

CRYOLIFE INC  
Form 10-K  
February 17, 2012

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

**(Mark One)**

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

For the fiscal year ended December 31, 2011

**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**

(State or other jurisdiction of incorporation or organization)

**59-2417093**

(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:

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
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

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

## Edgar Filing: CRYOLIFE INC - Form 10-K

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

Indicate by check mark 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  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  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

As of June 30, 2011 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was \$143,673,628 computed using the closing price of \$5.60 per share of Common Stock on June 30, 2011, 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 10, 2012 the number of outstanding shares of Common Stock of the registrant was 27,711,808.

### Documents Incorporated By Reference

Document	Parts Into Which Incorporated
Proxy Statement for the Annual Meeting of Stockholders	Part III

to be filed within 120 days after December 31, 2011.

---

**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<sup>®</sup> SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch<sup>®</sup> SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife's proprietary SynerGraft technology. CryoLife's surgical sealants and hemostats include BioGlue<sup>®</sup> Surgical Adhesive (BioGlue), BioFoam<sup>®</sup> Surgical Matrix (BioFoam), and PerClot<sup>®</sup> 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.

**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 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 75 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 liver and spleen when cessation of bleeding by ligature or conventional methods is ineffective or impractical. BioFoam has approval by the FDA for an investigational device exemption (IDE) to conduct a human clinical trial with BioFoam to determine its safety and effectiveness in sealing liver tissues in patients for whom cessation of bleeding by ligature or other 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 plans to file an IDE in early 2012 with the FDA to begin clinical trials for the purpose of obtaining Premarket Approval (PMA) to distribute PerClot in the U.S.

CryoLife distributed HemoStase under a private label Exclusive Distribution Agreement ( EDA ) with Medafor, from May 2008 to March 2011. CryoLife is currently in litigation with Medafor related to the EDA, discussed further below in Part I, Item 3, Legal Proceedings.

*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 Transmyocardial Revascularization ( TMR ) system, which includes the Holmium: YAG laser console and single use, fiber-optic handpieces. The system is FDA approved for performing a surgical procedure known as TMR, used 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. 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 conduct a pilot clinical evaluation in select European countries in 2012 while also investigating requirements to achieve an IDE approval for clinical evaluation of the Phoenix System in the U.S.

### ***Research and Business Development***

Through its continuing research and development activities, CryoLife uses its expertise in protein chemistry, biochemistry, cell 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, the Company is in the process of developing or investigating several products and technologies. Some of the products in development 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. The Company's current tissue preservation services were developed internally. The Company developed its BioGlue and BioFoam products from a technology originally developed by a third party and acquired by CryoLife. The Company purchased the rights to distribute and manufacture PerClot from a third party and is in the process of obtaining FDA approval to distribute PerClot in the U.S. The Company acquired Cardiogenesis and its revascularization technologies and is in the process of conducting preclinical and clinical evaluations of the Phoenix system.

### ***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.

*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, and revascularization technologies.

*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 have resulted in the acquisition of PerClot technologies in September 2010 and 2011 and the acquisition of Cardiogenesis and its revascularization technologies in May 2011, 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. 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. Additionally, the Company entered into an agreement with ValveXchange to make available up to \$2.0 million to ValveXchange in debt financing through a revolving credit facility.

## 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.

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. CryoLife uses the SynerGraft technology for a portion of its pulmonary valve and cardiac patch processing. In 2011 66% of pulmonary valves and 27% 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 77,600 heart valves and cardiac patch tissues from 1984 through 2011, including approximately 3,000 shipments in 2011. Revenues from cardiac tissue preservation services accounted for 22%, 24%, and 23% of total Company revenues in 2011, 2010, and 2009, respectively. The Company estimates that in 2011 the total annual heart valve replacement and cardiac patch market in the U.S. was approximately \$875 million. Management believes that of the \$875 million, approximately \$650 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 94,000 aortic, pulmonary, and tricuspid valve replacement surgeries were conducted in the U.S. in 2011.

*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 small diameter 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, 30% of patients have unsuitable vein tissue for transplantation, and the surgeon must consider using synthetic grafts or preserved human vascular tissue. Small diameter 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 66,100 human vascular tissues from 1986 through 2011, including approximately 4,500 shipments in 2011. Revenues from vascular preservation services accounted for 28%, 27%, and 27% of total Company revenues in 2011, 2010, and 2009, respectively. The Company estimates the aggregate U.S. vascular surgical graft market was approximately \$120 million in 2011.

## ***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, and 10cm and 27cm extender tips). CryoLife is in the process of obtaining approvals for another more rigid delivery tip extender ( DTE ) which will be available in a variety of lengths to accommodate different surgical needs. The DTE has received approval in Canada and is under review for CE Mark and FDA approvals.

CryoLife is authorized to distribute BioGlue throughout the U.S. and in more than 75 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 \$294 million in 2011.

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 41%, 41%, and 43% of total Company revenues in 2011, 2010, and 2009, 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. CryoLife plans to begin distribution of BioFoam in other international markets as required regulatory approvals are obtained.

BioFoam received initial approval by the FDA in October 2009 for an IDE to conduct a human clinical trial with BioFoam to help seal liver tissue in patients for whom cessation of bleeding by ligature or other conventional methods is ineffective or impractical. CryoLife received approval by the U.S. Department of Defense ( DOD ) in April 2010 to move forward with obtaining necessary Institutional Review Board ( IRB ) approvals using the FDA approved protocol. The DOD granted approval for the initial clinical trial investigation site in September 2010 and patient screening was initiated in October 2010. The first patient was enrolled into the trial in 2011. Due to slower than expected enrollment, CryoLife worked with the FDA to further modify the protocol to enhance the ability to enroll patients. This protocol amendment was approved in the fourth quarter of 2011 and is currently being implemented. This feasibility trial will involve 20 patients at three centers in the U.S. Upon successful completion of the feasibility study, a follow-on multi-center, randomized, and

controlled pivotal study will be conducted. The Company anticipates that the pilot study and a portion of the follow-up will be funded by grants from the DOD.

Revenues from BioFoam represented less than 1% of total Company revenues in 2011. The Company estimates that the aggregate European market opportunity for BioFoam is approximately \$30 million and approximately \$100 million worldwide.

#### *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 4% of total Company revenues in 2011. The Company estimates that aggregate U.S. sales for hemostatic agents were approximately \$800 million in 2011.

*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 particles 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 particles have a molecular structure that rapidly absorbs water from blood, creating a high concentration of platelets, red blood cells, and coagulation proteins at the bleeding site, which accelerates the physiologic clotting cascade. Upon contact with blood, PerClot rapidly produces a gelled matrix that adheres to and forms a mechanical barrier with the bleeding tissue. 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 sizes with a 100mm or 200mm applicator tip. PerClot Laparoscopic is available in 1 gram and 3 gram sizes 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, venous, 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. CryoLife anticipates re-filing its IDE for PerClot in early 2012.

CryoLife began distributing PerClot in Europe in the fourth quarter of 2010. Revenues for PerClot represented approximately 2% of total Company revenues in 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 EDA with Medafor from May 2008 to March 2011. Medafor fully, finally, and effectively terminated the agreement. CryoLife believes this termination was wrongful. Revenues for HemoStase represented 2%, 8%, and 5% of total Company revenues in 2011, 2010, and 2009, respectively. See Part I, Item 3, Legal Proceedings.

#### *Revascularization Technologies*

CryoLife's subsidiary, Cardiogenesis, markets the TMR system, which includes the Holmium: YAG laser console and single use, fiber-optic handpieces. The system is 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 while the new channels allow fresh blood to perfuse the heart wall immediately and may provide oxygen in the process. 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 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 for a minimally invasive thoracoscopic procedure. The PEARL 8.0 handpiece has been recommended for approval by the FDA pending agreement from the FDA of CryoLife's post approval study. The Company anticipates launching the PEARL 8.0 in late 2012. The PEARL 8.0 received a CE Mark in 2005.

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

#### *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 in January 2012. CryoLife is seeking commercialization for ProPatch, which may include partnering with one or more third parties as well as obtaining clinical data to support applications to be marketed directly.

#### *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 18 of the Notes to Consolidated Financial Statements regarding segment and geographic information.

---

## Procurement, 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 115,000 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 -135°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 275 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. Because fees for the Company's preservation services become due upon the shipment of tissue to the hospital, the use of such on-site freezers also reduces the Company's working capital needs.

### ***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. 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 has records of over 1,400 cardiac and vascular surgeons who implanted tissues preserved by the Company during 2011. The Company works to maintain relationships with and market to surgeons within these medical specialties. 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, and seven 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 directly to physicians, an important aspect of increasing the distribution of the Company's preservation services is educating physicians on the use of preserved human tissue and on proper implantation 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 including the Aortic Allograft Workshops and the TMR Workshops throughout the year. 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 preserved by the Company and help to differentiate the Company from other allograft processors.

In September 2011 CryoLife hosted the fourth annual Ross Summit at CryoLife's Corporate Headquarters with 51 cardiac surgeons and cardiologists from 14 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 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 25 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 products and services through its direct sales representatives in the United Kingdom, Germany, Austria and, beginning in 2012, 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.

### ***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, or TMR.

---

## 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 two domestic tissue banks offer 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 two domestic tissue banks offer 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 Arteriosus, 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 that 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 product 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; Nycomed'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; and Medafor's Arista. 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.

*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<sub>2</sub> Heart Laser System manufactured by Novadaq Technologies, Inc. Other medical device and pharmaceutical companies may also develop additional competitive products. The Company's TMR 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.

### **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 protein chemistry, biochemistry, 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 28 people in its research and development and clinical research departments, including five Ph.D.s with specialties in the fields of molecular biology, protein chemistry, biochemistry, bioengineering, biostatistics, and zoology.

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, and human tissue preservation.

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 2011, 2010, and 2009 the Company spent approximately \$6.9 million, \$5.9 million, and \$5.2 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 6%, 5%, and 5% of the Company's revenues for each of the years 2011, 2010, and 2009, respectively. Of these amounts spent on research and development activities, \$398,000, \$490,000, and \$799,000 was funded by the DOD in 2011, 2010, and 2009, 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 late 2013.

*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 expects to submit the HDE application in early 2012. If approval is obtained, the CryoValve SGAV can then be shipped to sites that have received prior IRB approval to implant the tissue. Additional jurisdictions for potential shipments of CryoValve SGAV also include Austria, and the United Kingdom.

*BioFoam.* In 2009 the Company received initial approval from the FDA for an IDE to conduct human clinical trials in the U.S. with BioFoam, a product in the PHT platform, for use in liver resection surgery in patients for whom cessation of bleeding by ligature or other conventional methods is ineffective or impractical. Since receiving initial FDA approval to

perform the study, CryoLife continued to work with the FDA to make additional protocol refinements. CryoLife received approval by the DOD in April 2010 to move forward with obtaining necessary IRB approvals using the FDA approved protocol. The DOD granted approval for the initial clinical trial investigation site in September 2010. In the fourth quarter of 2010 the Company began screening patients for enrollment into the BioFoam IDE clinical trial in the U.S. for the sealing of parenchymal liver tissue. The first patient was enrolled into the trial in 2011. Due to slower than expected enrollment, CryoLife worked with the FDA to further modify the protocol to enhance the ability to enroll patients. This protocol amendment was approved in the fourth quarter of 2011 and is currently being implemented. This feasibility trial will involve 20 patients at three centers in the U.S. Upon successful completion of the feasibility study, a follow-on multi-center, randomized, and controlled pivotal study will be conducted. 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. The Company anticipates that the pilot study and a portion of the follow-up will be funded by these grants from 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. CryoLife anticipates re-filing its IDE for PerClot in early 2012.

*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 conduct a pilot clinical evaluation in select European countries in 2012 while also investigating requirements to achieve an IDE approval for clinical evaluation of the Phoenix System in the U.S.

*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 is seeking commercialization for ProPatch, which may include partnering with one or more third parties as well as obtaining clinical data to support applications to be marketed directly. CryoLife is also researching other animal-based tissues that can be used in a wide variety of surgical indications similar to ProPatch using the SynerGraft technology.

#### **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 76 U.S. patents and 100 foreign patents, including patents relating to its technology for human cardiac and vascular tissue preservation, tissue preservation, decellularization, tissue revitalization prior to freezing, tissue transport, tissue packing, BioGlue manufacturing, PHT manufacturing, and revascularization technologies. The Company has approximately 7 pending U.S. patent applications and 10 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 16 years. The main patent for BioGlue expires in mid-2012 in the U.S. and 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 patent 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. For example, the Company has lawsuits pending in Germany related to a BioGlue patent that the Company believes is being infringed in Germany and the Company's subsidiary Cardiogenesis is currently being sued for patent infringement in the United States. See Part I, Item 3, Legal Proceedings.

