXchange informed CryoLife management of its intent to file for bankruptcy. If ValveXchange does file for bankruptcy, the bankruptcy process is expected to be lengthy, and the ultimate disposition of CryoLife s claim for amounts it is owed under the Loan is uncertain. Given this fact pattern, CryoLife believes that its Loan became fully impaired in the fourth quarter of 2014. As a result, during the three months ended December 31, 2014 the Company recorded other non-operating expense of $2.0 million to write-down its long-term note receivable from ValveXchange. The net carrying value of the long-term note receivable was zero and $2.0 million as of December 31, 2014 and 2013, respectively.

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Option Agreement

Concurrently with the Loan described above, CryoLife entered into an option agreement with ValveXchange through which CryoLife obtained the right of first refusal to acquire ValveXchange during a period that extends through the completion of initial commercialization milestones and the right to negotiate with ValveXchange for European distribution rights. The Company s rights may be modified or reduced in bankruptcy or in connection with a future round of financing.

7. CardioFocus Settlement

On June 14, 2012 CryoLife s former subsidiary, Cardiogenesis, entered into a settlement agreement with respect to its litigation with CardioFocus, Inc. (CardioFocus). Pursuant to the terms of the settlement agreement, Cardiogenesis paid $4.5 million in cash to CardioFocus. Cardiogenesis and CardioFocus agreed and acknowledged that each party would bear its own costs and expenses, including attorneys fees, incurred in or as a result of the litigation. On June 14, 2012 the parties filed a stipulation of dismissal with prejudice in the U.S. District Court for the District of Massachusetts.

As a result of the settlement, the Company recorded an additional loss of $3.6 million in general, administrative, and marketing expenses in the second quarter of 2012 for a total of $4.1 million in legal settlement expenses for the year ended December 31, 2012. The Company paid the $4.5 million settlement payment to CardioFocus in July 2012 using cash on hand.

8. Medafor Matters

Investment in Medafor Common Stock

In 2009 and 2010 CryoLife purchased shares of common stock in Medafor, Inc. (Medafor). The Company initially recorded its investment using the cost method as a long-term asset, investment in equity securities, on the Company s Consolidated Balance Sheets.

On October 1, 2013 C.R. Bard, Inc. (Bard) and subsidiaries completed its previously announced acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately $15.4 million in the fourth quarter of 2013 for its 2.4 million shares of Medafor common stock, and received an additional payment of $530,000 in the fourth quarter of 2014 related to the release of funds in escrow. Based on information provided by Medafor as part of its September 24, 2013 Proxy Statement, the Company could receive additional payments totaling up to $7.9 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015.

The Company recorded a gain on the sale of approximately $12.7 million in the fourth quarter of 2013 and $530,000 in the fourth quarter of 2014. Subsequent payments will be recorded as an additional gain if and when received by the Company.

Distribution Agreement and Legal Action

CryoLife distributed a powdered hemostat for Medafor from 2008 to 2010. CryoLife filed a lawsuit against Medafor in 2009 in the U.S. District Court for the Northern District of Georgia (Georgia Court). In 2010 Medafor filed counterclaims against CryoLife in the same case. The litigation related to an exclusive distribution agreement that the parties entered into in April 2008.

In June 2012 the parties entered into a settlement agreement. Per the settlement, Medafor paid $3.5 million in cash to CryoLife in the third quarter of 2012. On June 29, 2012 the parties jointly filed stipulated dismissals with prejudice with the Georgia Court. As a result of the settlement, CryoLife recorded a gain of $4.7 million as a reduction in general, administrative, and marketing expenses on its Consolidated Statements of Operations and Comprehensive Income in the second quarter of 2012 and recorded a reduction in accounts payable of $1.2 million to write off a payable for previous inventory purchases, which was discharged pursuant to the settlement agreement.

On April 28, 2014 CryoLife filed a declaratory judgment lawsuit (the Original Complaint) against Bard, and its subsidiaries Davol, Inc. and Medafor, Inc. (Medafor) (collectively, Defendants), in the U.S. District Court for the District of Delaware (the Court). CryoLife requested that the Court declare that CryoLife s manufacture, use, offer for sale, and

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sale of PerClot in the U.S. does not and would not infringe Bard s U.S. Patent No. 6,060,461 (the 461 Patent). In addition CryoLife requested that the Court declare that the claims of the 461 Patent are invalid. As part of the relief requested, CryoLife requested injunctive relief and an award of attorneys fees.

The lawsuit against the Defendants follows the receipt by CryoLife of a letter from Medafor in September 2012 stating that PerClot, when introduced in the U.S., will infringe the 461 Patent when used in accordance with the method published in CryoLife s literature and with the instructions for use. CryoLife received FDA 510(k) clearance for the sale of PerClot Topical in April 2014, began distributing PerClot Topical in September 2014, and received IDE approval in March 2014 to begin clinical trials for PerClot in certain surgical indications.

