CRYOLIFE INC
Form 10-K
February 21, 2014

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, 2013

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, 2013 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $155,031,053 computed using the closing price of $6.26 per share of Common Stock on June 30, 2013, the last trading day of the registrant s most recently completed second fiscal quarter, as reported by the New York Stock Exchange, based on management s belief that Registrant has no affiliates other than its directors and executive officers.

As of February 14, 2014 the number of outstanding shares of Common Stock of the registrant was 27,894,710.

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, 2013.	Part III

PART I

Item 1. Business.

Overview

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, develops, manufactures, and commercializes medical devices for cardiac and vascular applications and preserves and distributes human tissues for transplantation. CryoLife s surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and PerClot®, an absorbable powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI). CryoLife s subsidiary, Cardiogenesis Corporation (Cardiogenesis), specializes in the treatment of coronary artery disease using a laser console system and single use, fiber-optic handpieces to treat patients with severe angina. CryoLife and its subsidiary, Hemosphere, Inc. (Hemosphere), market the Hemodialysis Reliable Outflow Graft (HeRO® Graft), which is a solution 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.

Products and Preservation Services

Surgical Sealants and Hemostats. CryoLife s proprietary product, BioGlue, designed for cardiac, vascular, pulmonary, and general surgical applications, is a polymer based on bovine blood protein and an agent for cross-linking proteins. CryoLife distributes BioGlue throughout the U.S. and in approximately 80 other countries for designated applications. In the U.S., BioGlue is U.S. Food and Drug Administration (FDA) approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues) in the European Economic Area (EEA) (33 member state countries 28 European Union (EU) countries, 4 European Free Trade Association countries, and Turkey) under Conformité Européene Mark product certification (CE Mark). CryoLife 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 has a worldwide distribution agreement (except in China and certain related territories and governing areas) and a license and manufacturing agreement with SMI for PerClot, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powdered hemostat that has a CE Mark allowing commercial distribution into the EEA and other markets. It 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, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. In June 2013 CryoLife received conditional approval of its investigational device exemption (IDE) for PerClot from the FDA. IDE approval would allow the Company to begin clinical trials for the purpose of obtaining Premarket Approval (PMA) to distribute PerClot in the U.S. As part of the conditional approval for the PerClot IDE, the Company must make certain revisions to the investigational study protocol and clinical product labeling. The Company refiled the IDE submission on September 27, 2013. CryoLife received a second conditional approval on October 30, 2013. The Company has had multiple discussions with the FDA to resolve any remaining issues and expects to obtain FDA approval to begin enrollment into the pivotal trial in the first half of 2014.

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. Due to its foaming characteristic, BioFoam has the potential to rapidly seal organs, such as the liver, and may provide hemostasis in penetrating wounds and trauma. CryoLife distributes BioFoam under a CE Mark for use as an adjunct in the sealing of the liver and spleen and as an adjunct to hemostasis in cardiovascular surgery when cessation of bleeding by ligature or conventional methods is ineffective or impractical.

Revascularization Technologies. In May 2011 CryoLife acquired Cardiogenesis, a leading developer of surgical products used in the treatment of patients with severe angina resulting from diffuse coronary artery disease. Cardiogenesis markets the FDA approved Holmium: YAG laser console, single use, fiber-optic handpieces, and the servicing and maintenance of the console for performing a surgical procedure known as transmyocardial revascularization (TMR), used for treating patients with severe angina that is not responsive to conventional therapy. 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.

HeRO Grafts. In May 2012 CryoLife acquired Hemosphere. Hemosphere developed and markets the HeRO Graft, a proprietary graft-based solution for ESRD hemodialysis patients with limited access options. The HeRO Graft is the only fully subcutaneous arteriovenous (AV) access solution clinically proven to maintain long-term access for hemodialysis patients with central venous stenosis. The HeRO Graft is indicated 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.

Tissue Preservation Services. CryoLife distributes preserved human cardiac and vascular tissues to implanting institutions throughout the U.S., Canada, and Europe. CryoLife processes and preserves cardiac and vascular tissues using proprietary processing and freezing techniques, or cryopreservation. 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 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 portion of its pulmonary valve and pulmonary cardiac patch tissue processing. The Company s vascular tissues, including the CryoVein and CryoArtery, 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.

Research and Business Development

Through its continuing research and development activities, CryoLife uses its expertise in chemistry (protein, material, organic, and bio), biomaterials, molecular biology, and engineering, and its understanding of the cardiac and vascular surgery medical specialties to develop useful technologies, products, and services. In addition, CryoLife uses this expertise to acquire and license supplemental and complimentary products and technologies. CryoLife seeks to identify market areas that can benefit from medical devices, preserved tissues, and other related technologies, to develop innovative products and technologies within these areas, to secure their commercial protection, to establish their efficacy, and then to market these products and techniques. In order to expand its product and service offerings, CryoLife is in the process of developing or investigating several products and technologies. Some of the products in development and under investigation have not been subject to completed clinical trials and have not received FDA or other regulatory approval, so CryoLife may not derive any revenues from them. CryoLife performs significant research and development work before offering its products and services, building on either existing proprietary and non-proprietary knowledge or acquired technology and know-how. CryoLife developed its BioGlue and BioFoam products from a technology originally developed by a third-party and acquired by CryoLife. CryoLife purchased the rights to distribute and manufacture PerClot from a third-party and is working towards obtaining FDA approval to distribute PerClot in the U.S. CryoLife acquired Cardiogenesis and is evaluating the use of biologic materials in conjunction with TMR. CryoLife also acquired Hemosphere, and its HeRO Graft, and is working on product enhancements. CryoLife s current tissue preservation services were developed internally.

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.

Strategy

The key elements of the Company s strategy relate to growing its business and leveraging its strengths and expertise in its core marketplaces in order to generate revenue and earnings growth. These key elements are described below:

Identify and Evaluate Acquisition and Investment Opportunities of Complementary Product Lines and Companies. Leverage the Company s current distribution channels and its expertise in the cardiac and vascular medical specialties by selectively pursuing the potential acquisition, licensing, or distribution rights of additional technologies that complement existing products and services. Identify potential investment opportunities in companies that have complementary products that could, in the future, enhance the Company s current distribution channels and expertise in the cardiac and vascular medical specialties.

Expand Core Business. Expand the Company s core business in cardiac and vascular medical specialties by expanding the market penetration of BioGlue, BioFoam, PerClot, revascularization technologies, the HeRO Graft, heart valves, cardiac patch tissues, and vascular tissues.

Develop the Company s Pipeline of Products and Services. Develop the Company s technologies and intellectual property for additional service and product offerings and commercialization of new products and services.

License Company Technology to Third-Parties for Non-Competing Uses. Leverage the Company s current technology platforms, including its protein hydrogel technology (PHT) platform and SynerGraft technology, in medical specialties other than cardiac and vascular surgery through strategic alliances, licenses, or distribution arrangements for additional indications or product line extensions. The Company considers licensing or distribution opportunities for existing products or for products in its research and development pipeline if the Company determines that licensing or distribution opportunities could enhance shareholder value.

Analyze and Identify Underperforming Assets for Potential Sale or Disposal. Continue to analyze and identify underperforming assets not complementary to the strategies identified above for potential sale or disposal.

As a result of the above strategies, the Company has pursued several opportunities in the past few years that resulted in the acquisition of PerClot technologies in September 2010 and 2011, the acquisition of Cardiogenesis and its revascularization technologies in May 2011, and the acquisition of Hemosphere and its HeRO Graft in May 2012, as discussed above. Additionally, in July 2011 the Company purchased approximately 2.4 million shares of Series A Preferred Stock of ValveXchange, Inc. (ValveXchange) for approximately $3.5 million and in 2012 advanced $2.0 million to ValveXchange through a revolving credit facility. ValveXchange is a private medical device company that was spun off from the Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. CryoLife s investment represents an approximate 19% equity ownership in ValveXchange. See Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations Other Than Temporary Investment Impairment, regarding the impairment of CryoLife s investment in ValveXchange.

Products and Services

Medical Devices

PHT Platform

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, cerebral spinal 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 do not have inherent sealing capabilities, and they cannot consistently eliminate air and fluid leakage at the wound site. This is particularly the case when sutures and staples are 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, in minimally invasive surgical procedures where the physician must operate through small access devices, it can be difficult and time consuming for the physician to apply sutures and staples. 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 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.

BioGlue. BioGlue is the first product to be developed from the Company s PHT platform. BioGlue is a polymeric surgical adhesive based on bovine blood protein and an agent for cross-linking proteins. 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 pre-filled in 2ml, 5ml, and 10ml volumes. BioGlue is dispensed by a controlled delivery system that consists of either a reusable delivery device and disposable syringe or a disposable syringe alone. Both systems use an assortment of applicator tips (standard size tips, 12mm and 16mm spreader tips, 10cm and 27cm flexible extender tips, and 10cm, 27cm, and 35cm delivery tip extenders).

CryoLife is authorized to distribute BioGlue throughout the U.S. and in approximately 80 other countries for designated applications. In the U.S., BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. The Company estimates that the existing U.S. market for internal tissue surgical sealants was

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approximately $200 million in 2013. CryoLife distributes BioGlue under a CE Mark in the EEA for repair of soft tissues (which include cardiac, vascular, pulmonary, dura, and additional soft tissues). CryoLife has also received specified approvals and distributes BioGlue in several other countries throughout the world. Revenues from BioGlue represented 41%, 40%, and 41% of total Company revenues in 2013, 2012, and 2011, respectively.

BioFoam. BioFoam is the second product to be developed from the Company s PHT platform. 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. 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.

BioFoam received a CE Mark in August 2009 for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) when cessation of bleeding by ligature or conventional methods is ineffective or impractical. CryoLife began a controlled launch of BioFoam at three clinical centers in Europe in 2009 and, in 2010, began distribution of BioFoam in Europe. In November 2012 CryoLife received approval for an additional indication in Europe, allowing it to market BioFoam as an adjunct to hemostasis in cardiovascular surgery when cessation of bleeding by ligature or other conventional methods is ineffective or impractical. Revenues from BioFoam represented less than 1% of total Company revenues in 2013, 2012, and 2011.

Hemostatic Agents

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.

The Company estimates that the existing U.S. market for hemostatic agents was approximately $780 million in 2013. The Company estimates that the total existing European market for hemostatic agents was approximately $280 million in 2013. Revenues from hemostatic agents represented 3%, 2%, and 4% of total Company revenues in 2013, 2012, and 2011, respectively.

PerClot. PerClot is an absorbable, powdered hemostatic agent used in surgery. The PerClot technology modifies plant starch into ultra-hydrophilic adhesive forming hemostatic polymers. PerClot granules are biocompatible, absorbable polysaccharides containing no animal or human components. Utilizing this purified plant source material aids in minimizing 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. Easy to apply, PerClot does not require additional operating room preparation or special storage conditions. 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 worldwide distribution agreement and a license and manufacturing agreement with SMI for PerClot, which 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 is currently seeking approval to begin clinical trials for the purpose of obtaining PMA to distribute PerClot in the U.S., as discussed further in Research and Development and Clinical Research below. The Company expects to obtain FDA approval to begin enrollment into the pivotal trial in the first half of 2014.

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. Revenues from PerClot represented approximately 3%, 2%, and 2% of total Company revenues in 2013, 2012 and 2011, respectively.

HemoStase. CryoLife distributed HemoStase under a private label exclusive distribution agreement with Medafor, Inc. (Medafor) from May 2008 to March 2011. Medafor fully, finally, and effectively terminated the agreement in 2010. The

parties litigated the agreement and its termination and settled the litigation in 2012. Revenues from HemoStase represented 0%, 0%, and 2% of total Company revenues in 2013, 2012, and 2011, respectively.

Revascularization Technologies

CryoLife s subsidiary, Cardiogenesis, markets its Holmium: YAG laser console and single use, fiber-optic handpieces. These products are FDA approved for performing a surgical procedure known as TMR for treating patients with severe angina that is not responsive to conventional therapy. 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.

During TMR, the surgeon uses one of the flexible, fiber-optic handpieces to deliver precise bursts of Holmium: YAG laser energy directly to an area of heart muscle that is suffering from ischemic heart disease. This condition can manifest itself with severe persistent chest pain, or chronic angina. The surgical procedure is performed through a small incision or small ports with the patient under general anesthesia. The surgeon can position the laser fiber on the surface of the beating heart. It takes approximately 6 to 10 pulses of the laser to transverse the myocardium and create channels one millimeter in diameter. During a typical procedure, approximately 20 to 40 channels are made in the heart muscle.

The outside punctures seal over with little blood loss. Published research shows 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.

SolarGen 2100s Console. The 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 for the desired tissue effect. The Console implements an advanced electronic and cooling system technology to greatly reduce the size and weight of the unit, while providing 115V power capability. The Console was approved by the FDA in 2004 and received a CE Mark in 2005. The Company provides service plan options to ensure that the Console is operating within the critical factory specifications and to protect the customer s investment.

SoloGrip® III. The SoloGrip III handpiece contains multiple, fine fiber-optic strands in a one millimeter diameter bundle. The flexible fiber-optic delivery system combined with the ergonomic handpiece provides access for treating all regions of the left ventricle. The SoloGrip III handpiece fiber-optic delivery system has an easy to install connector that screws into the laser base unit, and the device is pre-calibrated in the factory so it requires no special preparation. The SoloGrip III handpiece received FDA approval in 1999 and received a CE Mark in 1997.

PEARL 5.0. The minimally invasive Port Enabled Angina Relief with Laser (PEARL) 5.0 handpiece is compatible for use with Intuitive Surgical s da Vinci Surgical System. The PEARL 5.0 handpiece received FDA approval in 2007 and received a CE Mark in 2005.

PEARL 8.0. The PEARL 8.0 handpiece has been designed for use in a minimally invasive thoracoscopic procedure. The PEARL 8.0 received FDA approval in 2012 and a CE Mark in 2005. As a condition of the FDA approval, the Company is currently conducting a post approval study. The Company anticipates the study will be completed in 2014, followed by full market launch of the PEARL 8.0.

CryoLife began distributing, primarily in the U.S., the revascularization technologies product line in May 2011 when it completed the acquisition of Cardiogenesis. Revenues from revascularization technologies represented 6%, 6%, and 5% of total Company revenues in 2013, 2012, and 2011, respectively. The Company estimates that the addressable U.S. market opportunity for TMR was approximately $200 million in 2013.

HeRO Grafts

CryoLife and its subsidiary Hemosphere market the HeRO Graft, a proprietary graft-based solution for ESRD hemodialysis patients with limited access options and central venous obstruction. The HeRO Graft received its initial FDA 510(k) clearance in 2008 and a CE Mark in 2013. It is indicated for ESRD patients who are 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. 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 (narrowing of the venous system). 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 is the only fully subcutaneous AV access solution clinically proven to maintain long-term access for hemodialysis patients with central venous stenosis. The HeRO Graft traverses the central venous stenosis allowing for long-term hemodialysis access.

In March 2013 the Company received a 510(k) clearance for a next generation HeRO Graft. The revised version features an adaptor that provides the option to pair the HeRO Graft s proprietary venous outflow component with certain other available dialysis access grafts, including early access arterial grafts. The Company anticipates launching the next generation HeRO Graft during 2014 following scale up and validation of the manufacturing process.

CryoLife began distributing the HeRO Graft in the U.S. in May 2012 when it acquired Hemosphere. The Company completed a controlled European market introduction of the product during the second half of 2013, which will be followed by a broader European launch in 2014.

The Company estimates that the addressable market opportunity for the HeRO Graft in the U.S. was approximately $135 million in 2013. Revenues from the HeRO Graft represented 4% and 2% of total Company revenues in 2013 and 2012, respectively.

Other Medical Devices

ProPatch Soft Tissue Repair Matrix (ProPatch). ProPatch is not currently distributed by CryoLife. ProPatch is manufactured from bovine pericardial tissue and treated with the SynerGraft process. It is used to reinforce weakened soft tissues and provides a resorbable scaffold that is replaced by the patient s own soft tissue. ProPatch is intended to be used for implantation to reinforce defects of the abdominal and thoracic wall, muscle flap reinforcement, hernias, suture-line reinforcement, and reconstructive procedures. ProPatch can also be used to reinforce tissues repaired by sutures or by suture anchors during tendon repair surgeries, including reinforcement of the rotator cuff, patellar tendon, Achilles tendon, biceps, quadriceps, or other tendons. Available in multiple size and shape configurations, ProPatch comes fully hydrated and ready to implant.

In late 2006 CryoLife received 510(k) clearance from the FDA for ProPatch, but did not pursue commercialization at that time. In 2011 CryoLife implemented modifications to streamline the manufacturing process. These modifications resulted in the submission of a new 510(k), which was cleared by the FDA in January 2012. CryoLife is evaluating its alternatives to commercialize ProPatch, which may include partnering with one or more third-parties as well as obtaining clinical data to support indications for direct distribution.