The Company may incur substantial legal fees in defending against a patent infringement claim or in asserting claims against third parties. 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 although the patent infringement lawsuit with Cardiogenesis only relates to damages as the patent in question has expired. 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.

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. Approximately 20,000 square feet are dedicated as class 10,000 clean rooms. An additional 5,500 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 -135°C. Two back-up emergency generators assure continuity of Company manufacturing operations. Additionally, 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 64 technicians employed in this area, and the laboratory is staffed 24 hours per day, 365 days per year. In 2011 the laboratory packaged approximately 11,000 tissues. The current processing level is estimated to be at about 30% of total capacity. To produce at full capacity levels, the Company would have to increase the amount of donated tissues, which the Company could attempt to do by revising its tissue acceptance criteria, increasing the number of relationships with OTPOs, or working to increase donor awareness to increase tissue donation. Any



attempt to increase the amount of tissues processed could be constrained by the availability of donated tissues. If significant additional donated tissues were obtained, the Company would also need to increase the number of employees or increase the number of hours worked by employees.

#### ***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 17 technicians employed in this area. The laboratory has a potential annual capacity of approximately 2 million syringes of BioGlue and BioFoam. 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.

#### ***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.

#### ***Other Medical Devices***

The Company's headquarters has additional laboratory space consisting of approximately 18,900 square feet with a suite of six 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'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.

---

## **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 European Union (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 industry. 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. 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.

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.

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 that 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, and ProPatch are classified as Class II medical devices.

#### ***U.S. Federal Regulation of Human Tissue***

The FDA regulates human tissues pursuant to Section 361 of the Public Health Services Act ( 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. For example, on December 30, 2011 the FDA issued final guidance for cGTPs and Additional Requirements for Manufacturers of HCT/Ps.

#### ***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, the Company has CE approval for the distribution of PerClot.

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 United Kingdom, Germany, and Austria. In 2004 and 2006 through three separate directives the European Union passed the European Union 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 United Kingdom, this Competent Authority is the Human Tissue Authority ( HTA ), which has promulgated various directives that affect CryoLife's shipment of tissues into the United Kingdom 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-Erich-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. Each Competent Authority could modify its regulations, rules, directives, or directions, which could impact the Company's ability to send preserved tissues into Europe.

#### ***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, 2011 CryoLife and its subsidiaries had approximately 430 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](http://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. Should this product be 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, the result could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

**The Continued Introduction Into The Market Of Products That Compete With BioGlue Could Have An Irreversible Adverse Impact On Our Sales Of BioGlue.**

In recent years competitors of BioGlue were able to obtain FDA approval for indications in which BioGlue had been used off-label. The continued introduction of these or similar competitive products could have an irreversible adverse impact on our sales of BioGlue and, therefore, our revenues, financial condition, profitability, and cash flows.

**Our BioGlue Patent Expires In The U.S. In Mid-2012 And In The Rest Of The World In Mid-2013.**

Our U.S. patent for BioGlue expires in mid-2012, and our patents in the rest of the world for BioGlue expire in mid-2013. Following expiration of these patents, competitors may utilize the inventions disclosed in the BioGlue patents in competing products, which could materially reduce our revenues and income from BioGlue, although any competing product would have to be approved by the appropriate regulatory authority, such as the FDA. In addition, the validity of our patent in Germany is being challenged. We filed suit in Germany against Tenaxis because we believe Tenaxis is infringing our main BioGlue patent in Germany. Tenaxis filed a separate nullity suit against this same BioGlue patent in Germany, and the lower court ruled that our BioGlue patent was nullified. We appealed this ruling, and the nullification was stayed pending resolution of the nullification case by the German Supreme Court, which will not occur until 2012 or potentially 2013. If we lose this appeal, we will lose intellectual property protection for our BioGlue product in Germany, potentially sooner than the expiration of our patent in mid-2013, which may cause us to lose revenues in Germany as competitors may legally offer similar products. Any such outcome could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

**We Are Currently Involved In Significant Litigation With Medafor And That Litigation Cost Has Had, And Is Likely To Continue To Have, A Material Adverse Impact On Our Profitability.**

We originally filed our lawsuit against Medafor in April of 2009 in the Northern District of Georgia. Discovery is ongoing, and, other than a few depositions, the parties have not begun the remainder of their depositions, which will be extensive. No trial date has been set by the Court, but we believe that any trial will not occur until 2013. The parties have also been, and continue to be, involved in other lawsuits in other venues. We incurred costs of approximately \$1.4 million in 2010 and \$2.3 million in 2011 on these lawsuits. Our costs in 2011 and 2010 have materially adversely impacted our financial condition, profitability, and cash flows, and we expect that our costs in 2012 and in 2013, which will likely be significantly higher than in 2011, will materially adversely impact, our financial condition, profitability, and cash flows.

**Our Tissues And Products Allegedly Have Caused, And May In The Future Cause, Injury To Patients, And We Have Been, And May In The Future Be, Exposed To Tissue Processing And Product Liability Claims, Including One Currently Outstanding Product Liability Lawsuit, And Additional Regulatory Scrutiny As A Result.**

The processing, preservation, and distribution of human tissues, and the manufacture and sale of medical devices entail inherent risks, including the possibility of medical complications for patients, and have resulted, and may in the future result in, tissue processing and product liability claims against us and adverse publicity. From time to time various plaintiffs have asserted that our tissues or medical devices have caused a variety of injuries, including death. We have been, and may be, sued and our insurance coverage has in the past been and may in the future be inadequate. Adverse judgments and settlements in excess of our available insurance coverage could materially adversely impact our financial condition, profitability, and cash flows.

Because medical complications are alleged to have been caused by or occur in connection with medical procedures involving our tissues or products, we have been, and may be, subject to additional FDA and other regulatory scrutiny, inspections, and adverse publicity. For example, in 2002 the FDA issued an order regarding our non-valved cardiac,

vascular, and orthopaedic tissues processed by us from October 3, 2001 until August 13, 2002, which we refer to as the FDA Order. Pursuant to the FDA Order, we recalled these tissues or placed them on quarantine hold. Shortly after the FDA Order, the FDA posted a notice, now archived, on its website stating its concerns regarding our heart valve tissues. As a result, some surgeons and hospitals decided not to use our heart valves. Cautionary statements from the FDA or other regulators, adverse publicity, changes to our labeling, required prominent warnings, or negative reviews from the FDA or other regulators of our processing and manufacturing facilities have in the past decreased, and may in the future decrease, demand for our tissues or products and could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

In addition to the recall resulting from the FDA Order, we have in the past suspended the distribution of, or recalled, certain tissues, and in the future may have to suspend the distribution of or recall particular types of tissues or products as a result of reported adverse events. Suspension of the distribution of, or recall of, our tissues or products could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

**Cardiogenesis Corporation, Our Wholly Owned Subsidiary, Has Been Named As A Defendant In A Patent Infringement Lawsuit, And Costly Litigation May Be Necessary To Protect Or Defend Its Intellectual Property Rights.**

In 2008 CardioFocus, Inc. ( CardioFocus ) filed a lawsuit against Cardiogenesis in the U.S. District Court for the District of Massachusetts alleging patent infringement of CardioFocus patents for the period 2002 to 2007. In the complaint CardioFocus alleges that Cardiogenesis and the other defendants had previously violated patent rights allegedly held by CardioFocus directed to the use of holmium-doped YAG lasers in connection with low-hydroxyl content silica fibers for use in performing surgery. All of the asserted patents have now expired, and Cardiogenesis is the sole remaining defendant in the action. CardioFocus seeks a royalty for Cardiogenesis sales of the products in question, namely, the SolarGen, TMR, and New Star lasers and lasers systems, during the period 2002 to 2007. Cardiogenesis has steadily maintained that it does not infringe the patent claims in question.

Trial for this case is scheduled in June of 2012. In the event that the District Court of Massachusetts decides that Cardiogenesis did infringe the claims of the patents in question, and awards damages, those damages could be significant and the possibility exists that such a decision against us could have a material adverse impact on our financial condition, profitability, and cash flows.

**Our Investment In Medafor Has Been Impaired Due To Medafor s Termination Of Our Exclusive Distribution Agreement With Medafor 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 of \$3.6 million in the third quarter of 2010 to write down our investment in Medafor common stock that we had purchased in 2009 and 2010. The carrying value of our 2.4 million shares of Medafor common stock after this write down was \$2.6 million. The carrying value of our 2.4 million shares of Medafor common stock remained \$2.6 million as of December 31, 2011.

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.

**Medafor Has Filed Counter-Claims Against Us With Respect To Our Lawsuit Against Medafor, And If Medafor Is Successful In Its Claims, Our Revenues And Profitability May Be Materially, Adversely Impacted.**

We filed a lawsuit against Medafor in 2009, alleging claims for, among other things, breach of contract, fraud, and negligent misrepresentation. The lawsuit arises out of the EDA that has recently been terminated by Medafor. Medafor has filed counter-claims against us. We have disputed the validity of all of Medafor s counter-claims and intend to vigorously defend against all claims. However, if Medafor is successful in its pursuit of the counter-claims and the Court rules in Medafor s favor, then we could be required to make substantial payments to Medafor as part of the judgment. While



the details of any judgment that may be rendered against us in such a scenario are uncertain, the possibility exists that a judgment against us could have a material adverse impact on our financial condition, profitability, and cash flows.

**We Will Not Fully Realize The Benefit Of Our Investment In Our Distribution And License And Manufacturing Agreements With Starch Medical, Inc. Unless We Are Able To Obtain FDA Approval For PerClot In The U.S., Which Will Require An Additional Commitment Of Funds.**

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 will, ultimately, manufacture PerClot. We were also authorized to pursue, obtain, and maintain regulatory approval for PerClot in the U.S. If this approval is not obtained prior to October 1, 2017, SMI may terminate our rights with respect to U.S. regulatory approval and require us to negotiate a reasonable revision to the agreement.

As part of the transaction, we paid SMI \$6.75 million in cash, which includes \$1.5 million in prepaid royalties, and \$1.25 million in restricted CryoLife common stock. 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 and will also pay royalties on 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 2012. 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 from plant starch modified by SMI, 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 in our agreements 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 2013 or 2014, or at all, and this failure 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. The FDA rejected our initial IDE application for PerClot and we are working to address its concerns; however, there is no guarantee that we can do so on a timely or cost efficient basis. Our approval efforts for PerClot in the United States 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.

**The Receipt Of Impaired Materials Or Supplies That Do Not Meet Our Standards Or The Recall Of Materials Or Supplies By Our Vendors Or Suppliers Could Have A Material Adverse Impact On Our Revenues, Financial Condition, Profitability, And Cash Flows.**

The materials and supplies used in our processing of tissue and our manufacturing processes for devices are subject to quality standards and requirements, and many of these supplies and products 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. 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.

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

**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 our tissues and BioGlue has fluctuated recently and may continue to fluctuate. In challenging economic environments, hospitals attempt to control costs by reducing spending on consumable items, which can result in reduced demand for some of our products and services. We believe that our tissues and products will continue to be in demand for the foreseeable future. However, 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 and cash flows would likely decrease, possibly materially. In addition, our processing throughput of tissue and our manufacturing throughput of BioGlue would necessarily need to decrease, which would likely adversely impact our margins, and, therefore, our profitability, possibly materially. Further, if demand for our tissues decreases in the future, we may not be able to ship our tissues before they expire, which would cause us to write down our deferred preservation costs. Since our international revenues are currently approximately one-fifth of our total revenues, our sales may be impacted by challenging economic conditions in countries around the world, in addition to the U.S., particularly in Europe and Japan. These factors could materially adversely impact our 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 Us.**

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 would 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, could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

On March 23, 2010 President Obama signed the Patient Protection and Affordable Care Act. This legislation imposes a new 2.3% tax on the sale after December 31, 2012 of a taxable medical device by the manufacturer, producer, or importer. We believe that, if this tax had been in effect in 2011, it would likely have cost the Company approximately \$1.1 million. However, the final regulations implementing the new tax have not been promulgated, so we are uncertain about the amount that ultimately will be paid. These taxes will result in a significant increase in the tax burden on us, which could have a material adverse impact on our financial condition, profitability, and cash flows.

**The Loss Of Any Of Our Sole-Source Suppliers Could Have A Material Adverse Impact On Our Revenues, Financial Condition, Profitability, And Cash Flows.**

We purchase certain supplies used in our processing of tissues and our manufacturing of products from single sources due to quality considerations, costs, or constraints resulting from regulatory requirements. With respect to BioGlue, for instance, we have only one supplier for our BioGlue syringe. Additionally, we have only two suppliers of bovine serum albumin, which is necessary for the manufacture of BioGlue. If we lose one or more of these suppliers, our ability to manufacture and sell BioGlue could be adversely impacted. We cannot be sure that we would be able to replace any such loss on a timely basis, if at all.

