CRYOLIFE INC
Form 10-K
February 15, 2013

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, 2012

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 nonaccelerated 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, 2012 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $130,523,457 computed using the closing price of $5.23 per share of Common Stock on June 30, 2012, 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 12, 2013 the number of outstanding shares of Common Stock of the registrant was 27,483,499.

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, 2012.	Part III

PART I

Item 1. Business.

Overview

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, preserves and distributes human tissues for transplantation and develops, manufactures, and commercializes medical devices for cardiac and vascular applications. 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 processed using CryoLife s proprietary SynerGraft® technology. 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 for Starch Medical, Inc. (SMI) in the European Community and other select international markets. 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.

Preservation Services and Products

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.

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 more than 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) 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, including Canada, Brazil, and Australia.

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 CE Mark certification 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.

CryoLife has a worldwide distribution agreement (except in China and certain related territories and governing areas) and a license and manufacturing agreement with SMI of San Jose, California for PerClot, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powdered hemostat that has CE Mark designation allowing commercial distribution into the European Community 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.

CryoLife refiled an investigational device exemption (IDE) in November 2012 with the FDA to begin clinical trials for the purpose of obtaining Premarket Approval (PMA) to distribute PerClot in the U.S. CryoLife has received questions from the FDA related to this filing and is currently working to address the questions and expects to respond to the FDA in the first quarter of 2013.

Revascularization Technologies. In May 2011 CryoLife completed its acquisition of Cardiogenesis. Cardiogenesis is 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 and 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. Cardiogenesis has also developed the Phoenix System, which is designed to combine the delivery of biologic materials 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 Phoenix System has received CE Mark designation allowing commercial distribution into the European Community. CryoLife intends to continue to investigate requirements to obtain an IDE for clinical evaluation of the Phoenix System in the U.S.

HeRO Grafts. In May 2012 CryoLife completed its acquisition of 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.

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, services, and products. 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 techniques within these areas, to secure their commercial protection, to establish their efficacy, and then to market these products and techniques. In order to expand CryoLife s service and product 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 services and products, building on either existing proprietary and non-proprietary knowledge or acquired technology and know-how. CryoLife s current tissue preservation services were developed internally. 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 its revascularization technologies and intends to continue to investigate requirements to obtain an IDE approval for clinical evaluation of the Phoenix System in the U.S. CryoLife also acquired Hemosphere, and its HeRO Graft, and is working on product enhancements.

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 channel 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 services and products. Identify potential investment opportunities in companies that have complementary products that could, in the future, enhance the Company s current distribution channel and expertise in the cardiac and vascular specialties.

3

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

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

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 million to ValveXchange through a revolving credit facility. 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. CryoLife s investment represents an approximate 19% equity ownership in ValveXchange.

Services and Products

Preservation Services

The Company s proprietary preservation process involves the recovery of tissue from deceased human donors by tissue banks and organ 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 application of the Company s cryopreservation technologies to donated tissue expands the amount of human cardiac and vascular tissues available to physicians for transplantation. Cryopreservation also expands the treatment options available to physicians and their patients 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.

CryoLife collects and maintains clinical data on the use and effectiveness of implanted human tissues that it has preserved and shares this data with implanting physicians and the OTPOs from which it receives tissue. The Company also uses this data to help direct its continuing efforts to improve its preservation services through ongoing research and development. Its physician relations and education staff, clinical research staff, and field representatives assist physicians by providing educational materials, seminars, and clinics on methods for handling and implanting the tissue preserved by the Company and the clinical advantages, indications, and applications for those tissues. The Company has ongoing efforts to train and educate physicians on the indications for, and uses 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 and, thereby, increase the yield of usable tissue.

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 primarily 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.

4

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 2012 71% of pulmonary valves and 46% of cardiac patch tissues shipped by CryoLife were processed with the SynerGraft technology.

Based on CryoLife s records 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 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 the Company s 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.

CryoLife shipped approximately 80,800 heart valves and cardiac patch tissues from 1984 through 2012, including approximately 3,200 shipments in 2012. Revenues from cardiac tissue preservation services accounted for 23%, 22%, and 24% of total Company revenues in 2012, 2011, and 2010, respectively. The Company estimates that in 2012 the total annual heart valve replacement and cardiac patch market in the U.S. was approximately $850 million. Management believes that of the $850 million, approximately $640 million or 75% of the procedures were for aortic, pulmonary, and tricuspid valve replacements for which the Company s tissues can be used. The Company believes that approximately 97,000 aortic, pulmonary, and tricuspid valve replacement surgeries were conducted in the U.S. in 2012.

Vascular Tissue. The human vascular tissues preserved by the Company, including the CryoVein and CryoArtery, are used to treat a variety of vascular reconstructions such as peripheral bypass, hemodialysis access, and aortic infections which have saved the lives and limbs of patients. 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 vein tissue. However, in cases of advanced vascular disease, as many as 30% of patients have unsuitable vein 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 shipped approximately 70,700 vascular tissues from 1986 through 2012, including approximately 4,600 shipments in 2012. Revenues from vascular preservation services accounted for 26%, 28%, and 27% of total Company revenues in 2012, 2011, and 2010, respectively. The Company estimates the aggregate U.S. vascular surgical graft market was approximately $120 million in 2012.

Medical Devices

PHT Platform

The effective closure of internal wounds 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. Air and fluid leaks resulting from surgical procedures can lead to significant post-operative morbidity resulting in prolonged hospitalization, higher levels of post-operative pain, higher costs, and a higher mortality rate.

Sutures and staples facilitate healing by joining wound edges and allowing the body to heal naturally. However, because sutures and staples do not have inherent sealing capabilities, 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. PHT 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 in some ways 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. 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 a 10cm, 27cm, and 35cm delivery tip extender).

CryoLife is authorized to distribute BioGlue throughout the U.S. and in more than 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 aggregate U.S. sales for surgical internal tissue sealants were approximately $335 million in 2012.

CryoLife distributes BioGlue under CE Mark product certification in the EEA for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). CryoLife has also received approval and distributes BioGlue for soft tissue repairs in Canada, Brazil, and Australia and for the repair of aortic dissections in Japan. Additional marketing approvals have been granted for specified applications in several other countries throughout the world.

Revenues from BioGlue represented 40%, 41%, and 41% of total Company revenues in 2012, 2011, and 2010, 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 intraoperatively to control internal organ hemorrhage, limit blood loss, and reduce the need for future re-operations in liver resections.

BioFoam received CE Mark certification 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. CryoLife plans to begin distribution of BioFoam in other international markets as required regulatory approvals are obtained.

Revenues from BioFoam represented less than 1% of total Company revenues in 2012, 2011, and 2010. CryoLife estimates the annual European market opportunity for cardiovascular and parenchymal tissue sealing, for which BioFoam can be used, is more than $100 million.

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 can, in many instances, 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.

Revenues from hemostatic agents represented 2%, 4%, and 8% of total Company revenues in 2012, 2011, and 2010, respectively. The Company estimates that aggregate U.S. sales for hemostatic agents were approximately $890 million in 2012.

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. The gelled adhesive matrix thus 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 within several days. PerClot is currently available in 1 gram, 3 gram, and 5 gram configurations with a 100mm or 200mm applicator tip. PerClot Laparoscopic is available in 1 gram and 3 gram configurations 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 CE Mark designation allowing commercial distribution into the European Community 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, venular, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

CryoLife filed an IDE with the FDA in March 2011 seeking approval to begin clinical trials for the purpose of obtaining a 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. CryoLife is currently working to address the questions and expects to respond to the FDA in the first quarter of 2013.

CryoLife began distributing PerClot in Europe in the fourth quarter of 2010. Revenues for PerClot represented approximately 2% of total Company revenues in 2012 and 2011. CryoLife plans to begin distribution of PerClot in other international markets as required regulatory approvals are obtained.

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 termination and settled the litigation in 2012. Revenues for HemoStase represented 0%, 2%, and 8% of total Company revenues in 2012, 2011, and 2010, 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 stable 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 implements advanced electronic and cooling system technology to greatly reduce the size and weight of the unit, while providing 115V power capability. The SolarGen 2100s 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 laser 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 has been designed for use in a minimally invasive thoracoscopic procedure. The PEARL 8.0 handpiece received FDA approval in 2012 and CE Mark in 2005. The Company anticipates launching the PEARL 8.0 in 2013.

CryoLife began distributing the TMR product line in May 2011 when it completed the acquisition of Cardiogenesis. Revenues from revascularization technologies represented 6% and 5% of total Company revenues in 2012 and 2011, respectively. The Company estimates that the addressable market opportunity for TMR is approximately $175 million.

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 application for the HeRO Graft is currently under review by the Company s Notified Body. 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 are higher cost, have high infection rates, limit a patient s lifestyle, and foster central venous stenosis, or 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. HeRO 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.

CryoLife began distributing the HeRO Graft in May 2012 when it completed the acquisition of Hemosphere. The Company estimates that the addressable market opportunity for the HeRO Graft in the U.S. is approximately $125 million worldwide. More than 6,000 HeRO Grafts were shipped from 2008 to 2012. Revenues from the HeRO Graft represented 2% of total Company revenues in 2012. CryoLife intends to introduce the HeRO graft into the European Union (EU) in mid-2013, upon receipt of its CE Mark, which it anticipates receiving in early 2013.

Other Medical Devices

ProPatch Soft Tissue Repair Matrix (ProPatch). ProPatch, manufactured from bovine pericardial tissue and treated with the SynerGraft process, 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, Achilles, 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. 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 intends 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.

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 preservation services and products.

See Part II, Item 8, Note 19 of the Notes to Consolidated Financial Statements regarding segment and geographic information.

Distribution and Marketing

Preservation Services

CryoLife markets its preservation services 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.

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. 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 120,000 donors. The Company has active relationships with approximately 40 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 35 individuals in donor services and donor quality assurance to work with OTPOs. This includes three 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 and gives it a control number. 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 -135º C. The entire preservation process is controlled by guidelines established by the Company and are 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 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. Once the tissue is approved, it is moved from quarantine to an implantable status. Tissue that does not pass testing is discarded as appropriate or used for research or other purposes if the donor s family has consented.