Preservation Services

The Company s proprietary preservation process involves the recovery of tissue from deceased human donors by tissue banks and organ and tissue procurement organizations (OTPOs), the timely and controlled delivery of such tissue to the Company, the screening, dissection, disinfection, processing, and preservation of the tissue by the Company, and the storage and shipment of the preserved tissue. In the operating room, the tissue undergoes a controlled thawing process under the supervision of the medical staff. Thereafter, the tissue is surgically implanted by a surgeon into a human recipient.

The transplant of human tissue that has not been preserved must be accomplished within extremely short time limits. Prior to the advent of human tissue cryopreservation, these time constraints resulted in the inability to use much of the tissue donated for transplantation. The Company s cryopreservation technologies applied to donated tissue expand the amount of human cardiac and vascular tissues available for transplantation. Cryopreservation also expands the treatment options available by offering alternatives to implantable mechanical, synthetic, and animal-derived devices. The tissues currently preserved by the Company include heart valves, cardiac patch tissues, and vascular tissues.

Cardiac Tissue. The human heart valves and cardiac patch tissues preserved by the Company are used in cardiac reconstruction and heart valve replacement surgeries. The Company currently preserves human aortic and pulmonary heart valves for implantation by cardiac surgeons. In addition, the Company preserves human cardiac patches for surgeons who wish to perform certain specialized cardiac repair procedures. The Company currently preserves human cardiac patches in three primary anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch. Each of these preserved cardiac tissues maintains a structure which more closely resembles and simulates the performance of the patient s own tissue compared to non-human tissue alternatives.

In 2008 CryoLife received 510(k) clearance from the FDA for its CryoValve SGPV, and in 2009 CryoLife received 510(k) clearance from the FDA for its CryoPatch SG, both processed with the Company s proprietary SynerGraft technology.

The SynerGraft process reduces the presence of allogeneic donor cells, while maintaining the structural integrity of the tissue. CryoLife uses the SynerGraft technology for a portion of its pulmonary valve and cardiac patch processing. In 2013 73% of pulmonary valves and 71% of cardiac patch tissues shipped by CryoLife were processed with the SynerGraft technology.

Based on CryoLife s records of over 25 years of documented implants, management believes that the acceptance of the Company s heart valves is due in part to physicians recognition of the longevity and natural functionality of the Company s procured cardiac tissues, the Company s documented clinical data, and the support of the Company s physician relations and education staff, clinical research staff, customer service department, and field representatives. Management believes the Company offers advantages in the areas of clinical data and field services as compared to other human tissue processors and that Company procured tissues offer advantages in certain areas over mechanical, porcine, and bovine heart valve alternatives. Management believes preserved human heart valves and cardiac patch tissues have characteristics that make them the preferred replacement option for many patients. Specifically, human heart valves, such as those preserved by the Company, allow for more normal blood flow and provide higher cardiac output than stented porcine, bovine, and mechanical heart valves. Human heart valves are not as susceptible to progressive calcification, or hardening, as are traditional glutaraldehyde-fixed porcine and bovine heart valves, and do not require anti-coagulation drug therapy, as do mechanical valves. The synthetic sewing rings contained in mechanical and stented porcine and bovine valves may harbor bacteria and lead to endocarditis. Furthermore, prosthetic valve endocarditis 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 mechanical and animal-derived tissue 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.

The Company estimates that the existing total annual heart valve replacement market in the U.S. was approximately $800 million in 2013. Management believes that its aortic and pulmonary valves compete for approximately 75% of the procedures, which make up this approximate $800 million valve replacement existing market. The Company estimates that in 2013 there were approximately 24,000 congenital heart repair procedures performed in the U.S. Management believes that its cardiac patches compete for 40% of this market. Revenues from cardiac tissue preservation services accounted for 21%, 23%, and 22% of total Company revenues in 2013, 2012, and 2011, respectively.

Vascular Tissue. The human vascular tissues preserved by the Company, including CryoVein and CryoArtery, save the lives and limbs of patients and are used in a variety of vascular reconstruction procedures such as peripheral bypass, hemodialysis access, and aortic infections. In addition, the Company preserves human saphenous vein conduits (3mm to 6mm) for use in peripheral vascular reconstructions. 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 vascular tissue. However, in cases of advanced vascular disease, as many as 30% of patients have unsuitable vascular tissue for transplantation, and the surgeon must consider using synthetic grafts or preserved human vascular tissue. Synthetic vascular grafts are generally not optimal for below-the-knee surgeries because they have a tendency to obstruct over time. Preserved human vascular tissues tend to remain open longer and, as such, are used in indications where synthetics 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. Preserved human vascular tissues have advantages for patients with previously infected graft sites. The Company also preserves femoral veins and arteries and aortoiliac arteries for bypass, hemodialysis access, or reconstruction within infected surgical areas.

The Company estimates that the existing U.S. vascular surgical graft market was approximately $120 million in 2013. Revenues from vascular preservation services accounted for 25%, 26%, and 28% of total Company revenues in 2013, 2012, and 2011, respectively.

Seasonality and Segment Information

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.

See Part II, Item 8, Note 18 of the Notes to Consolidated Financial Statements regarding segment and geographic information.

Distribution and Marketing

Medical Devices

In the U.S., the Company markets its products to physicians and distributes its products through its field representatives and cardiac specialists. Through its field representatives, the Company conducts field training for implanting surgeons regarding the application of its products.

The Company markets its products in the EEA, the Middle East, and Africa (EMEA) through its European subsidiary, CryoLife Europa Ltd. (Europa), based in Guildford, England. Europa employs direct field representatives in the U.K., Germany, Austria, and Ireland and manages relationships with other independent distributors in the EMEA region. Europa s team of approximately 30 employees provides customer service, logistics, marketing, and clinical support to cardiac, vascular, thoracic, and general surgeons throughout the EMEA region.

Additionally, the Company markets and distributes its products in other international markets through independent distributors in Canada, Asia Pacific, and the Americas. CryoLife Asia Pacific, Pte. Ltd. (Asia Pacific) was established in Singapore in November 2013 and is intended to provide sales and marketing support for the Asia Pacific region beginning in 2014.

Preservation Services

CryoLife markets its preservation services, primarily in the U.S., to OTPOs, implanting physicians, and prospective tissue recipients. The Company works with OTPOs to ensure consistent and continued availability of donated human tissue for transplant and educates physicians and prospective tissue recipients with respect to the benefits of preserved human 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 implanting tissue preserved by the Company and the clinical advantages, indications, and applications for those tissues. The Company continually trains and educates physicians on clinical aspects of the human tissues preserved by the Company. In addition, the Company sponsors programs where surgeons train other surgeons in best-demonstrated techniques. The Company also assists OTPOs through training and development of protocols and provides materials to improve their tissue recovery techniques to increase the yield of usable tissue.

Procurement of Tissue. Donated human tissue is procured from deceased human donors by OTPOs. After procurement, the tissue is packed and shipped, together with certain information about the tissue and its donor, to the Company in accordance with the Company s protocols. Additional information is provided to the Company later by the OTPOs, as needed. The tissue is transported to the Company s laboratory facilities via commercial airlines pursuant to arrangements with qualified courier services. Timely receipt of procured tissue is important, as tissue that is not received promptly cannot be cryopreserved successfully. The OTPOs are reimbursed by the Company for costs associated with these procurement services. The procurement fee, together with the charges for the preservation services of the Company, is ultimately paid to the Company by the hospital or healthcare facility with which the implanting physician is associated.

Since 1984 the Company has received tissue from over 127,000 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 employs approximately 40 individuals in donor services and donor quality assurance to work with OTPOs. This includes two account managers who are stationed throughout the country to work directly with the OTPOs. The Company s central office for procurement relations is staffed 24 hours per day, 365 days per year.

Preservation of Tissue. Upon receiving tissue, a Company technician completes the documentation control for the tissue prepared by the OTPO. The documentation identifies, among other things, donor age, and cause of death. A trained technician then removes the portion or portions of the delivered tissue that will be processed. The Company s cardiac and vascular tissues are preserved in a proprietary freezing process conducted according to Company protocols. After the preservation process, the tissues are transferred to liquid nitrogen freezers, initially under quarantine status, for long-term storage at temperatures at or below -135°C. The entire preservation process is controlled by guidelines established by the Company and is conducted under aseptic conditions in clean rooms.

At the same time the tissue is processed, samples are taken from the donated tissue and subjected to the Company s quality assurance program. This program, which includes microbiological testing and review of the donor and tissue charts by CryoLife s tissue quality assurance department and its medical directors, may identify characteristics which would disqualify the tissue for preservation or implantation. Tissue that does not pass testing is disposed of as appropriate or used for research or other purposes if the donor s family has consented. Once the tissue is approved, it is moved from quarantine to an implantable status.

Distribution of Tissue to Implanting Physicians. After the tissue has cleared quality control assurance and is moved to an implantable status, the tissue is stored by the Company until it is shipped to hospitals at the implanting physician s request. Cryopreserved tissue must be transported under stringent handling conditions and maintained within specific temperature tolerances at all times. Cryopreserved tissue is packaged for shipment using the Company s proprietary processes. After the Company delivers the tissue to the courier or shipping company, the Company invoices the institution for its services, which include procurement, preservation, and transportation. At the hospital, the tissue is thawed and implanted immediately or is held in a liquid nitrogen freezer in accordance with Company protocols pending implantation. The Company provides a detailed protocol for thawing the cryopreserved tissue. The Company also makes its field personnel available by phone or in person to answer questions.

The Company provides Company-owned liquid nitrogen freezers to certain client hospitals. The Company currently has approximately 260 of these freezers installed at hospitals throughout the U.S. Participating hospitals generally pay the cost of liquid nitrogen. The availability of on-site freezers makes it easier for a hospital s physicians to utilize the Company s tissues by making the tissue more readily available.

The Company has historically shipped tissues into certain countries in Europe, primarily the U.K., Germany, and Austria. Per EU Directives, the regulation of tissue processing in Europe is governed by the relevant country s Competent Authority. Europa has a license that allows for both marketing and importation through the U.K. s Human Tissue Authority (HTA). Separately, Europa has a marketing license through the German Competent Authority, the Paul-Erlich-Institute (PEI). However, because the PEI marketing license does not allow for the importation of tissue into Germany or Austria, Europa has historically relied on the HTA importation license to import tissue into those countries. (At this time, Austria does not have a Competent Authority that has its own regulations.)

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. Europa will be required to comply with those additional requirements beginning on March 31, 2014. Management does not believe those requirements are necessary in order to ensure the safety of the processed tissue; therefore, management has determined that rather than comply with the additional processing requirements, Europa will cease importing tissues into Europe through the HTA license.

Europa is in discussions with PEI regarding certain requirements that are scheduled to apply to Europa s marketing license beginning in the later part of 2014. If Europa were able to reach satisfactory agreement with the PEI regarding those requirements, it would still need an import license from one of the regional authorities of the Federal States in Germany to allow it to ship tissues into Germany and Austria. Even if it were to obtain the import license, Europa would not be able to import tissues into the U.K. due to the HTA s tissue processing requirements. It would, however, be able to import tissues into Germany and Austria. Europa may choose to end these discussions at any time.

Marketing, Educational, and Technical Support

The Company works to maintain relationships with, and market to, surgeons within the cardiac and vascular medical specialties. In the U.S., the Company has approximately 19 cardiac specialists who focus primarily on cardiac surgeons, approximately 28 cardiovascular representatives who focus primarily on vascular surgeons, approximately eight vascular access representatives who focus primarily on nephrologists and dialysis clinics, and seven region managers, in addition to national accounts managers, and sales and marketing management.

Because the Company markets its products and services directly to physicians, an important aspect of increasing the distribution of the Company s products and preservation services is educating physicians on the use of the Company s medical device products and preserved human tissues and on proper surgical and implantation techniques. The Company s trained medical relations and education staff and field support personnel provide support to surgical institutions and surgeons. The Company sponsors training seminars where physicians teach other physicians the proper surgical techniques for the Company s products and for handling and implanting preserved human tissue. The Company also produces educational videos for physicians and coordinates peer-to-peer training at various medical institutions. In addition, the Company hosts

several workshops throughout the year including the Central Venous Pathology Summit, Aortic Allograft Workshops, and TMR Workshops. These workshops aim to provide didactic and hands-on training to surgeons. Management believes that these activities improve 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 allograft processors.

To assist OTPOs, the Company provides educational materials and training on procurement, dissection, packaging, and shipping techniques. The Company also produces educational videos and coordinates laboratory sessions on procurement techniques for OTPO personnel. To supplement its educational activities, the Company employs a full-time technical trainer, who provides technical information and assistance and maintains a staff 24 hours per day, 365 days per year for OTPO support.

Backlog

The Company currently does not have a backlog of orders related to BioGlue, BioFoam, PerClot, revascularization technologies, or HeRO Grafts. The limited supply of certain types or sizes of preserved tissue, primarily for use in pediatric surgeries, 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.

Competition

Medical Devices

The Company faces competition from several domestic and international medical device, pharmaceutical, and biopharmaceutical companies in its surgical sealants and hemostats product lines. Many of the Company s current and potential surgical adhesives, sealants, and hemostats competitors have substantially greater financial and personnel resources than the Company. These competitors may also have greater experience in developing products, conducting clinical trials, and obtaining regulatory approvals and may have large contracts with hospitals under which they can impose purchase requirements that place our products at a disadvantage. Certain of these competitors may obtain patent protection or approval or clearance by the FDA or foreign countries earlier than the Company. The Company may also compete with companies that have superior manufacturing efficiency and marketing capabilities. Additional competitive products may be under development by other large medical device, pharmaceutical, and biopharmaceutical companies. Any of these competitive disadvantages could materially, adversely affect the Company.

BioGlue. The Company s BioGlue products compete primarily with Baxter International, Inc. s Tisseel, CoSeal, and TachoSil; Ethicon, Inc. s (a Johnson & Johnson Company) Evicel and Omnex; Integra LifeSciences Holdings Corporation s Duraseal product; C.R. Bard, Inc. s ProGEL; and Tenaxis, Inc. s ArterX. The Company s BioGlue competes with these products based on its benefits and features, such as strength and ease of use.

BioFoam. The Company s BioFoam product competes with other surgical hemostatic agents that include Pfizer, Inc. s Gelfoam; Baxter International, Inc. s FloSeal and TachoSil; Ethicon, Inc. s Spongostan, Instat, Surgicel, and Surgicel Nu-Knit; C.R. Bard, Inc. s Avitene; and Orthovita, Inc. s Vitagel. The Company s BioFoam product competes on the basis of its clinical efficacy and ease of use.

PerClot. The Company s PerClot product competes with thrombin products, including Pfizer, Inc. s Thrombin JMI; The Medicines Company s Recothrom; and Ethicon, Inc. s Evithrom; and surgical hemostats, including Pfizer, Inc. s Gelfoam; C.R. Bard, Inc. s Arista and Avitene; Baxter International, Inc. s FloSeal; Ethicon, Inc. s Surgicel, Surgiflo, and Surgifoam products; and BioCer s HaemoCer. 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 product competes on the basis of its safety profile, clinical efficacy, absorption rates, and ease of use.

Revascularization Technologies. The Company s revascularization technologies compete 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.

HeRO Grafts. The Company s HeRO Graft competes with balloon angioplasty products, including C.R. Bard, Inc. s Conquest and Boston Scientific s Mustang. 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 on the market currently 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, such as Artegraft, Inc. s Artegraft Bovine Carotid Artery Graft; W.L. Gore & Associates Hybrid Vascular Graft; C.R. Bard, Inc. s Impra; and Atrium s Flixene, or they have a chronic dialysis catheter for maintaining access in patients with central venous stenosis. 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.

Preservation Services

The Company currently faces competition from at least one non-profit tissue bank that preserves and distributes human cardiac heart valves and cardiac patch tissues and at least two non-profit tissue banks that preserve and distribute human vascular tissues, as well as from several companies that market mechanical, porcine, and bovine heart valves, and synthetic vascular grafts for implantation. Many established companies, some with financial and personnel resources greater than those of the Company, are engaged in manufacturing, marketing, and selling alternatives to preserved human tissue. These competitors may also have greater experience in developing products, conducting clinical trials, and obtaining regulatory approvals. Certain of these competitors may obtain patent protection, approval, or clearance by the FDA or foreign countries earlier than the Company. The Company may also compete with companies that have superior manufacturing efficiency and marketing capabilities. Companies offering mechanical, synthetic, bovine, porcine, or allograft products may enter this market in the future. Any newly developed treatments may also compete with the use of tissues preserved by the Company. Management believes that it competes with other entities that preserve human tissue on the basis of the preference of surgeons and patients for human tissues versus other types of tissues or mechanical devices and on technology, customer service, and quality assurance. Any of these competitive disadvantages could materially, adversely affect the Company.