Agreements with certain suppliers are terminable by either party or may expire. Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our tissue processing and product manufacturing, and the complex nature of the manufacturing processes employed by many suppliers. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such supplier by a competitor, which may cause the supplier to stop selling its products to us, or the bankruptcy of such a supplier, which may cause the supplier to cease operations. A reduction or interruption by a sole-source supplier of the supply of materials or key components used in our tissue processing or our product manufacturing or an increase in the price of those materials or components could materially adversely impact our revenues, financial condition, profitability, and cash flows.

**We May Be Unsuccessful In Our Efforts To Market And Sell PerClot In The U.S. And Internationally.**

Even if we are able to obtain FDA approval to distribute PerClot in the U.S. according to our estimated timeline, 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. Also, while we do not believe Medafor would have a valid reason to do so, based on our past history with Medafor, it is possible that Medafor may attempt to challenge the legality of our distribution of PerClot in both the U.S. and international markets or file a patent infringement action against us or SMI, the company that manufactures PerClot for us. If we are ultimately unable to distribute PerClot in the U.S., we would not be able to fully realize the benefit of our investment in PerClot, which could materially adversely impact our financial condition, profitability, and future revenues. If Medafor were successful in its challenge to the legality of our distribution agreement or in a patent infringement action against us or SMI, it could materially adversely impact our revenues, financial condition, profitability and cash flows.

**We Have Inherited Risks And Uncertainties Related To Cardiogenesis Business.**

In May 2011 we acquired Cardiogenesis, and Cardiogenesis is now operating as a subsidiary of CryoLife. We have inherited certain risks and uncertainties related to Cardiogenesis business. These risks and uncertainties include the following:

We may be unable to maintain revenues and achieve growth in revenues from Cardiogenesis revascularization technologies in the future due to our dependence upon physician awareness of this technology as a safe, efficacious, and appropriate treatment for their patients;

We will continue to purchase some of Cardiogenesis key product components from single suppliers, and the loss of these suppliers could prevent or delay shipments of its products, delay its clinical trials, or otherwise adversely affect our Cardiogenesis business;

If Cardiogenesis independent contract manufacturers fail to timely deliver sufficient quantities of some of Cardiogenesis products and components, our Cardiogenesis operations may be harmed;

Cardiogenesis contract manufacturers are at locations that may be at risk from earthquakes or other natural disasters;

Cardiogenesis may have liability for actions that occurred prior to our acquisition of Cardiogenesis which could adversely affect us; and

Cardiogenesis internal control over financial reporting may not have been effective prior to the merger, which could impact the value of our investment in Cardiogenesis and potentially lead to lawsuits from former Cardiogenesis shareholders, which could have a significant and 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.

**We May Expand Through Acquisitions, Or Licenses Of, Or Investments In, Other Companies Or Technologies, Which May Result In Additional Dilution To Our Stockholders And Consume Resources That May Be Necessary To Sustain Our Business.**

One of our business strategies is to acquire technologies, products, and licenses 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; and

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.

Business acquisitions also involve the risk of unknown liabilities associated with the acquired business. In addition, we may not realize the anticipated benefits of any acquisition, including securing the services of key employees. Incurring unknown liabilities or the failure to realize the anticipated benefits of an acquisition could materially adversely impact our business.

**We May Not Realize The Anticipated Benefits From Acquisitions And We May Find It Difficult To Integrate Recent Or Potential Future Acquisitions Of Technology Or Business Combinations, Which Could Disrupt Our Business, Dilute Stockholder Value, And Adversely Impact Our Operating Results.**

Acquisitions involve the integration of companies that have previously operated independently. We expect that future acquisitions may result in financial and operational benefits, including increased revenues, cost savings, and other financial and operating benefits. We cannot be certain, however, that we will be able to realize increased revenues, cost savings, or other benefits from any acquisition, or to the extent such benefits are realized, that they are realized timely. Integration may also be difficult, unpredictable, and subject to delay because of possible cultural conflicts and different opinions on product roadmaps or other strategic matters. We may integrate or, in some cases, replace numerous systems, including those involving purchasing, accounting and finance, sales, billing, employee benefits, payroll, and regulatory compliance, many of

which may be dissimilar. Difficulties associated with integrating an acquisition's service and product offering into ours, or with integrating an acquisition's operations into ours, could have a material adverse impact on the combined company and the market price of our common stock. Our integration efforts may not succeed or may distract our management's attention from existing business operations. Our failure to successfully manage and integrate recent technology acquisitions and any future acquisitions could materially adversely impact our business.

**We Are Subject To Stringent Domestic And Foreign Regulation Which May Impede The Approval Process Of Our Tissues And Products, Hinder Our Development Activities And Manufacturing Processes, And, In Some Cases, Result In The Recall Or Seizure Of Previously Cleared Or Approved Tissues And Products.**

Our tissues, products, development activities, tissue processing, and manufacturing processes are subject to extensive and rigorous regulation by the FDA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under applicable law, processors of human tissues and manufacturers of medical devices must comply with certain regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging, and distribution of tissues and products. In addition, medical devices must receive FDA clearance or approval before they can be commercially marketed in the U.S., and the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized and can prevent or limit further marketing of a product based on the results of these post-marketing programs. The process of obtaining marketing approval or clearance can take a significant period of time, require expenditure of substantial resources, and result in limitations on the indicated uses of the tissues and products. Furthermore, most major markets for tissues and products outside of the U.S. require clearance, approval, or compliance with certain standards before tissues and products can be commercially available. We cannot be certain that we will receive these required clearances or approvals from the FDA and foreign regulatory agencies on a timely basis. The failure to receive clearance or approval for significant new tissues and products on a timely basis could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

The FDA may conduct periodic inspections to determine compliance with applicable tissue and product regulations for any of our marketed tissues and products. Approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. In addition, the FDA could reevaluate our tissues or products, or the processes or solutions used with our tissues or products, and determine that they must go through additional approvals or require approvals where none were previously required. The failure to comply with regulatory standards, the discovery of previously unknown problems with tissues or products, or reevaluation of our tissues and products or the processes and solutions used with our tissues and products could result in fines; delays or suspensions of regulatory clearances; seizures or recalls of tissues, products, or solutions; the banning of a particular device; operating restrictions; or criminal prosecution. The related expenses and decreased revenues as a result of negative publicity and legal claims could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

For example, in 2002 the FDA issued the FDA Order discussed above at [Our Tissues And Products Allegedly Have Caused And May In The Future Cause, Injury To Patients, And We Have Been, And May In The Future Be, Exposed To Tissue Processing And Product Liability Claims, Including One Currently Outstanding Product Liability Lawsuit, And Additional Regulatory Scrutiny As A Result.](#)

**Our HemoStase Sales Ceased In Late March 2011, And We Will Not Be Able To Participate In The Hemostats Market In The U.S. Or Other Markets Where We Lack Regulatory Approval Unless We Can Obtain FDA Or Other Regulatory Approval For PerClot.**

On September 27, 2010 Medafor sent CryoLife a letter stating that Medafor was fully, finally and immediately terminating our EDA.

We have not had any revenues from HemoStase since first quarter of 2011. We began selling PerClot internationally in the fourth quarter of 2010, but unlike HemoStase, PerClot is not approved for sales in the U.S. where we sold the majority of our HemoStase product. In addition, PerClot is not approved for sales in all countries of the world in which HemoStase was approved. As a result, our anticipated 2012 revenues from PerClot will be materially lower than our 2010 HemoStase revenues. The FDA approval process for U.S. sales of PerClot is expected to be expensive and time-consuming, is not expected to be completed any sooner than 2013 or 2014, and is subject to many risks that could increase the costs or time involved or even prevent sales from ever occurring in the United States. See [We Will Not Fully Realize The Benefit Of Our Investment In Our Distribution And License And Manufacturing Agreements With Starch Medical, Inc. Unless We Are Able To Obtain FDA Approval For PerClot In The U.S., Which Will Require An Additional Commitment Of Funds,](#) above, for a discussion of these risks. The reduction in our revenues due to the loss of the HemoStase product, together with the

uncertainty surrounding our ability to obtain FDA approval to market PerClot in the U.S., is expected to continue to materially adversely impact our revenues, financial condition, profitability, and cash flows.

**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.

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 include the following:

PerClot in the U.S. and other jurisdictions,

CryoValve SGAV,

BioFoam in the U.S.,

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

ProPatch and related products,

SynerGraft processed tissues, and

New indications for BioGlue.

**Uncertainties Related To Patents And Protection Of Proprietary Technology May Adversely Impact The Value Of Our Intellectual Property.**

## Edgar Filing: CRYOLIFE INC - Form 10-K

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. 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.

For example, we filed suit in Germany against Tenaxis because we believe that Tenaxis is infringing our main BioGlue patent in Germany. Tenaxis filed a separate suit to nullify this same BioGlue patent in Germany, and the Patent Court issued an order nullifying this patent. We appealed the nullification, which means the patent stays in effect while the appeal is pending; however, there can be no guarantee that we will succeed. The ultimate nullification of this patent, if it occurs, will not prohibit us from selling BioGlue in Germany, but would allow Tenaxis and others to market competing products based on the BioGlue technology. Tenaxis has been selling its competing product in Germany since at least 2009 and has been competing with our BioGlue product since that time. Should we be unsuccessful in our lawsuit regarding infringement of our BioGlue patent, in our appeal of the nullification, or in prohibiting any other infringements of our patents, or should the validity of our patents be successfully challenged by other third parties in Germany or other countries, we may face increased competition from products based on the BioGlue technology, and our revenues, financial condition, profitability, and cash flows could be materially, adversely impacted.

**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, and

Cardiogenesis TMR System.

Management believes that at least two domestic tissue banks offer preserved human heart valves and many companies offer porcine, bovine, and mechanical heart valves, including St. Jude Medical, Inc., Medtronic, Inc., and Edwards Life Sciences.

Our BioGlue product competes with other surgical adhesives and surgical sealants, including 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; Tenaxis's ArterX; and Neomend, Inc.'s ProGel. Other large medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our BioGlue product competes on the basis of its high tensile strength and ease of use.

Our 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; Nycomed's TachoSil; and Orthovita, Inc.'s Vitagel. Other medical device, pharmaceutical, and biopharmaceutical companies may also develop competitive products. Our BioFoam product competes on the basis of its clinical efficacy and ease of use.

Our 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; and Medafor's Arista, which we previously distributed as HemoStase. We are also aware that a few companies have surgical hemostat products under development. Other medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our PerClot product competes on the basis of its safety profile, clinical efficacy, absorption rates, and ease of use.

Many of our competitors have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets. We have increased fees and prices on some of our international services and products since January 1, 2011. This increase may provide an opportunity for our competitors to gain market share. If we are unable to continue to increase prices as planned and retain or improve our market share, our ability to grow revenues and profits may be materially adversely impacted.

We cannot give assurance that our tissues and products will be able to compete successfully. Any products that we develop that gain regulatory clearance or approval will have to compete for market acceptance and market share. 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, We May Be Unable To Increase Our Revenues.**

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,

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.

**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,

## Edgar Filing: CRYOLIFE INC - Form 10-K

License Company technology to third parties for non-competing uses, and

Analyze and identify underperforming assets for potential sale or disposal.

Although management has begun implementing these strategies, we cannot be certain that they will ultimately enhance shareholder value.

### **Investments In New Technologies And Acquisitions Of Products Or Distribution Rights May Not Be Successful.**

We may invest in new technology licenses and acquire products or distribution rights that may not succeed in the marketplace. In such cases we may be 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 may materially adversely impact our financial condition and profitability.

---

**Regulatory Action Outside Of The U.S. Has Affected Our Business In The Past And May Affect Our Business In The Future.**

After the FDA issued the FDA Order, discussed above at Our Tissues And Products Allegedly Have Caused, And May In The Future Cause, Injury To Patients, And We Have Been, And May In The Future Be, Exposed To Tissue Processing And Product Liability Claims, Including One Currently Outstanding Product Liability Lawsuit, And Additional Regulatory Scrutiny As A Result, Health Canada also issued a recall of the same types of tissue. In addition, other countries have made inquiries regarding the tissues that we export, although these inquiries are now, to our knowledge, complete. In the event other countries raise additional regulatory concerns, we may be unable to export tissues to those countries. Regulatory concerns could also be raised regarding the products we market internationally, including BioGlue, BioFoam and PerClot. Revenues from international tissue preservation services were approximately \$2.7 million, \$2.3 million, and \$1.6 million, for the years ended December 31, 2011, 2010, and 2009, respectively. International revenues from product sales, which includes international BioGlue, BioFoam, HemoStase, and PerClot revenues, were approximately \$21.0 million, \$17.3 million, and \$16.0 million, for the years ended December 31, 2011, 2010, and 2009, respectively. Loss of all or a material portion of our international revenues would 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.