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 delivered 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 transports the tissue to the hospital, 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.

Medical Devices

In the U.S. the Company markets its products to physicians and distributes its products through its field service representatives and cardiac specialists. The Company markets and distributes its products in international markets through independent distributors in Canada, Asia Pacific, and the Americas and through the Company s wholly owned European subsidiary, CryoLife Europa, Ltd. (Europa), which employs direct field representatives and manages relationships with other independent distributors in Europe, the Middle East, and Africa. Through its field representatives and distributors, the Company conducts field training for implanting surgeons regarding the application of its products.

Marketing, Educational, and Technical Support

The Company works to maintain relationships with, and market to, surgeons within the cardiac and vascular medical specialties. The Company has records of over 1,400 cardiac and vascular surgeons who implanted tissues preserved by the Company during 2012. In the U.S., the Company has 20 cardiac specialists who focus primarily on cardiac surgeons, approximately 28 cardiovascular representatives who focus primarily on vascular surgeons, eight dialysis therapy representatives who focus primarily on nephrologists and dialysis clinics, and eight region managers. A small number of these positions are open, and the Company is actively recruiting for these positions.

Because the Company markets its preservation services and products directly to physicians, an important aspect of increasing the distribution of the Company s preservation services and products is educating physicians on the use of the Company s preserved human tissues and medical device products and on proper implantation and surgical techniques. The Company s trained medical relations and education staff and field support personnel provide support to implanting institutions and surgeons. The Company sponsors training seminars where physicians teach other physicians the proper technique 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 Ross Summit, Aortic Allograft Workshops, TMR Workshops, and beginning in 2013, the Central Venous Pathology Summit. 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 tissues and products offered by the Company and help to differentiate the Company from other allograft processors and medical device companies.

In September 2012 CryoLife hosted the fourth annual Ross Summit at CryoLife s Corporate Headquarters with 48 cardiac surgeons and cardiologists from 17 countries in attendance. The primary goal of the meeting was to facilitate and encourage the use of the Ross Procedure. The Ross Procedure is an operation in which a patient s defective aortic valve is removed and replaced with his own pulmonary valve, and then a replacement pulmonary valve (typically a valve from a human donor) is surgically implanted to replace the removed native pulmonary valve.

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.

European Operations

The Company markets its tissue services and products in the EEA, the Middle East, and Africa (EMEA) region through its European subsidiary, Europa, based in Guildford, England. Europa, with its team of approximately 26 employees, provides customer service, logistics, marketing, and clinical support to cardiac, vascular, thoracic, and general surgeons throughout the EMEA region. Europa markets and distributes the Company s complete range of services and products, in both of its reportable segments, through its direct sales representatives in the U.K., Germany, Austria, and Ireland and through a network of independent distributors in the rest of the EMEA region. Europa also distributes tissue to certain hospitals in the EMEA region, primarily in Germany, Austria, and the U.K.

Backlog

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. The Company currently does not have a backlog of orders related to BioGlue, BioFoam, PerClot, revascularization technologies, or HeRO Grafts.

Competition

Preservation Services

The Company currently faces competition from at least two non-profit tissue banks that preserve and distribute human cardiac heart valves, cardiac patch tissues, and 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. Any of these competitive disadvantages could materially, adversely impact the Company. 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 technology, customer service, and quality assurance.

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 six 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 HLA 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., and St. Jude Medical, Inc. 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 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. 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.

Generally, for each procedure that may utilize vascular human tissue that the Company preserves, there are alternative treatments. Often, in the case of veins, 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.

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. Any of these competitive disadvantages could materially, adversely impact 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; Covidien Ltd. s U.S. Surgical Division s Duraseal product; NeoMend, Inc. s ProGEL; and Tenaxis, Inc. s (Tenaxis) ArterX. The Company currently competes with these products based on BioGlue s benefits and features, such as strength and ease of use. Additional competitive products may be under development by other large medical device, pharmaceutical, and biopharmaceutical companies.

BioFoam. The Company s BioFoam product competes with other surgical hemostatic agents that include Pfizer, Inc. s Gelfoam; Baxter International, Inc. s FloSeal; Ethicon, Inc. s Spongostan, Instat, Surgicel, and Surgicel Nu-Knit; C.R. Bard, Inc. s Avitene; Baxter International s TachoSil; and Orthovita, Inc. s Vitagel. Other medical device, pharmaceutical, and biopharmaceutical companies may also develop competitive products. 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 King Pharmaceuticals, Inc. s Thrombin JMI; ZymoGenetics, Inc. s Recothrom; and Omrix Biopharmaceuticals, Inc. s (a Johnson & Johnson Company) Evithrom; and surgical hemostats, including Pfizer, Inc. s Gelfoam; C.R. Bard, Inc. s Avitene; Baxter International, Inc. s FloSeal; Ethicon, Inc. s Surgicel, Surgiflo, and Surgifoam products; Medafor s Arista; 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. Other medical device, pharmaceutical, and biopharmaceutical companies may also develop competitive products. The Company s PerClot products compete on the basis of safety profile, clinical efficacy, absorption rates, and ease of use.

12

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. Other medical device and pharmaceutical companies may also develop additional competitive products. The Company s revascularization technology competes on the basis of 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. Additional competitive products may be under development by other large medical device, pharmaceutical, and biopharmaceutical companies. 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 compared to catheters.

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 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 impacted. See Part I, Item 1A, Risk Factors Risks Relating To Our Business Rapid Technological Change Could Cause Our Services And Products To Become Obsolete.

Research and Development and Clinical Research

The Company uses its expertise in chemistry (protein, material, organic, and bio), cell biology, and engineering, and its understanding of the needs of the cardiac and vascular surgery medical specialties to attempt to expand its preservation services and surgical adhesives, sealants, and hemostats businesses and to develop or acquire products and technologies for these specialties. The Company identifies market areas that can benefit from preserved tissues, medical devices, and other related technologies and then attempts to develop innovative techniques, services, and products within these areas, to secure their commercial protection, to establish their clinical efficacy, and then to market these techniques, services, and products. The Company employs approximately 36 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 service and product offerings, the Company is currently in the process of obtaining approvals, developing, or investigating several technologies and products, including technologies related to additional applications of its SynerGraft technology, including the CryoValve SGAV and ProPatch, the PHT product platform used in BioGlue, BioFoam, and other PHT derivatives, PerClot, revascularization technologies, human tissue preservation, and the HeRO Graft.

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 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 2012, 2011, and 2010 the Company spent approximately $7.3 million, $6.9 million, and $5.9 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 6%, 6%, and 5% of the Company s revenues for each of the years 2012, 2011, and 2010, respectively. Of these amounts spent on research and development activities, $604,000, $398,000, and $490,000 was funded by the U.S. Department of Defense (DOD) in 2012, 2011, and 2010, respectively.

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 early 2014.

CryoValve SGAV. In September 2009 the FDA granted a Humanitarian Use Device (HUD) designation for the CryoValve SGAV for aortic valve replacement in patients aged 0 to 21 years. An HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease that affects fewer than 4,000 people in the U.S. per year. The HUD designation is the first step in obtaining a Humanitarian Device Exemption (HDE), which if obtained would allow the Company to market the CryoValve SGAV in the U.S. market. The Company submitted an HDE application in February 2012. The FDA responded with comments and requested additional information in September 2012. The Company is currently developing plans to respond to these questions. Additional jurisdictions for potential shipments of CryoValve SGAV also include Austria and the U.K.

BioFoam. In November 2012 CryoLife received an additional indication in Europe to also 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 2013. BioFoam received initial approval by the FDA in late 2009 for an IDE to conduct a pilot human clinical trial to help seal liver tissue in patients for whom cessation of bleeding by ligature or other conventional methods is ineffective or impractical. The first patient was enrolled into the trial in 2011 after receiving the required DOD and Institutional Review Board (IRB) approvals. Due to slower than expected enrollment, CryoLife worked with the FDA to further modify the protocol to enhance the ability to enroll patients. This modification was received in the fourth quarter of 2011. Even with the protocol modifications, the study design made it extremely difficult to recruit patients, due to the restrictive inclusion/exclusion criteria. As a result, CryoLife made the decision in the third quarter of 2012 to discontinue the U.S. BioFoam IDE study. CryoLife has been awarded a total of $6.1 million in funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2010 for the continued development of PHT for use on the battlefield. CryoLife has received $5.4 million of that funding. Unused funds will be returned to the DOD.

PerClot. In September 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI for PerClot, a polysaccharide hemostatic agent used in surgery. As part of the consideration paid to SMI, the Company allocated $3.5 million to an intangible asset for PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This $3.5 million is considered in-process research and development as it is dependent upon regulatory approvals which have not yet been obtained. Therefore, CryoLife expensed the $3.5 million as in-process research and development upon acquisition. 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. CryoLife is currently working to address the questions and expects to respond to the FDA in the first quarter of 2013.

Revascularization Technologies. In May 2011 CryoLife completed its acquisition of Cardiogenesis. Along with the TMR technology, Cardiogenesis has developed the Phoenix System, which is designed to combine the delivery of biologic materials 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 Phoenix System has received a CE Mark designation allowing commercial distribution into the European Community. CryoLife intends to continue to investigate requirements to obtain an IDE for clinical evaluation of the Phoenix System in the U.S.

The PEARL 8.0 handpiece received FDA approval in February 2012. A condition of approval is to conduct a post approval study on 10 to 22 patients at up to 5 centers with 30 day follow-up.

HeRO Grafts. The Company is currently working on improvements to the HeRO Graft which may include product enhancements to facilitate easier implantation of the device. Additionally a CE Mark application for the HeRO graft is currently under review by the Company s Notified Body.

ProPatch. In late 2006 CryoLife received 510(k) clearance from the FDA for ProPatch. In 2011 CryoLife implemented modifications to streamline the manufacturing process. These modifications resulted in the submission of a new 510(k), which was cleared in January 2012. CryoLife intends to commercialize ProPatch, which may include partnering with one or more third-parties as well as obtaining clinical data to support indications to be marketed directly.