Heart Valves. Alternatives to human heart valves preserved by the Company include valve repair and valve replacement with mechanical valves, porcine valves, or valves constructed from bovine pericardium. St. Jude Medical, Inc. is the leading supplier of mechanical heart valves. Medtronic, Inc. is the leading supplier of porcine heart valves. Edwards Life Sciences, Inc. is the leading supplier of bovine pericardial heart valves. The Company is aware of at least five companies that offer porcine, bovine, and mechanical heart valves. In addition, management believes that at least one domestic tissue bank offers preserved human heart valves in competition with the Company.

Management believes that the human heart valves preserved by the Company, as compared to mechanical, porcine, and bovine heart valves, compete on the factors set forth above, as well as by providing a tissue that is the preferred replacement alternative with respect to certain medical conditions, such as pediatric cardiac reconstruction, valve replacements for women in their child-bearing years, and valve replacements for patients with endocarditis. The Company believes the CryoValve SGPV enables the Company to compete with other valves by providing a valve processed with a technology designed to remove donor cells and cellular remnants from the valve without compromising the integrity of the underlying collagen matrix. The Company also believes that the CryoValve SGPV and the CryoValve SG aortic heart valve (CryoValve SGAV) are important to patient management issues for potential whole organ transplant recipients. 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. While the link between immune response and allograft tissue performance is still being debated, there is evidence that an elevated PRA poses a significant risk to future organ transplant patients. Avoiding elevated PRA is important for patients receiving cardiac tissues as some of these patients may ultimately require a heart transplant. In these patients, an increased PRA can decrease the number of possible donors for subsequent organ transplants and increase time on transplant waiting lists.

Cardiac Patches. Alternatives to human cardiac patches preserved by the Company include cardiac repair and reconstruction with small intestine submucosa (SIS) or patches constructed from bovine pericardium. CorMatrix Cardiovascular, Inc. is the leading supplier of SIS for cardiac repair and reconstruction with its CorMatrix ECM technology. There are several suppliers of bovine pericardial patches targeted for cardiac repair and reconstruction, including Edwards Life Sciences, Inc., Neovasc, Inc., St. Jude Medical, Inc., and Synovis Surgical Innovations. Management believes that at least one domestic tissue bank offers preserved human cardiac patches in competition with the Company, including LifeNet Health, Inc., which processes allograft patches using its Matracell technology.

Management believes that the human cardiac patches preserved by the Company, as compared to SIS, bovine, or other allograft patches, compete on the factors set forth above with respect to heart valves, and that these human cardiac tissues are the preferred repair and reconstruction alternative for use for cardiac defect repair including Tetralogy of Fallot, Truncus Arteriosis, and Pulmonary Atresia. The Company believes the CryoPatch SG enables the Company to compete with other patches by providing a patch processed with a technology designed to remove donor cells and cellular remnants from the patch without compromising the integrity of the underlying collagen matrix. As discussed above for the CryoValve SGPV

and CryoValve SGAV, the Company also believes that the CryoPatch SG is important to patient management issues for potential whole organ transplant recipients.

Vascular Tissue. Generally, for each procedure that may utilize vascular human tissue that the Company preserves, there are alternative treatments. Often, in the case of vascular tissue, these alternatives include the repair, partial removal, or complete removal of the damaged tissue and may utilize other tissues from the patients themselves or synthetic products. The attending physician, in consultation with the patient, makes the selection of treatment choices. Any newly developed treatments may also compete with the use of vascular tissue preserved by the Company.

There are a number of providers of synthetic alternatives to veins preserved by the Company and those alternatives are available primarily in medium and large diameters. Two primary synthetic grafts that compete with the Company s vascular tissue for below-the-knee surgery are W.L. Gore & Associates Propaten and C.R. Bard, Inc. s Distaflo. Artegraft s bovine carotid artery graft and Hancock Jaffe Laboratories, Inc. s ProCol can be used for hemodialysis access, and Maquet, Inc. s Hemashield woven grafts can be used for aortoiliac aneurysm surgery. Currently, management believes there are at least two other non-profit tissue banks that preserve and distribute human vascular tissue in competition with the Company.

General

Other recently developed technologies or procedures are, or may in the future be, the basis of competitive products. There can be no assurance that the Company s current competitors or other parties will not succeed in developing alternative technologies and products or product enhancements that are more effective, easier to use, or more economical than those which have been or are being developed by the Company or that would render the Company s technology and products obsolete and non-competitive in these fields. In such event, the Company s business, financial condition, profitability, and cash flows could be materially, adversely affected. See Part I, Item 1A, Risk Factors Risks Relating To Our Business Rapid Technological Change Could Cause Our Products and Services To Become Obsolete.

Research and Development and Clinical Research

The Company uses its technical and scientific expertise and its understanding of the needs of the cardiac and vascular surgery medical specialties to attempt to expand its surgical adhesives, sealants, and hemostats businesses and preservation services and to develop or acquire products and technologies for these specialties. The Company identifies market areas that can benefit from medical devices, preserved tissues, and other related technologies and then attempts to develop innovative techniques, products, and services within these areas, to secure their commercial protection, to establish their clinical efficacy, and then to market these techniques, products, and services. The Company employs approximately 37 people in its research and development and clinical research departments, including five Ph.D.s with specialties in the fields of chemistry (protein, material, organic, and bio); biomaterials; molecular biology; and engineering.

In order to expand the Company s product and service offerings, the Company is currently in the process of obtaining approvals, developing, or investigating several technologies and products, including PerClot, the PHT product platform used in BioGlue and BioFoam, the HeRO Graft, revascularization technologies, human tissue preservation, and technologies related to additional applications of its SynerGraft technology, including ProPatch.

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 of such applications or seek funding from outside sources to continue the commercial development of such technologies. The Company may also attempt to acquire or license additional technologies from third-parties to supplement its product lines.

The Company collects and maintains clinical data on the use and effectiveness of its products and services. The Company uses this data to help direct its continuing efforts to improve its products and services through ongoing research and development and shares this data with surgeons. The Company s research and development strategy is to allocate available resources among the Company s core market areas of cardiac and vascular surgery, sealants, and hemostats, based on the size of the potential market for any specific product candidate, the estimated development time and cost required to bring the product to market, and the expected efficacy of the potential product. 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. The Company s medical and scientific advisory board consults on various research and development programs. The Company s preclinical studies are conducted at universities and other locations outside the Company s facilities by third-parties under contract with the Company. In addition to these efforts, the Company may pursue other research and development activities.

In 2013, 2012, and 2011 the Company spent approximately $8.5 million, $7.3 million, and $6.9 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 the years 2013, 2012, and 2011. Of these amounts spent on research and development activities, $69,000, $604,000, and $398,000 was funded by the U.S. Department of Defense in 2013, 2012, and 2011, respectively.

PerClot. CryoLife filed an IDE with the FDA in March 2011 seeking approval to begin clinical trials for the purpose of obtaining PMA to distribute PerClot in the U.S. In April 2011 the FDA disapproved CryoLife s IDE filing. In March 2012 CryoLife refiled its IDE and the FDA responded with comments in the second quarter of 2012. CryoLife filed a revised IDE in November 2012 and received questions from the FDA in December 2012 related to this filing. In June 2013 CryoLife received conditional approval of its IDE for PerClot from the FDA. As part of the conditional approval for the PerClot IDE, the Company must make certain revisions to the investigational study protocol and clinical product labeling. The Company refiled the IDE submission on September 27, 2013. CryoLife received a second conditional approval on October 30, 2013. The Company has had multiple discussions with the FDA to resolve any remaining issues and expects to obtain FDA approval to begin enrollment into the pivotal trial in the first half of 2014.

BioFoam. 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 will be conducting a 45 patient post-market study in Europe on BioFoam used in cardiovascular applications in 2014. The Company has no current plans to introduce BioFoam in the U.S. Introducing BioFoam in the U.S. would require a clinical trial and FDA premarket approval.

Revascularization Technologies. Cardiogenesis is evaluating the use of biologic materials in conjunction with TMR. The synergy of injecting biologics, such as stem cells or growth factors, with TMR may provide greater angina reduction and improve cardiac function in patients with diffuse coronary artery disease who are not candidates for surgical bypass or intervention.

The PEARL 8.0 handpiece received FDA approval in February 2012. A condition of the approval is to conduct a post approval study on 10 to 22 patients at up to five centers with 30 day follow-up. The Company anticipates the study will be completed in 2014.

HeRO Grafts. The Company is currently working on improvements to the HeRO Graft which may include, among other things, product enhancements to facilitate easier implantation of the device. In April 2013 CryoLife received a CE Mark for the HeRO Graft.

CryoValve SGPV. At the FDA s request, the Company has committed to 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 is expected to be completed in mid-2014.

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 owns or has licensed rights to 60 U.S. patents and 40 foreign patents, including patents that relate to its technology for BioGlue, PHT, revascularization technologies, HeRO Graft, human cardiac and vascular tissue preservation, and decellularization of tissue. The Company has approximately 14 pending U.S. patent applications and 20 pending foreign applications that relate to the Company s, PHT, tissues, and other areas. 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 17 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. However, for a competitor to copy BioGlue they would have to develop parts of the manufacturing process that are trade secrets of the Company and then seek FDA approval, which would likely require human clinical trials, or other regulatory approvals. In September 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI for PerClot. Once the Company begins to manufacture PerClot, it will be required to pay royalties based on revenues of PerClot manufactured by the Company. The Company has already prepaid $1.5 million of these royalties. In addition, the Company has a distribution agreement with a third-party for the distribution of PerClot. These products have license rights and trade secrets that provide competitive advantages.

There can be no assurance that the claims allowed in any of the Company s existing or future patents will provide competitive advantages for the Company s products, preserved tissues, and technologies or will not be successfully challenged or circumvented by competitors. There can also be no assurances that the claims allowed in patents licensed or owned by third-parties for products distributed by the Company will not be successfully challenged or circumvented by competitors. To the extent that any of the Company s products, whether manufactured by the Company or distributed by it, are not effectively patent protected, the Company s business, financial condition, profitability, and cash flows could be materially, adversely affected. Under current law, patent applications in the U.S. and patent applications in foreign countries are maintained in secrecy for a period after filing. The Company cannot be sure that products manufactured or distributed by it, or the technologies developed by it, do not infringe patents that may be granted in the future pursuant to pending patent applications or that they do not infringe any patents or proprietary rights of third-parties.

The Company may incur substantial legal fees in defending against a patent infringement claim or in asserting claims against third-parties. If the Company loses such litigation, it could be forced to cease marketing the products or services related to the infringing technology or pay significant license fees or damages. In the event that any relevant claims of third-party patents are upheld as valid and enforceable, the Company could be prevented from marketing certain of its products, could be required to obtain licenses from the owners of such patents, or could be required to redesign its products or services to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be on terms acceptable to the Company or that the Company would be successful in any attempt to redesign its products or services to avoid infringement. The Company s failure to obtain licenses or to redesign its products or services could materially, adversely affect the Company s business, financial condition, profitability, and cash flows. For example, in September of 2012, the Company received a letter from Medafor stating that PerClot, when introduced in the U.S., will, when used in accordance with the method published in the Company s literature and with the instructions for use, infringe their U.S. patent. See Part I, Item 1A, Risk Factors Risks Relating To Our Business 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.

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. Litigation may be necessary to defend against claims of infringement, to enforce patents and trademarks of the Company, or to protect trade secrets and confidential information, and such litigation could result in substantial cost to, and diversion of effort by, the Company. There can be no assurance that the Company would prevail in any such litigation. In addition, the laws of some foreign countries do not protect the Company s proprietary rights to the same extent as do the laws of the U.S.

Preservation, Manufacturing, and Operations

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 in suburban Atlanta, Georgia, with an additional 14,400 square feet of off-site warehouse space and an additional 15,500 square feet of combined manufacturing and office space in Atlanta, Georgia. Approximately 20,000 square feet are dedicated as class 10,000 clean rooms. An additional 8,000 square feet are dedicated as class 100,000 clean rooms. The extensive clean room environment provides a controlled aseptic environment for tissue manufacturing, preservation, and packaging. Approximately 55 liquid nitrogen freezers maintain preserved tissue at or below 135°C. Two back-up emergency generators assure continuity of Company manufacturing operations. 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.

BioGlue and BioFoam

BioGlue and BioFoam are manufactured at the Company s headquarters facility. The laboratory contains approximately 13,500 square feet, including a suite of six clean rooms. Currently, there are approximately 19 technicians and supervisors employed in this area. The laboratory has a potential annual capacity of approximately 2 million syringes of BioGlue and BioFoam. The current production level is about 7% of total capacity. To produce at full capacity levels, the Company would need to increase the number of employees, add work shifts, and install automated filling and pouching equipment.

Revascularization Technologies

Revascularization technologies consist of laser consoles and handpieces. The manufacturing of the laser consoles is outsourced to a single contract manufacturer. The manufacturing and assembly of the handpieces is outsourced to a different single contract manufacturer. The Company s corporate headquarters has approximately 1,200 square feet of laser maintenance and evaluation laboratory space.

HeRO Grafts

The manufacturing space for the HeRO Grafts in Atlanta, Georgia contains approximately 3,300 square feet including approximately 1,000 square feet allocated to a suite of eight clean rooms. There are approximately five technicians employed in this area. The Company believes that production levels are at approximately 20% to 25% of total capacity. To produce at full capacity levels, the Company would need to install a second component spraying hood and purchase some additional small equipment, as well as increase the number of technicians and the number of shifts worked.

Other Medical Devices

The Company s headquarters and off-site manufacturing has additional laboratory space consisting of approximately 20,400 square feet with a suite of eight clean rooms. This laboratory space is expected to house the manufacturing of PerClot and ProPatch.

Tissue Preservation

The Company s tissue processing laboratory is responsible for the processing and preservation of human cardiac and vascular tissues for transplant. This laboratory contains approximately 17,500 square feet with a suite of seven clean rooms dedicated to tissue processing. Currently, there are approximately 75 technicians and supervisors employed in this area, and the laboratory is staffed 24 hours per day, 365 days per year. In 2013 the laboratory packaged approximately 11,700 tissues. The current processing level is estimated to be at about 30% of total capacity. To produce at full capacity levels, the Company would have to increase the amount of donated tissues, which the Company could attempt to do by revising its tissue acceptance criteria, increasing the number of relationships with OTPOs, or working to increase donor awareness to increase tissue donation. Any attempt to increase the amount of tissues processed could be constrained by the availability of donated tissues. If significant additional donated tissues were obtained, the Company would also need to increase the number of employees or increase the number of hours worked by employees.

Europa

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.

Suppliers, Sources, and Availability of Tissues and Raw Materials

The Company s BioGlue and BioFoam products are comprised of bovine protein and a cross linker that is delivered to the surgical site through a delivery device. The delivery devices are manufactured by a single supplier. Although the Company maintains an inventory of devices, if the single supplier ceased producing delivery devices for other than a short period of time, this would materially, adversely affect the Company s ability to manufacture BioGlue and could therefore affect the Company s revenues.

PerClot is produced by SMI for the Company pursuant to a distribution agreement. If SMI were unable to obtain the appropriate raw materials to manufacture PerClot for the Company or if SMI were unable to manufacture PerClot due to other factors, it would materially, adversely affect the Company s ability to sell PerClot and could therefore materially, adversely affect the Company s revenues. In addition, if SMI breached its distribution agreement or attempted to terminate the distribution agreement, it would materially, adversely affect the Company s ability to sell PerClot and obtain revenue growth from the product.

The contract manufacturers for the revascularization technologies consoles and handpieces generally acquire certain components from multiple sources. Other laser and fiber-optic components and subassemblies are purchased from single sources. Any significant supply interruption would materially, adversely affect the Company s ability to sell the revascularization technologies products and obtain revenue growth from these products.

HeRO Graft components are purchased from single sources in some instances, and switching to a secondary supplier may be difficult. For example, the ePTFE arterial graft used in the HeRO Graft is provided by one manufacturer, and using a secondary supplier may be difficult because of certain of this manufacturer s patent rights. Any significant supply interruption would materially, adversely affect the Company s ability to sell HeRO Graft and obtain revenue growth from the product.

The Company s preservation services business and its ability to supply needed tissues is dependent upon donation of tissues from human donors. The Company must rely on the OTPOs that it works with to educate the public on the need for donation and to foster a willingness to donate tissue. The Company must also maintain good relationships with its OTPOs to ensure that it will receive donated tissue. In addition, future regulations could reduce the tissues available for implantation. The Company also uses various medicines and solutions in its processing. Some of these medicines and solutions are only manufactured by single suppliers, which means if the single supplier ceased or was unable to manufacture a medicine or solution, this could materially, adversely affect the Company s ability to accept or process tissue, which could materially, adversely affect the Company s revenues.