**Extensive Government Regulation May Adversely Impact Our Ability To Develop And Market Services And Products.**

Government regulation in the U.S., Europe, Asia and other jurisdictions can determine the success of our efforts and our competitors' efforts to market and develop services and products. Most of our services and products in development, if successfully developed, will require regulatory approvals from the FDA and perhaps other regulatory authorities before they may be commercially distributed, including in most instances a PMA. The process of obtaining a PMA from the FDA normally involves clinical trials as well as an extensive PMA application and often takes many years. 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. While more streamlined than the full PMA process, the 510(k) notification process may also require clinical trials and take many years. For example, the 510(k) clearance for the CryoValve SGPV took four years. The process for approval or clearance from the FDA is expensive and can vary significantly based on the type, complexity, and novelty of the product. We cannot give any assurance that any services and products developed by us, independently or in collaboration with others, will receive the required approvals or clearances for processing or manufacturing and marketing.

Delays in obtaining U.S. or foreign approvals could result in substantial additional costs and adversely impact our competitive position. The FDA may also place conditions on service or product approvals that could restrict commercial applications of our services or products. The FDA may withdraw service and product marketing approvals or clearances if we do not maintain compliance with regulatory standards, if problems occur following initial marketing, or based on the results of post-market studies. Delays imposed by the governmental approval and clearance process may materially reduce the period during which we have the exclusive right to commercialize patented services and products.

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.

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, the National Organ Transplant Act of 1984, or NOTA, prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs. Congress could adopt more restrictive interpretations of NOTA in the future that challenge one or more aspects of industry methods of charging for preservation services. Our laboratory operations, and those of our competitors, are subject to the 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. Some states have enacted statutes and regulations which govern the processing, transportation, and storage of human organs and tissue.

The EU has three separate directives called the EUCTD that establish a benchmark standard for the regulation of tissues and cells to be implanted in humans. The EUCTD requires that countries in the European Economic Area take responsibility for regulating tissues and cells through a Competent Authority. Although Europa, our subsidiary, has a license to ship tissue into the United Kingdom and a provisional license to distribute tissue into Germany through those countries' Competent Authorities, these countries could change their regulations or processes, and, thereby, increase the cost to us of distribution, or modify or eliminate our ability and Europa's ability to distribute tissue into the United Kingdom and Germany. In addition, Europa ships tissue into Austria, which currently has no Competent Authority. When Austria puts in place its Competent Authority, it could cause CryoLife and Europa to cease distribution of tissue into Austria temporarily or permanently or increase the costs to do so materially.

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

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

## Edgar Filing: CRYOLIFE INC - Form 10-K

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 is existing legislation and regulations that govern interactions with physicians and other healthcare professionals, and there is 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, unless implementation is further delayed by the Department of Health and Human Services, Congress, or the courts, beginning in 2013, we will have to disclose payments made to physicians for meals or other services in 2012 to the Department of Health and Human Services. These existing regulations and legislation currently impact our ability to maintain strong relationships with physicians and, may in the future, further impact our relationships with physicians and the proposed regulations and legislation, 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 To Cover Our Actual Claims Liability.**

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. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period.

Our December 31, 2011 Consolidated Balance Sheet reflects a \$2.0 million liability for the estimated cost of resolving unreported tissue processing and product liability claims. We believe that the liability could be estimated to be as high as \$3.7 million, after including a reasonable margin for statistical fluctuations. Based on an actuarial valuation, we estimated that as of December 31, 2011, \$700,000 of the accrual for unreported liability claims would be recoverable under our insurance policies. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported liability claims related to services performed and products sold prior to December 31, 2011. Actual results may differ from this estimate. Our tissue processing and product liability insurance policies do not include coverage for any punitive damages.

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. Additionally, if one or more claims with respect to which we become hereafter 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, if the costs of pending or incurred but unreported tissue processing and product liability claims exceed our current estimates, our financial condition, profitability, and cash flows may be materially adversely impacted. If we do not have sufficient resources to pay any future verdicts rendered against us, we may be forced to cease operations or seek protection under applicable bankruptcy laws.

**We May Be Unable To Obtain Adequate Insurance At A Reasonable Cost, If At All.**

If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from tissue processing and product liability claims. Additionally, insurance rates may be significantly higher than in the past, and insurers may provide less coverage, which may materially adversely impact our financial condition, profitability, and cash flows. In addition, should we be subject to liability, whether imposed by a court or due to a settlement that results in a large insurance claim, our insurance rates could increase significantly. Our current tissue processing and product liability insurance policy is a nine-year claims-made policy covering claims incurred during the period April 1, 2003 through March 31, 2012 and reported during the period April 1, 2011 through March 31, 2012. Claims incurred prior to April 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

**We Are Not Insured Against All Potential Losses. Natural Disasters Or Other Catastrophes Could Adversely Impact Our Business, Financial Condition, And Profitability.**

Our facilities could be materially damaged by tornadoes, flooding, other natural disasters, or catastrophic circumstances. For example, our current facility in Kennesaw, Georgia, is the central location for all of our tissue processing and most of our BioGlue manufacturing. If this facility were to be materially damaged by a natural disaster it would cause a loss of processing and production and additional expenses to us to the extent any such damage is not fully covered by our business interruption and disaster insurance.

Even with insurance coverage, natural disasters or other catastrophic events could cause us to suffer substantial losses in our operational capacity and could also lead to a loss of opportunity and to a potential adverse impact on our relationships with our existing customers resulting from our inability to process tissues or produce products for them, for which we would not be compensated by existing insurance. This in turn could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

**Our Credit Facility, Which Expires In October Of 2014, Limits Our Ability To Pursue Significant Acquisitions.**

Our credit facility, which expires in October of 2014, prohibits mergers and acquisitions other than certain permitted acquisitions. 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. 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.

**Our Ability To Borrow Under Our Credit Facility May Be Limited.**

Our credit facility contains a number of affirmative covenants that we must satisfy before we can borrow. For example, 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.

**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.

**Our CryoValve SGPV Post-Clearance Study May Not Provide Expected Results.**

At the FDA's request, we are conducting a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process used to process the CryoValve SGPV. The data to be collected includes long-term information on safety, hemodynamic function, immune response, and explant analysis. Although we believe that this information may help us ascertain whether the SynerGraft process reduces the immune response of the transplanted human heart valve and allows for the collagen matrix to recellularize with the recipient's own cells, it is possible that the results of the study will not be as expected. If this study shows that the SynerGraft process does not reduce immune response and/or cause the collagen matrix to recellularize with the recipient's cells, we may be unable to realize some or all of the long-term benefits that we anticipated for the use of this process, and the Company may not be able to continue to process a portion of its human pulmonary valves and cardiac patch tissues with the SynerGraft technology.



---

**Our Investment In ValveXchange, Inc. May Become Impaired, Which Could Have A Material Adverse Impact On Our Earnings.**

In July 2011 we purchased approximately 2.4 million shares of Series A Preferred Stock of ValveXchange, Inc. ( ValveXchange ) for approximately \$3.5 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. 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. ( GAAP ), we regularly review our investments based on available information and make determinations regarding the value of our investments. While we are not currently aware of any factors that would require us to reevaluate our investment in ValveXchange or record an impairment of this investment, we have in the past recorded an impairment of our investment in Medafor, as described above at Our Investment In Medafor May Have Been Further Impaired Due To Medafor's Termination Of Our Exclusive Distribution Agreement With It, Which Could Have A Material Adverse Impact On Our Financial Condition And Profitability. In the future, factors beyond our control could cause us to take similar action with respect to our ValveXchange investment. In such an event, if we ultimately determined that we were required to write down the carrying value of our investment in ValveXchange, our earnings could be materially adversely impacted, depending on the extent of the impairment.

**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 2012. 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.

**Risks Related To Our Common Stock**

**Trading Prices For Our Common Stock, And For The Securities Of Biotechnology Companies In General, Have Been, And May Continue To Be, Volatile.**

The trading price of our common stock has been subject to wide fluctuations and may continue to be volatile in the future. Trading price fluctuations can be caused by a variety of factors, many of which are beyond our control, including:

Governmental regulatory acts,

Regulatory actions such as adverse FDA activity,

Other actions taken by government regulators,

General conditions in the medical device or service industries,

Announcement of technological innovations or new products by us or our competitors,

Tissue processing and product liability claims,

Developments with respect to patents or proprietary rights,

## Edgar Filing: CRYOLIFE INC - Form 10-K

Variations in operating results, and

Changes in earnings estimates by securities analysts.

If our revenues or operating results in future quarters fall below the expectations of securities analysts and investors, the price of our common stock would likely decline, perhaps substantially. If our share prices do not meet the requirements of the New York Stock Exchange, our shares may be delisted. The closing price of our common stock has ranged from a high of \$16.35 to a low of \$4.00 in the period from January 1, 2008 to January 31, 2012.

In addition, changes in the trading price of our common stock may bear no relation to our actual operational or financial results. The market prices of the securities of biotechnology companies have been highly volatile and are likely to remain

highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. In the past, companies that experienced volatility in the market price of their securities have often faced securities class-action litigation. Moreover, market prices for stocks of biotechnology and technology companies frequently reach levels that bear no relationship to the operating performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources, and materially adversely impact our financial condition, profitability, and cash flows.

**Anti-Takeover Provisions May Discourage Or Make More Difficult An Attempt To Obtain Control Of Us.**

Our Articles of Incorporation and Bylaws contain provisions that may discourage or make more difficult any attempt by a person or group to obtain control of our Company, including provisions authorizing the issuance of preferred stock without shareholder approval, restricting the persons who may call a special meeting of the shareholders, and prohibiting shareholders from taking action by written consent. In addition, we are subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of our common stock. Further, pursuant to the terms of a shareholder rights plan adopted in 1995 and amended in 2005, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire our Company on terms not approved by the Board of Directors and may deter hostile takeover attempts. These provisions could potentially deprive our stockholders of opportunities to sell shares of our stock at above-market prices.

**We Have Not Paid Cash Dividends On Our Common Stock And May Be Unable To Do So Due To Contractual Restrictions.**

We have not paid cash dividends on our common stock. In addition, our credit agreement prohibits us from paying cash dividends without the lender's approval, and under Florida law, we may not be able to pay cash dividends on our capital stock. The terms of any future financing arrangements that we may enter into may also restrict our ability to pay dividends.

### 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, and similar expressions generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-K. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Part I, Item 1A. Risk Factors and elsewhere in this Form 10-K.

All statements, 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, and the distribution of PerClot in certain markets after the requisite regulatory approvals are obtained;

Benefits of TMR treatment and the Phoenix System;

Estimates regarding the addressable market opportunity for TMR;

Plans and expected timeline regarding regulatory approval for the Phoenix System;

Anticipated timing of the PEARL 8.0 launch;

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;

Potential benefits of the Company's surgical adhesives and sealants;

Plans regarding regulatory approval in certain markets for BioFoam, including the expected timeline and source of funding for related studies, and the subsequent distribution of BioFoam in those markets;

The estimated European and worldwide market for BioFoam;

Commercialization plans for ProPatch;

## Edgar Filing: CRYOLIFE INC - Form 10-K

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

Plans and expected timeline regarding regulatory approval for CryoValve SGPV and CryoValve SGAV, and the benefits of related studies;

Expected use of the Company's additional laboratory space;

The Company's intentions with respect to lawsuits and the expected timeline, costs and impact of current litigation;

Expectations regarding the stock repurchase plan, including market conditions and other factors affecting the plan, and the Company's ability to fund repurchases from working capital and cash flow;

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

The Company's estimates of unreported loss liabilities, including the assumptions used to establish those estimates and its 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 Company's belief that decreases in shipments of cardiac valves due to increasing pressure from lower cost competitive products will be largely offset by increases in revenues due to its expanded sales staff;

The Company's anticipated significant decrease in total hemostat sales in 2012;

The potential impact of stock repurchases or additional sales of common stock on the Company's stock price;

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

Estimates and assumptions related to unreported loss liability;

Beliefs regarding the realizability of the Company's deferred tax assets;

Expectations regarding the impact of new accounting pronouncements;

Expectations regarding the recognition of stock compensation expense;

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

Expected benefits of acquisitions;

Anticipated future demand for our tissues and products;

Beliefs regarding domestic and international BioGlue sales and the factors affecting such sales;

The impact of expenses associated with lawsuits and business development opportunities;

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;

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

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;

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 Securities and Exchange Commission regarding its periodic or current reports under the Securities Exchange Act of 1934 not less than 180 days before December 31, 2011 (the end of the fiscal year to which this Form 10-K relates).