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 65 U.S. patents and 66 foreign patents, including patents relating to its technology for human cardiac and vascular tissue preservation, decellularization of tissue, tissue revitalization prior to freezing, tissue transport, tissue packing, BioGlue manufacturing, PHT manufacturing, revascularization technologies, and HeRO Graft. The Company has approximately 11 pending U.S. patent applications and 18 pending foreign applications that relate to the Company s tissues, PHT, 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 ranges from 2 months to 15 years. The main patent for BioGlue expired in mid-2012 in the U.S. and expires in mid-2013 in 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. The Company has an agreement with a third-party that calls for the payment of royalties based on BioGlue revenues while the main BioGlue patent is in effect. Once the Company begins to manufacture PerClot, it will also be required to pay royalties based on revenues of PerClot manufactured by the Company. The Company has $1.5 million in prepaid royalties under this agreement. 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 preserved tissues, products, 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 impacted. 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, and if it loses litigation, could be forced to no longer market the services or products that are 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 services or products 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 services or products to avoid infringement. The Company s failure to obtain licenses or to redesign its services or products could have a material, adverse impact on 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 our 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.

The Company has entered into 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 employees of the Company 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 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 200,000 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 9,000 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 preservation, manufacturing, and packaging. Approximately 55 liquid nitrogen freezers maintain preserved tissue at or below 135º 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.

Tissue Preservation

The tissue processing laboratory is responsible for the processing and preservation of human cardiac and vascular tissues for transplant. This laboratory contains approximately 15,600 square feet with a suite of seven clean rooms dedicated to tissue processing. Currently, there are approximately 76 technicians employed in this area, and the laboratory is staffed 24 hours per day, 365 days per year. In 2012 the laboratory packaged approximately 12,000 tissues. The current processing level is estimated to be at about 35% 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.

BioGlue and BioFoam

BioGlue and BioFoam are presently 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 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 5% 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 1,100 square feet of laser maintenance and evaluation laboratory space.

HeRO Grafts

The HeRO Graft manufacturing was in the process of relocating at the end of 2012 to Atlanta, Georgia from Eden Prairie, Minnesota. The manufacturing space for the HeRO Grafts in Atlanta, Georgia contains approximately 4,000 square feet including a suite of two clean rooms. There are approximately 4 technicians employed in this area. The Company believes that once manufacturing commences in early 2013, the production levels will be at approximately 12% of total capacity, increasing to approximately 25% of full capacity by the end of 2013. 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.

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 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 availability of tissue 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 have a material, adverse impact on the Company s ability to accept or process tissue which could materially, adversely impact the Company s revenues. See also Part I, Item 1A, Risk Factors.

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 have a material, adverse impact on our ability to manufacture BioGlue and would materially, adversely impact the Company s revenues.

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

The contract manufacturers for the revascularization technologies laser console 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 impact 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; however, secondary suppliers can be approved. Any significant supply interruption would materially, adversely impact the Company s ability to sell HeRO Graft and obtain revenue growth from the product.

Quality Assurance

The Company s operations encompass the preservation of human tissue and the manufacturing of medical devices. In all of its facilities, the Company is subject to regulatory standards for good manufacturing practices, including current Good Tissue Practices (cGTPs), which are the FDA regulatory requirements for the processing of human tissue, and current Quality System Regulations, which are the FDA regulatory requirements for medical device manufacturers. 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.

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 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 the 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 the countries regulations.

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.

18

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.

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 can 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 required by FDA regulations.

The FDCA provides for an IDE which authorizes distribution for clinical evaluation of devices that lack a 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 IRB 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 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.

Under certain circumstances, the FDA may grant an HDE. The FDA grants HDE s in an attempt to encourage the development of medical devices for use in the treatment of rare conditions that affect small patient populations (less than 4,000 patients per year). Such approval by the FDA exempts the device from full compliance with clinical study requirements for a PMA, although recipients of an HDE must still obtain institutional approvals from an implanting institution s IRB to begin marketing the device at such institution.

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, 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, ProPatch, and HeRO Graft 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 (PHS Act), which in turn provides the regulatory framework for regulation of human cellular and tissue products. The FDA issued new regulations (21 C.F.R. Part 1270), in 1998, which focused on donor screening and testing to prevent the introduction, transmission, and spread of HIV-1 and -2 and Hepatitis B and C. 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, and product listing.

On January 19, 2001 the FDA published regulations that require establishments that process or use in manufacturing human cells, tissue, and cellular and tissue-based products to register with the agency and list their human cells, tissues, and cellular and tissue-based products (HCT/Ps). The final rule, 21 C.F.R. Parts 1271, became effective on April 4, 2001 for human tissues intended for transplantation that are regulated under section 361 of the PHS Act as well as part 1270 and for all other HCT/Ps.

In May 2004 the FDA published regulations governing the eligibility of donors of human cell and tissue products. This rule expands previous requirements for testing and screening for risks of communicable diseases that could be spread by the use of these tissues. In November 2004 the FDA published regulations governing the procedures and processes related to the manufacture of human cell and tissue products under the cGTPs. Both the new donor eligibility rule and the cGTP rule became effective on May 25, 2005 and designate human heart valves preserved on or after May 25, 2005 as human tissue rather than medical devices.

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 have a material, adverse impact on the Company.

Possible Other FDA Regulation

Other tissues and products 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 tissues and products is likely to be a time consuming and expensive process, and there can be no assurance that any of these tissues and products 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

Shipments of preserved human tissues and sales of medical devices outside the U.S. are subject to international regulatory requirements that vary widely from country to country. Compliance with applicable regulations for tissues must be met and approval of a product by comparable regulatory authorities of other countries must be obtained prior to commercial distribution of the preserved human tissues or products 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 (32 member state countries 27 EU countries, 4 European Free Trade Association (EFTA) countries, and Turkey) 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, and the laser console and handpieces used for TMR. Additionally, PerClot, which the Company distributes, holds 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 ships 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. The EUTCD set a benchmark for the standards that must be met when carrying out any activity involving tissues and cells that would be implanted in humans. The EUTCD also require that systems be put in place to ensure that all tissues and cells used in human application are traceable from donor to recipient. Pursuant to the EUTCD, each country in the EEA has responsibility for regulating tissues and cells and distribution and procurement of tissues and cells for use in humans through a Competent Authority. In the U.K., this Competent Authority is the Human Tissue Authority (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 Paul-Erlich-Institute (PEI), which enforces various regulations passed by the regulatory authorities in Germany. Europa has a provisional license in Germany and is awaiting PEI s final approval of its license. In addition, Europa ships tissue into Austria, which currently has no Competent Authority. Other countries in the EEA are in the process of implementing the EUTCD, and if CryoLife chooses to ship tissues into these countries, it will likely need to obtain licenses to do so. If any of these Competent Authorities were to deny, revoke, or not approve a license to distribute into their country, it could have a material, adverse impact on the Company s revenues. Each Competent Authority could modify its regulations, rules, directives, or directions, which could impact the Company s ability to send preserved tissues into Europe.

Recent Regulatory Approvals

December 2012 An additional indication was approved in Europe for BioFoam for use as an adjunct to hemostasis in cardiovascular surgery when cessation of bleeding by ligature or other conventional methods is ineffective or impractical.

January 2012 510(k) clearance was received in the U.S. for ProPatch Soft Tissue Repair Matrix.

Certifications, Accreditations and Inspections

January 2013 CryoLife received a warning letter from the FDA related to certain observations from the October 2012 Form 483, Notice of Inspectional Observations from the FDA (Form 483).

October 2012 LRQA ISO 13485 conducted a routine surveillance audit. Two minor observations were noted.

September and October 2012 The FDA conducted a routine quality system inspection of CryoLife s Kennesaw, GA facilities. CryoLife received a Form 483 related to its processing, preservation, and distribution of human tissue and the manufacture of our medical devices.

August 2012 The State of Georgia conducted a routine Tissue Bank/CLIA inspection. No observations were noted.

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

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 have a material, adverse impact on the Company s business.

Employees

As of December 31, 2012 CryoLife and its subsidiaries had approximately 488 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 (SEC), 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 (the Exchange Act), 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 is a significant source of our revenues. Any of the following could have a material, adverse impact on 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 the rest of the world for BioGlue expire 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 FDA; 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 the addressable procedures for BioGlue and such actions could continue to reduce the addressable procedures.

Our Tissues And Products Are Subject To Many Significant Risks.

The processing, preservation, and distribution of human tissues, and the manufacture and sale of medical devices has inherent risks. Any of the following could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows:

- Our tissues and products 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;
- Our tissues, which are not sterile when processed, and our medical devices allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose us to tissue processing and product liability claims, including the one current product liability claim that we have; such claims could lead to additional regulatory scrutiny and inspections;
- Our processing and manufacturing operations are subject to regulatory scrutiny and inspections, including by the FDA and foreign regulatory agencies, and these agencies could require us to change or modify our processes, procedures, and manufacturing operations;
- Regulatory agencies could reclassify or reevaluate our clearances and approvals to sell our tissue services and medical devices; and
- Adverse publicity associated with our processed tissues or medical devices or the industries as a whole that our processed tissues and medical devices are a part of could lead to a decreased use of our processed tissues or medical devices and additional regulatory scrutiny or tissue processing or product liability lawsuits.

As an example of the inherent risks of our tissue processing and manufacturing of medical devices, 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 our processing, preservation, and distribution of human tissue and the manufacture of our medical devices. The 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 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 are generated pursuant to procedures.