Certain raw material components used in the Company s products and tissue processing have stringent specifications. Accordingly, the Company may need to reject non-compliant raw materials, which could limit the Company s ability to manufacture its products or process tissues and could materially, adversely affect the Company s revenues

See also Part I, Item 1A, Risk Factors.

Quality Assurance

The Company s operations encompass the manufacturing of medical devices and the preservation of human tissue. In all of its 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 FDA periodically inspects Company facilities to review Company compliance with these and other regulations. 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. LRQA performs periodic on-site inspections, generally at least annually, of the Company s quality systems.

The Company s quality assurance staff is comprised primarily of experienced professionals from the medical device manufacturing and tissue processing industries. The quality assurance department, in conjunction with the Company s research and development department, routinely evaluates the Company s processes and procedures.

Medical Device Manufacturing

The Company employs a comprehensive quality assurance program in all of its manufacturing activities. The Company is subject to many quality system requirements, including Quality System Regulations, ISO 13485, and Medical Device Directive requirements.

All materials and components utilized in the production of the products manufactured by the Company are received and inspected by trained quality control personnel according to written specifications and standard operating procedures. Only materials and components found to comply with Company standards are accepted by quality control and utilized in production.

Materials, components, and resulting sub-assemblies are documented throughout the manufacturing process to assure traceability. Processes in manufacturing are validated to produce products meeting the Company s specifications. The Company maintains a quality assurance program to evaluate and inspect its own manufactured products and distributed products to ensure conformity to product specifications. Each process is documented along with all inspection results, including final finished product inspection and acceptance. Records are maintained as to the consignees of products to track product performance and to facilitate product removals or corrections, if necessary.

The Company s manufacturing facilities are subject to periodic inspection by the FDA and LRQA to independently review the Company s compliance with its systems and regulatory requirements.

Preservation Services

The Company employs a comprehensive quality assurance program in all of its tissue preservation activities. The Company is subject to human cell and tissue regulations, including donor eligibility and cGTPs, as well as other FDA Quality System Regulations, ISO 13485 requirements, and other specific country requirements. The Company s quality assurance program begins with the development and implementation of training policies and procedures for the employees of OTPOs. To assure uniformity of procurement practices among the tissue recovery teams, the Company provides procurement protocols, transport packages, and tissue transport liquids to the OTPOs. The Company periodically audits OTPOs to ensure compliance with Company policy and enhance recovery practices.

Upon receipt by the Company, each incoming tissue is assigned a unique control number that provides traceability of tissue from procurement through the preservation processes and, ultimately, to the tissue recipient. Samples from each tissue donor are subjected to a variety of tests to screen and test for infectious diseases. Samples of some tissues are also provided for pathology testing. Following dissection of the tissue to be preserved, the tissue is treated with a proprietary antimicrobial solution and aseptically packaged. After antimicrobial treatment, each tissue must be shown to be free of detectable microbial contaminants before being considered releasable for distribution.

The materials and solutions used by the Company in preserved tissue must meet the Company s quality standards and be approved by quality assurance personnel. Throughout the tissue preservation process, detailed records of the tissues, materials, and processes used are maintained and reviewed by quality assurance personnel.

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. The States of California, Delaware, Florida, Georgia, Illinois, Maryland, New York, Oregon, and Pennsylvania license or register the Company s tissue preservation facilities as facilities that preserve, store, and distribute human tissue for implantation. The regulatory bodies of these states may perform inspections of the Company s facilities as required to ensure compliance with state laws and regulations. Additionally, countries in which CryoLife distributes tissue may also perform inspections of the Company facilities to ensure compliance with those countries regulations.

Government Regulation

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. There are two review procedures by which medical devices may receive such approval or clearance.

Some products may qualify for clearance to be marketed under a Section 510(k) process, in which the 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. In order for the device to be found substantially equivalent to the predicate device, the device must be 1) for the same intended use and 2) 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.

If the product does not qualify for the 510(k) process, it must be approved through the IDE/PMA process. This can be required either because it is not substantially equivalent to a legally marketed 510(k) device or because it is a Class III device and, therefore, the IDE/PMA process is required by FDA regulations.

The FDCA provides for an IDE which authorizes distribution for clinical evaluation of devices that lack PMA or 510(k) clearance. Devices subject to an IDE are subject to various restrictions imposed by the FDA. The number of patients that may be treated with the device is limited, as is 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, may not be advertised or otherwise promoted, and 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.

The FDA must approve a PMA application before marketing can begin. 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

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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.

The FDCA requires all medical device manufacturers and distributors to register with the FDA annually and to provide the FDA with a list of those medical devices they distribute commercially. The FDCA also requires manufacturers of medical devices to comply with labeling requirements and to manufacture devices in accordance with Quality System Regulations, which require that companies manufacture their products and maintain their documents in 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 inspects medical device manufacturers and distributors 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.

These Company products are, or would, upon approval, be classified as Class III medical devices: BioGlue, BioFoam, PerClot, and revascularization technologies. CryoValve SGPV, CryoPatch SG, HeRO Graft, and ProPatch are classified as Class II medical devices.

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.

It is likely that the FDA s regulation of preserved human tissue will continue to evolve in the future. Complying with FDA regulatory requirements or obtaining required FDA approvals or clearances may entail significant time delays and expense or may not be possible, any of which could materially, adversely affect the Company.

Possible Other FDA Regulation

Other products and tissues under development by the Company are likely to be subject to regulation by the FDA. Some may be classified as medical devices or human cells and tissue products, while others may be classified as drugs or biological products, or may be subject to a regulatory process that the FDA may adopt in the future. Regulation of drugs and biological products is substantially similar to regulation of Class III medical devices. Obtaining FDA approval to market these products and tissues is likely to be a time consuming and expensive process, and there can be no assurance that any of these products and tissues will ever receive FDA approval.

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.

International Approval Requirements

Sales of medical devices and shipments of preserved 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 preserved human tissues in those countries. The time required to obtain these approvals may be longer or shorter than that required for FDA approval.

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. 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, the consoles and handpieces used for TMR, and the HeRO Graft. Additionally, PerClot, which the Company distributes, has a CE Mark.

In addition, the distribution of CryoLife s preserved human tissues in certain countries in Europe is subject to regulatory approvals or requirements. CryoLife has historically shipped tissues into the U.K., Germany, and Austria. In 2004 and 2006 through three separate directives, the EU passed the EU Tissue and Cells Directives (EUTCD), which 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. In the U.K. this Competent Authority is the HTA, which has promulgated various directives that affect CryoLife s shipment of tissues into the U.K. and Europa s import of these tissues. Europa is a Licensed Establishment under HTA Directions, and both Europa and CryoLife are subject to certain regulatory requirements under HTA Directions, including maintenance of records and tracing of shipments from donor to recipient. In Germany, this Competent Authority is the PEI, which enforces various regulations passed by the regulatory authorities in Germany. See discussion above in Distribution and Marketing Preservation Services for the Company s current regulatory activities with the HTA and PEI.

Recent Regulatory Approvals

June 2013 PMA supplement approval was received for a design change to the Cardiogenesis SoloGrip III, PEARL 5.0, and PEARL 8.0 fiberoptic handpieces.

June and October 2013 Conditional IDE approval was received for PerClot.

April 2013 CE Mark was received for the manufacturing of the HeRO Graft.

March 2013 510(k) clearance was received for the HeRO Graft Adaptor.

Certifications, Accreditations, and Inspections

February 2014 The FDA commenced its reinspection related to the Warning Letter, as defined in the Ongoing Regulatory Items Section below, which will include a quality system inspection of the Company s products, services, and facilities.

February 2014 The FDA conducted an inspection of Hemosphere. An FDA Form 483, Notice of Inspectional Observations, was issued.

October and November 2013 LRQA conducted a routine ISO 13485 and Canadian Medical Devices Conformity Assessment System inspection. Four minor observations were noted.

September 2013 The American Association of Tissue Banks conducted a re-accreditation inspection. Three non-conformities were noted.

May 2013 The FDA conducted an inspection of Cardiogenesis. A Form 483, Notice of Inspectional Observations, was issued.

May 2013 The South Korean Ministry of Food and Drug Safety conducted a routine quality system inspection. No observations were noted.

April 2013 The Brazilian National Health Surveillance Agency conducted a routine quality system inspection. One minor recommendation was noted.

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

Ongoing Regulatory Items

On January 30, 2013 CryoLife received a warning letter (Warning Letter) dated January 29, 2013 from the FDA. The Warning Letter followed a Form 483, Notice of Inspectional Observations, from the FDA (CryoLife Form 483) related to the Company s processing, preservation, and distribution of human tissue and the manufacture of medical devices. The CryoLife Form 483 followed a routine quality system inspection of the Company s facilities by the FDA during the period September 17, 2012 to October 16, 2012. The Warning Letter relates to certain observations from the CryoLife Form 483 that the FDA believes were either inadequately addressed by the Company s responses or for which the FDA required further information to fully assess the Company s corrective actions. The Company responded to the FDA s requests and implemented corrective actions. The Company believes that these corrective actions have adequately addressed the FDA s notice of violations contained in the Warning Letter; however, it is possible that the Company s actions ultimately may not be satisfactory to the FDA. During the second quarter of 2013 the Company received verbal communication from the FDA indicating that these corrective actions appear satisfactory in addressing the issues raised in the Warning Letter. On February 18, 2014 the FDA commenced its reinspection of the Company with respect to the Warning Letter to determine whether it is satisfied with the Company s actions and responses. This reinspection will include a quality system inspection of the Company s products, services, and facilities. The Company believes that the Warning Letter and its actions regarding the Warning Letter and CryoLife Form 483 will not have a material effect on the Company. However, it is possible that further actions the Company may be required to take in response to the reinspection or the quality system inspection could materially, adversely affect the availability of the Company s products and tissues and cost structure, which could affect the Company s revenues, financial condition, profitability, or cash flows.

On May 23, 2013 CryoLife received a Form 483 related to the Company s subsidiary Cardiogenesis (Cardiogenesis Form 483). The Cardiogenesis Form 483 followed a quality system inspection of the Company s facilities by the FDA in May 2013. The Cardiogenesis Form 483 includes observations concerning labeling, complaint handling, and field actions. The Company has responded to the FDA s requests and implemented changes that it believes address the FDA s observations. Subsequent to receipt of the Cardiogenesis Form 483, as discussed above, Cardiogenesis received PMA supplement approval from the FDA for its redesigned Sologrip and PEARL handpieces. See also Part I, Item 1A, Risk Factors.

On February 14, 2014, CryoLife received an FDA Form 483 related to the Company s subsidiary Hemosphere (Hemosphere Form 483). The Hemosphere Form 483 followed a quality system inspection of the Company s facilities by the FDA in February 2014. The Hemosphere Form 483 includes observations concerning nonconformance inspections and manufacturing, the Company s corrective and preventive action procedures, and documentation issues. The Company has already had verification of its implementation of corrective action with respect to one observation and expects to respond to the remaining observations from the Hemosphere Form 483 within 15 business days, as required by law. The Company believes that the changes that it will implement will 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 actions, including requiring a recall or manufacturing hold. The Company believes that the Hemosphere Form 483 will not have a material effect on the Company. However, it is possible that actions it may be required to take in response to the Hemosphere Form 483 could materially, adversely affect the Company s revenues, financial condition, profitability, or cash flows.

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 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.

Employees

As of December 31, 2013 CryoLife and its subsidiaries had approximately 510 employees. These employees included seven persons with Ph.D. degrees, three with M.D. degrees, and one with a D.O. degree. 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.

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.

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 has 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 non-valved cardiac, 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, on January 30, 2013 we received a warning letter (Warning Letter) dated January 29, 2013 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 (CryoLife Form 483). The CryoLife Form 483 followed a routine quality system inspection of our facilities by the FDA during the period September 17, 2012 to October 16, 2012.

The Warning Letter relates to certain observations from the CryoLife Form 483 that the FDA believes were either inadequately addressed by the Company s responses or for which the FDA required further information to fully assess the Company s corrective actions. Concerns expressed by the FDA include but are not limited to:

The Company s responses did not identify adequate corrective actions to be taken to ensure that all complaint investigations are adequately conducted;

The Company s responses did not identify corrective actions to assure that management reviews the Company s quality system on a regular and sufficiently frequent basis;

The Company s responses did not identify corrective actions to prevent the reoccurrence of deficiencies noted in personnel training;

The Company should provide additional information describing changes to the Company s disinfectant system as well as additional information concerning its environmental monitoring program; and

The Company s responses did not identify corrective actions to ensure environmental trending reports were generated pursuant to procedures.

On May 23, 2013 CryoLife received a Form 483 related to CryoLife s subsidiary, Cardiogenesis Corporation (Cardiogenesis) (Cardiogenesis Form 483). The Cardiogenesis Form 483 followed a quality system inspection of the Company s facilities by the FDA in May 2013. The Cardiogenesis Form 483 contains certain observations including observations concerning labeling, complaint handling, and field actions. Subsequent to receipt of the Cardiogenesis Form 483, the Company received Premarket Approval (PMA) supplement approval from the FDA for its redesigned Sologrip and Port Enables Angina Relief with Laser (PEARL) handpieces. We have received no warning letter related to the Cardiogenesis Form 483.

We have responded fully to the FDA s requests for the CryoLife Form 483 and Cardiogenesis Form 483 and have addressed the FDA s notice of violations contained in the Warning Letter. On February 18, 2014 the FDA commenced its reinspection of the Company with respect to the Warning Letter to determine whether it is satisfied with our actions and responses. This reinspection will include a quality system inspection of our products, services, and facilities.

In addition, on February 14, 2014, CryoLife received an FDA Form 483 related to the Company s subsidiary Hemosphere (Hemosphere Form 483). The Hemosphere Form 483 followed a quality system inspection of the Company s facilities by the FDA in February 2014. The Hemosphere Form 483 includes observations concerning nonconformance inspections and manufacturing, the Company s corrective and preventive action procedures, and documentation issues. The Company has already had verification of its implementation of corrective action with respect to one observation and expects to respond to the remaining observations from the Hemosphere Form 483 within 15 business days, as required by law.

We believe that any further actions regarding the Warning Letter or the CryoLife, Cardiogenesis, or Hemosphere Forms 483 will not have a material impact on the Company. However, it is possible that actions we may be required to take in response to the reinspection or quality system inspection or the Cardiogenesis or Hemosphere Forms 483 could materially, adversely affect our cost structure and the availability of our products and tissues, which could affect our revenues, financial condition, profitability, and cash flows.

If we are unable to satisfy the notice of violations in the Warning Letter, the FDA can institute a wide variety of enforcement actions ranging from making additional public statements to more severe sanctions such as fines; injunctions; civil penalties; recall 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, recall, hold, or other negative publicity from the FDA resulting from the reinspection or quality system inspection or the Cardiogenesis or Hemosphere Forms 483, or otherwise may decrease demand for our tissues or products or cause us to write down our deferred preservation costs or inventories 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 tissues and our medical devices 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 an additional contingent payment of $250,000 in 2011 and will pay additional contingent amounts of up to $2.5 million to SMI if certain U.S. regulatory and other commercial milestones are achieved. We will also pay royalties on any sales of PerClot manufactured by us. 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 to gain U.S. regulatory approval in the next several years, most of which we expect to be incurred in 2014 and 2015. 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.

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 PerClot within the timetable anticipated. In June 2013 we received conditional approval of our investigational device exemption (IDE) for PerClot from the FDA. IDE approval would allow us to begin clinical trials for the purpose of obtaining PMA to distribute PerClot in the U.S. As part of the conditional approval for the PerClot IDE, we must make certain revisions to the investigational study protocol and clinical product labeling. We refiled the IDE submission on September 27, 2013 and received a second conditional approval on October 30, 2013. We have had multiple discussions with the FDA to resolve any remaining issues and expect to obtain FDA approval to begin enrollment into the pivotal trial in the first half of 2014, but there can be no guarantee that this will occur as we expect. The Company will not be able to sell PerClot in the U.S. in future years unless and until FDA approval is granted. 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 CryoLife s license to apply for FDA approval, and the parties will have to, in good faith, renegotiate CryoLife s 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.

In addition, if we are ultimately able to obtain approval from the FDA to sell PerClot, we will likely end up in a patent infringement lawsuit with Medafor, Inc. (Medafor) or its parent entity C. R. Bard, Inc. (Bard). See also If We Sell PerClot In The U.S., We Will Likely End Up In A Patent Infringement Lawsuit, Which 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.

If We Sell PerClot In The U.S., We Will Likely End Up In A Patent Infringement Lawsuit, Which 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.