In June 2014 CryoLife filed an amended complaint, and the Defendants filed a counterclaim for infringement in August 2014. The Defendants filed various motions to dismiss; the Court has not yet ruled on those motions. On September 19, 2014 the Defendants filed a motion for a preliminary injunction, asking the Court to enjoin CryoLife s marketing and sale of PerClot in the U.S. The hearing with respect to the preliminary injunction motion was held on January 23, 2015; the Court is expected to issue a ruling on the motion imminently.

9. Inventories and Deferred Preservation Costs

Inventories at December 31, 2014 and 2013 are comprised of the following (in thousands):

	2014	2013
Raw materials and supplies	$ 7,942	$ 5,706
Work-in-process	1,006	767
Finished goods	3,791	3,298
Total inventories	$ 12,739	$ 9,771

Deferred preservation costs at December 31, 2014 and 2013 are comprised of the following (in thousands):

	2014	2013
Cardiac tissues	$ 10,875	$ 12,239
Vascular tissues	14,321	15,058
Total deferred preservation costs	$ 25,196	$ 27,297

10. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of December 31, 2014 and 2013 the carrying values of the Company s indefinite lived intangible assets are as follows (in thousands):

	2014	2013
Goodwill	$ 11,365	$ 11,365
Procurement contracts and agreements	2,013	2,013
Trademarks	853	841

Based on its prior experience with similar agreements, the Company believes that its acquired contracts and procurement agreements have an indefinite useful life, as the Company expects to continue to renew these contracts for the foreseeable future. The Company believes that its trademarks have an indefinite useful life as the Company currently anticipates that these trademarks will contribute cash flows to the Company indefinitely.

As of December 31, 2014 and 2013 the Company s entire goodwill balance is related to its Medical Devices segment, and there has been no change from the balance recorded as of December 31, 2012.

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Definite Lived Intangible Assets

As of December 31, 2014 and 2013 gross carrying values, accumulated amortization, and approximate amortization periods of the Company s definite lived intangible assets are as follows (dollars in thousands):

December 31, 2014	Gross Carrying Value	Accumulated Amortization	Amortization Period	
Acquired technology	$ 14,020	$ 3,815	11-16	Years
Patents	4,281	2,497	17	Years
Distribution and manufacturing rights and know-how	4,559	989	11-15	Years
Customer lists and relationships	3,370	813	13-17	Years
Non-compete agreement	381	305	10	Years
Other	461	239	1-5	Years

December 31, 2013	Gross Carrying Value	Accumulated Amortization	Amortization Period	
Acquired technology	$ 14,020	$ 2,677	11-16	Years
Patents	4,348	2,414	17	Years
Distribution and manufacturing rights and know-how	3,559	714	15	Years
Customer lists and relationships	3,370	572	13-17	Years
Non-compete agreement	381	267	10	Years
Other	202	171	1-3	Years

Amortization Expense

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

	2014	2013	2012
Amortization expense	$ 2,027	$ 2,006	$ 1,971

As of December 31, 2014 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2015	2016	2017	2018	2019	Total
Amortization expense	$ 2,417	$ 2,410	$ 2,355	$ 2,347	$ 2,298	$ 11,827

11. Income Taxes

Income Tax Expense

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

	2014	2013	2012
Domestic	$ 8,350	$ 23,004	$ 11,686
Foreign	353	288	366
Income before income taxes	$ 8,703	$ 23,292	$ 12,052

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

	2014	2013	2012
Current:			
Federal	$ 898	$ 6,304	$ 2,778
State	211	396	180
Foreign	99	96	98
	1,208	6,796	3,056
Deferred:			
Federal	127	1,142	1,274
State	46	(818)	(227)
Foreign			3
	173	324	1,050
Income tax expense	$ 1,381	$ 7,120	$ 4,106

The Company s income tax expense in 2014, 2013, and 2012 included the Company s federal, state, and foreign tax obligations. The Company s effective income tax rate was approximately 16%, 31%, and 34% for the years ended December 31, 2014, 2013, and 2012, respectively. The Company s income tax rate for the twelve months ended December 31, 2014 was favorably affected by the reduction in uncertain tax positions, nontaxable gains recorded as change in stock basis of subsidiary, and favorable deductions taken on the Company s 2013 federal tax return, which was filed in 2014. The Company s income tax rate for the twelve months ended December 31, 2013 was favorably affected by adjustments to valuation allowances on certain of the Company s state net operating loss carryforwards, based on revised estimates of utilization of these carryforwards, and by the 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company s tax expense during 2013. The Company s income tax rates for the twelve months ended December 31, 2012 were favorably affected by adjustments to valuation allowances on certain of the Company s state net operating loss carryforwards, based on revised estimates of utilization of these carryforwards, and unfavorably affected by the tax treatment of certain acquisition related expenses due to the acquisition of Hemosphere and by the research and development tax credit, which had not been enacted during the 2012 tax year.