We intend to respond fully to the FDA s requests and we believe that we will be able to address the FDA s notice of violations contained in the Warning Letter; however, it is possible that we may not be able to do so in a manner satisfactory to the FDA. We believe that the Warning Letter and our actions regarding the Warning Letter and Form 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 Form 483 and Warning Letter could materially, adversely impact the availability of our tissues and products and our cost structure, which could impact our revenues, financial condition, profitability, or 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. This Warning Letter and any further warning letters, recall, hold, or other negative publicity from the FDA resulting from the observations contained in this Form 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 have a material, adverse impact on 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 SMI, pursuant to which we distribute and expect to, ultimately, manufacture PerClot. We were also authorized to pursue, obtain, and maintain regulatory approval for PerClot in the U.S. 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 2013 and 2014. 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 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, which is currently 2015, or at all. On March 30, 2012 CryoLife refiled for an IDE with the FDA seeking approval to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S. The FDA responded to the Company s IDE during the second quarter of 2012, and the Company filed a revised IDE in November 2012. CryoLife has received questions from the FDA related to this filing and is currently working to address the questions and expects to respond to the FDA in the first quarter of 2013. 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 impact 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. 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. 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. 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. We do not believe that PerClot will infringe their patent. 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 are found by a court to have infringed

Medafor s patent rights, we may ultimately not be able to distribute 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. Any of these occurrences could materially, adversely impact our future revenues, financial condition, profitability, and cash flows.

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.

As discussed above in 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., 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. We do not believe that PerClot will infringe Medafor s U.S. patent. If we are able to obtain FDA approval for PerClot, we will likely end up in a patent infringement lawsuit with Medafor. 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. Any of these occurrences could materially, adversely impact our future revenues, financial condition, profitability, and cash flows. In addition, patent litigation is expensive, and if we are involved in patent litigation with Medafor or another party, it could materially, adversely impact our financial condition, profitability, or cash flows, whether we prevail or not.

We Have Inherited Risks And Uncertainties Related To Cardiogenesis And Hemosphere s Businesses.

In May 2011 we acquired Cardiogenesis and in May 2012 we acquired Hemosphere. We have inherited certain risks and uncertainties related to each company s business. These risks and uncertainties include the following:

- We may be unable to maintain revenues and achieve growth in revenues from either party s technologies in the future due to our dependence upon physician awareness of each technology as a safe, efficacious, and appropriate treatment for their patients;
- We will continue to purchase product components for each acquisition from single suppliers, and the loss of these suppliers could prevent or delay shipments of our products, delay the timing of our planned clinical trials, or otherwise adversely affect our business;
- If Cardiogenesis independent contract manufacturers, which manufacture at locations that are at risk from earthquakes or other natural disasters, fail to timely deliver sufficient quantities of some of Cardiogenesis products and components, our Cardiogenesis operations may be harmed;
- Cardiogenesis and Hemosphere may have liability for actions that occurred prior to our acquisition, which could adversely affect us; and
- Either company s internal controls over financial reporting may not have been effective prior to the merger, which could impact the value of our investment in either company and potentially lead to lawsuits from former shareholders of those companies, which could have a significant, adverse effect on us.

Any of these conditions or contingencies could have a material, adverse effect on our revenues, financial condition profitability, and cash flows.

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 Have A Material, Adverse Impact On Our Business.

The materials and supplies used in our processing of tissue and our medical device manufacturing are subject to 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 preservation or manufacturing. In addition, if these materials and supplies are recalled or the facilities that make them are shut down temporarily or permanently, 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. In

2012 due to problems caused by FDA inspections at the only papaverine manufacturer in the U.S., there was, and currently is, a shortage of papaverine, a medicine used in our tissue processing and by many of our recovery partners. If this manufacturer is unable to begin producing papaverine before our supplies or our recovery partners supplies run out, we will be forced to change the way we process tissue.

Any of these occurrences or actions could materially, adversely impact our revenues, financial condition, profitability, and cash flows.

Our Investment In ValveXchange May Be Further Impaired, Or Our Loan To ValveXchange May Become Uncollectible, Which Could Have A Material, Adverse Impact On Our Business.

In July 2011 we purchased approximately 2.4 million shares of Series A Preferred Stock of ValveXchange for approximately $3.5 million. In addition, in 2012, we loaned ValveXchange approximately $2 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. CryoLife s carrying value of this investment includes the purchase price and certain transaction costs, and CryoLife s investment represents an approximate 19% equity ownership in ValveXchange.

In accordance with accounting principles generally accepted in the U.S., we regularly review our investments and long-term notes receivable based on available information and make determinations regarding the value of our investments and collectability of our long-term notes receivable. During 2012 we loaned ValveXchange $2 million under a note receivable. Also during 2012, we recorded an impairment of our investment in the preferred stock of ValveXchange. See Part II, Item 8, Notes to Consolidated Financial Statements for further discussion of the Company s investment in ValveXchange preferred stock, including the carrying value of our investment and our note receivable.

We will continue to evaluate the carrying value of this investment if changes to impairment factors or additional impairment factors become known to us that indicate that we should evaluate our investment in ValveXchange for further impairment. We will continue to evaluate the value of our note receivable from ValveXchange for collectability. Also, our investment in ValveXchange is subject to certain risks, including business and operational risks of ValveXchange outside of our control. These business risks include that ValveXchange must raise money for Series B financing, which could cause an immediate reduction in the value of our previous investments if the pricing for the Series B financing is lower than the value we paid in our Series A investment or if ValveXchange runs out of money. If we subsequently determine that the value of our ValveXchange investment or loan has been impaired further, the resulting impairment charges or write-down of the value of the loan could materially, adversely impact our financial condition and profitability. In addition, ValveXchange may be unable to raise additional monies, and if they are unable to, this could severely diminish our investment and the collectability of our loan.

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 licenses 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 impact 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 impact our business if we are unable to recover our initial investment, which could include the cost of acquiring license 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 impact our financial condition and profitability.

Our Sales Are Impacted By Challenging Domestic And International Economic Conditions And Their Constraining Effect On Hospital Budgets, And Demand For Our Tissues And Products Could Decrease In The Future, Which Could Have A Material, Adverse Impact On Our Business.

The demand for certain of our products, including BioGlue, 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 services and products. If the economic recession continues or worsens, changes occur in healthcare policies that force or encourage our customers to limit their use of our tissues and products, or if new competitive tissues or products are introduced, demand for our tissues and products could decrease in the future. If demand for our tissues or products decreases significantly in the future, our revenues, profitability, and cash flows would likely decrease, possibly materially. In addition, our processing throughput of tissue and our manufacturing throughput of our products would necessarily need to decrease, which would likely adversely impact our margins, and, therefore, our profitability, possibly materially. Further, if demand for our tissues and products materially decreases in the future, we may not be able to ship our tissues or products before they expire, which would cause us to write down our deferred preservation costs and inventories.

Our sales may also be impacted 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 impact our revenues, financial condition, and profitability.

Healthcare Policy Changes, Including Recent Federal Legislation To Reform The U.S. Healthcare System, May Have A Material, Adverse Impact On 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 services or products and could limit the acceptance and availability of our services and products. In addition, as discussed below, recent federal legislation is imposing, and could in the future impose, significant new taxes on medical device makers such as us. The adoption of some or all of these proposals, including the recent federal legislation, is expected to have a material, adverse impact on our profitability, and cash flows, and could have a material, adverse impact on our revenues and financial condition.

On March 23, 2010 President Obama signed the Patient Protection and Affordable Care Act. This legislation imposes a new 2.3% tax on the domestic sales of taxable medical devices by the manufacturer, producer, or importer beginning January 1, 2013. We believe that, if this tax had been in effect in 2012 and 2011, the majority of our domestic sales of medical devices would have been subject to the tax. We do not anticipate billing our customers separately for these taxes, which will result in a significant increase in our tax burden, which could have a material, adverse impact on our financial condition, profitability, and cash flows.

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 services and products,

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.

We May Not Be Successful In Obtaining Necessary Clinical Results And Regulatory Approvals For Services And Products In Development, And Our New Services And Products May Not Achieve Market Acceptance.

Our growth and profitability will depend, in part, upon our ability to complete development of, and successfully introduce, new services and products. We are uncertain whether we can develop commercially acceptable new services and products. We must also expend significant time and resources to obtain the required regulatory approvals. Although we have conducted preclinical studies on certain services and products under development which indicate that such services and products 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 services and products. We also cannot give assurance that the regulatory agencies will clear or approve these or any new services and products on a timely basis, if ever, or that the new services and products 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 particular tissue, product, 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 services and products is subject to all of the risks associated with the commercialization of new services and products based on innovative technologies. Such risks include unanticipated technical or other problems, processing or manufacturing 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 services or products which are under development, or we may not be able to do so on a timely basis. These services and products may not meet price or performance objectives and may not prove to be as effective as competing services and products.

If we are unable to successfully complete the development of a service, product, or application, or if we determine for financial, technical, or other reasons not to complete development or obtain regulatory approval or clearance of any service, product, or application, particularly in instances when we have expended significant capital, this could have a material, adverse impact on 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 service or product 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:

CryoValve SGAV,

Cardiogenesis Phoenix System, for combining TMR with the delivery of biologics, such as stem cells,

ProPatch and related products,

Product enhancements to the HeRO Graft, and

New indications for BioGlue.

Even if we are able to obtain regulatory approval for any services or products offered, the scope of the approval may significantly limit the indicated usage for which such services or products may be marketed. The unapproved use of our tissues or products could adversely impact the reputation of our company and our services and products. Services or products 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 provisional 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.

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 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 impacted.

Our Investment In Medafor Has Been Impaired, And Our Investment Could Be Further Impaired By Risks Associated With Medafor s Business Or By Medafor s Actions, Which Could Have A Material, Adverse Impact On Our Financial Condition And Profitability.

We recorded an impairment in the third quarter of 2010 to write down our investment in Medafor common stock that we had purchased in 2009 and 2010. See Part II, Item 8, Notes to Consolidated Financial Statements for further discussion of the Company s investment in Medafor common stock.

We will continue to evaluate the carrying value of this investment if changes to impairment factors or additional impairment factors become known to us that indicate that we should evaluate our investment in Medafor common stock for further impairment. Also, our investment in Medafor is subject to certain risks, including business and operational risks of Medafor outside of our control that could further impair the value of our investment, including the issuance of shares of Medafor common stock that could dilute our investment in Medafor. If we subsequently determine that the value of our Medafor common stock has been impaired further or if we decide to sell our Medafor common stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in Medafor could be material. In addition, if we prevail in any future patent litigation with Medafor over PerClot, the value of our investment could be materially impaired.