**Item 2. Properties.**

The Company's facilities are located in suburban Atlanta, Georgia, and in Guildford, England. The corporate headquarters in Atlanta 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 the manufacturing of PerClot and ProPatch. 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 30% of total capacity. To increase the current processing levels, the Company could increase the number of employees and expand its second and third shift. The BioGlue and BioFoam manufacturing laboratory contains approximately 13,500 square feet with a suite of six clean rooms. The current processing level is about 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. 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.**

**Medafor**

***Background of Georgia Lawsuit***

On April 29, 2009 CryoLife filed a lawsuit against Medafor in the U.S. District Court for the Northern District of Georgia (the Georgia Court). The lawsuit arises out of CryoLife's now terminated exclusive distribution agreement (EDA) with Medafor, pursuant to which CryoLife had the right to distribute a product manufactured by Medafor (the Product) under the name HemoStase. The EDA gave CryoLife exclusive rights to market and distribute the Product in all applications in cardiac and vascular surgery in most of the U.S. and for all cardiac and vascular surgeries and most other types of general surgery applications in much of the rest of the world.

On March 18, 2010 Medafor notified CryoLife of its contention that CryoLife had repudiated the EDA, and that Medafor was thereby entitled to terminate the contract. Medafor asserted that it had made a valid statutory demand, in a February 10, 2010 letter to CryoLife, for adequate assurances of CryoLife's future performance under the EDA, and that CryoLife had repudiated the EDA by failing to respond in a timely manner. CryoLife filed a motion for preliminary injunction, on March 29, 2010, asking the Georgia Court to enjoin Medafor from proceeding with its termination of the EDA.

After two hearings, the Georgia Court, on September 20, 2010, issued an order denying CryoLife's request for a preliminary injunction against Medafor. Although the order denied the preliminary injunction, it did not address the merits of the parties' respective positions on the underlying issue of whether Medafor's termination of the EDA was wrongful. The Georgia Court stated that it viewed this question as more appropriately addressed after discovery and at summary judgment. On September 27, 2010 Medafor sent CryoLife a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes Medafor's termination of the EDA was wrongful.

### ***Overview of CryoLife's Claims***

CryoLife's lawsuit, as amended and supplemented, alleges that Medafor unlawfully terminated the EDA. It also asserts claims for breach of the EDA and fraud. CryoLife alleges that contrary to Medafor's representations in the EDA, Medafor had numerous distribution agreements regarding the Product with other distributors in the U.S. and internationally, allowing these distributors to market and distribute the Product in the medical fields and territories given exclusively to the Company. Medafor is alleged to have knowingly and purposefully withheld from CryoLife disclosure that these competing agreements existed at the time the EDA was executed and to have intentionally misrepresented to CryoLife that no similar contracts existed, or that their timely termination was being arranged. The lawsuit also alleges that Medafor failed to take reasonable steps to prevent other distributors from distributing the Product in CryoLife's exclusive field within its exclusive territory, and that Medafor failed to take necessary actions to ensure the value of CryoLife's distributorship. Medafor denies these allegations.

CryoLife alleges that it brought these transgressions to Medafor's attention on numerous occasions and attempted to work with Medafor to secure its compliance with the terms of the parties' agreement, but Medafor refused to follow the terms of the EDA. Medafor's actions are alleged to have deprived CryoLife of significant sales volume and to have impaired and delayed CryoLife's development of relationships with customers in its exclusive field and territory. Medafor denies these allegations.

### ***CryoLife's Potential Damages***

CryoLife seeks to recover its damages from Medafor, punitive damages, and reimbursement of its attorneys' fees. In addition, CryoLife is seeking damages related to Medafor's wrongful termination of the EDA, which will be based upon CryoLife's lost profits for the period of time during which the EDA would have continued in effect but for Medafor's wrongful termination of it. The amount of these damages will be determined through discovery in the lawsuit. Also, CryoLife has alleged that Medafor has violated the Lanham Act and the Georgia Uniform Deceptive Trade Practices Act. No trial date has been set, although based on the Georgia Court's schedule, trial is not likely until 2013.

### ***Medafor's Counterclaims***

Medafor has asserted counterclaims against CryoLife that allege, among other things, breach of contract, violation of the Georgia Trade Secrets Act, tortious interference with business relationships, libel, violation of the Lanham Act, violation of Georgia's Uniform Deceptive Trade Practices Act, fraud and negligent misrepresentation, and conversion. In addition, Medafor requests that the Georgia Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Georgia Uniform Commercial Code.

### ***Summary of Medafor's Potential Damages Claims***

Pursuant to its counterclaims, Medafor seeks to recover its alleged damages from CryoLife, including from the alleged repudiation of the EDA, injunctive relief, prejudgment interest, punitive damages, and attorneys' fees and expenses. Until such time as the Georgia Court rules on Medafor's counterclaims and discovery in the lawsuit has finished, assessing the potential or likelihood that Medafor could prevail and the amount of damages that could be awarded to Medafor if it were to prevail will be difficult. CryoLife intends to vigorously prosecute the case, defend itself, and contest the matter.

### ***Discovery is Ongoing***

Written discovery began in this case on October 8, 2010. On July 5, 2011 the Georgia Court appointed a Discovery Special Master to manage and supervise discovery pursuant to a Joint Motion for Appointment of Special Master filed by the parties. Pursuant to that appointment, the parties have met repeatedly with the Special Master regarding discovery issues. A few depositions have been taken and depositions will continue through September 15, 2012, the date on which the Georgia Court has ordered that non-expert discovery end. The Georgia Court has scheduled a status conference for parties on April 10, 2012. Expert witness testimony and other pre-trial motions likely will not be concluded until 2013.

Pursuant to the Georgia Court's order, the parties have mediation scheduled for March 22 and March 23, 2012.

### ***Background of Minnesota Lawsuit***

On July 14, 2011 following CryoLife's demand to Medafor's Board of Directors that Medafor register its common stock under Section 12(g) of the Securities Exchange Act of 1934, as amended (the Exchange Act), Medafor filed a lawsuit



against CryoLife in the U.S. District Court for the District of Minnesota ( Minnesota Court ). In that lawsuit, Medafor seeks a declaratory judgment that its December 31, 2010 reverse stock split reduced the number of Medafor shareholders to less than 500 and that, therefore, Medafor is not required to comply with the registration requirements of Section 12(g) of the Exchange Act (*i.e.*, not required to register as a public company with the SEC). Medafor's lawsuit also requests that the Minnesota Court award Medafor its costs and expenses in the lawsuit. On August 5, 2011 CryoLife filed a Motion to Dismiss Medafor's claims, arguing that there was no subject matter jurisdiction over the claims because there was no private right cause of action under Section 12(g) of the Securities Exchange Act of 1934 and, therefore, Medafor had no right to the relief it sought *vis a vis* CryoLife. The Minnesota Court held a hearing on CryoLife's motion to Dismiss on October 11, 2011, and took the matter under advisement. The Minnesota Court ordered the parties to mediation, but cancelled that mediation in light of the upcoming mediation ordered by the Georgia Court. As of February 15, 2012 the Minnesota Court had not ruled on the Motion to Dismiss. At this time, CryoLife is unable to predict the outcome of this matter. The Company believes that the outcome of this Minnesota Court matter will not have a material adverse effect on its financial position, result of operations, or cash flow. But because this matter is ongoing, it is unclear whether this matter will ultimately be resolved in the Company's favor.

### **CardioFocus**

On February 19, 2008 CardioFocus, Inc. ( CardioFocus ) filed a complaint in the U.S. District Court for the District of Massachusetts (the Massachusetts Court ) against Cardiogenesis Corporation ( Cardiogenesis ), CryoLife's wholly owned subsidiary, acquired on May 17, 2011 and a number of other companies. In the complaint CardioFocus alleges that Cardiogenesis and the other defendants had previously violated patent rights allegedly held by CardioFocus directed to the use of holmium-doped YAG lasers in connection with low-hydroxyl content silica fibers for use in performing surgery. All of the asserted patents have now expired and the Company is the sole remaining defendant in the action. CardioFocus seeks a reasonable royalty pursuant to the Georgia Pacific factors for Cardiogenesis's sales of its accused products, namely, the SolarGen, TMR, and New Star lasers and lasers systems, during the period 2002 to 2007.

Since the filing of the lawsuit in February of 2008, Cardiogenesis has filed numerous requests for reexamination of the two patents being asserted against Cardiogenesis with the U.S. Patent and Trademark Office ( USPTO ). Through these reexaminations three asserted claims from two patents have survived. Specifically, Claim 2 of U.S. Patent No. 6,547,780 (the 780 Patent ) and Claims 2 and 7 of U.S. Patent No. 5,843,073 (the 073 Patent ) were confirmed by the USPTO. Notwithstanding the confirmation of the asserted claims, CryoLife and Cardiogenesis believe that significant issues concerning the validity, enforceability, and non-infringement of the asserted patents continue to exist.

On August 15, 2011 at the request of both parties, the Massachusetts Court lifted the stay and entered a Scheduling Order. Pursuant to the Scheduling Order, a claims construction hearing or so-called Markman Hearing occurred on October 21, 2011. On November 3, 2011 the Massachusetts Court issued a claim construction ruling that construed certain claim terms in favor of CardioFocus's position. On November 14, 2011 Cardiogenesis filed a motion for reconsideration of the Massachusetts Court's construction of certain claim terms. In addition, Cardiogenesis has filed additional reexamination requests for the three claims with the USPTO, but the USPTO has denied the reexamination requests. Cardiogenesis has filed petitions with the USPTO for reconsideration of those denials. The parties are currently in the expert witness phase of discovery, with trial scheduled for June 18, 2012.

The Company intends to defend itself vigorously in this action. At this time the Company is unable to predict the outcome of this matter and believes that the outcome of this matter will not have a material adverse effect on the Company's results of operations or cash flows as there are still many pre-trial motions to be addressed and expert witness testimony to be analyzed. However, as this matter is ongoing, there is no assurance that this matter will be resolved favorably by the Company or will not result in a material liability to the Company, which could materially affect its results of operations and cash flows.

### **Tenaxis**

On October 1, 2008 Tenaxis, Inc. ( Tenaxis ) filed a nullity action against CryoLife's main BioGlue patent in Federal Patent Court in the State of Bavaria in the Federal Republic of Germany that seeks to invalidate this patent in Germany. The Federal Patent Court held a hearing on the nullity action on November 24, 2009. On April 22, 2010 the Federal Patent Court in Munich issued a judgment declaring the German part of this BioGlue patent as void. CryoLife has filed an appeal against this judgment with the German Supreme Court. Until the decision is made on the appeal, the patent formally remains in force. It is likely that the appeal will not be heard until 2013. The German Supreme Court appointed a technical expert through June 30, 2012 to assist it with this patent appeal.

On October 30, 2008 CryoLife filed a patent infringement action in a Patent Court in the State of North Rhein-Westphalia in Düsseldorf in the Federal Republic of Germany. This complaint alleges that Tenaxis is infringing CryoLife's main BioGlue patent by selling a surgical adhesive made up of a mixture of among other things, bovine serum albumin and glutaraldehyde. CryoLife is seeking an injunction, damages, and a list of customers to which Tenaxis has sold or is planning to sell its products. The District Court has stayed the proceedings pending the issuance of judgment of the German Supreme Court in the nullity appeal proceeding.

#### 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	73	President, Chief Executive Officer, and Chairman
Jeffrey W. Burris	Since 2010	40	Vice President and General Counsel
Scott B. Capps	Since 2007	45	Vice President, Clinical Research
David M. Fronk	Since 1998	48	Vice President, Regulatory Affairs and Quality Assurance
David C. Gale, Ph.D	Since 2012	44	Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	47	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Gerald B. Seery	Since 2005	55	Senior Vice President Sales and Marketing

**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.

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

**David M. Fronk** was appointed to the position of Vice President of Regulatory Affairs and Quality Assurance in April 2005 and has been with the Company since 1992, serving as Vice President of Clinical Research from December 1998 to April 2005 and Director of Clinical Research from December 1997 until December 1998. Mr. Fronk is responsible for developing and implementing improved safety processes and procedures for new and existing medical products. Prior to joining the Company,

Mr. Fronk held engineering positions with Zimmer, Inc. from 1986 until 1988 and Baxter Healthcare Corporation from 1988 until 1991. Mr. Fronk served as a market manager with Baxter Healthcare Corporation from 1991 until 1992. Mr. Fronk received his B.S. in Mechanical Engineering from the Ohio State University and his M.S. in Biomedical Engineering from the Ohio State University.