The income tax expense amounts differ from the amounts computed by applying the U.S. federal statutory income tax rate of 34% for the year ended December 31, 2014 and 35% for the years ended December 31, 2013 and 2012 to pretax income as a result of the following (in thousands):

	2014	2013	2012
Tax expense at statutory rate	$ 2,959	$ 8,152	$ 4,220
Increase (reduction) in income taxes resulting from:			
State income taxes, net of federal benefit	220	183	296
Non-deductible entertainment expenses	218	207	188
State valuation allowance adjustment	83	(760)	(427)
Foreign income taxes	69	96	(199)
Equity compensation	63	(29)	32
Non-deductible transaction costs			151
Net change in uncertain tax positions	(781)	104	(15)
Non-deductible change in stock basis of subsidiary	(641)		
Domestic production activities deduction	(486)	(402)	(407)
Research and development credit	(221)	(392)	
Other	(102)	(39)	267
	$ 1,381	$ 7,120	$ 4,106

Deferred Taxes

The Company generates deferred tax assets primarily as a result of write-downs of inventory and deferred preservation costs; accruals for product and tissue processing liability claims; investment and asset impairments; and, in prior periods, due to operating losses. The Company acquired significant deferred tax assets, primarily net operating loss carryforwards, from its acquisitions of Hemosphere and Cardiogenesis in the second quarters of 2012 and 2011, respectively.

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

	2014	2013
Deferred tax assets:		
Allowance for bad debts	$ 853	$ 131
Inventory and deferred preservation costs write-downs	873	1,077
Investment in equity securities	1,913	1,959
Property	2,934	2,737
Intangible assets	400	422
Accrued expenses	3,864	3,766
Loss carryforwards	14,141	15,689
Credit carryforwards	635	241
Stock compensation	2,367	2,409
Other	1,402	1,108
Less valuation allowance	(2,145)	(1,532)
Total deferred tax assets	27,237	28,007
Deferred tax liabilities:		
Prepaid items	(420)	(451)
Intangible assets	(4,652)	(5,289)
Other	(296)	(220)
Total deferred tax liabilities	(5,368)	(5,960)
Total net deferred tax assets	$ 21,869	$ 22,047

As of December 31, 2014 the Company maintained a total of $2.1 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of $21.9 million. As of December 31, 2013 the Company maintained a total of $1.5 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of $22.0 million.

As of December 31, 2014 the Company had approximately $11.0 million tax-effected federal net operating loss carryforwards related to the acquisitions of Cardiogenesis and Hemosphere that will begin to expire in 2017, $3.1 million of tax-effected state net operating loss carryforwards that began to expire in 2014, $459,000 in research and development tax credit carryforwards that will begin to expire in 2022, and $158,000 in credits from the state of Texas that will fully expire by 2027.

Uncertain Tax Positions

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

	2014	2013	2012
Beginning balance	$ 2,100	$ 2,004	$ 1,788
Increases related to current year tax positions	92	281	231
Decreases related to prior year tax positions	(265)	(185)	(15)
Decreases due to the lapsing of statutes of limitations	(490)		
Ending balance	$ 1,437	$ 2,100	$ 2,004

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

	2014	2013	2012
Beginning balance	$ 422	$ 489	$ 418
Accrual of interest and penalties	91	66	79
Decreases related to prior year tax positions	(147)	(133)	(8)
Ending balance	$ 366	$ 422	$ 489

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As of December 31, 2014 the Company s uncertain tax liability, including interest and penalties of $1.8 million, was recorded as a reduction to deferred tax assets of $108,000 and a non-current liability of $1.7 million on the Company s Consolidated Balance Sheets, which is expected to impact the Company s tax rate when recognized. The Company believes it is reasonably possible that approximately $940,000 of its uncertain tax liability will be recognized in 2015 due to the lapsing of various federal and state statutes of limitations. As of December 31, 2013 the Company s total uncertain tax liability, including interest and penalties of $2.5 million, was recorded as a non-current liability on the Company s Consolidated Balance Sheets.

Other

The Company s tax years 2011 through 2013 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2011, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

12. Debt

GE Credit Agreement

On September 26, 2014 CryoLife amended and restated its credit agreement with GE Capital, extending the expiration date and amending other terms, which are discussed further below. CryoLife s amended and restated credit agreement with GE Capital (the GE Credit Agreement) provides revolving credit for working capital, permitted acquisitions, and general corporate purposes. The GE Credit Agreement has aggregate commitments of $20.0 million for revolving loans, including swing loans, subject to a sublimit, and letters of credit, and expires on September 26, 2019. The commitments may be reduced from time to time pursuant to the terms of the GE Credit Agreement. The GE Credit Agreement also permits CryoLife to request a term loan in an aggregate amount of up to $25.0 million to finance the purchase price of a permitted acquisition.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest, based on the Company s election, at either LIBOR or GE Capital s base rate plus the respective applicable margins. All swing loans will, however, bear interest at the base loan rate. Commitment fees are paid based on the unused portion of the facility. If an event of default occurs, the applicable interest rate will increase by 2.0% per annum. The aggregate interest rate was 4.75% and 6.50% as of December 31, 2014 and 2013, respectively. As of December 31, 2014 and 2013 the outstanding balance of the GE Credit Agreement was zero, and the remaining availability was $20.0 million.