Intense Competition May Impact Our Ability To Operate Profitably.

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

The processing and preservation of human tissue,

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, and

The marketing of products addressing dialysis therapies.

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 tissues and products 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 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,

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,

Unexpected changes in regulatory requirements and tariffs,

Potential trade restrictions, exchange controls, and import and export licensing requirements, 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.

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.

Consolidation In The Healthcare Industry Could Continue To Result In Demands For Price Concessions, Limits On The Use Of Our Tissues And Products, 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 fees charged for our tissues and prices for our products, which could materially, adversely impact our revenues, financial condition, profitability, and cash flows.

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

If we fail to maintain our working relationships with physicians, many of our tissues and products may not be developed and marketed to appropriately meet the needs and expectations of the professionals who use and support our tissues and products. The research, development, marketing, and sales of many of our new and improved tissues and products are dependent upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding our tissues and products 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, and there are proposed legislation and regulations that govern interactions with physicians and other healthcare professionals that are currently before state legislatures and the U.S. Congress. 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 and the proposed legislation and regulations, if passed or implemented, may impact our ability to maintain strong relationships with physicians in the future. 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 tissue processing, product liability, 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 tissues and products allegedly have caused, and may in the future cause, injury to patients using our tissues or products, and we have been, and may be, exposed to tissue processing and product liability claims. We maintain claims-made insurance policies to mitigate our financial exposure to tissue processing and product 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 tissue processing and product liability insurance policies do not include coverage for any punitive damages.

31

If we are unsuccessful in arranging acceptable settlements of future tissue processing or product 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 tissue processing, product liability, or securities. 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 impact our financial condition, profitability, and cash flows. Further, although we have an estimated reserve for our unreported tissue processing and product 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.

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 fiscal 2012, and 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.

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 impact our liquidity. Therefore, as a result, our ability to consummate acquisitions and fully realize our growth strategy may be materially, adversely impacted 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.

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

The majority of our foreign tissue processing and product 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.

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

The technologies underlying our services and products 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 services, products, 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.

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. We do not have key life insurance policies on any of our key 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.

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 and efforts to respond to the FDA questioning related to the revised IDE filed for PerClot;

Benefits of TMR treatment and the Phoenix System;

Estimates regarding the addressable market opportunity for TMR;

Plans related to seeking regulatory approval for the Phoenix System;

Anticipated timing of the PEARL 8.0 launch;

Potential benefits of the Company s surgical adhesives, sealants and hemostats;

Plans related to regulatory approval in certain markets for BioFoam, and the subsequent distribution of BioFoam in those markets after approval, plans to conduct a post-market study in Europe on BioFoam, and the Company s intentions to refund unspent DOD funds related to the BioFoam U.S. clinical trial;

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

Commercialization plans for ProPatch;

Plans regarding product enhancements of the HeRO Graft;

Estimates regarding the addressable worldwide market opportunity for the HeRO graft, and the Company s intentions to introduce the HeRO graft into the European Union in mid-2013;

The Company s beliefs regarding production levels of the HeRO graft;

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.;

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

Plans regarding regulatory approval for CryoValve SGPV and CryoValve SGAV, the benefits of related studies, the expected completion date of the CryoValve SGPV study, and the Company s plans to respond to FDA comments related to the HDE application for CryoValve SGAV;

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 tissue processing and product 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;

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

Expectations that research and development spending will increase materially in 2013;

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

Beliefs regarding BioGlue sales, PerClot sales, and handpiece sales and laser console sales, and the factors affecting such sales;

The Company s belief that its SynerGraft processed tissues and the majority of its medical devices will be subject to the new excise tax on the sale of medical devices, and the Company s anticipation that it will not pass along the new excise tax to its customers;

The anticipation that the Company s 2013 tax rate will be favorably impacted by the research and development tax credit, and the belief that cash payments for federal income taxes will be reduced for the 2013 tax year;

Plans related to the debt financing of ValveXchange;

The Company s belief that it will be able to address the FDA s observations in the Form 483 and the Warning Letter and that the related issues will not have a material impact 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;

The Company s expectation that it will not have significant business development costs related to the acquisitions of Hemosphere and Cardiogenesis in 2013;

Expectations that general, administrative, and marketing expenses will increase in 2013;

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 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 tissue processing or product liability claims;

Anticipated impact of changes in interest rates and foreign currency exchange rates;

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

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

Issues that may impact 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, 2012 (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 200,000 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 15,600 square feet with a suite of seven clean rooms. The current processing level is estimated to be at about 35% 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 5% 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 10,500 square feet with a suite of five clean rooms. The microbiology laboratory is approximately 8,000 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 1,100 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 9,000 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	74	President, Chief Executive Officer, and Chairman
Bruce G. Anderson	Since 2012	46	Vice President, U.S. Sales and Marketing
Jeffrey W. Burris	Since 2010	41	Vice President and General Counsel
Scott B. Capps	Since 2007	46	Vice President, Clinical Research
David M. Fronk	Since 1998	49	Vice President, Regulatory Affairs and Quality Assurance
David C. Gale, Ph.D.	Since 2012	45	Vice President, Research and Development
David P. Lang	Since 2012	66	Senior Vice President, International Sales and Marketing
D. Ashley Lee, CPA	Since 2000	48	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.

37

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 30 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 a 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.

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

2011	High	Low
First quarter	$ 6.11	$ 5.01
Second quarter	6.17	5.14
Third quarter	6.00	4.35
Fourth quarter	5.02	4.00

As of February 12, 2013 the Company had 401 shareholders of record.

Dividends

On August 21, 2012 the Company announced that its Board of Directors had approved the initiation of the first dividend in Company history, a quarterly cash dividend of $0.025 per share of common stock outstanding. In 2012 cash dividends of $0.025 per share were paid on September 21, 2012 to all common stockholders of record as of September 14, 2012 and on December 21, 2012 to all common stockholders of record as of December 14, 2012. In February 2013 the Company announced a quarterly cash dividend for the first quarter of 2013 of $0.025 per share, which will be paid on March 21, 2013 to all common stockholders of record as of March 14, 2013. 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.

In September 2012 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 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, 2012 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
10/01/12 10/31/12		$		$ 10,263,880
11/01/12 11/30/12				10,263,880
12/01/12 12/31/12				
Total				

On June 1, 2010 the Company announced that its Board of Directors had authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. On November 1, 2011 the Company announced that its Board of Directors had authorized the Company s purchase of $15.0 million of its common stock through December 31, 2012, which included approximately $7.7 million remaining from the June 1, 2010 repurchase program and an additional $7.3 million, for a total authorization of $22.3 million. The purchase of shares were made from time to time in the open market or through privately negotiated transactions, on such terms as management deemed appropriate, and were dependent upon various factors, including: price, regulatory requirements, and other market conditions. For the year ended December 31, 2012 the Company purchased approximately 639,000 shares of its common stock for an aggregate purchase price of $3.3 million. This program expired on December 31, 2012. In February 2013 the Company s Board of Directors authorized the purchase of up to $15.0 million of its common stock through October 31, 2014.

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 approximately $10.2 million under the February 2013 authorization without obtaining its lender s consent.

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,				
	2012	**2011**	**2010**	**2009**	**2008**
Operations					
Revenues	$ 131,718	$ 119,626	$ 116,645	$ 111,685	$ 105,059
Operating income	12,612	11,643	9,868	14,496	13,654
Net income	7,946	7,371	3,944	8,679	31,950
Net income applicable to common shareholders - diluted	7,768	7,224	3,894	8,605	31,950
Research and development expense as a percentage of revenues	5.5%	5.8%	5.1%	4.7%	5.1%
Income Per Common Share					
Basic	$ 0.29	$ 0.26	$ 0.14	$ 0.31	$ 1.15
Diluted	$ 0.28	$ 0.26	$ 0.14	$ 0.30	$ 1.13
Year-End Financial Position					
Total assets	$ 157,156	$ 147,864	$ 137,438	$ 133,859	$ 125,037
Working capital	56,073	62,413	82,162	76,312	59,370
Long-term liabilities	7,614	4,869	4,168	4,197	5,672
Shareholders equity	128,112	121,538	113,942	110,446	98,368
Current ratio[1]	4:1	4:1	5:1	5:1	4:1

[1] Current assets divided by current liabilities.

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

Overview

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, preserves and distributes human tissues for transplantation and develops, manufactures, and commercializes medical devices for cardiac and vascular applications. 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 processed using CryoLife s proprietary SynerGraft® technology. 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 for Starch Medical, Inc. (SMI) in the European Community and other select international markets. 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 in certain hemodialysis patients.

For the year ended December 31, 2012 CryoLife had record annual revenues of $131.7 million. During 2012 CryoLife reported its highest revenues ever for a first, second, third, and fourth quarter, with each quarter exceeding $32 million in revenues. The Company s acquisition of Hemosphere in May 2012 coupled with its acquisition of Cardiogenesis in May 2011 continued to add revenue generating product lines to the Company s existing tissue services and products portfolio. The Company also reported new record annual revenues for its vascular preservation services and BioGlue. The Company s cash position was strong as the Company generated $19.0 million in cash flows from operations during 2012. This cash was used to fund the Company s acquisition of Hemosphere, the common stock buyback, and the $0.025 per share quarterly cash dividend that the Company initiated in the third quarter of 2012. The Company experienced increases in selling, general, and administrative expenses during 2012 due to increased spending on business development activities and additional general, administrative, and marketing costs related to the Company s recent acquisitions of Hemosphere and Cardiogenesis. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2012 results. See Part I, Item 1, Business, for further discussion of the Company s business and activities during 2012.