Medafor sent us a letter in September 2012 stating that PerClot, when introduced in the U.S., will, when used in accordance with the method published in our literature and with the instructions for use, infringe their U.S. patent. Subsequent to that event, Medafor was acquired by Bard. We do not believe that PerClot will infringe Medafor s/Bard s U.S. patent. If we do obtain FDA approval for PerClot, we will likely end up in a patent infringement lawsuit with Medafor/Bard. We believe the potential patent infringement litigation between CryoLife and Medafor/Bard could occur as early as 2014, and we believe that if litigation occurs, the costs of this litigation would be material. If we do obtain FDA approval, but are found by a court to have infringed Medafor 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 used to offset our legal fees and certain damages associated with this potential patent litigation. However, the availability of these monies and the timing of these offsets will not likely precisely match the timing of any related legal expenses incurred. 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.

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; and

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 Of Up To $8.4 Million 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 $8.4 Million.

As discussed elsewhere in this Form 10K, we received approximately $15.4 million for our shares of Medafor common stock due to Bard s acquisition of Medafor. We could receive up to an estimated additional $8.4 million from this transaction in the future, based on information provided by Medafor as part of the September 24, 2013 Medafor Proxy Statement (Medafor Proxy). We estimate that up to $525,000 could be paid to us in the fourth quarter of 2014, up to $987,000 could be paid to us in the second quarter of 2015, and up to $168,000 could be paid to us in 2017 related to an escrow release, plus 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 the Company could receive under this earnout could range from zero to $8.4 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 occurred. As a result, the amount of additional monies that could be paid to us may be significantly less than the $8.4 million 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, 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, it is likely the outcome of this event will be the rejection or recall of the 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 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. For example, in 2011 certain supplies of processing solution used in our processing of tissue did not meet our quality requirements. As a result, we ceased processing the tissues that used this solution and expensed $674,000 related to the preservation costs for these tissues, none of which were implanted. Additionally, in 2012, due to problems caused by FDA inspections at the only papaverine manufacturer in the U.S., there was a shortage of papaverine, a

medicine used in our tissue processing and by many of our recovery partners, which could have disrupted our tissue processing. We were able to change our processing to no longer require the use of papaverine.

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, or the amounts of reimbursement available for our products or services and could limit the acceptance and availability of our products and services.

Our Loan To ValveXchange May Become Uncollectible, Which Could Materially, Adversely Affect Our Business.

In July 2011 we purchased approximately 2.4 million shares of Series A Preferred Stock of ValveXchange, Inc. (ValveXchange) for approximately $3.5 million. This investment represents an approximate 19% equity ownership in ValveXchange. 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. During 2012 we loaned ValveXchange $2 million under a note receivable. See Part II, Item 5, Notes to Consolidated Financial Statements for further discussion of the Company s note receivable, its investment in ValveXchange preferred stock, and the impairment and write-off of such investment.

In accordance with accounting principles generally accepted in the U.S., we regularly review our long-term notes receivable based on available information and make determinations regarding their collectability. We will continue to evaluate our note receivable from ValveXchange for collectability.

The collectability of our note receivable from ValveXchange is subject to certain risks, including business and operational risks of ValveXchange that are outside of our control. These business risks include the fact that ValveXchange must secure material amounts of additional financing, and if it cannot do so, it will likely be unable to meet its obligations. As a result, we may need to foreclose on the underlying collateral to secure repayment under the note receivable. Although CryoLife currently believes that the value of the collateral is adequate to satisfy the note receivable, there is no guarantee of such adequacy. If we subsequently determine that some portion, or all, of the note receivable has become uncollectable, the resulting write-down could materially, adversely affect our financial condition and profitability. In addition, ValveXchange may be unable to raise additional monies in the future, which could severely diminish the collectability of our note receivable.

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, our manufacturing throughput of our products and our processing throughput of tissue would necessarily need to decrease, which would likely adversely impact our margins and, therefore, our profitability, possibly materially. Further, if demand for our products or tissues materially decreases in the future, we may not be able to ship our products or tissues before they expire, which would cause us to write down our inventories and 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.

Key Growth Strategies May Not Generate The Anticipated Benefits.

The key elements of our strategy related to growing our business and leveraging our strength and expertise in our core marketplaces to generate revenue and earnings growth are to:

- Identify and evaluate acquisition opportunities of and investments in complementary product lines and companies,
- Expand our core business,
- Develop our pipeline of products and services,
- License company technology to third parties for non-competing uses, and
- Analyze and identify underperforming assets for potential sale or disposal.

Although management continues to implement these strategies, we cannot be certain that they will ultimately 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, that 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. For example, in 2008 litigation began against Tenaxis, Inc. (Tenaxis) in Germany because we believed that Tenaxis was infringing our patent, and Tenaxis was attempting to nullify our patent. We ultimately settled the lawsuits against Tenaxis after incurring considerable expense. 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, If We Sell PerClot In The U.S., We Will Likely End Up In A Patent Infringement Lawsuit, Which 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 revascularization technologies,

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.

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. We are uncertain whether we can 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 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. Delays or rejections may also be encountered by us 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 sure 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 services or products may require significant physician training and years of clinical evidence derived from follow-up studies on human implant recipients in order to gain acceptance in the medical community. Our potential new

services or products currently under development that are not otherwise discussed in a previous risk factor include the following:

New indications for BioGlue,

Product enhancements to the Hemodialysis Reliable Outflow Graft (HeRO® Graft),

ProPatch and related products, and

Use of biologic materials in conjunction with transmyocardial revascularization (TMR).

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.

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 processing and manufacturing operations; 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, and which require us to license Europa, our subsidiary, to ship tissue into the U.K. and a license to distribute tissue into Germany through those countries Competent Authorities.

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 regulation 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 legislation and regulations that govern interactions with physicians and other healthcare professionals. For example, beginning in 2014, we will have to disclose payments made after August 2013 to physicians for meals or other services to the Department of Health and Human Services. These existing legislation 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 be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve any outstanding or any future claims, this will materially, adversely affect our financial condition, profitability, and cash flows. Further, although we have an estimated reserve for our unreported product and tissue processing liability claims for which we do expect that we will obtain recovery for 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,

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 the second quarter of 2013. We anticipate the continued payment of a cash dividend to our shareholders in future quarters. However, 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.

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 our leverage ratio at a certain level and 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, Which Expires In October Of 2014, Limits Our Ability To Pursue Significant Acquisitions And Also May Limit Our Ability To Borrow.

Our credit facility, which expires in October of 2014, 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 $15.0 million. Although our lender has modified the credit facility in the past to allow us to make acquisitions that do not affect this aggregate of $15.0 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, including our Chief Executive Officer, Steven G. Anderson, whose employment agreement expires in December 2015. 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 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.

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:

Advantages of the human tissues the Company distributes;

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;

Expectations regarding, and efforts to respond to the FDA questioning related to, the revised IDE filed for PerClot and the anticipated clinical trials to obtain PMA to distribute PerClot in the U.S.;

Potential benefits and additional applications of the Company s surgical adhesives, sealants, hemostats, and TMR treatment;

Anticipated timing of completion of the PEARL 8.0 post-approval study and full-market launch;

Revenue trend estimates for the Company s products and services for 2014;

Plans related to regulatory approval in certain markets for BioFoam, and the subsequent distribution of BioFoam in those markets;

The estimated European market opportunity for cardiovascular and parenchymal tissue sealing;

Commercialization plans for ProPatch;

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

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

Plans regarding HeRO Graft product enhancements, estimates regarding the addressable worldwide market opportunity for the HeRO Graft, and the Company s intentions to introduce the HeRO Graft more broadly within Europe in 2014;

The Company s beliefs that the HeRO Graft will fit well within the Company s product portfolio and that a significant opportunity exists to introduce and expand the utilization of the HeRO Graft in the U.S.;

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

Expected benefits of the Company s marketing, educational and technical support efforts;

Anticipated benefits of providing on-site freezers;

Expected effect of discontinuance of tissue shipments into Europe beginning April 2014;

The Company s estimates and assessments of production levels and production capacity;

Expected use of the Company s additional laboratory space;

Anticipated payment of quarterly dividends each year;

The Company s expectations regarding the recoverability and realizability of deferred tax assets;

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

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

Expectations regarding the recognition of stock compensation expense;

The Company s assessment of the effect of adopting new accounting standards regarding the testing of certain intangible assets for impairment and the reporting of certain reclassified amounts;

Plans and expectations regarding research and development of new technologies and products;

The Company s expectations about whether and when it may receive additional payments related to its sale of Medafor stock;

The Company s expectation that general, administrative, and marketing expenses will increase in 2014 as compared to 2013, before consideration of the effects of litigation and business development expenses;

Management s beliefs that the potential patent infringement litigation between CryoLife and Medafor or Bard could occur as early as 2014, and management s belief that if litigation occurs the cost of this litigation would be material;

Expectations that research and development spending will increase materially in 2014;

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

The Company s beliefs regarding sales of BioGlue, PerClot, handpieces, and laser consoles and the factors affecting such sales;

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

The Company s belief that the underlying collateral is sufficient to secure the Company s $2.0 million loan to ValveXchange;

The Company s belief that any issues related to the FDA s observations in the CryoLife Form 483 and the Warning Letter will not have a material effect on the Company;

The Company s belief that any issues related to the FDA s observations in the Hemosphere Form 483 will not have a material effect on the Company;

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;

Estimates of contingent payments and royalties that may be paid by the Company and the timing of such payments;

The possibility of a patent infringement lawsuit with Medafor, the impact of such a lawsuit, and the Company s belief that PerClot will not infringe Medafor s patent;

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

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

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

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

Plans regarding acquisition and investment opportunities of complementary product lines and companies;

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

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

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;

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.

Item 1B. Unresolved Staff Comments.

The Company has no unresolved written comments received from the staff of the SEC regarding its periodic or current reports under the Securities Exchange Act of 1934 not less than 180 days before December 31, 2013 (the end of the fiscal year to which this Form 10-K relates).

Item 2. Properties.

The Company s facilities are located in multiple sites in Atlanta, Georgia, and in Guildford, England. The corporate headquarters in suburban Atlanta (Kennesaw) consists of approximately 190,400 square feet of leased manufacturing, administrative, laboratory, and warehouse space with an additional 14,400 square feet of off-site warehouse space. Approximately 26,000 square feet are dedicated to clean room work areas. The primary facility has seven main laboratory facilities: human tissue preservation, BioGlue and BioFoam manufacturing, research and development, microbiology, pathology, the revascularization technologies laser maintenance and evaluation laboratory, and additional space expected to house a portion of the PerClot manufacturing with availability for manufacturing of other products. Each of these areas consists of a general technician work area and adjoining clean rooms for aseptic processing or testing of human tissue or for aseptic manufacturing and testing of medical devices. The clean rooms are supplied with highly filtered air that provides a near-sterile environment. The human tissue preservation laboratory contains approximately 17,500 square feet with a suite of seven clean rooms. The current processing level is estimated to be at about 30% of total capacity. To increase the current processing levels, the Company could increase the number of employees and expand its second and third shift. The BioGlue and BioFoam manufacturing laboratory contains approximately 13,500 square feet with a suite of six clean rooms. The current processing level is about 7% of total capacity. To produce at full capacity levels, the Company would need to increase the number of employees, add work shifts, and install automated filling and pouching equipment. The research and development laboratory is approximately 10,200 square feet with a suite of five clean rooms. The microbiology laboratory is approximately 7,300 square feet with a suite of five clean rooms. The pathology laboratory is approximately 1,100 square feet. The revascularization technologies laser maintenance and evaluation laboratory is approximately 1,200 square feet. The additional manufacturing laboratory contains approximately 18,900 square feet with a suite of six clean rooms.

An additional combined manufacturing and office space of approximately 15,500 square feet with a suite of eight clean rooms is in a facility located within the city of Atlanta. This space is used for the manufacturing of the HeRO Graft and is expected to be used for a portion of the PerClot manufacturing.

The Europa facility located in Guildford, England contains approximately 3,400 square feet of leased office and warehousing space. In addition, Europa has shared warehousing space utilized by its third-party shipper.

Item 3. Legal Proceedings.

None.

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
Steven G. Anderson	Since 1984	75	President, Chief Executive Officer, and Chairman
Bruce G. Anderson	Since 2012	47	Vice President, U.S. Sales and Marketing
Jeffrey W. Burris	Since 2010	42	Vice President and General Counsel
Scott B. Capps	Since 2007	47	Vice President, Clinical Research
David M. Fronk	Since 1998	50	Vice President, Regulatory Affairs and Quality Assurance
David C. Gale, Ph.D	Since 2012	46	Vice President, Research and Development
David P. Lang	Since 2012	67	Senior Vice President, International Sales and Marketing
D. Ashley Lee, CPA	Since 2000	49	Executive Vice President, Chief Operating Officer, and Chief Financial Officer

Steven G. Anderson, a founder of CryoLife, has served as CryoLife s President, Chief Executive Officer, and Chairman of the Board of Directors since its inception. 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.

Jeffrey W. Burris was appointed to the position of Vice President and General Counsel in February 2010. Mr. Burris has been with the Company since February 2008, serving as General Counsel from February of 2008 until February 2010. From 2003 to 2008, Mr. Burris served as Senior Legal Counsel and Legal Counsel for Waste Management, where he was the attorney responsible for acquisitions and divestitures for Waste Management s Southern Group. From 1997 to 2003, Mr. Burris was an associate with the law firm Arnall Golden Gregory, LLP, focusing on biotechnology and mergers and acquisitions. Mr. Burris received his B.A. in History and Economics from the University of Tennessee and his J.D. from the University of Chicago Law School.

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

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 1, 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 forty 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.

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.

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

2012	High	Low
First quarter	$ 6.02	$ 4.72
Second quarter	5.55	4.19
Third quarter	7.27	4.85
Fourth quarter	6.99	5.52

As of February 14, 2014 the Company had 381 shareholders of record.

Dividends

On August 21, 2012 the Company announced that its Board of Directors had approved the initiation of a quarterly cash dividend of $0.025 per share of common stock outstanding. In May 2013 the Company announced that its Board of Directors approved a 10% increase in the quarterly cash dividend beginning in the second quarter of 2013 from $0.025 to $0.0275 per share of common stock outstanding. Cash dividends have been paid every three months since their initiation in September 2012. In February 2014 the Company announced a quarterly cash dividend for the first quarter of 2014 of $0.0275 per share, which will be paid on March 21, 2014 to all common stockholders of record as of March 14, 2014. 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 amended its credit agreement with General Electric Capital Corporation (GE Capital) to allow the payment of cash dividends up to a maximum of $3.5 million per year, 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.

Issuer Purchases of Equity Securities

The following table provides information about purchases by the Company during the quarter ended December 31, 2013 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
10/01/13 10/31/13	29,062	$ 8.95		$ 13,476,633
11/01/13 11/30/13	28,204	9.80		13,476,633
12/01/13 12/31/13	50,696	10.94		13,476,633
Total	107,962	10.11		13,476,633

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 through October 31, 2014. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions. For the year ended December 31, 2013 the Company purchased 253,000 shares of its common stock through this authorization for an aggregate purchase price of $1.5 million.

Under the Company s 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 entitled to repurchase up to an additional $8.7 million of common stock under the February 2013 authorization without obtaining its lender s consent.

The common shares purchased during the quarter ended December 31, 2013 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.

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,				
	2013	**2012**	**2011**	**2010**	**2009**
Operations					
Revenues	$ 140,763	$ 131,718	$ 119,626	$ 116,645	$ 111,685
Operating income	13,820	12,612	11,643	9,868	14,496
Net income[2]	16,172	7,946	7,371	3,944	8,679
Net income applicable to common shareholders - Diluted[2]	15,813	7,768	7,224	3,894	8,605
Research and development expense as a percentage of revenues	6.0%	5.5%	5.8%	5.1%	4.7%
Income Per Common Share					
Basic	$ 0.59	$ 0.29	$ 0.26	$ 0.14	$ 0.31
Diluted	$ 0.57	$ 0.28	$ 0.26	$ 0.14	$ 0.30
Dividend Declared Per Common Share	**$ 0.108**	**$ 0.050**	**$**	**$**	**$**
Year-End Financial Position					
Total assets	$ 174,683	$ 157,156	$ 147,864	$ 137,438	$ 133,859
Working capital	85,605	56,073	62,413	82,162	76,312
Long-term liabilities	9,214	7,614	4,869	4,168	4,197
Shareholders equity	144,747	128,112	121,538	113,942	110,446
Current ratio[1]	5:1	4:1	4:1	5:1	5:1

1 Current assets divided by current liabilities.

2 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.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Overview

CryoLife, Inc. (CryoLife, the Company, we, or us) develops, manufactures, and commercializes medical devices for cardiac and vascular applications and preserves and distributes human tissues for transplantation. CryoLife s surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and PerClot®, an absorbable powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI). CryoLife s subsidiary, Cardiogenesis Corporation (Cardiogenesis), specializes in the treatment of coronary artery disease using a laser console system and single use, fiber-optic handpieces to treat patients with severe angina. CryoLife and its subsidiary, Hemosphere, Inc. (Hemosphere), market the Hemodialysis Reliable Outflow Graft (HeRO® Graft), which is a solution 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, 2013 CryoLife had record annual revenues of $140.8 million, increasing 7% over the prior year. The Company s cash position was strong as the Company generated $16.8 million in cash flows from operations during 2013 and an additional $15.4 million in cash proceeds from the sale of its investment in Medafor, Inc. (Medafor) common stock. The Company experienced increases in research and development expenses during 2013 related to the development of PerClot. During the fourth quarter of 2013 the Company recognized a $3.2 million other than temporary impairment of its investment in the preferred stock of ValveXchange, Inc. (ValveXchange). See the Results of Operations section below for additional analysis of the fourth quarter and full year 2013 results. See Part I, Item 1, Business, for further discussion of the Company s business and activities during 2013.