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio and (ii) maintain minimum earnings subject to defined adjustments as of specified dates. The agreement also (i) limits the payment of cash dividends, up to specified maximums and subject to satisfaction of specified conditions, (ii) requires that, after giving effect to stock repurchases, the Company maintain liquidity, as defined within the agreement, of at least $20.0 million, (iii) limits acquisitions or mergers except for certain permitted acquisitions, (iv) sets specified limits on the amount the Company can pay to purchase or redeem CryoLife common stock pursuant to a stock repurchase program and to fund estimated tax liabilities incurred by officers, directors, and employees as a result of awards of stock or stock equivalents, and (v) includes customary conditions on incurring new indebtedness. As of December 31, 2014 the Company was in compliance with the covenants of the GE Credit Agreement.

As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least $5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as long-term restricted cash as of December 31, 2014 on the Company s Consolidated Balance Sheet, as they are restricted for the term of the GE Credit Agreement. As of December 31, 2013 $5.0 million of the Company s cash was designated as short-term restricted cash on the Company s Consolidated Balance Sheet under the Company s credit agreement with GE Capital prior to the September 26, 2014 amendment.

Interest

Total interest expense was $175,000, $71,000, and $179,000 in 2014, 2013, and 2012, respectively, which included interest on debt and uncertain tax positions.

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13. Commitments and Contingencies

Leases

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

The Company had deferred rent obligation of $1.6 million and $1.7 million as of December 31, 2014 and 2013, respectively, primarily related to the lease on its corporate headquarters, which expires in 2022. Total rental expense for operating leases was $3.0 million in both 2014 and 2013 and $2.7 million in 2012.

Future minimum operating lease payments under non-cancelable leases as of December 31, 2014 are as follows (in thousands):

	Operating Leases
2015	$ 3,073
2016	3,364
2017	3,431
2018	3,486
2019	3,460
Thereafter	10,505
Total minimum lease payments	$ 27,319

Liability Claims

At December 31, 2014 and 2013 the Company s unreported loss liability was $1.4 million and $1.5 million, respectively. The related insurance recoverable amounts were $600,000 and $580,000 as of December 31, 2014 and 2013, respectively. The Company accrues its estimate of unreported product and tissue processing liability claims as other long-term liabilities and records the related recoverable insurance amounts as other long-term assets. Further analysis indicated that the liability as of December 31, 2014 could be estimated to be as high as $2.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreement

In July 2014 the Company s Board of Directors appointed Mr. James P. Mackin as President and Chief Executive Officer (CEO), and the Company and Mr. Mackin entered into an employment agreement, which became effective September 2, 2014. The employment agreement has an initial three-year term. Beginning on the second anniversary of the effective date, and subject to earlier termination pursuant to the agreement, the employment term will, on a daily basis, automatically extend by one day. In accordance with the agreement, on September 2, 2014, Mr. Mackin received a one-time signing bonus of $200,000, a grant of 400,000 stock options, and a performance stock award grant of 250,000 shares. The agreement also provides for a severance payment, which would become payable upon the occurrence of certain employment termination events, including termination by the Company without cause.

The Company s employment agreement, as amended, with its former President and CEO, and current Executive Chairman, Mr. Steven G. Anderson, confers benefits, which become payable upon the occurrence of certain events, including the voluntary retirement of Mr. Anderson or termination of his employment in conjunction with certain change in control events. As of December 31, 2014 and 2013 the Company had $2.2 million and $2.1 million, respectively, in accrued expenses and other current liabilities on the Consolidated Balance Sheets representing benefits payable upon Mr. Anderson s voluntary retirement, for which he is currently eligible. Mr. Anderson s employment agreement took effect on January 1, 2013 and terminates on December 31, 2016.

PerClot Technology

On September 28, 2010 the Company entered into a worldwide distribution agreement (the Distribution Agreement) and a license and manufacturing agreement (the License Agreement) with SMI for PerClot, a polysaccharide hemostatic

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agent used in surgery. The Distribution Agreement contains certain minimum purchase requirements and has a term of 15 years. Following the start of manufacturing and U.S. regulatory approval, CryoLife may terminate the Distribution Agreement and the related minimum purchase requirements and sell PerClot pursuant to the License Agreement. The Company will pay royalties to SMI at stated rates on net revenues of products manufactured under the License Agreement.