Recent Events

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 (Form 483) related to the Company s processing, preservation, and distribution of human tissue and the manufacture of medical devices. The 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 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 intends to respond fully to the FDA s requests and believes that it will be able to address the FDA s notice of violations contained in the Warning Letter; however, it is possible that the Company may not be able to do so in a manner satisfactory to the FDA. The Company believes that the Warning Letter and its actions regarding the Warning Letter and Form 483 will not have a material impact on the Company. However, it is possible that actions it may be required to take in response to the Form 483 and Warning Letter could materially, adversely impact the availability of the Company s tissues and products and cost structure, which could impact 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, 2012 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 it 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 accumulated and deferred. Deferred preservation costs are stated at the lower of cost or market value on a first-in, first-out basis and are deferred until revenue is recognized. Upon shipment of 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 tissue banks and organ 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.

Total deferred preservation costs are then allocated among tissues processed during the period based on cost drivers, such as the number of donors or number of tissues processed. At each balance sheet date, a portion of the deferred preservation costs relates to tissues currently in active processing or held in quarantine pending release to implantable status. 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

43

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.

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 impact 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 and can only be used by the Company s subsidiaries Hemosphere and Cardiogenesis. Due to the history of losses of these subsidiaries when operated as stand-alone companies, 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.

The Company s tax years 2009 through 2012 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2009, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

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 engages external advisors to assist it in determining the fair value of acquired asset groups or business combinations, using cost, market, or income valuation methodologies, as appropriate, including: the excess earnings, the discounted cash flow, or the relief from royalty methods. The determination of fair value 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 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 2012 the Company adopted Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820): *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs,* which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The adoption of ASU 2011-04 did not have a material effect on the Company s financial condition, profitability, and cash flows.

In January 2012 the Company adopted ASU 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income,* and ASU 2011-12 related to presentation of comprehensive income in interim and annual financial statements.

In January 2012 the Company adopted ASU 2011-08, Intangibles-Goodwill and Other (Topic 350): *Testing Goodwill for Impairment,* which gives entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of a reporting unit in step 1 of the goodwill impairment test. The adoption of ASU 2011-08 did not have a material effect on the Company s financial condition, profitability, and cash flows.

Results of Operations

(In thousands)

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**
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%
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%
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**
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%
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%
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 preservation services revenues, product revenues, and

other revenues for the three and twelve months ended December 31, 2012 is presented below.

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 impacted 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.

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 months 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.

BioGlue is a mature product in the U.S. and Europe that has experienced increasing competitive pressures. Management believes that BioGlue sales volume in domestic markets will continue to be impacted by the factors discussed above, and that poor economic conditions in Europe could negatively impact sales in future periods. Management also believes that international BioGlue sales will be positively impacted by increased shipments to Japan in 2013 as compared to the corresponding periods in 2012, although this increase will be less than the increase experienced in 2012 over 2011.

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

48

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. On March 30, 2012 CryoLife refiled for an investigational device exemption (IDE) with the FDA seeking approval to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S. The FDA responded to the Company s IDE during the second quarter of 2012, and the Company filed a revised IDE in November 2012. CryoLife has received questions from the FDA related to this filing and is currently working to address the questions and expects to respond to the FDA in the first quarter of 2013.

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. If the exchange rates between the U.S. Dollar and the British Pound or Euro decline materially in future periods, this would have a material, adverse impact on the Company s revenues denominated in these currencies. Changes in exchange rates will have a more material impact on hemostat revenues than the Company s other product lines, as a larger percentage of the Company s hemostat sales are denominated in foreign currencies.

Management believes that competitive pressures and economic conditions in Europe could negatively impact PerClot sales in 2013. Poor economic conditions and their constraining effect on hospital budgets are expected to drive continued pricing pressures, especially due to the many hemostatic agents currently competing for market share in Europe.

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 impacted handpiece revenues. Revenues from laser consoles have been negatively impacted by the current economic environment, which makes hospitals reluctant to invest in large capital purchases.

The Company believes that the effects of competitive pressures and challenges in selling laser consoles may continue to negatively impact handpiece sales and laser console sales into 2013. The amount of revenues from the sale of laser consoles can vary significantly from quarter-to-quarter due to the long lead time required to generate sales of capital equipment and due to the higher selling price of consoles as compared to handpieces. Handpieces and laser consoles are primarily distributed in domestic markets.

HeRO Graft

Revenues from HeRO Grafts for the three and twelve months ended December 31, 2012 were a result of the Company s acquisition of Hemosphere in May 2012. 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.

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 remains 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 has discontinued its BioFoam U.S. clinical trial and, after the trial is formally closed out, any remaining unspent funds will be returned to the U.S. Department of Defense (DOD).

Cost of Preservation Services and Products

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.

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.

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, Inc. (Medafor) and a $4.1 million loss for the settlement of the lawsuit with CardioFocus, Inc. (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. The Company does not

anticipate that it will have significant business development costs related to the acquisitions of Hemosphere and Cardiogenesis in 2013.

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.

The Company expects that its general, administrative, and marketing expenses will increase in 2013 as compared to 2012 due to increased costs related to its acquisition of Hemosphere and due to the 2.3% excise tax on the sale of medical devices in the U.S. that went into effect on January 1, 2013 as part of the Patient Protection and Affordable Care Act passed in 2010. The Company believes that its SynerGraft processed tissues and the majority of its medical devices will be subject to the tax and that its traditionally processed tissues will not be subject to the tax.

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 tissues and products, and BioFoam. The Company expects that research and development spending will increase materially in 2013 due to planned increases in spending on clinical studies related to PerClot.

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 impacted 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. Actual usage will be dependent on a variety of factors and could change, although this favorable impact is not expected to recur in future periods. The Company s income tax rates for the three and twelve months ended December 31, 2012 were also impacted 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 impacted 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.

The Company anticipates that its 2013 tax rate will be favorably impacted by the research and development tax credit. As this credit was enacted for the 2012 tax year in January 2013, the Company will record the favorable impact of the full year 2012 credit in the first quarter of 2013.

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.

Diluted income per common share could be unfavorably impacted in future periods by the issuance of additional shares of common stock and favorably impacted by the Company s repurchase of its common stock. Stock repurchases are impacted 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. This program expired on December 31, 2012. In February 2013 the Company s Board of Directors authorized the purchase of up to $15.0 million of its common stock through October 31, 2014.

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2011	2010	2011	2010
Preservation services:				
Cardiac tissue	$ 6,629	$ 7,044	22%	24%
Vascular tissue	8,146	6,981	27%	24%
Total preservation services	14,775	14,025	49%	48%
Products:				
BioGlue and BioFoam	12,519	12,164	41%	42%
PerClot	617	264	2%	1%
HemoStase	(96)	2,666	%	9%
Revascularization technologies	2,415		8%	%
Total products	15,455	15,094	51%	52%
Other	167	103	%	%
Total	$ 30,397	$ 29,222	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2011	2010	2011	2010
Preservation services:				
Cardiac tissue	$ 26,618	$ 27,997	22%	24%
Vascular tissue	33,175	31,727	28%	27%
Total preservation services	59,793	59,724	50%	51%
Products:				
BioGlue and BioFoam	49,455	47,383	41%	41%
PerClot	2,528	264	2%	%
HemoStase	1,699	8,793	2%	8%
Revascularization technologies	5,705		5%	%
Other medical devices		(70)	%	%
Total products	59,387	56,370	50%	49%
Other	446	551	%	%
Total	$ 119,626	$ 116,645	100%	100%

Revenues increased 4% for the three months and 3% for the twelve months ended December 31, 2011 as compared to the three and twelve months ended December 31, 2010, respectively. A detailed discussion of the changes in preservation services revenues, product revenues, and other revenues for the three and twelve months ended December 31, 2011 is presented below.

Preservation Services

Revenues from preservation services increased 5% for the three months ended December 31, 2011 as compared to the three months ended December 31, 2010. The increase for the three months ended December 31, 2011 was primarily due to an increase in vascular preservation services revenues. Preservation services revenues for the twelve months ended December 31, 2011 were comparable to revenues for the twelve months ended December 31, 2010. 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) decreased 6% for the three months ended December 31, 2011 as compared to the three months ended December 31, 2010. This decrease was primarily due to the aggregate impact of a decrease in volume and tissue mix, which decreased revenues by 7%, partially offset by an increase in average service fees, which increased revenues by 1%.

Revenues from cardiac preservation services decreased 5% for the twelve months ended December 31, 2011 as compared to the twelve months ended December 31, 2010. This decrease was primarily due to the aggregate impact of a decrease in volume and tissue mix, which decreased revenues by 6%, partially offset by an increase in average service fees, which increased revenues by 1%.

The reduction in revenues from the decrease in volume and cardiac tissue mix for both the three and twelve months ended December 31, 2011 was primarily due to a decrease in volume of cardiac valve shipments. For the twelve months ended December 31, 2011 this decrease was partially offset by an increase in the volume of lower fee cardiac patch tissues. The Company believes that the decrease in unit shipments of cardiac valves was primarily due to increasing pressure from lower cost competitive products and to continuing cost containment practices at certain hospitals.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 39% and 40% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2011, respectively, and 40% and 35% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2010, respectively. Domestic revenues accounted for 92% and 91% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2011, respectively, and 91% and 93% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2010, respectively.

54

Vascular Preservation Services

Revenues from vascular preservation services increased 17% for the three months ended December 31, 2011 as compared to the three months ended December 31, 2010, primarily due to a 14% increase in unit shipments of vascular tissues, which increased revenues by 16%, and by an increase in average service fees, which increased revenues by 1%.

Revenues from vascular preservation services increased 5% for the twelve months ended December 31, 2011 as compared to the twelve months ended December 31, 2010, primarily due to a 3% increase in unit shipments of vascular tissues, which increased revenues by 4%, and by an increase in average service fees, which increased revenues by 1%.

The increase in vascular tissue volume for the three and twelve months ended December 31, 2011 was primarily due to increases in shipments of saphenous veins, resulting from the strong demand for these tissues in domestic markets, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations.