**David C. Gale, Ph.D.** has served as Vice President, Research and Development since January 1, 2012. Dr. Gale joined the Company in August 2009 as the Director, Biomaterials and Product Development. He was promoted to Senior Director, Biomaterials and Device Engineering in April 2011. Prior to joining CryoLife, Dr. Gale was with Sinexus, Inc., a start-up medical device company, from January 2007 to August 2009. He joined Sinexus as their Vice President of Research and was promoted to the position of Vice President, Research and Development in July 2007. Dr. Gale has 17 years of experience in biomaterials and medical device product research and development including roles at Abbott Vascular and Guidant Corporation. Dr. Gale is the inventor or co-inventor on over 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 an M.Sc. in Instrumentation and Analysis and a B.Sc. in Chemistry from Manchester University in the U.K.

**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.

**Gerald B. Seery** has served as Senior Vice President of Sales and Marketing since October 2005. Mr. Seery has been with the Company since July 1993 serving as Vice President of International Operations from July 2005 to October 2005, President of CryoLife Europa from April 2002 to July 2005, President of AuraZyme from March 2001 to April 2002, and Vice President of Marketing from August 1995 to March 2001. Mr. Seery is responsible for developing and implementing the Company's sales and marketing plans and supervising all tissue procurement activities. Prior to joining the Company, Mr. Seery held senior marketing management positions with Meadox Medicals from 1982 until 1985, Electro Catheter Corporation from 1985 until 1989, and Daig Corporation from 1992 until 1993, accumulating fifteen years of specialized marketing experience in cardiac medical devices. Mr. Seery received his B.A. in International Economics at The Catholic University of America in Washington, D.C. and completed his M.B.A. at Columbia University in New York.

## 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.

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
2010	High	Low
First quarter	\$ 7.45	\$ 6.02
Second quarter	6.75	4.80
Third quarter	6.28	5.05
Fourth quarter	6.79	5.25

As of February 10, 2012 the Company had 417 shareholders of record.

The Company has never declared or paid any cash dividends on its common stock, and its credit agreement with General Electric Capital Corporation ( GE Capital ) prohibits payment of cash dividends on the Company's common stock without GE Capital's consent. 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, 2011 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
10/01/11 - 10/31/11		\$		\$ 7,739,911
11/01/11 - 11/30/11	113,075	4.41	113,075	14,501,073
12/01/11 - 12/31/11	202,330	4.64	199,897	13,573,977
Total	315,405	4.56	312,972	13,573,977

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. From June 1, 2010 to September 30, 2011 the Company purchased a total of 1.3 million shares of its common stock for an aggregate purchase price of \$7.3 million. 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

## Edgar Filing: CRYOLIFE INC - Form 10-K

million remaining from the June 1, 2010 \$15.0 million stock repurchase program and an additional \$7.3 million. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, including pursuant to Rule 10b5-1 plans, at management's discretion, and will be dependent upon various factors, including:

price, regulatory requirements, and other market conditions. 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 common shares purchased that were not part of a publically announced plan or program were tendered to the Company in payment of the exercise price of outstanding options and taxes on stock compensation.

#### 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,				
	2011	2010	2009	2008	2007
<b>Operations</b>					
Revenues	\$ 119,626	\$ 116,645	\$ 111,685	\$ 105,059	\$ 94,763
Operating income	11,643	9,868	14,496	13,654	8,299
Net income	7,371	3,944	8,679	31,950	7,201
Net income applicable to common shareholders	7,222	3,893	8,605	31,950	6,958
Research and development expense as a percentage of revenues	5.8%	5.1%	4.7%	5.1%	4.7%
<b>Income Per Common Share</b>					
Basic	\$ 0.26	\$ 0.14	\$ 0.31	\$ 1.15	\$ 0.26
Diluted	\$ 0.26	\$ 0.14	\$ 0.30	\$ 1.13	\$ 0.26
<b>Year-End Financial Position</b>					
Total assets	\$ 147,864	\$ 137,438	\$ 133,859	\$ 125,037	\$ 92,684
Working capital	62,413	82,162	76,312	59,370	40,750
Long-term liabilities	4,869	4,168	4,197	5,672	5,355
Shareholders' equity	121,538	113,942	110,446	98,368	62,627
Current ratio <sup>1</sup>	4:1	5:1	5:1	4:1	3:1
Shareholders' equity per diluted common share	\$ 4.38	\$ 4.03	\$ 3.90	\$ 3.47	\$ 2.32

<sup>1</sup> 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<sup>®</sup> SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch<sup>®</sup> SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife's proprietary SynerCryo<sup>®</sup> technology. CryoLife's surgical sealants and hemostats include BioGlue<sup>®</sup> Surgical Adhesive (BioGlue), BioFoam<sup>®</sup> Surgical Matrix (BioFoam), and PerCryo<sup>®</sup> 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.

For the year ended December 31, 2011 CryoLife had record annual revenues of \$119.6 million. During 2011 CryoLife reported its highest revenues ever for a first, second, and third quarter. The Company's fourth quarter was both the highest



fourth quarter revenue performance ever for CryoLife and the highest quarterly revenues in any quarter in Company history of \$30.4 million. The Company's acquisition of Cardiogenesis in May 2011 added to the revenue growth as revenues from revascularization technologies increased quarter-over-quarter in the third and fourth quarters as the Company integrated Cardiogenesis operations. The Company's cash position was strong as the Company generated \$16.8 million in cash flows from operations during 2011. The Company experienced increases in selling, general, and administrative expenses during 2011 due to increased spending on business development activities and additional costs related to the acquisition of Cardiogenesis. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2011 results. See Part I, Item 1, Business, for further discussion of the Company's business and activities during 2011.

## Recent Events

### *Revised Credit Agreement with GE Capital*

On October 28, 2011 CryoLife amended and restated its March 26, 2008 credit agreement with GE Capital (the GE Credit Agreement) which provides revolving credit for working capital, acquisitions, and other corporate purposes. The amendment increased the borrowing capacity under the GE Credit Agreement from \$15.0 million to \$20.0 million (including a letter of credit subfacility) and extended the expiration from October 31, 2011 to October 28, 2014. As of December 31, 2011 the outstanding balance under the GE Credit Agreement was zero, and \$19.8 million was available for borrowing.

### *Stock Repurchase Program*

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 \$15.0 million stock repurchase program and an additional \$7.3 million. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions.

## 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 and may involve a higher degree of judgment and complexity.

### *Deferred Preservation Costs*

By federal law, human tissues cannot be bought or sold. Therefore, the tissues the Company preserves and processes are not held as inventory. 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. Although the Company cannot own human tissue, the preservation process is a manufacturing process that is accounted for using the same principles as inventory costing. Preservation costs consist primarily of direct labor and materials (including salary and fringe benefits, laboratory expenses, tissue procurement fees, and freight-in charges) and indirect costs (including allocations of costs from departments that support processing and preservation activities and facility allocations).

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. The allocation of fixed production overhead costs is based on actual production levels, to the extent that they are within the range of the facility's normal capacity. Cost of preservation services also includes, as incurred, idle facility expense, excessive spoilage, extra freight, and rehandling costs.

The calculation of deferred preservation costs involves a high degree of judgment and complexity. The costs included in deferred preservation costs contain several estimates due to the timing differences between the occurrence of the cost and receipt of final bills for services. Costs that contain estimates include tissue procurement fees, which are estimated based on the Company's contracts with independent OTPOs, and freight-in charges, which are estimated based on the Company's prior experiences with these charges. These costs are adjusted for differences between estimated and actual fees when



invoices for these services are received. Management believes that its estimates approximate the actual costs of these services, but estimates could differ from actual costs. Total deferred preservation costs are then allocated among the different tissues processed during the period based on specific cost drivers such as the number of donors and the 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 determines this estimate of quarantine yields based on its experience in prior periods and reevaluates this estimate periodically. Due to the nature of this estimate and the length of the processing times experienced by the Company, actual yields could differ from the Company's estimates. A significant change in quarantine yields could result in an adjustment to or write-down of deferred preservation costs and, therefore, materially affect the amount of deferred preservation costs on the Company's Consolidated Balance Sheets and the cost of preservation services on the Company's Consolidated Statements of Operations.

As a part of the normal course of business, the Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value or if there is any impairment to the costs for tissues not expected to ship prior to the expiration date of its packaging. CryoLife records a charge to cost of preservation services to write-down the amount of deferred preservation costs not deemed to be recoverable. Typically, lower of cost or market value write-downs are primarily due to excess tissue processing costs incurred that exceed the estimated market value of the tissue services, based on then recent average service fees. Impairment write-downs are recorded based on the book value of the impaired tissues. Actual results may differ from these estimates. These write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if the market value of tissue services increase or when tissues are shipped or become available for shipment.

The Company recorded write-downs to its deferred preservation costs totaling \$270,000, \$187,000, and \$91,000 for the years ended December 31, 2011, 2010, and 2009, respectively.

As of December 31, 2011 deferred preservation costs consisted of \$10.2 million for heart valves, \$2.4 million for cardiac patch tissues, and \$16.4 million for vascular tissues. As of December 31, 2010 deferred preservation costs consisted of \$12.0 million for heart valves, \$2.5 million for cardiac patch tissues, and \$17.1 million for vascular tissues.

#### ***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 a high degree of 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 deferred tax assets will be limited in future periods due to a change in control of its subsidiary Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, as a result of the Company's acquisition of Cardiogenesis in the second quarter of 2011. 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 this change in control.

The Company's tax years 2008 through 2011 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2008, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

### *Liability Claims*

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

The Company estimates its liability for and any related recoverable under the Company's insurance policies as of each balance sheet date. The Company uses a frequency-severity approach to estimate its unreported tissue processing and product liability claims, whereby, projected losses are calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims are determined based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim is calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The Company uses a number of assumptions in order to estimate the unreported loss liability including:

A ceiling of \$5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5.0 million,

The future claim reporting lag time would be a blend of the Company's experiences and industry data,

The frequency of reported claims would be based on the Company's past experience for policy years 1993/1994 through the present with consideration given to the frequency spike experienced in policy year 2002/2003,

The average cost per claim would be consistent with the Company's historical experience, adjusted to current cost levels,

The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on these product lines,

The number of BioGlue claims per million dollars of BioGlue revenue would be 60% lower than non-BioGlue claims per million dollars of revenue. The 60% factor was selected based on BioGlue claims experience to date and consultation with the actuary, and

The number of Cardiogenesis claims per million dollars of Cardiogenesis revenue would be 85% lower than non-Cardiogenesis claims per million dollars of revenue. The 85% factor was selected based on Cardiogenesis claims experience to date and consultation with the actuary.

The Company believes that the assumptions it uses to determine its unreported loss liability provide a reasonable basis for its calculation. However, the accuracy of the estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors, actual results may differ significantly from the assumptions used and amounts accrued.

## Edgar Filing: CRYOLIFE INC - Form 10-K

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

The Company expenses the costs of legal services, including legal services related to tissue processing and product liability claims, as they are incurred.

---

### ***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 May 2011 the Financial Accounting Standard Board (FASB) issued 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. ASU 2011-04 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-04 to have a material effect on its financial condition, profitability, and cash flows.

In June 2011 the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income* which requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income, or in two separate but consecutive statements and eliminates the option to present components of other comprehensive income as part of the statement of equity. In December 2011 the FASB issued ASU 2011-12, which deferred the guidance on whether to require entities to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement where net income is presented and the statement where other comprehensive income is presented for both interim and annual financial statements. ASU 2011-12 reinstated the requirements for the presentation of reclassifications that were in place prior to the issuance of ASU 2011-05 and did not change the effective date for ASU 2011-05. ASU 2011-05 and ASU 2011-12 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-05 and ASU 2011-12 to have a material effect on its financial condition, profitability, and cash flows.

In September 2011 the FASB issued 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. If the qualitative assessment indicates that the fair value of a reporting unit is more likely than not less than the carrying amount, the two-step impairment test would be required. Otherwise, further testing would not be needed. ASU 2011-08 will be effective for the Company

beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-08 to have a material effect on its financial condition, profitability, and cash flows.

## Results of Operations

(In thousands)

### 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
<b>Preservation services:</b>				
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%
<b>Products:</b>				
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
<b>Preservation services:</b>				
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%
<b>Products:</b>				
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%

Edgar Filing: CRYOLIFE INC - Form 10-K

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. The Company believes that these pressures will persist, but that they will be largely offset in 2012 by the activities of its expanded sales staff which increased as a result of the Company's acquisition of Cardiogenesis.

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.

#### *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.

The Company's sales of surgical sealants through its direct sales force to United Kingdom hospitals are denominated in British Pounds, and its sales to German 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 Euro or British Pound decline materially in 2012 compared to the corresponding periods in 2011, this would have a material adverse impact on the Company's revenues denominated in these currencies.