In April 2014 CryoLife received 510(k) clearance for PerClot Topical from the FDA, which allowed CryoLife to begin commercialization of PerClot Topical in the U.S. The Company began shipping PerClot Topical in August 2014 and is currently in the early stages of this product launch. As a result of this approval and clearance, CryoLife paid $1.0 million to SMI in the second quarter of 2014 pursuant to the terms of the agreements between CryoLife and SMI.

In March 2014 CryoLife received approval of its investigational device exemption (IDE) for PerClot from the FDA. IDE approval allows the Company to begin clinical trials for the purpose of obtaining a PMA to distribute PerClot in the U.S. As part of the approval for the PerClot IDE, the FDA recommended several study design considerations. The Company made revisions to the investigational study protocol and most recently refiled the IDE submission on December 2, 2014. In December 2014 CryoLife received approval of the supplement to its IDE for PerClot from the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company is now actively initiating the clinical trial and plans to begin enrollment in the first half of 2015. CryoLife currently expects to receive PMA from the FDA during 2017.

CryoLife paid $500,000 to SMI in January 2015 related to the achievement of a contingent milestone. The Company expects to make additional contingent payments to SMI of up to $1.0 million if certain FDA regulatory and other commercial milestones are achieved.

14. Shareholders Equity

Common Stock Repurchase

In February 2013 the Company s Board of Directors authorized the purchase of up to $15.0 million of its common stock. This program expired on October 31, 2014.

For the year ended December 31, 2014 the Company purchased approximately 585,000 shares of its common stock for an aggregate purchase price of $5.6 million. For the year ended December 31, 2013 the Company purchased approximately 253,000 shares of its common stock for an aggregate purchase price of $1.5 million. These shares were recorded, at cost, as part of treasury stock on the Company s Consolidated Balance Sheets.

Cash Dividends

The Company initiated a quarterly cash dividend of $0.025 per share of common stock outstanding in the third quarter of 2012 and increased this dividend to $0.0275 per share in the second quarter of 2013 and $0.03 per share in the second quarter of 2014. The Company paid dividend payments from cash on hand of $3.3 million and $3.0 million for the years ended December 31, 2014 and 2013, respectively. The dividend payments were recorded as a reduction to retained earnings on the Company s Consolidated Balance Sheets.

Shareholder Rights Plan

The Company has a shareholder rights agreement entered into in 1995 and amended in 2005. Under the rights agreement, each share of the Company s common stock outstanding on December 11, 1995 is entitled to one Right, as defined in, and subject to, the terms of the rights agreement. A Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock (Series A Stock) of the Company at $33.33 per one one-hundredth of a Preferred Share, subject to adjustment. Additionally, each common share that has or shall become outstanding after December 11, 1995 is also entitled to a Right, subject to the terms and conditions of the rights agreement. The Rights, which expire on November 23, 2015, may be exercised only if certain conditions are met, such as the acquisition of 15% or more of the Company s common stock by a person or affiliated group (together with its affiliates, associates, and transferees, an Acquiring Person). Rights beneficially owned by an Acquiring Person become void from and after the time such persons become Acquiring Persons, and Acquiring Persons have no rights whatsoever under the rights agreement.

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Each share of Series A Stock purchasable upon exercise of a Right will be entitled, when, as, and if declared, to a minimum preferential quarterly dividend payment of $1.00 per share but will be entitled to an aggregate dividend of 100 times the dividend declared per share of common stock. In the event of liquidation, each share of the Series A Stock will be entitled to a minimum preferential liquidation payment of 100 times the payment made per share of common stock. Finally, in the event of any merger, consolidation, or other transaction in which shares of common stock are exchanged, each share of Series A Stock will be entitled to receive 100 times the amount received per share of common stock. These rights are protected by customary antidilution provisions.

In the event the Rights become exercisable, each Right will enable the owner, other than Acquiring Persons, to purchase shares of the Company s Series A Stock as described above. Alternatively, if the Rights become exercisable, the holder of a Right may elect to receive, upon exercise of the Right and in lieu of receiving Series A Stock, that number of shares of common stock of the Company having an exercise value of two times the exercise price of the Right. In the event that, after a person or group has become an Acquiring Person, the Company is acquired in a merger or other business combination transaction or 50% or more of its consolidated assets or earning power are sold, proper provision will be made so that each holder of a Right will thereafter have the right to receive, upon the exercise of a Right, and in lieu of Series A Stock of the Company, that number of shares of common stock of the person with whom the Company has engaged in the foregoing transaction (or its parent) that at the time of such transaction will have a market value of two times the exercise price of the Right. In addition, after any person or group becomes an Acquiring Person and prior to the acquisition by the person or group of 50% or more of the outstanding common stock, the Board of Directors may elect to exchange all outstanding Rights at an exchange ratio of one share of common stock (or fractional share of Series A Stock or other preferred shares) per Right (subject to adjustment).