Products

Revenues from products increased 2% for the three months and 5% for the twelve months ended December 31, 2011 as compared to the three and twelve months ended December 31, 2010, respectively. These increases were primarily due to revenues from revascularization technologies as a result of the Company s acquisition of Cardiogenesis in the second quarter of 2011 and, to a lesser extent, due to an increase in PerClot and BioGlue revenues, partially offset by a decrease in HemoStase revenues. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot and HemoStase; and revascularization technologies is presented below.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 3% for the three months ended December 31, 2011 as compared to the three months ended December 31, 2010. This increase was primarily due to a 2% increase in the volume of milliliters sold, which increased revenues by 2%, and by an increase in average service fees, which increased revenues by 1%.

Revenues from the sale of surgical sealants increased 4% for the twelve months ended December 31, 2011 as compared to the twelve months ended December 31, 2010. This increase was primarily due to a 4% increase in the volume of milliliters sold, which increased revenues by 3%, and the favorable impact of foreign exchange rates, which increased revenues by 1%.

The increase in sales volume of surgical sealants for the three and twelve months ended December 31, 2011 was due to an increase in shipments of BioGlue in certain international markets, primarily Japan. 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, 2011 were $869,000 and $2.0 million, respectively. These increases were partially offset by volume decreases in the Company s more mature domestic and European markets.

Management believes that the decrease in BioGlue shipments in its domestic markets is a result of various factors, including: 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, 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, and the efforts of some large competitors in imposing and enforcing contract purchasing requirements for competing non-CryoLife products. Management believes that the decline in European volume may be due to general economic conditions in Europe, specifically in the Euro zone countries.

Domestic revenues accounted for 63% and 64% of total BioGlue revenues for the three and twelve months ended December 31, 2011, respectively, and 67% and 69% of total BioGlue revenues for the three and twelve months ended December 31, 2010, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2011. BioFoam is currently approved for sale in certain international markets.

PerClot and HemoStase

Revenues from the sale of hemostats, consisting of PerClot and HemoStase, decreased 82% for the three months ended December 31, 2011 as compared to the three months ended December 31, 2010. Revenues from the sale of hemostats decreased 53% for the twelve months ended December 31, 2011 as compared to the twelve months ended December 31, 2010. The revenue decreases in the three and twelve months ended December 31, 2011 were primarily due to a decrease in hemostat sales volume in domestic markets, as discussed further below. For the twelve months ended December 31, 2011 this decrease was partially offset by an increase in sales volume in international markets in the year to date period.

International hemostat revenues decreased 38% for the three months ended December 31, 2011 as compared to the three months ended December 31, 2010. This decrease was primarily due to a decrease in sales in certain international markets, particularly in Canada and South America due to large orders filled in the fourth quarter of 2010 in anticipation of a disruption in the availability of hemostats to the Company s distributors in these countries beginning in early 2011. This disruption was due to the Company s planned March 2011 discontinuance of HemoStase sales subsequent to the termination of its EDA for this product, discussed further below. International hemostat revenues increased 23% for the twelve months ended December 31, 2011 as compared to the twelve months ended December 31, 2010. This increase is primarily due to an increase in international sales of PerClot in the 2011 periods over the international sales of HemoStase in the corresponding 2010 periods. Management believes that international PerClot revenues were favorably impacted by the Company s ability to market PerClot for all surgical specialties, expanding the direct European sales force into Austria, and PerClot s product performance when compared to other hemostatic agents.

The decrease in domestic sales volume for the three and twelve months ended December 31, 2011 was due to the Company s planned discontinuation of sales of HemoStase in late March 2011, as a result of Medafor s termination of its EDA with the Company. The Company recognized no domestic hemostat sales in the second, third, or fourth quarters of 2011, subsequent to the discontinuance of HemoStase sales, as PerClot has not yet been approved for commercial distribution in domestic markets.

Revascularization Technologies

Revenues from revascularization technologies for the three and twelve months ended December 31, 2011 were a result of the Company s acquisition of Cardiogenesis in May 2011. Revascularization technologies includes revenues related to the sale of laser consoles, handpieces, and related products. Revascularization technologies revenues for the three and twelve months ended December 31, 2011 consisted primarily of handpiece sales and, to a lesser extent, laser console sales.

Revenues from the sale of laser consoles accounted for 22% and 9% of total revascularization technologies revenues for the three and twelve months ended December 31, 2011, respectively.

Other Revenues

Other revenues for the three and twelve months ended December 31, 2011 and 2010 included revenues related to funding allocated from the DOD Grants. As of December 31, 2011 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, 2011 CryoLife had $1.6 million included in deferred income on the Company s Consolidated Balance Sheet from the DOD Grants.

Cost of Preservation Services and Products

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2011	2010	2011	2010
Cost of preservation services	$ 8,631	$ 8,546	$ 34,340	$ 35,868

Cost of preservation services increased 1% for the three months and decreased 4% for the twelve months ended December 31, 2011, as compared to the respective periods in 2010. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The increase in cost of preservation services for the three months ended December 31, 2011 was primarily due to $674,000 in unusual processing expenses due to certain supplies of processing solutions used in our processing of tissues that did not meet our quality requirements, partially offset by cost decreases discussed below.

The decrease in cost of preservation services in the twelve months ended December 31, 2011 was primarily due to a decrease in the per unit cost of processing tissues. The decrease in the per unit cost of processing tissues in 2011 was largely a result of increased processing and packaging throughput, as fixed costs were allocated to a greater volume of processed tissues.

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2011	2010	2011	2010
Cost of products	$ 2,391	$ 3,091	$ 9,442	$ 12,409

Cost of products decreased 23% for the three months and 24% for the twelve months ended December 31, 2011 as compared to the three and twelve months ended December 31, 2010, respectively. Cost of products in 2011 included costs related to BioGlue, BioFoam, PerClot, and revascularization technologies, and includes HemoStase for the year to date period. The Company began distributing revascularization technologies products in the second quarter of 2011 through CryoLife s subsidiary Cardiogenesis. Cost of products in 2010 includes costs related to BioGlue, BioFoam, HemoStase, and PerClot.

The decrease in cost of products in the three months ended December 31, 2011 was primarily due to a decrease in shipments of HemoStase, partially offset by costs for revascularization technologies, which the Company began selling in the second quarter of 2011 through Cardiogenesis, and by increased shipments of PerClot, which the Company began distributing in the fourth quarter of 2010.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2011	2010	2011	2010
General, administrative, and marketing expenses	$ 14,626	$ 12,201	$ 57,302	$ 49,064
General, administrative, and marketing expenses as a percentage of total revenues	48%	42%	48%	42%

General, administrative, and marketing expenses increased 20% for the three months and 17% for the twelve months ended December 31, 2011 as compared to the three and twelve months ended December 31, 2010, respectively.

The increase in general, administrative, and marketing expenses for the three months ended December 31, 2011 was primarily due to expenses related to the sales personnel and ongoing operations of Cardiogenesis, which the Company acquired in May 2011. The increase in general, administrative, and marketing expenses for the twelve months ended December 31, 2011 was primarily due to expenses for business development activities and additional expenses related to the sales personnel and ongoing operations of Cardiogenesis. The Company s business development activities included transaction and integration expenses related to the Company s acquisition of Cardiogenesis and additional business development activities. The Company s business development expenses, including: outgoing personnel costs, exit activities, and legal, professional, and regulatory fees, were $4.2 million and $1.0 million for the twelve months ended December 31, 2011 and 2010, respectively.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2011	2010	2011	2010
Research and development expenses	$ 1,800	$ 1,801	$ 6,899	$ 5,923
Research and development expenses as a percentage of total revenues	6%	6%	6%	5%

The Company s research and development expenses include both research and development and clinical research expenses for tissues and products. Research and development spending in 2011 and 2010 was primarily focused on the Company s SynerGraft tissues and products, including: CryoValve SGPV, CryoValve SG aortic heart valves, CryoPatch SG, and xenograft SynerGraft tissue products; PerClot; and the Company s BioGlue family of products, including: BioGlue and BioFoam.

Acquired In-Process Research and Development

Acquired in-process research and development was $3.5 million for the twelve months ended December 31, 2010. As part of the consideration paid to SMI in the third quarter of 2010, the Company allocated $3.5 million to an intangible asset for PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This $3.5 million was considered in-process research and development as it was dependent upon regulatory approvals, which had not yet been obtained. Therefore, CryoLife expensed the $3.5 million as in-process research and development upon acquisition.

Other Income and Expenses

The gain on valuation of derivative was $1.3 million for the twelve months ended December 31, 2010. The gain on valuation of derivative was due to the decrease in the value of embedded derivatives related to Medafor common stock previously purchased by the Company.

The other than temporary investment impairment was $3.6 million for the twelve months ended December 31, 2010. This was due to the impairment in the value of the Company s investment in Medafor common stock during the third quarter of 2010.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2011	2010	2011	2010
Income before income taxes	$ 2,863	$ 3,458	$ 11,466	$ 7,277
Income tax expense	997	1,343	4,095	3,333
Net income	$ 1,866	$ 2,115	$ 7,371	$ 3,944
Diluted income per common share	$ 0.07	$ 0.08	$ 0.26	$ 0.14
Diluted weighted-average common shares outstanding	27,745	28,030	27,759	28,274

Income before income taxes decreased 17% for the three months and increased 58% for the twelve months ended December 31, 2011 as compared to the three and twelve months ended December 31, 2010, respectively. Income before income taxes for the three and twelve months ended December 31, 2011 was negatively impacted by increases in general, administrative, and marketing costs, including costs related to the acquisition of Cardiogenesis, other business development costs, and legal costs. Income before income taxes for the twelve months ended December 31, 2010 was negatively impacted primarily by acquired in-process research and development expense, the other than temporary investment impairment, and the write-down of HemoStase inventory, as discussed above. These effects were partially offset by the gain on valuation of derivative for the twelve months ended December 31, 2010.

The Company s effective income tax rate was approximately 35% for the three months and 36% for the twelve months ended December 31, 2011, as compared to 39% for the three months and 46% for the twelve months ended December 31, 2010. The Company s effective income tax rate for the twelve months ended December 31, 2011 was impacted 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 for the three and twelve months ended December 31, 2011 changed compared to the corresponding periods in 2010 due to the changes in income before income taxes, adjusted by the effect of income tax expense, as discussed above.