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.

BioGlue is a mature product 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. Management believes that surgical sealant sales into Europe may continue to be effected by poor economic conditions in Europe and that these conditions may worsen in 2012. Management believes that international BioGlue sales will be positively impacted in the first half of 2012 by sales to Japan, as there are no sales to Japan in the corresponding period in 2011.

#### *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 Exclusive Distribution Agreement (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 have been 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 is not yet approved for commercial distribution in domestic markets. The Company anticipates this loss of domestic hemostat sales to result in a significant decrease in total hemostat sales for the first quarter of 2012 when compared to the corresponding 2011 period.

The Company will not be able to sell PerClot in the U.S. in future years unless and until U.S. Food and Drug Administration (FDA) approval is granted. On March 31, 2011 CryoLife filed 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. On April 29, 2011 the FDA disapproved CryoLife's IDE filing. CryoLife anticipates refiling its IDE for PerClot in early 2012.

#### *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 U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the (DOD Grants). As of December 31, 2011 CryoLife has been awarded \$6.1 million and has 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, of which \$1.2 million remains in unspent cash advances recorded as cash and cash equivalents.

#### **Cost of Preservation Services and Products**

##### *Cost of Preservation Services*

	<b>Three Months Ended December 31,</b>		<b>Twelve Months Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Cost of preservation services	\$ 8,631	\$ 8,546	\$ 34,340	\$ 35,868
Cost of preservation services as a percentage of preservation services revenues	58%	61%	57%	60%

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 is 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 and the decrease in cost of preservation services as a percentage of preservation services revenues in the three and twelve months ended December 31, 2011 were 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		Twelve Months Ended	
	December 31,		December 31,	
	2011	2010	2011	2010
Cost of products	\$ 2,391	\$ 3,091	\$ 9,442	\$ 12,409
Cost of products as a percentage of product revenues	15%	20%	16%	22%

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 includes 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.

The decrease in cost of products as a percentage of product revenues for the three and twelve months ended December 31, 2011 was primarily due to decreased HemoStase revenues, as HemoStase had a higher cost as a percentage of revenue than BioGlue and revascularization technologies revenues. The decrease in the twelve month period was also due to the write-down of HemoStase inventory in the prior year period.

**Operating Expenses****General, Administrative, and Marketing Expenses**

	Three Months Ended		Twelve Months Ended	
	December 31,		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.

The Company expects that its general, administrative, and marketing expenses in 2012 will be significantly higher than in the comparative periods in 2011 due to legal expenses related to its ongoing litigation. See also Part I, Item 1A, Risk Factors, and Part I, Item 3, Legal Proceedings. The Company continues to evaluate potential business development opportunities and may continue to incur costs related to these activities in 2012, which may be material. The Company expects that it will incur additional general, administrative, and marketing expenses in the first half of 2012 related to the sales personnel and ongoing operations of Cardiogenesis which were not present in the corresponding 2011 periods.

**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 have not yet been obtained. Therefore, CryoLife expensed the \$3.5 million as in-process research and development upon acquisition.

**Other Income and Expenses**

Interest expense was \$26,000 for the three months and \$142,000 for the twelve months ended December 31, 2011, and \$35,000 for the three months and \$180,000 for the twelve months ended December 31, 2010. Interest expense for all periods presented included interest incurred related to the Company's debt, capital leases, and interest related to uncertain tax positions.

Interest income was \$1,000 for the three months and \$14,000 for the twelve months ended December 31, 2011, and \$7,000 for the three months and \$23,000 for the twelve months ended December 31, 2010. Interest income for all periods presented was for interest earned on the Company's cash, cash equivalents, and restricted securities.

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

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

Edgar Filing: CRYOLIFE INC - Form 10-K

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 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.

Diluted income per common share could be impacted in future periods unfavorably by the issuance of additional shares of common stock and favorably 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.

*Year Ended December 31, 2010 Compared to Year Ended December 31, 2009*

**Revenues**

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2010	2009	2010	2009
Preservation services:				
Cardiac tissue	\$ 7,044	\$ 6,697	24%	23%
Vascular tissue	6,981	7,054	24%	25%
Orthopaedic tissue		33	%	%
Total preservation services	14,025	13,784	48%	48%
Products:				
BioGlue and BioFoam	12,164	12,583	42%	44%
PerClot	264		1%	%
HemoStase	2,666	1,869	9%	7%
Other medical devices		41	%	%
Total products	15,094	14,493	52%	51%
Other	103	338	%	1%
Total	\$ 29,222	\$ 28,615	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2010	2009	2010	2009
<b>Preservation services:</b>				
Cardiac tissue	\$ 27,997	\$ 26,074	24%	24%
Vascular tissue	31,727	30,201	27%	27%
Orthopaedic tissue		181	%	%
<b>Total preservation services</b>	<b>59,724</b>	<b>56,456</b>	<b>51%</b>	<b>51%</b>
<b>Products:</b>				
BioGlue and BioFoam	47,383	47,906	41%	43%
PerClot	264		%	%
HemoStase	8,793	6,008	8%	5%
Other medical devices	(70)	248	%	%
<b>Total products</b>	<b>56,370</b>	<b>54,162</b>	<b>49%</b>	<b>48%</b>
Other	551	1,067	%	1%
<b>Total</b>	<b>\$ 116,645</b>	<b>\$ 111,685</b>	<b>100%</b>	<b>100%</b>

Revenues increased 2% for the three months and 4% for the twelve months ended December 31, 2010 as compared to the three and twelve months ended December 31, 2009, 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, 2010 is presented below.

#### **Preservation Services**

Revenues from preservation services increased 2% for the three months and 6% for the twelve months ended December 31, 2010 as compared to the three and twelve months ended December 31, 2009, respectively. The increase for the three months ended December 31, 2010 was primarily due to an increase in cardiac preservation service revenues. The increase for the twelve months ended December 31, 2010 was due to an increase in both cardiac and vascular 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, cardiac patch tissues, and minimally processed tissues that are distributed to a third party tissue processor) increased 5% for the three months ended December 31, 2010 as compared to the three months ended December 31, 2009, primarily due to the impact of a 4% increase in shipments of heart valves and cardiac patch tissues and favorable tissue mix.

Revenues from cardiac preservation services increased 7% for the twelve months ended December 31, 2010 as compared to the twelve months ended December 31, 2009, primarily due to the aggregate impact of favorable tissue mix and a 4% increase in shipments of heart valves and cardiac patch tissues.

For the three and twelve months ended December 31, 2010, shipments of CryoValve SGPV, CryoPatch SG, and aortic valves increased, partially offset by a decrease in traditionally processed cardiac patch tissues and pulmonary valves. The favorable tissue mix in the three and twelve months ended December 31, 2010 was primarily due to the favorable impact of SynerGraft tissues including the CryoValve SGPV and CryoPatch SG, which command a premium fee over standard processed tissues.

In both the three and twelve months ended December 31, 2010, the decrease in revenues from traditionally processed pulmonary valves was more than offset by an increase in revenues related to the CryoValve SGPV, as hospitals continue to transition to the SynerGraft processed product, particularly after the Company received FDA clearance to extend the shelf-life of the CryoValve SGPV to five years in the second quarter of 2010. In the three and twelve months ended December 31, 2010 the decrease in revenues from traditionally processed cardiac patch tissues was not fully offset by increases in revenues from the CryoPatch SG. The Company believes that these revenues were unfavorably impacted by increasing competitive pressures and by a reduced supply of certain patch tissues available for shipment during the period as the Company works to achieve an optimal balance among its offered tissues.





Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 40% and 35% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2010, respectively, and 33% and 26% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2009, respectively. Domestic revenues accounted for 91% and 93% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2010, respectively, and 93% and 94% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2009, respectively.

#### *Vascular Preservation Services*

Revenues from vascular preservation services decreased 1% for the three months ended December 31, 2010 as compared to the three months ended December 31, 2009, primarily due to a 5% decrease in unit shipments of vascular tissues, which decreased revenues by 4%, largely offset by an increase in average service fees, which increased revenues by 3%.

Revenues from vascular preservation services increased 5% for the twelve months ended December 31, 2010 as compared to the twelve months ended December 31, 2009, primarily due to a 2% increase in unit shipments of vascular tissues, which increased revenues by 3% and an increase in average service fees, which increased revenues by 2%.

The decrease in vascular volume for the three months ended December 31, 2010 was primarily due to decreases in shipments of femoral veins and arteries. CryoLife believes that vascular revenues in the fourth quarter of 2010 were lower due to increasing pressure from lower cost competitive products, which may continue into 2011. The increase in vascular volume for the twelve months ended December 31, 2010 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.

The increase in average service fees for the three and twelve months ended December 31, 2010 was due in part to list fee increases on certain vascular preservation services, fee differences due to vascular tissue characteristics, and due to the negotiation of pricing contracts with certain customers.

#### **Products**

Revenues from products increased 4% for both the three and twelve months ended December 31, 2010 as compared to the three and twelve months ended December 31, 2009, respectively. These increases were primarily due to an increase in HemoStase revenues and, to a lesser extent, PerClot revenues. See further discussions of BioGlue, BioFoam, PerClot, and HemoStase revenues below.

#### *BioGlue and BioFoam*

Revenues from the sale of BioGlue and BioFoam decreased 3% for the three months ended December 31, 2010 as compared to the three months ended December 31, 2009. This decrease was primarily due to a 6% decrease in the volume of milliliters sold, which decreased revenues by 7% and the unfavorable impact of foreign exchange rates, which decreased revenues by 1%, partially offset by an increase in average selling prices, which increased revenues by 5%.

Revenues from the sale of BioGlue and BioFoam decreased 1% for the twelve months ended December 31, 2010 as compared to the twelve months ended December 31, 2009. The revenues were impacted by a 6% decrease in the volume of milliliters sold, which decreased revenues by 5% and the unfavorable impact of foreign exchange rates, which decreased revenues by 1%, largely offset by an increase in average selling prices, which increased revenues by 5%.

The decrease in sales volume for BioGlue and BioFoam for the three and twelve months ended December 31, 2010 was primarily due to a decrease in shipments of BioGlue in domestic markets, particularly in the northeast region of the U.S. Management believes that the decrease in domestic BioGlue shipments 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 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.

The impact of foreign exchange rates for the three months ended December 31, 2010 was due to changes in the exchange rates in the three and twelve months ended December 31, 2010 as compared to the respective periods in 2009 between the U.S. Dollar and the Euro and, to a lesser extent, between the U.S. Dollar and the British Pound. The Company's sales of

BioGlue and BioFoam to German hospitals, Austrian hospitals, and certain distributors are denominated in Euros, and its sales through its direct sales force to United Kingdom hospitals are denominated in British Pounds.

The increase in average selling prices for the three and twelve months ended December 31, 2010 was primarily due to list price increases on certain BioGlue products that went into effect during 2009 and 2010 and the negotiation of pricing contracts with certain customers.

Sales of BioGlue and BioFoam for the three and twelve months ended December 31, 2010 included international sales of BioFoam following receipt of the CE Mark approval during the third quarter of 2009. BioFoam sales accounted for less than 1% of total BioGlue and BioFoam sales for the three and twelve months ended December 31, 2010 and 2009. Domestic revenues accounted for 66% and 68% of total BioGlue and BioFoam revenues for the three and twelve months ended December 31, 2010, respectively, and 69% and 70% of total BioGlue and BioFoam revenues for the three and twelve months ended December 31, 2009.

#### *PerClot and HemoStase*

Revenues from the sale of PerClot and HemoStase increased 57% for the three months ended December 31, 2010 as compared to the three months ended December 31, 2009. This increase was primarily due to a 94% increase in the volume of grams sold, which increased revenues by 65%, partially offset by a decrease in average selling prices, which decreased revenues by 8%.

Revenues from the sale of PerClot and HemoStase increased 51% for the twelve months ended December 31, 2010 as compared to the twelve months ended December 31, 2009. This increase was primarily due to a 66% increase in the volume of grams sold, which increased revenues by 52%.

The increase in sales volume for the three and twelve months ended December 31, 2010 was primarily due to an increase in shipments of HemoStase in domestic markets and to a lesser extent shipments of PerClot and HemoStase in international markets. CryoLife began commercial distribution of PerClot in international markets in the fourth quarter of 2010.

Management believes that the Company lost additional sales of HemoStase during the third and fourth quarters of 2010 due to uncertainty in the market as to whether the Company had authority to market HemoStase and as to whether it would be able to continue to supply the product in the future. Management believes that third and fourth quarter HemoStase sales were also adversely impacted by continued sales by Medafor of Medafor's product into the Company's exclusive territory in violation of the private label exclusive distribution agreement between the parties.