15. Employee Benefit Plans

401(k) Plan

The Company has a 401(k) savings plan (401(k) Plan) providing retirement benefits to all employees who have completed at least three months of service. The Company made matching contributions of 40% of each participant s contribution for up to 5% of each participant s salary in 2014, 2013, and 2012. Total Company contributions approximated $553,000, $541,000, and $500,000 for the years ended December 31, 2014, 2013, and 2012, respectively. Additionally, the Company may make discretionary contributions to the 401(k) Plan; however, no discretionary contributions were made in any of the past three years.

Deferred Compensation Plan

On January 1, 2011 the Company initiated a nonqualified Deferred Compensation Plan (Deferred Plan). The Deferred Plan allows certain employees of CryoLife to defer receipt of a portion of their salary and cash bonus. The Deferred Plan provides for tax-deferred growth of deferred compensation. Pursuant to the terms of the Deferred Plan, the Company agrees to return the deferred amounts plus gains and losses, based on investment fund options chosen by each respective participant, to the plan participants upon distribution. All deferred amounts and deemed earnings thereon are vested at all times. The Company has no current plans to match any contributions. Amounts owed to plan participants are unsecured obligations of the Company. CryoLife has established a rabbi trust in which it will make contributions to fund its obligations under the Deferred Plan. Pursuant to the terms of the trust, the Company will be required to make contributions each year to fully match its obligations under the Deferred Plan. The trust s funds are invested in Company Owned Life Insurance (COLI), and the Company plans to hold the policies until the deaths of the insured.

The Company s deferred compensation liabilities are recorded as a component of other current liabilities or long-term deferred compensation liabilities, as appropriate, based on anticipated distribution dates. The cash surrender value of COLI is recorded in other long-term assets. Changes in the value of participant accounts and changes in the cash surrender value of COLI are recorded as part of the Company s operating expenses and are subject to the Company s normal allocation of expenses to inventory and deferred preservation costs.

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16. Stock Compensation

Overview

The Company is currently authorized to grant and has available for grant the following number of shares under the Company s stock plans as of December 31, 2014 and 2013:

Plan	Authorized Shares	Available for Grant 2014	Available for Grant 2013
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	638,000	749,000
2004 Employee Stock Incentive Plan	2,100,000		60,000
2009 Employee Stock Incentive Plan	7,100,000	3,929,000	2,221,000
Total	11,100,000	4,567,000	3,030,000

During 2014 the Company amended the 2009 Employee Stock Incentive Plan to increase the authorized shares under the plan by 3.0 million shares. Upon the exercise of stock options or grants of RSAs, PSAs, RSUs, or PSUs, the Company may issue the required shares out of authorized but unissued common stock or out of treasury stock, at management s discretion.

Stock Awards

In 2014 the Compensation Committee of the Company s Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee directors, RSUs to certain employees, and RSAs, PSUs, and PSAs to certain Company officers, which, counting PSUs at target levels, together totaled 655,000 shares and had an aggregate grant date market value of $6.6 million. The PSUs granted in 2014 represented the right to receive from 50% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2014 was based on the attainment of specified levels of adjusted earnings, as defined in the PSU grant documents, for the 2014 calendar year. The PSUs granted in 2014 earned 50% of the target number of shares. The performance component of the PSA award granted in 2014 was based upon attaining specified levels of adjusted earnings over any four consecutive calendar quarters during a three-year employment period, as defined in the PSA grant document. The Company currently believes that achievement of the performance component is probable, and it will reevaluate this likelihood on a quarterly basis.

In 2013 the Compensation Committee of the Company s Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee Directors, RSUs to certain employees, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 467,000 shares of common stock and had an aggregate grant date market value of $3.1 million. The PSUs granted in 2013 earned approximately 115% of the target number of shares.

In 2012 the Compensation Committee of the Company s Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee Directors, RSUs to certain employees, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 451,000 shares of common stock and had an aggregate market value of $2.4 million. The PSUs granted in 2012 earned approximately 125% of the target number of shares.

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A summary of stock grant activity for the years ended December 31, 2014, 2013, and 2012 for RSAs, PSAs, RSUs, and PSUs, based on the target number of shares, is as follows:

RSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2011	552,000	$ 5.91
Granted	229,000	5.39
Vested	(142,000)	7.00
Unvested at December 31, 2012	639,000	5.48
Granted	232,000	6.10
Vested	(215,000)	5.80
Forfeited	(34,000)	5.31
Unvested at December 31, 2013	622,000	5.62
Granted	232,000	9.97
Vested	(324,000)	5.55
Forfeited	(35,000)	7.22
Unvested at December 31, 2014	495,000	7.65

PSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2013		
Granted	250,000	$ 10.18
Vested		
Forfeited		
Unvested at December 31, 2014	250,000	10.18

RSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2011	97,000	1.66	$ 466,000
Granted	64,000		
Vested	(37,000)		
Forfeited	(4,000)		