Recent Events

C.R. Bard s Acquisition of Medafor

On October 1, 2013 C.R. Bard, Inc. (Bard) completed its previously announced acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of $15.4 million for its 2.4 million shares of Medafor common stock and recorded an initial gain of approximately $12.7 million on the sale in the fourth quarter of 2013. The Company could receive additional payments totaling up to an additional $8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to approximately $525,000, if released, would be received in late 2014, although this amount is subject to possible offsets. See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Although We May Receive Additional Cash Of Up To $8.4 Million 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 $8.4 Million. These payments will be recorded as an additional gain when and if received by the Company.

Regulatory Activity

On January 30, 2013 CryoLife received a warning letter (Warning Letter) dated January 29, 2013 from the U.S. Food and Drug Administration (FDA). The Warning Letter followed a Form 483, Notice of Inspectional Observations, from the FDA (CryoLife Form 483) related to the Company s processing, preservation, and distribution of human tissue and the manufacture of medical devices. The CryoLife Form 483 followed a routine quality system inspection of the Company s facilities by the FDA during the period September 17, 2012 to October 16, 2012. The Warning Letter relates to certain observations from the CryoLife Form 483 that the FDA believes were either inadequately addressed by the Company s responses or for which the FDA required further information to fully assess the Company s corrective actions. The Company responded to the FDA s requests and implemented corrective actions. The Company believes that these corrective actions have adequately addressed the FDA s notice of violations contained in the Warning Letter, however, it is possible that the Company s actions ultimately may not be satisfactory to the FDA.

During the second quarter of 2013 the Company received verbal communication from the FDA indicating that these corrective actions appear satisfactory in addressing the issues raised in the Warning Letter. On February 18, 2014 the FDA commenced its reinspection of the Company with respect to the Warning Letter to determine whether it is satisfied with the Company s actions and responses. This reinspection will include a quality system inspection of the Company s products, services, and facilities. The Company believes that the Warning Letter and its actions regarding the Warning Letter and CryoLife Form 483 will not have a material effect on the Company. However, it is possible that further actions the Company

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may be required to take in response to the reinspection or the quality system inspection could materially, adversely affect the availability of the Company s products and tissues and cost structure, which could affect the Company s revenues, financial condition, profitability, or cash flows.

Following the receipt of the Warning Letter, on March 28, 2013 CryoLife received a letter from the Human Tissue Authority (HTA) in London, U.K., which governs the distribution of tissues into markets in Europe by the Company s subsidiary, CryoLife Europa, Ltd. (Europa). The letter temporarily suspended Europa s license to import human tissue, due to concerns the HTA had related to the FDA Warning Letter, and directed Europa to issue a recall for tissues previously distributed which had not been implanted. The HTA subsequently issued a variance to allow Europa to continue to import tissue into Europe under certain circumstances for critically ill patients. Subsequent to the issuance of the variance, the HTA reinstated Europa s license but placed certain conditions on the processing of tissue, which would generate significant additional costs when compared to the Company s current processes. As a result, the Company plans to cease shipment of tissues into Europe as of March 31, 2014.

On May 23, 2013 CryoLife received a Form 483 related to the Company s subsidiary Cardiogenesis (Cardiogenesis Form 483). The Cardiogenesis Form 483 followed a quality system inspection of the Company s facilities by the FDA in May 2013. The Cardiogenesis Form 483 includes observations concerning labeling, complaint handling, and field actions. The Company has responded to the FDA s requests and implemented changes that it believes address the FDA s observations. Subsequent to receipt of the Cardiogenesis Form 483, as discussed above, Cardiogenesis received Premarket Approval (PMA) supplement approval from the FDA for its redesigned Sologrip and Port Enabled Angina Relief with Laser (PEARL) handpieces.

On February 14, 2014 CryoLife received a Form 483 related to the Company s subsidiary Hemosphere (Hemosphere Form 483). The Hemosphere Form 483 followed a quality system inspection of the Company s facilities by the FDA in February 2014. The Hemosphere Form 483 includes observations concerning nonconformance inspections and manufacturing, the Company s corrective and preventive action procedures, and documentation issues. The Company has already had verification of its implementation of corrective action with respect to one observation and expects to respond to the remaining observations from the Hemosphere Form 483 within 15 business days, as required by law. The Company believes that the changes that it will implement will 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 actions, including requiring a recall or manufacturing hold. The Company believes that the Hemosphere Form 483 will not have a material effect on the Company. However, it is possible that actions it may be required to take in response to the Hemosphere Form 483 could materially, adversely affect the Company s revenues, financial condition, profitability, or cash flows.

See also Part I, Item 1A, Risk Factors.

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, 2013 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.

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

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. At each balance sheet date, deferred preservation costs includes costs of tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status.

Upon shipment of the 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 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.

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The Company recorded write-downs to its deferred preservation costs totaling $448,000, $195,000, and $270,000 for the years ended December 31, 2013, 2012, and 2011, 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 the deferred tax asset 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 materially, adversely affect the Company s ability to use its deferred tax assets. Such changes could have a material, adverse impact on the Company s operations, financial condition, 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 subsidiaries Hemosphere and Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisition of Hemosphere 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 Company also believes that its acquisition of Cardiogenesis constituted 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 evaluate 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.

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 January 2013 the Company adopted Accounting Standards Update (ASU), 2012-02, Intangibles-Goodwill and Other (Topic 350): *Testing Indefinite-Lived Intangible Assets for Impairment*, which gives entities testing indefinite-lived intangible assets for impairment the option of performing a qualitative assessment before performing the quantitative impairment test as well as the option to bypass the qualitative assessment in any period and proceed directly to performing the quantitative impairment test. The adoption of ASU 2012-02 did not have a material effect on the Company s financial condition, profitability, or cash flows.

In February 2013 the Company adopted ASU 2013-02, Comprehensive Income (Topic 220): *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, which requires separate presentation of the components that are reclassified out of accumulated other comprehensive income either on the face of the financial statements or in the notes to the financial statements. This update also requires companies to disclose the income statement line items affected by any significant reclassifications. The adoption of ASU 2013-02 did not have a material effect on the Company s financial disclosures.

Results of Operations

(In thousands)

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%
Revascularization technologies	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%
Revascularization technologies	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 product revenues for BioGlue and BioFoam; PerClot; revascularization technologies; 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 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, 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 is currently seeking expanded indications for BioGlue in Japan and regulatory approval for BioGlue in China and, if successful, believes this will provide additional international growth opportunities for BioGlue in future years.

Management believes that the decrease in BioGlue shipments in its domestic markets for the twelve months ended December 31, 2013 is 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 has seen the effect of these factors on its domestic BioGlue shipments slow in recent quarters. In both the third and fourth quarters of 2013 domestic shipments showed a 2% increase in the volume of milliliters sold over the same quarters in 2012. Management believes that BioGlue sales volume in domestic markets could continue to be affected by the factors discussed above, and this may make the recent increases unsustainable in the near or long term.

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 currently 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 is 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. The Company expects that overall PerClot revenues will increase in 2014 as compared to 2013; however, revenues may show some variability from quarter-to-quarter.

In June 2013 CryoLife received conditional approval of its investigational device exemption (IDE) for PerClot from the FDA. IDE approval would allow the Company to begin clinical trials for the purpose of obtaining PMA to distribute PerClot in the U.S. As part of the conditional approval for the PerClot IDE, the Company must make certain revisions to the investigational study protocol and clinical product labeling. The Company refiled the IDE submission on September 27, 2013. CryoLife received a second conditional approval on October 30, 2013. The Company has had multiple discussions with the FDA to resolve any remaining issues and expects to obtain FDA approval to begin enrollment into the pivotal trial in the first half of 2014.

Revascularization Technologies

Revenues from revascularization technologies include revenues related primarily to the sale of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from revascularization technologies 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 revascularization technologies 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. The Company anticipates that handpiece sales will increase slightly in the first quarter of 2014 as compared to the fourth quarter of 2013, as the new handpiece becomes more widely used and adopted.

The Company expects that overall revascularization technologies revenues will increase in 2014 as compared to 2013. The amount of 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 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.

The Company expects that overall HeRO Graft revenues will increase in 2014 as compared to 2013. As the HeRO Graft implant is currently performed by a relatively small number of physicians, HeRO Graft revenues are subject to more variability quarter-to-quarter due to the timing of surgical cases. As the population of implanting physicians increases, the Company expects this variability in revenues will decrease.

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.

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, 2013 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.

Unit shipments of cardiac tissues into Europe decreased for the twelve months ended December 31, 2013 as a result of the 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 expects to cease 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.

The Company expects that overall cardiac preservation services revenues in 2014 will be comparable to the revenues in 2013.

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.

The Company expects that overall vascular preservation services revenues will increase in 2014 as compared to 2013.

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 includes costs related to BioGlue, BioFoam, PerClot, revascularization technologies, and HeRO Grafts.

Cost of products for the twelve months ended December 31, 2013 includes $483,000 in additional costs for revascularization technologies 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 includes $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 are 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%

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.

The Company expects that general, administrative, and marketing expenses will increase in 2014 as compared to 2013 before Consideration of the effects of litigation and business development expenses. Management believes the potential patent infringement litigation between CryoLife and Medafor or Bard, discussed elsewhere in this Form 10-K, could occur as early as 2014, and management believes that if this litigation occurs, the costs of this litigation would be material.

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, revascularization technologies, 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. The Company expects that research and development spending will also increase materially in 2014 due to planned increases in spending on PerClot clinical studies.

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 and could receive additional payments totaling up to an additional $8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to approximately $525,000, if released, would be received in late 2014, although this amount is subject to possible offsets. See also Part I, Item 1A, Risk Factors Risks Relating to Our Business Although We May Receive Additional Cash Of Up To $8.4 Million 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 $8.4 Million. These payments will be recorded as an additional gain when and if received by the Company.

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.

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.

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.

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2012	2011	2012	2011
Products:				
BioGlue and BioFoam	$ 13,353	$ 12,519	41%	41%
PerClot	1,009	617	3%	2%
HemoStase		(96)	%	%
Revascularization technologies	1,985	2,415	6%	8%
HeRO Graft	1,106		3%	%
Total products	17,453	15,455	53%	51%
Preservation services:				
Cardiac tissue	7,094	6,629	22%	22%
Vascular tissue	8,138	8,146	25%	27%
Total preservation services	15,232	14,775	47%	49%
Other	115	167	%	%
Total	$ 32,800	$ 30,397	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2012	2011	2012	2011
Products:				
BioGlue and BioFoam	$ 53,211	$ 49,455	41%	41%
PerClot	3,078	2,528	2%	2%
HemoStase		1,699	%	2%
Revascularization technologies	8,092	5,705	6%	5%
HeRO Graft	3,115		2%	%
Total products	67,496	59,387	51%	50%
Preservation services:				
Cardiac tissue	29,756	26,618	23%	22%
Vascular tissue	33,847	33,175	26%	28%
Total preservation services	63,603	59,793	49%	50%
Other	619	446	%	%
Total	$ 131,718	$ 119,626	100%	100%

Revenues increased 8% for the three months and 10% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. A detailed discussion of the changes in product revenues, preservation services revenues, and other revenues for the three and twelve months ended December 31, 2012 is presented below.

Products

Revenues from products increased 13% for the three months and 14% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. The increase for the three months

ended December 31, 2012 was primarily due to the addition of HeRO Graft revenues as a result of the Company s acquisition of Hemosphere in the second quarter of 2012, and an increase in BioGlue revenues. The increase for the twelve months ended December 31, 2012 was primarily due to an increase in BioGlue revenues, the addition of HeRO Graft revenues, and an increase in revascularization technologies revenues as a result of the Company s acquisition of Cardiogenesis in the second quarter of 2011, partially offset by a lack of HemoStase revenues as the Company is no longer distributing this product. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot and HemoStase; revascularization technologies; and HeRO Grafts are presented below.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 7% for the three months ended December 31, 2012 as compared to the three months ended December 31, 2011. This increase was primarily due to a 4% increase in the volume of milliliters sold, which increased revenues by 3%, and by an increase in average sales prices, which increased revenues by 4%.

Revenues from the sale of surgical sealants increased 8% for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011. This increase was primarily due to an 8% increase in the volume of milliliters sold, which increased revenues by 5%, and by an increase in average sales prices, which increased revenues by 4%, partially offset by the unfavorable impact of foreign exchange rates, which decreased revenues by 1%.

The increase in sales volume of surgical sealants for the three and twelve months ended December 31, 2012 was due to an increase in shipments of BioGlue in certain international markets. For the three months ended December 31, 2012 these increases were primarily in Europe, and for the twelve months ended December 31, 2012 these increases were primarily in Japan and Europe. These increases were partially offset by decreases in the volume of milliliters sold in the Company s more mature domestic markets of 2% for the three months and 3% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. The Company began shipping BioGlue to Japan in late April 2011, following the Japanese approval of BioGlue for use in the repair of aortic dissections. Revenues from shipments to Japan for the three and twelve months ended December 31, 2012 were $697,000 and $4.1 million, respectively.

Management believes that the decrease in BioGlue shipments in its domestic markets is a result of various factors, including: poor economic conditions and their constraining effect on hospital budgets, 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.

The Company s sales of surgical sealants 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 or Euro decline materially in the future, this would have a material, adverse impact on the Company s revenues denominated in these currencies.

Domestic revenues accounted for 61% and 60% of total BioGlue revenues for the three and twelve months ended December 31, 2012, respectively, and 63% and 64% of total BioGlue revenues for the three and twelve months ended December 31, 2011, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2012. BioFoam is currently approved for sale in certain international markets.

PerClot and HemoStase

Revenues from the sale of PerClot increased 63% for the three months ended December 31, 2012 as compared to the three months ended December 31, 2011. This increase was primarily due to a 68% increase in the volume of grams sold, which increased revenues by 71%, partially offset by a decrease in average sales prices and the unfavorable impact of foreign exchange rates. Revenues during these three month periods were for sales in certain international markets, as PerClot has not yet been approved for domestic distribution or widespread international distribution. This increase was primarily due to increased sales in the Company s markets in Europe and due to the recent approval of PerClot in additional countries. HemoStase was not distributed during the three months ended December 31, 2012 or 2011.

Revenues from the sale of hemostats, consisting of PerClot and HemoStase, decreased 27% for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011. The revenue decrease in the twelve

months ended December 31, 2012 was primarily due to a decrease in hemostat sales volume in domestic markets, as discussed further below, and the unfavorable impact of foreign exchange rates, which decreased revenues by 2%.

International hemostat revenues increased 5% for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011. This increase in international hemostat revenues was primarily due to increased PerClot sales into the Company s markets in Europe and due to the recent approval of PerClot in additional countries, partially offset by the unfavorable impact of foreign exchange rates. International PerClot sales for the twelve months ended December 31, 2012 exceeded combined PerClot and HemoStase international sales for the twelve months ended December 31, 2011, which included large HemoStase orders filled in the first quarter of 2011 in anticipation of a disruption in the availability of hemostats to the Company s distributors in these countries beginning in 2011. This disruption was due to the Company s planned March 2011 discontinuance of HemoStase sales subsequent to the termination of its Exclusive Distribution Agreement (EDA) for this product.

The decrease in domestic sales volume for the twelve months ended December 31, 2012 was due to the Company s discontinuation of sales of HemoStase as discussed above. The Company recognized domestic hemostat sales in the first quarter of 2011 and recognized no domestic hemostat sales in the corresponding period in 2012. Domestic hemostat sales ended with the discontinuance of HemoStase sales, as PerClot has not yet been approved for commercial distribution in domestic markets. The Company will not be able to sell PerClot in the U.S. in future years unless and until FDA approval is granted.

The Company s sales of hemostats 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. The unfavorable effect of foreign exchange rates for the three and twelve months ended December 31, 2012 was primarily due to a decline in the value of the Euro when compared to the corresponding periods in 2011.

Revascularization Technologies

Revenues from revascularization technologies include revenues related to the sale of handpieces and accessories and, in certain periods, revenues from the sale of laser consoles. Revenues from revascularization technologies decreased 18% for the three months ended December 31, 2012 as compared to the three months ended December 31, 2011. Revenues from the sale of laser consoles were zero and $541,000 in the three months ended December 31, 2012 and 2011, respectively. Revenues from the sale of handpieces and accessories increased 6% for the three months ended December 31, 2012 as compared to the three months ended December 31, 2011. This increase was primarily due to an increase in average sales prices, which increased revenues by 4%, and an increase in volume, which increased revenues by 2%.