Seasonality

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.

The Company believes the 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 surgeries being scheduled during the winter holiday months.

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 fewer surgeries being performed on adult patients in the summer months in the U.S.

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 only recently acquired this product line in May 2011, and the historical data does not indicate a significant trend.

The Company is uncertain whether the demand for HeRO Grafts will be seasonal, as the Company only recently acquired this product line in May 2012, and the historical data does not indicate a significant trend.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2012 net working capital (current assets of $77.5 million less current liabilities of $21.4 million) was $56.1 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of $62.4 million and a current ratio of 4 to 1 at December 31, 2011.

Overall Liquidity and Capital Resources

The Company s largest non-operating cash requirements for the twelve months ended December 31, 2012 were the acquisition of Hemosphere and the related transaction and integration costs. The total acquisition cost, net of cash acquired, was $17.0 million. CryoLife used cash on hand to fund the acquisition and operates Hemosphere as a wholly owned subsidiary. In addition, during the twelve months ended December 31, 2012 the Company paid $4.5 million in a settlement to CardioFocus, which was largely offset by $3.5 million received in a settlement from Medafor. See Liability Claims below for further discussion of these settlements. The Company s other cash requirements included cash for general working capital needs, repurchases of the Company s common stock, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves and its operating activities, which generated cash during the period.

CryoLife s credit agreement with GE Capital (the GE Credit Agreement) provides revolving credit for working capital, acquisitions, and other corporate purposes. The borrowing capacity under the GE Credit Agreement is $20.0 million (including a letter of credit subfacility), and the GE Credit Agreement expires on October 28, 2014. 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 GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company s liquidity needs during the term of the GE Credit Agreement and, as such, have been recorded as 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, 2012 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, 2012 the Company purchased approximately 639,000 shares of its common stock for an aggregate purchase price of $3.3 million under the common stock repurchase program previously authorized by the Company s Board of Directors. This program expired on December 31, 2012. In February 2013 the Company s Board of Directors authorized the purchase of up to $15.0 million of its common stock through October 31, 2014.

The Company s cash equivalents include advance funding received under the DOD Grants for the continued development of protein hydrogel technology. As of December 31, 2012 $668,000 of the Company s cash equivalents were related to these DOD Grants, which must be used for the specified purposes or repaid to the DOD. The Company has discontinued its BioFoam U.S. clinical trial and, after the trial is formally closed out, any remaining unspent funds will be returned to the DOD.

As of December 31, 2012 approximately 9% of the Company s cash, cash equivalents, and restricted cash and securities were held in foreign jurisdictions.

During the third and fourth quarters of 2012 the Company advanced a total of $2.0 million in debt financing to ValveXchange, Inc. (ValveXchange) through a revolving credit facility. The Company may decide to allow ValveXchange to issue shares in payment of some or all of the outstanding debt balance in connection with a currently proposed financing or a future round of financing.

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 may include cash to fund the PerClot clinical trials, research and development expenditures for revascularization technologies and HeRO Graft, and other business development activities, to purchase license agreements, for general working capital needs, to repurchase the Company s common stock, to fund the cash dividend to common shareholders, and for other corporate purposes. These items may have a significant impact on its cash flows during 2013. 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 2013, it will likely 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 2013 tax year.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $19.0 million for the twelve months ended December 31, 2012 as compared to $16.8 million for the twelve months ended December 31, 2011. The current year cash provided was primarily due to net income generated by the Company during the period and non-cash expenses. In addition, during the twelve months ended December 31, 2012 the Company paid $4.5 million in a settlement to CardioFocus, which was largely offset by $3.5 million received in a settlement from Medafor, as discussed above.

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 and for changes in operating assets and liabilities from the prior year end. For the twelve months ended December 31, 2012 these non-cash items included a favorable $5.6 million in depreciation and amortization expense, $3.2 million in non-cash stock based compensation, and $1.2 million in deferred income taxes.

The Company s working capital needs, or changes in operating assets and liabilities, did not have an overall material impact on cash from operations. However, for the twelve months ended December 31, 2012 the changes to specific working capital items included an unfavorable $1.6 million due to increases in deferred preservation costs and inventory balances and an unfavorable $583,000 due to the timing difference between making cash payments and the expensing of assets, including prepaid insurance policy premiums, offset by a favorable $1.4 million due to the timing difference between recording receivables and the receipt of cash and a favorable $529,000 due to the timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the actual payment of cash.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $22.9 million for the twelve months ended December 31, 2012 as compared to $27.7 million for the twelve months ended December 31, 2011. The current year cash used was primarily due to the payment of $17.0 million for the acquisition of Hemosphere, net of cash acquired, $3.1 million in capital expenditures, and $2.0 million in advances to ValveXchange under the revolving credit facility.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $4.7 million for the twelve months ended December 31, 2012 as compared to $2.8 million for the twelve months ended December 31, 2011. The current year cash used was primarily due to $3.5 million in purchases of treasury stock, largely related to the Company s publicly announced stock repurchase plan, and $1.4 million in cash dividends paid on the Company s common stock.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of December 31, 2012 are as follows (in thousands):

	Total	2013	2014	2015	2016	2017	Thereafter
Operating leases	$ 26,626	$ 2,674	$ 2,902	$ 2,868	$ 2,852	$ 2,907	$ 12,423
Purchase commitments	5,769	3,969	1,800				
Contingent payments	4,500	500		4,000			
Compensation payments	1,985				1,985		
Research obligations	1,927	1,657	270				
Total contractual obligations	$ 40,807	$ 8,800	$ 4,972	$ 6,868	$ 4,837	$ 2,907	$ 12,423

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

The Company s purchase commitments include minimum purchase requirements for PerClot related to the Company s transaction with SMI. These minimum purchases are included through 2014, as the Company expects to receive FDA approval for PerClot in 2015. Upon FDA approval, the Company may terminate its minimum purchase requirements, which it 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 and contractual payments for licensing computer software and telecommunication services.

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 2015, although the timing of this payment may change. The schedule excludes one 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 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 an estimated payment for post-employment benefits for the Company s Chief Executive Officer (CEO). The timing of the CEO s post-employment benefit payment is based on the December 31, 2015 expiration date of the CEO s new employment agreement. The new agreement, which was signed in October 2012, was used to determine the timing of the payment even though it did not take effect until January 1, 2013, as the prior agreement expired effective December 31, 2012. Payment of the benefit under the new agreement may be accelerated by the voluntary retirement of the CEO or upon certain termination events.

61

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, (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $2.4 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, and (iii) $668,000 in unspent funds that the Company will spend during the close out of its BioFoam U.S. clinical trial or will refund to the DOD.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2012 were $3.1 million compared to $2.5 million for the twelve months ended December 31, 2011. Capital expenditures in the twelve months ended December 31, 2012 were primarily related to the routine purchases of tissue processing, manufacturing, computer, and office equipment; laser consoles; computer software; and renovations to the Company s corporate headquarters and manufacturing facilities 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 $13.0 million and restricted securities of $5.0 million and interest paid on the Company s variable rate line of credit as of December 31, 2012. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the twelve months ended December 31, 2012, affecting the Company s cash and cash equivalents, restricted securities, and line of credit would not have 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, 2012 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, 2012 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.

None.

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.

Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of December 31, 2012 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.

The Securities and Exchange Commission s general guidance permits the exclusion of an assessment of the effectiveness of a registrant s disclosure controls and procedures as they relate to its internal control over financial reporting for an acquired business during the first year following such acquisition if, among other circumstances and factors, there is not adequate time between the acquisition date and the date of assessment. As previously noted in this Form 10-K, the Company completed the acquisition of Hemosphere, Inc. (Hemosphere) during the second quarter of 2012. Management s assessment and conclusion on the effectiveness of the Company s disclosure controls and procedures as of December 31, 2012 excludes an assessment of the internal control over financial reporting of Hemosphere. See Part II, Item 8, Note 4, Notes to Consolidated Financial Statements contained in this Form 10-K for a description of the significance of the acquired business to the Company.

During the quarter ended December 31, 2012 there were no other 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, 2012, 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, 2012.

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, 2012.

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, 2012.

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, 2012.

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	Agreement and Plan of Merger Among CryoLife, Inc., CL Falcon, Inc., and Cardiogenesis Corporation dated March 28, 2011. (Incorporated herein by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K filed March 29, 2011.)
2.1(a)	Amended and Restated Agreement and Plan of Merger Among CryoLife, Inc., CL Falcon, Inc., and Cardiogenesis Corporation dated April 14, 2011. (Incorporated herein by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K filed April 15, 2011.)
2.2+	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.)
2.3	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.)

Exhibit Number	Description
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.)
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.)
10.3	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.)

Exhibit Number	Description
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.
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.
10.9(a)*	Form of Change of Control Agreement (entered into with respect to Jeffrey W. Burris, David M. Fronk and Scott B. Capps).
10.9(b)*	Form of Change of Control Agreement (entered into with respect to D. Ashley Lee).
10.9(c)	Change of Control Agreement, by and between the Company and Gerald B. Seery, dated November 2, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed November 3, 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(a)*	Summary of Salaries for Named Executive Officers.
10.12(b)	Reserved.
10.12(c)*	Release and Noncompete Agreement, by and between the Company and Gerald B. Seery.
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.)
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.)

Exhibit Number	Description
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.)
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.)

Exhibit Number	Description
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.)
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 2011 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan.
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.)

70

Exhibit

Number	Description
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.)
10.51+	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.)
10.52	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.)
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.)

Exhibit

Number	Description
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.)
21.1*	Subsidiaries of CryoLife, Inc.
23.1*	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. Pursuant to applicable securities laws and regulations, the Company is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Company has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

\+ 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.

3. *Form of Change of Control Agreement (entered into with respect to Jeffrey W. Burris, David M. Fronk, and Scott B. Capps).

4. *Form of Change of Control Agreement (entered into with respect to D. Ashley Lee).

5. Change of Control Agreement, by and between the Company and Gerald B. Seery, dated November 2, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed November 3, 2008.)

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 2011 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan.

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 ref