Outstanding at December 31, 2012	120,000	1.54	747,000
Granted	73,000		
Vested	(54,000)		
Forfeited	(10,000)		
Outstanding at December 31, 2013	129,000	1.56	1,425,000
Granted	5,000		
Vested	(52,000)		
Forfeited	(21,000)		
Outstanding at December 31, 2014	61,000	1.21	687,000
Vested and expected to vest	57,000	1.21	$ 651,000

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PSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2012	159,000	0.93	$ 989,000
Granted	182,000		
Vested	(99,000)		
Forfeited	(6,000)		
Outstanding at December 31, 2013	236,000	0.81	2,612,000
Granted	185,000		
Vested	(143,000)		
Forfeited	(21,000)		
Outstanding at December 31, 2014	257,000	0.73	2,907,000
Vested and expected to vest	240,000	0.69	$ 2,722,000

Stock Options

The Compensation Committee of the Company s Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers and employees totaling 562,000, 162,000, and 159,000 shares in 2014, 2013, and 2012, respectively, with exercise prices equal to the stock prices on the respective grant dates.

A summary of the Company s stock option activity for the years ended December 31, 2014, 2013, and 2012 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2011	2,200,000	$ 6.83	4.00	$
Granted	159,000	5.67		
Exercised	(48,000)	5.64		
Forfeited	(2,000)	7.01		
Expired	(249,000)	7.03		
Outstanding at December 31, 2012	2,060,000	6.74	3.66	1,225,000.0
Granted	162,000	6.12		
Exercised	(365,000)	7.48		
Forfeited	(49,000)	5.56		
Expired	(14,000)	6.69		
Outstanding at December 31, 2013	1,794,000	6.57	3.31	8,274,000
Granted	562,000	10.12		
Exercised	(297,000)	7.26		
Forfeited	(23,000)	7.97		
Expired	(15,000)	7.34		

Outstanding at December 31, 2014	2,021,000	7.43	3.54	8,021,000
Vested and expected to vest	1,961,000	$ 7.36	3.46	$ 7,938,000
Exercisable at December 31, 2014	1,333,000	$ 6.48	2.21	$ 6,604,000

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

	2014	2013	2012
Weighted-average fair value of options granted	$ 4.14	$ 2.54	$ 2.67
Intrinsic value of options exercised	918,000	673,000	10,000

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Employees purchased common stock totaling 111,000, 97,000, and 72,000 shares in 2014, 2013, and 2012, respectively, through the Company s ESPP.

Stock Compensation Expense

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

	2014		2013		2012	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	4.2 Years	0.5 Years	4.3 Years	0.5 Years	4.3 Years	0.5 Years
Expected stock price volatility	0.55	0.36	0.60	0.39	0.60	0.48
Dividend yield	1.16%	1.12%	1.91%	1.59%	N/A	N/A
Risk-free interest rate	1.34%	0.08%	0.70%	0.13%	0.71%	0.12%

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

	2014	2013	2012
RSA, PSA, RSU, and PSU expense	$ 2,855	$ 2,616	$ 2,204
Stock option and ESPP option expense	842	852	1,172
Total stock compensation expense	$ 3,697	$ 3,468	$ 3,376

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, PSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the Company s ESPP. These amounts were recorded as stock compensation expense and were subject to the Company s normal allocation of expenses to inventory costs and deferred preservation costs. The Company capitalized $261,000, $228,000 and $214,000 in the years ended December 31, 2014, 2013, and 2012, respectively, of the stock compensation expense into its inventory costs and deferred preservation costs.

As of December 31, 2014 the Company had total unrecognized compensation costs of $5.3 million related to RSAs, PSAs, RSUs, and PSUs and $2.1 million related to unvested stock options, before considering the effect of expected forfeitures. As of December 31, 2014 this expense is expected to be recognized over a weighted-average period of 2.7 years for PSAs, 1.6 years for RSUs, 1.1 years for RSAs, 0.7 years for PSUs, and 2.2 years for stock options.

17. Income Per Common Share

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

	2014	2013	2012
Basic income per common share			
Net income	$ 7,322	$ 16,172	$ 7,946
Net income allocated to participating securities	(161)	(367)	(180)
Net income allocated to common shareholders	$ 7,161	$ 15,805	$ 7,766
Basic weighted-average common shares outstanding	27,379	26,885	26,967
Basic income per common share	$ 0.26	$ 0.59	$ 0.29

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	2014	2013	2012
Diluted income per common share			
Net income	$ 7,322	$ 16,172	$ 7,946
Net income allocated to participating securities	(158)	(359)	(178)
Net income allocated to common shareholders	$ 7,164	$ 15,813	$ 7,768
Basic weighted-average common shares outstanding	27,379	26,885	26,967
Effect of dilutive options and awards[a]	934	813	444
Diluted weighted-average common shares outstanding	28,313	27,698	27,411
Diluted income per common share	$ 0.25	$ 0.57	$ 0.28

[a] The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares, because the inclusion of these stock options would be antidilutive to income per common share. Accordingly, stock options to purchase 335,000, 656,000, and 1.7 million, shares for the years ended December 31, 2014, 2013, and 2012, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

18. Transactions with Related Parties

A member of the Company s Board of Directors and a shareholder of the Company is an employee of an investment banking services company. The Company made stock repurchases of $5.6 million, $321,000, and $794,000 in 2014, 2013, and 2012, respectively, which includes the cost of stock and commissions of less than 1% to that investment banking services company.