Revenues from revascularization technologies increased for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011, as revascularization technologies were not marketed by the Company for the full twelve month prior year period. The Company began marketing revascularization technologies following its acquisition of Cardiogenesis in May 2011. Revenues from the sale of laser consoles were $279,000 and $541,000 in the twelve months ended December 31, 2012 and 2011, respectively.

Revascularization technologies revenues for the twelve months ended December 31, 2012 decreased when compared to the combined pre- and post-acquisition revenues for the twelve months ended December 31, 2011. Revenues from the sale of laser consoles were $279,000 in the twelve months ended December 31, 2012 and $1.4 million in the combined pre- and post-acquisition period ended December 31, 2011. Revenues from the sale of handpieces and accessories decreased 10% for the twelve months ended December 31, 2012 when compared to the combined pre- and post-acquisition revenues for the twelve months ended December 31, 2011. These decreases were primarily due to increasing competitive pressures and challenges in selling laser consoles in recent periods, both of which have negatively affected handpiece revenues. Revenues from laser consoles were negatively affected by the economic environment, which made hospitals reluctant to invest in large capital purchases.

Preservation Services

Revenues from preservation services increased 3% for the three months and 6% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. The increase for the three and twelve months ended December 31, 2012 was primarily due to an increase in cardiac preservation 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 7% for the three months ended December 31, 2012 as compared to the three months ended December 31, 2011. This increase was primarily due to an increase in average service fees, which increased revenues by 4%, and by the aggregate impact of an increase in volume and tissue mix, which increased revenues by 3%.

Revenues from cardiac preservation services increased 12% for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011. This increase was primarily due to the aggregate impact of an increase in volume and tissue mix, which increased revenues by 9%, and by an increase in average service fees, which increased revenues by 3%.

The increase in revenues from volume and tissue mix for the three months ended December 31, 2012 was primarily due to an increase in cardiac patch shipments, partially offset by a decrease in shipments of pulmonary valves, and the increase for the twelve months ended December 31, 2012 was primarily due to an increase in cardiac valve shipments. Changes in unit shipments of cardiac valves and patches in any one quarter can be affected by the timing of release of these tissues for shipment, which can vary from quarter to quarter. The Company believes that the increase in unit shipments of cardiac valves for the twelve months ended December 31, 2012 was primarily due to the activities of its expanded cardiac sales staff and the Company s ongoing physician education activities, and may have also benefited from the guidance issued by The Society of Thoracic Surgeons, which indicates that human aortic valves are the ideal replacement in certain cardiac reconstructive procedures involving endocarditis. The Company s cardiac valves are primarily used in cardiac replacement and reconstruction surgeries for patients with congenital heart defects.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 50% and 47% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2012, respectively, and 39% and 40% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2011, respectively. Domestic revenues accounted for 90% of total cardiac preservation services revenues for both the three and twelve months ended December 31, 2012, and 92% and 91% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2011, respectively.

Vascular Preservation Services

Revenues from vascular preservation services for the three months ended December 31, 2012 were comparable to revenues for the three months ended December 31, 2011. Revenues from vascular preservation services increased 2% for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011, primarily due to a 3% increase in unit shipments of vascular tissues, which increased revenues by 4%, partially offset by a decrease in average service fees, which decreased revenues by 2%.

The increase in vascular tissue volume for the twelve months ended December 31, 2012 was primarily due to increases in shipments of saphenous veins and aortoiliac grafts, which increased due to improved availability of certain tissues. Saphenous veins are primarily used in peripheral vascular reconstruction surgeries to avoid limb amputations, and aortoiliac grafts are primarily used in surgeries to treat abdominal aortic aneurisms. These tissues are primarily distributed in domestic markets.

The decrease in average service fees for the twelve months ended December 31, 2012 was due in part to a list fee decrease for certain vascular tissues in 2012 and fee differences due to physical characteristics of vascular tissues, partially offset by the routine negotiation of pricing contracts with certain customers.

Other Revenues

Other revenues for the three and twelve months ended December 31, 2012 and 2011 included revenues related to funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the (DOD Grants). As of December 31, 2012 CryoLife had been awarded $6.1 million and had received a total of $5.4 million for the development of protein hydrogel technology, which the Company is currently developing for use in organ sealing. At December 31, 2012 CryoLife had $1.0 million included in deferred income on the Company s Consolidated Balance Sheet from the DOD Grants, of which $668,000 remained in unspent cash advances recorded as cash and cash equivalents. In early 2013 the DOD Grants were amended to reduce the total award to $5.4 million. The Company discontinued its BioFoam U.S. clinical trial in the first quarter of 2013 and the remaining unspent funds were returned to the U.S. Department of Defense.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Cost of products	$ 3,080	$ 2,391	$ 11,380	$ 9,442

Cost of products increased 29% for the three months and 21% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. Cost of products in 2012 includes costs related to BioGlue, BioFoam, PerClot, revascularization technologies, and HeRO Grafts. Cost of products in 2011 includes costs related to BioGlue, BioFoam, PerClot, HemoStase, and revascularization technologies.

The increase in cost of products in the three months ended December 31, 2012 was primarily due to the addition of HeRO Graft revenues. The increase in cost of products in the twelve months ended December 31, 2012 was primarily due to the addition of HeRO Graft and revascularization technologies handpiece revenues, and the increase in BioGlue sales volume, partially offset by the discontinuation of HemoStase sales.

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Cost of preservation services	$ 8,675	$ 8,631	$ 35,320	$ 34,340

Cost of preservation services increased 1% for the three months and 3% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The increase in cost of preservation services in the three and twelve months ended December 31, 2012 was primarily due to increased shipments of cardiac and vascular tissues during these periods, partially offset by a decrease in costs. Cost of preservation services for the three and twelve months ended December 31, 2011 included $674,000 in unusual processing expenses due to certain supplies of processing solutions used in the processing of tissues that did not meet the Company s quality requirements.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Gross margin	$ 21,045	$ 19,375	$ 85,018	$ 75,844
Gross margin as a percentage of total revenues	64%	64%	65%	63%

Gross margin increased 9% for the three months and 12% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. Gross margin increased primarily due to an increase in revenues during the periods. Gross margin as a percentage of total revenues increased in the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011, primarily due to a change in service and product mix as the Company s higher margin medical devices segment made up a larger percentage of its business in 2012.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
General, administrative, and marketing expenses	$ 16,775	$ 14,626	$ 65,149	$ 57,302
General, administrative, and marketing expenses as a percentage of total revenues	51%	48%	49%	48%

General, administrative, and marketing expenses increased 15% for the three months and 14% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively.

General, administrative, and marketing expenses for the twelve months ended December 31, 2012 include a $4.7 million gain on the settlement of the lawsuit with Medafor and a $4.1 million loss for the settlement of the lawsuit with CardioFocus related to a claim of 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. Business development costs, primarily related to the acquisition and integration of Cardiogenesis, were $144,000 and $4.2 million for the three and twelve months ended December 31, 2011, respectively.

General, administrative, and marketing expenses for the three and twelve months ended December 31, 2012 also increased due to an increase in marketing expenses, including the costs of the Company s expanded sales staff from its recent acquisitions of Hemosphere and Cardiogenesis and increases in spending on advertising.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Research and development expenses	$ 2,065	$ 1,800	$ 7,257	$ 6,899
Research and development expenses as a percentage of total revenues	6%	6%	6%	6%

Research and development expenses increased 15% for the three months and 5% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. Research and development spending for the three and twelve months ended December 31, 2012 was primarily focused on PerClot, HeRO Graft, revascularization technologies, the Company s SynerGraft products and tissues, and BioFoam.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Income before income taxes	$ 2,242	$ 2,863	$ 12,052	$ 11,466
Income tax expense	159	997	4,106	4,095
Net income	$ 2,083	$ 1,866	$ 7,946	$ 7,371
Diluted income per common share	$ 0.07	$ 0.07	$ 0.28	$ 0.26

Diluted weighted-average common shares outstanding	27,357	27,745	27,411	27,759

Income before income taxes decreased 22% for the three months and increased 5% for the twelve months ended December 31, 2012 as compared to the three and twelve months ended December 31, 2011, respectively. The decrease in income before income taxes for the three months ended December 31, 2012 was primarily caused by an increase in operating expenses as discussed above, partially offset by an increase in gross margin. The increase in income before income taxes for the twelve months ended December 31, 2012 was primarily caused by an increase in gross margin, partially offset by an increase in operating expenses as discussed above.

The Company s effective income tax rate was approximately 7% for the three months and 34% for the twelve months ended December 31, 2012 as compared to 35% for the three months and 36% for the twelve months ended December 31, 2011. 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. The Company s income tax rates for the three and twelve months ended December 31, 2012 were also affected by the unfavorable 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. The Company s effective income tax rate for the twelve months ended December 31, 2011 was affected by the discrete and favorable effect of deductions taken on the Company s 2010 federal tax returns, which were filed in the third quarter of 2011. This favorable effect was largely offset by the unfavorable tax treatment, recognized in the second quarter of 2011, of certain acquisition related expenses, which the Company incurred related to its acquisition of Cardiogenesis.

Net income and diluted income per common share increased for the three months ended December 31, 2012 as compared to the three months ended December 31, 2011, primarily due to the decrease in income tax expense. Net income and diluted income per common share increased for the twelve months ended December 31, 2012 as compared to the twelve months ended December 31, 2011, 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 s market for BioGlue in Japan is still in a growth phase, however, 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 PerClot will be seasonal, as PerClot is a new product and the nature of any seasonal trends in PerClot sales may be obscured.

The Company is uncertain whether the demand for revascularization technologies will be seasonal, as the Company s data does not indicate a significant trend.

The Company is uncertain whether the demand for HeRO Grafts will be 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 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 to 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.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2013 net working capital (current assets of $106.3 million less current liabilities of $20.7 million) was $85.6 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $56.1 million and a current ratio of 4 to 1 at December 31, 2012.

Overall Liquidity and Capital Resources

The Company s largest cash requirement for the twelve months ended December 31, 2013 was cash for general working capital needs, as the Company s accounts receivable balance increased significantly from December 31, 2012. The accounts receivable increase was due to the Company s recent sales, which have not yet been converted to cash, along with the fact that accounts receivable as of December 31, 2012 was lower than normal due to timing of payments. In addition, the Company s other cash requirements included capital expenditures, repurchases of the Company s common stock, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves, its operating activities, which generated cash during the period, and the $15.4 million in proceeds from the sale of the Company s investment in Medafor common stock, discussed further below.

CryoLife s credit agreement with General Electric Capital Corporation (the GE Credit Agreement) provides revolving credit for working capital, acquisitions, and other corporate purposes. The borrowing capacity under the GE Credit Agreement, which expires October 28, 2014, is $20.0 million (including a letter of credit subfacility). The borrowing capacity may be reduced or increased from time to time pursuant to the terms 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 General Electric Capital Corporation 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 restricted cash and securities on the Company s Consolidated Balance Sheets. Also, the GE Credit Agreement requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined in the agreement, of at least $20.0 million. As of December 31, 2013 the outstanding balance under the GE Credit Agreement was zero, and $20.0 million was available for borrowing.

In the twelve months ended December 31, 2013 the Company purchased approximately 253,000 shares of its common stock for an aggregate purchase price of $1.5 million. As of December 31, 2013 the Company had $13.5 million in remaining authorizations under common stock repurchase programs authorized by the Company s Board of Directors. The Company is entitled to repurchase an additional $8.7 million in additional common stock without obtaining its lender s consent. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions.

As of December 31, 2013 approximately 5% of the Company s cash and cash equivalents were held in foreign jurisdictions.

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 for its 2.4 million shares of Medafor common stock and recorded an initial gain of $12.7 million on the sale in the fourth quarter of 2013. The Company could receive additional payments totaling up to an additional $8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to approximately $525,000, if released, would be received in late 2014, although this amount is subject to possible offsets. These payments will be recorded as an additional gain when and if received by the Company.

As discussed elsewhere in this Form 10-K, in September 2012, CryoLife received a letter from Medafor stating that PerClot, when introduced in the U.S., will, when used in accordance with the method published in CryoLife s literature and with the instructions for use, infringe Medafor s U.S. patent. CryoLife does not believe that it will infringe Medafor s patent. There have been no further communications between CryoLife and Medafor, or CryoLife and Medafor s parent company, Bard, related to the September letter. Management believes that patent infringement litigation between CryoLife and Medafor or Bard could occur as early as 2014, and management believes that if litigation occurs, the costs of this litigation would be material.

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. During 2013 CryoLife repeatedly notified ValveXchange that ValveXchange was in default of certain loan covenants, due to factors including ValveXchange s failure to obtain CryoLife s consent for certain convertible note financings that ValveXchange obtained during the year. These events of default were ongoing as of February 15, 2014. If ValveXchange is unable to secure material amounts of additional financing, it will likely be unable to meet its obligations, and, therefore, CryoLife may need to foreclose on the related collateral to secure repayment of the Loan. Although CryoLife currently believes that the value of the collateral is adequate to repay the Loan, there is no guarantee of such adequacy.

The Company believes that its anticipated 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 business development activities, to fund the PerClot clinical trials, to repurchase the Company s common stock, to fund the cash dividend to common shareholders, to fund additional research and development expenditures, for general working capital needs, for capital expenditures, and for other corporate purposes. These items may have a significant effect on the Company s cash flows during 2014. The Company may seek additional borrowing capacity or financing, pursuant to its shelf registration statement, for general corporate purposes or to fund other future cash requirements. If the Company undertakes further significant business development activity in 2014, it may need to finance such activities by drawing down monies under the GE Credit Agreement, obtaining additional debt financing, or using its shelf registration statement to sell equities.

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

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $16.8 million for the twelve months ended December 31, 2013 as compared to $19.0 million for the twelve months ended December 31, 2012. The decrease in net cash provided is primarily due to an increase in working capital needs, largely as a result of an increase in receivable balances driven by an increase in revenues, 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, 2013 these items included a $12.7 million gain on the sale of Medafor common stock, as the cash proceeds are reported in investing activities below, a favorable $5.8 million in depreciation and amortization expense, a $3.2 million impairment expense related to the Company s investment in ValveXchange, $3.2 million in non-cash compensation, and $1.7 million in write downs of inventory and deferred preservation costs.

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, 2013 the increase in working capital needs of $1.6 million was primarily due to the timing difference between recording receivables and the receipt of cash.

Net Cash Flows from Investing Activities

Net cash provided by investing activities was $10.9 million for the twelve months ended December 31, 2013 as compared to $22.9 million used in investing activities for the twelve months ended December 31, 2012. The current year cash provided was primarily due to $15.4 million in proceeds from the sale of the Company s 2.4 million shares of Medafor common stock, as a result of that company s acquisition by Bard, partially offset by $4.3 million in capital expenditures. The prior year cash used was primarily due to the payment of $17.0 million for the acquisition of Hemosphere, net of cash acquired.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $3.1 million for the twelve months ended December 31, 2013 as compared to $4.7 million for the twelve months ended December 31, 2012. The current year cash used was primarily due to $3.0 million in cash dividends paid on the Company s common stock, and $1.5 million in purchases of treasury stock related to the Company s publicly announced stock repurchase plan, partially offset by $2.2 million in proceeds from the exercise of options and the issuance of stock under the Company s employee stock purchase plan.

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, 2013 are as follows (in thousands):

	Total	2014	2015	2016	2017	2018	Thereafter
Operating leases	$ 24,887	$ 2,799	$ 3,031	$ 2,943	$ 2,980	$ 3,010	$ 10,124
Purchase commitments	4,452	2,739	1,713				
Contingent payments	4,500	1,000		3,500			
Compensation payments	1,985			1,985			
Research obligations	2,246	1,841	376	29			
Total contractual obligations	$ 38,070	$ 8,379	$ 5,120	$ 8,457	$ 2,980	$ 3,010	$ 10,124

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 2015, which assumes that the Company receives FDA approval for PerClot in 2016. Upon FDA approval, the Company may terminate its minimum purchase requirements, per the terms of the agreements between the parties, which the Company expects to do. However, if the Company does not terminate this provision, it will have minimum purchase obligations of $1.75 million per year through the end of the contract term in 2025. The Company s purchase commitments also include obligations from agreements with suppliers.

The contingent payment obligations include obligations related to the Company s acquisition of Hemosphere and transaction with SMI. The contingent payment obligation for Hemosphere represents the payments that the Company will make if certain revenue milestones are achieved. The schedule includes one contingent milestone payment for $2.5 million that the Company believes it is likely to pay in 2016, although the timing of this payment may change. The schedule excludes one Hemosphere contingent milestone payment of up to $2.0 million, as the Company cannot make a reasonably reliable estimate of when this future payment may be made, if at all. The contingent payment obligation for PerClot represents the payments that the Company will make if certain FDA regulatory approvals and other commercial milestones are achieved. The schedule excludes one PerClot contingent milestone payment of $500,000, as the Company cannot make a reasonably reliable estimate of timing of this future payment.