A member of the Company s Board of Directors and a shareholder of the Company was the former Chief of Thoracic Surgery of a university hospital that generated product and preservation services revenues of $273,000, $353,000, and $267,000 for the Company in 2014, 2013, and 2012, respectively. Additionally, the son of this member of the Company s Board of Directors receives a retainer for performing heart and lung transplants from a medical center that generated product and preservation services revenues of $616,000, $345,000, and $312,000 for the Company in 2014, 2013, and 2012, respectively.

The Company expensed $45,000, $47,000, and $22,000 in 2014, 2013, and 2012, respectively, relating to supplies for clinical trials purchased from a company whose Chief Financial Officer is a member of the Company s Board of Directors and a shareholder of the Company.

A relative of the Company s Executive Chairman is employed as a vice president of the Company. His compensation and benefits are set and subject to review by the Compensation Committee of the Board of Directors.

19. Segment and Geographic Information

The Company has two reportable segments organized according to its products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Graft, and ProCol. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company s management, is segment gross margin, or net external revenues less cost of products and preservation services. The Company does not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below.

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The following table summarizes revenues, cost of products and preservation services, and gross margins for the Company s operating segments (in thousands):

	2014	2013	2012
Revenues:			
Medical devices	$ 81,883	$ 76,194	$ 67,496
Preservation services	62,758	64,498	63,603
Other[a]		71	619
Total revenues	144,641	140,763	131,718
Cost of products and preservation services:			
Medical devices	17,167	15,147	11,380
Preservation services	36,183	35,230	35,320
Total cost of products and preservation services	53,350	50,377	46,700
Gross margin:			
Medical devices	64,716	61,047	56,116
Preservation services	26,575	29,268	28,283
Other[a]		71	619
Total gross margin	$ 91,291	$ 90,386	$ 85,018

Net revenues by product for the years ended December 31, 2014, 2013, and 2012 were as follows (in thousands):

	2014	2013	2012
Products:			
BioGlue and BioFoam	$ 62,091	$ 58,004	$ 53,211
PerClot	4,289	3,494	3,078
CardioGenesis cardiac laser therapy	8,225	8,965	8,092
HeRO Graft	7,131	5,731	3,115
ProCol	147		
Total products	81,883	76,194	67,496
Preservation services:			
Cardiac tissue	29,437	29,523	29,756
Vascular tissue	33,321	34,975	33,847
Total preservation services	62,758	64,498	63,603
Other[a]		71	619
Total revenues	$ 144,641	$ 140,763	$ 131,718

[a] For the years ended December 31, 2013 and 2012 the Other designation includes grant revenue.

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2014, 2013, and 2012 were as follows (in thousands):

	2014	2013	2012
U.S.	$ 110,533	$ 109,325	$ 103,804
International	34,108	31,438	27,914
Total revenues	$ 144,641	$ 140,763	$ 131,718

At December 31, 2014 and 2013 over 95% of the long-lived assets of the Company were held in the U.S., where all of the Company s manufacturing facilities and the corporate headquarters are located. At December 31, 2014 and 2013 the Company s $11.4 million of goodwill was allocated entirely to its Medical Devices segment.

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SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE:				
2014	$ 35,731	$ 34,690	$ 37,069	$ 37,151
2013	35,536	33,520	36,250	35,457
2012	32,301	33,188	33,429	32,800
GROSS MARGIN:				
2014	$ 22,473	$ 22,384	$ 23,799	$ 22,635
2013	23,276	21,479	23,349	22,282
2012	21,292	21,371	21,310	21,045
NET INCOME:				
2014	$ 1,059	$ 2,161	$ 2,326	$ 1,776
2013	2,192	1,785	3,169	9,026*
2012	991	3,334	1,538	2,083
INCOME PER COMMON SHARE DILUTED:				
2014	$ 0.04	$ 0.08	$ 0.08	$ 0.06
2013	0.08	0.06	0.11	0.31*
2012	0.04	0.12	0.06	0.07

* The fourth quarter 2013 net income and income per common share-diluted includes the favorable effect of a $12.7 million pre-tax gain on the sale of an investment in the common stock of Medafor, Inc. as a result of C.R. Bard, Inc. s acquisition of the outstanding common shares of Medafor, Inc. and the unfavorable effect of a $3.2 million other than temporary investment impairment as a result of the impairment and write-down of the Company s investment in ValveXchange preferred stock.