The Company s compensation payment obligations represent estimated payments for post-employment benefits for the Company s Chief Executive Officer (CEO). The timing of the CEO s post-employment benefits is based on the December 2015 expiration date of the CEO s current employment agreement; however, payment of this benefit may be accelerated upon the occurrence of certain events, including the voluntary retirement of the CEO or termination of the CEO s employment in conjunction with certain change in control events, and payment could be extended in the event the term of the CEO s employment contract is extended.

The Company s research obligations represent commitments for ongoing studies and payments to support research and development activities.

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 and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $2.5 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made for specific litigation or by any taxing authorities.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2013 were $4.3 million as compared to $3.1 million for the twelve months ended December 31, 2012. Capital expenditures in the twelve months ended December 31, 2013 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; revascularization technologies lasers; computer and office equipment; computer software; and leasehold improvements needed to support the Company s business.

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 $37.6 million, restricted cash of $5.0 million, and interest paid on the Company s variable rate line of credit as of December 31, 2013. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the twelve months ended December 31, 2013, 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 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 and Euros. 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, 2013 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, 2013 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.

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, 2013, 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, 2013 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.

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, 2013, 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, 2013.

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, 2013.

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, 2013.

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, 2013.

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 Form S-3 filed February 22, 2012.)
3.2	Reserved.
3.3	Reserved.
3.4	Reserved.
3.5	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.)
4.1	Reserved.
4.2	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.)
4.3	Reserved.
4.4	Reserved.
4.5	Reserved.
4.6	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.)
10.1	Reserved.
10.2+	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.)
10.2(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.)

Exhibit Number	Description
10.2(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.)
10.2(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.)
10.2(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.)
10.2(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.)
10.2(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.)
10.2(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.)
10.2(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.)
10.2(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.)
10.2(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.)

Exhibit Number	Description
10.2(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.)
10.3	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.)
10.3(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.)
10.4	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.)
10.5	Reserved.
10.6	Reserved.
10.7	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.)
10.7(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.)
10.7(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.)
10.8	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.)
10.9	Employment Agreement by and between the Company and Steven G. Anderson dated as of October 23, 2012. (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.)
10.9(a)	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.)
10.9(b)	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.)
10.10	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).)
10.11	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.).
10.12*	Summary of Salaries for Named Executive Officers.
10.13	Form of Non-Qualified Stock Option Grant Agreement under 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)

Exhibit Number	Description
10.14	Amended and Restated Technology Acquisition Agreement between the Company and Nicholas Kowanko, Ph.D., dated March 14, 1996. (Incorporated herein by reference to Exhibit 10.14 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2004.)
10.15	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.)
10.16	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.)
10.16(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.)
10.16(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.)
10.16(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.)
10.17	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.)
10.17(a)	Form of Non-Employee Director Stock Grant Agreement pursuant to the CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.)
10.18	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.19	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.)
10.19(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.)
10.19(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.)
10.20	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.)
10.21	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.)
10.22	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.)

Exhibit Number	Description
10.23	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.)
10.24	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.)
10.25	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.)
10.26	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.)
10.27	Grant of Incentive Stock Option to D. Ashley Lee, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006.)
10.27(a)	First Amendment to Award Agreement between CryoLife and D. Ashley Lee dated May 24, 2011, relating to a Stock Option Grant to D. Ashley Lee dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)
10.28	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.)
10.29	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.30(a) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.30	Form of Director Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.30(b) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.31	Form of Non-Employee Directors Stock Option Agreement and Grant pursuant to the Amended and Restated Non-Employee Directors Stock Option Plan. (Incorporated herein by reference to Exhibit 10.31 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.32	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.)
10.33	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.)
10.34	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.)
10.35	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.)
10.36	Form of Grant of Non-Qualified Stock Option to Directors. (Incorporated herein by reference to Exhibit 10.36 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.37	Grant of Incentive Stock Option to Steven G. Anderson, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

Exhibit Number	Description
10.38	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.)
10.39	CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan, as amended, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.40	Form of Directors Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)
10.41	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.)
10.42	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.)
10.43	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.)
10.44*	Summary of Compensation Arrangements with Non-Employee Directors.
10.45	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.)
10.46	Reserved.
10.47	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.)
10.48	Reserved.
10.49	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.)
10.50+	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 January 18, 2012.)
10.50(a)+	First Amendment to the Distribution Agreement between the Company and Starch Medical, Inc., dated May 18, 2011. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed January 30, 2012.)
10.50(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.)
10.51+	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 January 18, 2012.)
10.51(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.)
10.52	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.)

Exhibit Number	Description
10.53	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.)
10.54	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.)
10.55	First Amendment to Award Agreement between CryoLife and D. Ashley Lee dated May 24, 2011, relating to a Stock Option Grant to D. Ashley Lee dated February 21, 2006. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)
10.56+	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.)
10.56(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.)
10.56(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.)
10.57	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.)
10.58	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.)
10.59	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.)
10.59(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.)
10.60	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.)
10.60(a)	First Amendment, dated July 24, 2012, to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.61	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.)
10.62	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.)
10.63	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.)

Exhibit Number	Description
21.1*	Subsidiaries of CryoLife, Inc.
23.1*	Consent of Ernst & Young LLP.
23.2*	Consent of Deloitte & Touche LLP.
31.1*	Certification by Steven G. Anderson 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.

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 by and between the Company and Steven G. Anderson dated as of October 23, 2012. (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. 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.)

4. 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.)

5. Reserved.

6. 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).)

7. 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.)

8. 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.)

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. 2004 Non-Employee Directors Stock Option Plan, as amended, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)

13. 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.)

14. Form of Directors Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)

15. 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.)

16. 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.)

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.)

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.)

19. Grant of Incentive Stock Option to D. Ashley Lee, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006.)

20. First Amendment to Award Agreement between CryoLife and D. Ashley Lee dated May 24, 2011, relating to a Stock Option Grant to D. Ashley Lee dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)

21. * Summary of Salaries for Named Executive Officers.

22. 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.)

23. Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.30(a) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

24. Form of Director Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.30(b) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

25. Form of Non-Employee Directors Stock Option Agreement and Grant pursuant to the Amended and Restated Non-Employee Directors Stock Option Plan. (Incorporated herein by reference to Exhibit 10.31 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

26. 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.)

27. 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.)

28. 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.)

29. 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.)

30. Form of Grant of Non-Qualified Stock Option to Directors. (Incorporated herein by reference to Exhibit 10.36 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

31. Grant of Incentive Stock Option to Steven G. Anderson, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

32. 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.)

33. 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.)

34. Form of Non-Qualified Stock Option Grant Agreement under 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)

35. Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)

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

37. 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.)

38. 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.)

39. Form of Non-Employee Director Stock Grant Agreement pursuant to the CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.)

40. 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.)

41. 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.)

42. 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.)

43. 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.)

44. 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.)

45. 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.)

46. 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.)

47. 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.)

48. 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.)

49. First Amendment to Award Agreement between CryoLife and D. Ashley Lee dated May 24, 2011, relating to a Stock Option Grant to D. Ashley Lee dated February 21, 2006. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)

50. Reserved.

51. 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.)

52. 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.)

53. 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.)

54. 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.)

55. 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.)

56. 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.)

57. 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.)

58. 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.)

* Filed herewith.

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 21, 2014 By /s/ Steven G. Anderson

Steven G. Anderson

President, Chief Executive Officer, and

Chairman of the Board of Directors

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

Signature	Title	Date
/s/ Steven G. Anderson	President, Chief Executive Officer, and	February 21, 2014
Steven G. Anderson	Chairman of the Board of Directors	
	(Principal Executive Officer)	
/s/ D. Ashley Lee	Executive Vice President,	February 21, 2014
D. Ashley Lee	Chief Operating Officer, and	
	Chief Financial Officer	
	(Principal Financial Officer)	
/s/ Amy D. Horton	Chief Accounting Officer	February 21, 2014
Amy D. Horton	(Principal Accounting Officer)	
/s/ Thomas F. Ackerman	Director	February 21, 2014
Thomas F. Ackerman		
/s/ James S. Benson	Director	February 21, 2014
James S. Benson		
/s/ Daniel J. Bevevino	Director	February 21, 2014
Daniel J. Bevevino		
/s/ Ronald C. Elkins, M.D.	Director	February 21, 2014

Ronald C. Elkins, M.D.		
/s/ Ronald D. McCall	Director	February 21, 2014
Ronald D. McCall		
/s/ Harvey Morgan	Director	February 21, 2014
Harvey Morgan		
/s/ Jon W. Salveson	Director	February 21, 2014
Jon W. Salveson		

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, 2013. In making this assessment, we used the criteria set forth in the Internal Control-Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment, we believe that, as of December 31, 2013, 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, 2013.

CryoLife, Inc.

February 21, 2014

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 sheet of CryoLife, Inc. and subsidiaries as of December 31, 2013, and the related consolidated statements of operations and comprehensive income, shareholders equity, and cash flows for the year ended December 31, 2013. 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 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 audit provides 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, 2013, and the consolidated results of their operations and their cash flows for the year ended December 31, 2013, 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, 2013, 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 21, 2014 expressed an unqualified opinion thereon.

Ernst & Young LLP

Atlanta, GA

February 21, 2014

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, 2013, 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, 2013, 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 sheet of CryoLife, Inc. and subsidiaries as of December 31, 2013, and the related consolidated statements of operations and comprehensive income, shareholders equity, and cash flows for the year ended December 31, 2013 of CryoLife, Inc. and subsidiaries and our report dated February 21, 2014 expressed an unqualified opinion thereon.

Ernst & Young, LLP

Atlanta, Georgia

February 21, 2014

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 balance sheet of CryoLife, Inc. and subsidiaries (the Company) as of December 31, 2012, 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, 2012. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the 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, such consolidated financial statements present fairly, in all material respects, the financial position of CryoLife, Inc. and subsidiaries at December 31, 2012, and the results of its operations and its cash flows for each of the two years in the period 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

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2013	2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,643	$ 13,009
Restricted cash and securities	5,350	323
Receivables:		
Trade accounts, net	17,838	15,941
Other	469	579
Total receivables	**18,307**	**16,520**
Deferred preservation costs	27,297	27,954
Inventories	9,771	10,557
Deferred income taxes	5,162	6,100
Prepaid expenses and other	2,797	3,040
Total current assets	**106,327**	**77,503**
Property and equipment:		
Equipment and software	26,976	24,007
Furniture and fixtures	4,390	4,339
Leasehold improvements	30,051	29,440
Total property and equipment	61,417	57,786
Less accumulated depreciation and amortization	49,246	46,119
Net property and equipment	**12,171**	**11,667**
Other assets:		
Investment in equity securities		5,908
Restricted cash		5,000
Goodwill	11,365	11,365
Patents, less accumulated amortization of $2,414 in 2013 and $2,530 in 2012	1,934	2,114
Trademarks and other intangibles, less accumulated amortization of $4,593 in 2013 and $2,886 in 2012	19,985	21,968
Notes receivable	2,000	2,000
Deferred income taxes	16,885	16,564
Other	4,016	3,067
Total assets	**$ 174,683**	**$ 157,156**

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31, 2013	2012
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,137	$ 3,156
Taxes payable	1,377	619
Accrued compensation	4,886	5,055
Accrued procurement fees	5,427	4,762
Accrued expenses	2,411	4,205
Deferred income	316	1,401
Other	2,168	2,232
Total current liabilities	**20,722**	**21,430**
Contingent consideration liability	1,884	1,912
Deferred compensation liability	1,533	796
Deferred rent obligations	1,686	1,603
Other	4,111	3,303
Total liabilities	**29,936**	**29,044**
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 authorized, no shares issued		
Convertible preferred stock, 460 shares authorized, no shares issued		
Common stock $0.01 par value per share, 75,000 shares authorized, 28,244 shares issued in 2013 and 27,486 shares issued in 2012	282	275
Additional paid-in capital	128,585	122,414
Retained earnings	18,741	5,536
Accumulated other comprehensive income (loss)	7	(39)
Treasury stock at cost, 413 shares in 2013 and 14 shares in 2012	(2,868)	(74)
Total shareholders equity	**144,747**	**128,112**
Total liabilities and shareholders equity	**$ 174,683**	**$ 157,156**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

(in thousands, except per share data)

	Year Ended December 31,		
	2013	**2012**	**2011**
Revenues:			
Products	$ 76,194	$ 67,496	$ 59,387
Preservation services	64,498	63,603	59,793
Other	71	619	446
Total revenues	**140,763**	**131,718**	**119,626**
Cost of products and preservation services:			
Products	15,147	11,380	9,442
Preservation services	35,230	35,320	34,340
Total cost of products and preservation services:	**50,377**	**46,700**	**43,782**
Gross margin	**90,386**	**85,018**	**75,844**
Operating expenses:			
General, administrative, and marketing	68,112	65,149	57,302
Research and development	8,454	7,257	6,899
Total operating expenses	**76,566**	**72,406**	**64,201**
Operating income	**13,820**	**12,612**	**11,643**
Interest expense	71	179	142
Interest income	(4)	(6)	(14)
Gain on sale of Medafor investment	(12,742)		
Other than temporary investment impairment	3,229	340	
Other (income) expense, net	(26)	47	49
Income before income taxes	**23,292**	**12,052**	**11,466**
Income tax expense	7,120	4,106	4,095
Net income	**$ 16,172**	**$ 7,946**	**$ 7,371**
Income per common share:			
Basic	**$ 0.59**	**$ 0.29**	**$ 0.26**
Diluted	**$ 0.57**	**$ 0.28**	**$ 0.26**
Dividends declared per common share	**$ 0.108**	**$ 0.050**	**$**
Weighted-average common shares outstanding:			
Basic	26,885	26,967	27,441
Diluted	27,698	27,411	27,759
Net income	**$ 16,172**	**$ 7,946**	**$ 7,371**
Other comprehensive income (loss)	46	(33)	26

Comprehensive income	**$ 16,218**	**$ 7,913**	**$ 7,397**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2013	**2012**	**2011**
Net cash flows from operating activities:			
Net income	$ 16,172	$ 7,946	$ 7,371
Adjustments to reconcile net income to net cash from operating activities:			
Gain on sale of Medafor investment	(12,742)		
Depreciation and amortization	5,843	5,633	4,960
Non-cash compensation	3,240	3,162	2,790
Other than temporary investment impairment	3,229	340	
Write-down of deferred preservation costs and inventories	1,693	288	270
Deferred income taxes	617	1,227	1,767
Other non-cash adjustments to income	298	683	767
Changes in operating assets and liabilities:			
Receivables	(1,637)	1,363	(2,230)
Deferred preservation costs and inventories	193	(1,598)	2,445
Prepaid expenses and other assets	(706)	(583)	(617)
Accounts payable, accrued expenses, and other liabilities	572	529	(772)
Net cash flows provided by operating activities	**16,772**	**18,990**	**16,751**
Net cash flows from investing activities:			
Proceeds from sale of Medafor investment	15,421		
Acquisition of Hemosphere, net of cash acquired		(17,040)	
Acquisition of Cardiogenesis, net of cash acquired			(21,062)
Capital expenditures	(4,338)	(3,070)	(2,538)
Advances under notes receivable		(2,000)	
Purchases of restricted securities and investments			(3,569)
Other	(206)	(810)	(547)
Net cash flows provided by (used in) investing activities	**10,877**	**(22,920)**	**(27,716)**
Net cash flows from financing activities:			
Proceeds from exercise of stock options and issuance of common stock	2,207	330	694
Cash dividends paid	(2,967)	(1,373)	
Repurchases of common stock	(1,523)	(3,529)	(3,064)
Other	(768)	(143)	(476)
Net cash flows used in financing activities	**(3,051)**	**(4,715)**	**(2,846)**
Increase (decrease) in cash and cash equivalents	**24,598**	**(8,645)**	**(13,811)**
Effect of exchange rate changes on cash	36	(51)	19
Cash and cash equivalents, beginning of year	13,009	21,705	35,497
Cash and cash equivalents, end of year	**$ 37,643**	**$ 13,009**	**$ 21,705**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands)

	Common Stock		Additional Paid In Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Shareholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2010	**29,950**	**$ 300**	**$ 133,845**	**$ (8,408)**	**$ (32)**	**(2,049)**	**$ (11,763)**	**$ 113,942**
Net income				7,371				7,371
Other comprehensive income					26			26
Comprehensive income								7,397
Equity compensation	(25)		965			360	2,049	3,014
Exercise of options	84	1	380			37	27	408
Employee stock purchase plan	64		286					