The decrease in average selling prices for the three months ended December 31, 2010 was primarily due to discounting of HemoStase inventory in an attempt to sell off the Company's remaining inventory balances prior to the Company's planned cessation of HemoStase sales in late March 2011, as discussed further below.

Domestic revenues accounted for 71% and 74% of total PerClot and HemoStase revenues for the three and twelve months ended December 31, 2010, respectively, and 77% of total HemoStase revenues for both the three and twelve months ended December 31, 2009.

#### *Other Revenues*

Other revenues for the three and twelve months ended December 31, 2010 and 2009 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, 2010 CryoLife had been awarded 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, 2010 CryoLife had \$2.1 million of deferred income on the Company's Consolidated Balance Sheet from the DOD Grants, of which \$1.7 million remains in unspent cash advances recorded as cash and cash equivalents. As of December 31, 2009 the Company had \$2.6 million remaining in unspent cash advances recorded as cash and cash equivalents and deferred income on the Company's Consolidated Balance Sheet.

**Cost of Preservation Services and Products***Cost of Preservation Services*

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Cost of preservation services	\$ 8,546	\$ 8,346	\$ 35,868	\$ 32,767
Cost of preservation services as a percentage of preservation services revenues	61%	61%	60%	58%

Cost of preservation services increased 2% and 9% for the three and twelve months ended December 31, 2010, respectively, as compared to the respective periods in 2009.

Cost of preservation services in the three months ended December 31, 2010 was primarily impacted by an increase in the per unit cost of processing tissues and due to an increase in cardiac tissues shipped, partially offset by a decrease in vascular tissues shipped, as discussed above. The increase in cost of preservation services in the twelve months ended December 31, 2010 was primarily due to an increase in the per unit cost of processing tissues, and to a lesser extent due to an increase in cardiac and vascular tissues shipped, as discussed above.

The increase in cost of preservation services as a percentage of preservation services revenues for the twelve months ended December 31, 2010 was primarily due to the increase in the per unit cost of processing tissues. The increase in the per unit cost of processing tissues in 2010 was largely a result of decreased processing and packaging throughput due to changes implemented in the second half of 2009.

*Cost of Products*

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Cost of products	\$ 3,091	\$ 2,672	\$ 12,409	\$ 9,150
Cost of products as a percentage of product revenues	20%	18%	22%	17%

Cost of products increased 16% and 36% for the three and twelve months ended December 31, 2010, respectively, as compared to the respective periods in 2009.

The increase in cost of products for the three months ended December 31, 2010 was primarily due to the increase in shipments of PerClot and HemoStase, as discussed above. The increase in cost of products for the twelve months ended December 31, 2010 was primarily due to a \$1.6 million write-down of HemoStase inventory in the third quarter of 2010 and an increase in shipments of PerClot and HemoStase, as discussed above. To a lesser extent the increase in the twelve months ended December 31, 2010 was due to a slight increase in the per unit cost of manufacturing BioGlue.

The write-down of HemoStase inventory was based on the Company's review of its inventory balances after Medafor's September 27, 2010 termination of the EDA. Based on its review of the EDA, the Company determined that the carrying value of the HemoStase inventory was impaired and increased its cost of products by \$1.6 million to write down HemoStase inventory in the third quarter of 2010. The Company continued to sell HemoStase through late March 2011. See also Revenues above, Part I, Item 1A, Risk Factors, and Part I, Item 3, Legal Proceedings.

The amount of this write-down reflects management's estimate based on information currently available. Management will continue to evaluate the recoverability of its HemoStase inventory as more information becomes available and may record additional write-downs if it becomes clear that additional impairments have occurred. The write-down creates a new cost basis which cannot be written back up if the inventory becomes saleable.

The increase in cost of products as a percentage of product revenues for the three months ended December 31, 2010 was primarily due to increasing sales volume of PerClot and HemoStase, which have a lower profit margin than BioGlue. The increase in cost of products as a percentage of product revenues for the twelve months ended December 31, 2010 was primarily due to a \$1.6 million write-down of HemoStase inventory and increasing revenues from PerClot and HemoStase,



which have a lower profit margin than BioGlue, and to a lesser extent a slight increase in the per unit cost of manufacturing BioGlue.

## Operating Expenses

### General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
General, administrative, and marketing expenses	\$ 12,201	\$ 12,585	\$ 49,064	\$ 50,025
General, administrative, and marketing expenses as a percentage of total revenues	42%	44%	42%	45%

General, administrative, and marketing expenses decreased 3% and 2% for the three and twelve months ended December 31, 2010, respectively, as compared to the three and twelve months ended December 31, 2009.

The decrease in general, administrative, and marketing expenses for the three and twelve months ended December 31, 2010 was primarily due to a decrease in marketing expenses, including personnel costs and spending on marketing materials, partially offset by an increase in spending on legal and professional fees and marketing expenses for the Ross Summit, which were incurred in the fourth quarter of 2010, while comparable marketing expenses for the 2009 Ross Summit were incurred in the third quarter of 2009.

Expenses in the three months ended December 31, 2010 included approximately \$268,000 in costs associated with litigation with Medafor and \$474,000 in business development costs. Expenses in the twelve months ended December 31, 2010 included \$729,000 in previously capitalized legal fees associated with BioGlue patent litigation in Germany, approximately \$1.4 million in costs associated with litigation with Medafor, and approximately \$1.0 million in business development costs. The Company's business development costs in 2010 were associated with the Company's proposal to acquire Medafor, the license of technology and purchase of assets from SMI, and other business development activities.

The Company's general, administrative, and marketing expenses included \$611,000 and \$566,000 for the three months ended December 31, 2010 and 2009, respectively, and \$2.3 million and \$2.2 million for the twelve months ended December 31, 2010 and 2009, respectively, related to the grant of stock options, restricted stock awards, and restricted stock units.

General, administrative, and marketing expenses for 2009 included \$377,000 in costs related to a reduction in workforce implemented during the fourth quarter of 2009.

### Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Research and development expenses	\$ 1,801	\$ 1,393	\$ 5,923	\$ 5,247
Research and development expenses as a percentage of total revenues	6%	5%	5%	5%

Research and development spending in 2010 and 2009 was primarily focused on the Company's BioGlue family of products, including: BioGlue and BioFoam, and SynerGraft tissues and products, including: CryoValve SGPV, CryoValve SG aortic heart valves, CryoPatch SG, and xenograft SynerGraft tissue products, including ProPatch. Research and development spending in the three months ended December 31, 2010 also included spending on PerClot.

### Acquired In-Process Research and Development

On September 28, 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI for PerClot. 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 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.

### Other Income and Expenses

Interest expense was \$35,000 and (\$85,000) for the three months ended December 31, 2010 and 2009, respectively, and \$180,000 and \$83,000 for the twelve months ended December 31, 2010 and 2009, respectively. Interest expense for the three and twelve months ended December 31, 2010 and 2009 included interest incurred related to the Company's debt and interest related to uncertain tax positions. The decrease in interest expense in 2009 was primarily due to a reversal of interest expense related to the Company's uncertain tax positions in the fourth quarter of 2009.

Interest income was \$7,000 and \$3,000 for the three months ended December 31, 2010 and 2009, respectively, and \$23,000 and \$76,000 for the twelve months ended December 31, 2010 and 2009, respectively. Interest income for the three and twelve months ended December 31, 2010 and 2009 was primarily due to interest earned on the Company's cash, cash equivalents, and restricted securities. The decrease in interest income in 2010 was primarily due to a decline in interest rates paid on the Company's cash and cash equivalents, partially offset by an increase in the balance in these accounts.

Other than temporary investment impairment was \$3.6 million for the twelve months ended December 31, 2010, due to the impairment of the Company's investment in Medafor common stock during the third quarter of 2010. The Company determined that no additional impairment of the value of Medafor common stock had occurred in the fourth quarter of 2010. The carrying value of the Company's investment in Medafor common stock after this write-down was \$2.6 million or \$1.09 per share as of September 30, 2010 and December 31, 2010. The Company will continue to evaluate the carrying value of this investment as appropriate. If the Company subsequently determines that the value of its Medafor common stock has been impaired further or if the Company decides to sell its 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.

The gain on valuation of derivative was zero and \$1.3 million for the three and twelve months ended December 31, 2010, respectively. During the fourth quarter of 2009 and during 2010, the Company made several purchases of Medafor common stock that contained purchase price make-whole provisions, which the Company accounted for as embedded derivatives. The decrease in the value of the liability for these embedded derivatives, largely resulting from a significant decrease in the likelihood of a triggering event occurring, resulted in a non-cash gain for the twelve months ended December 31, 2010. CryoLife believes that the likelihood of a triggering event occurring was substantially reduced in the first quarter of 2010 and was zero as of December 31, 2010 and thereafter.

### Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Income before income taxes	\$ 3,458	\$ 3,672	\$ 7,277	\$ 14,354
Income tax expense	1,343	1,306	3,333	5,675
Net income	\$ 2,115	\$ 2,366	\$ 3,944	\$ 8,679
Diluted income per common share	\$ 0.08	\$ 0.08	\$ 0.14	\$ 0.31

Income before income taxes decreased for the three months and the twelve months ended December 31, 2010 as compared to the three and twelve months ended December 31, 2009. Income before income taxes for the three and 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 39% and 46% for the three and twelve months ended December 31, 2010, respectively, as compared to 36% and 40% for the three and twelve months ended December 31, 2009. The Company's income tax rate for the twelve months ended December 31, 2010 was negatively impacted by the write-downs and expenses discussed above, which reduced income before income taxes.





Net income and diluted income per common share for the three and twelve months ended December 31, 2010 decreased compared to the corresponding periods in 2009 due to the decrease in income before income taxes and income taxes 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. Management believes that this trend is lessening in recent years as the Company is distributing a higher percentage of its tissues to adult populations.

The Company believes the demand for its vascular preservation services is seasonal, with lowest demand generally occurring in the fourth quarter, although this trend was not apparent in 2011. Management will continue to evaluate this trend in future periods to determine if its vascular business continues to be seasonal.

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 in a growth phase generally associated with a recently introduced product that has not fully penetrated the marketplace, the nature of any seasonal trends in PerClot sales may be obscured, although management believes that PerClot may exhibit a similar trend as BioGlue, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter.

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.

### **Liquidity and Capital Resources**

#### ***Net Working Capital***

At December 31, 2011 net working capital (current assets of \$83.9 million less current liabilities of \$21.5 million) was \$62.4 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of \$82.2 million and a current ratio of 5 to 1 at December 31, 2010.

#### ***Overall Liquidity and Capital Resources***

The Company's largest cash requirement for the twelve months ended December 31, 2011 was the acquisition of all of the outstanding common stock of Cardiogenesis and related transaction costs. On May 17, 2011 CryoLife completed its acquisition of all of the outstanding shares of Cardiogenesis for \$0.457 per share or approximately \$21.7 million. CryoLife used cash on hand to fund the transaction and operates Cardiogenesis as a wholly owned subsidiary. In July 2011 the Company paid approximately \$3.5 million to purchase an equity investment in ValveXchange, 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 used cash on hand to fund this investment. The Company's other cash requirements included cash for general working capital needs, the payment of legal and professional fees, and repurchases of the Company's common stock. Legal and professional fees during the three and twelve months ended December 31, 2011 included business development costs, primarily costs associated with the Company's acquisition of Cardiogenesis, other business development activities, and costs associated with the Company's litigation with Medafor. The Company funded its cash requirements primarily through its existing cash reserves and its operating activities, which generated cash during the period.

On October 28, 2011 CryoLife amended and restated its March 26, 2008 credit agreement with GE Capital (the GE Credit Agreement) which provides revolving credit for working capital, acquisitions, and other corporate purposes. The amendment increased the borrowing capacity under the GE Credit Agreement from \$15.0 million to \$20.0 million (including a letter of credit subfacility) and extended the expiration from October 31, 2011 to October 28, 2014. The initial commitment may continue to 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 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, 2011 the outstanding balance under the GE Credit Agreement was zero and \$19.8 million was available for borrowing.

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 a previously announced June 1, 2010 \$15.0 million stock repurchase program and an additional \$7.3 million. For the year ended December 31, 2011 the Company purchased approximately 593,000 shares of its common stock for an aggregate purchase price of \$2.9 million. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions. The Company expects to have sufficient working capital and cash flow from operations to fund its common stock repurchases.

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, 2011 \$1.2 million of the Company's cash equivalents were related to these DOD Grants, which must be used for the specified purposes. As of December 31, 2011 less than 5% of the Company's cash and cash equivalents were held in foreign jurisdictions.

The Company has agreed to provide funding of up to \$2.0 million in debt financing to ValveXchange through a revolving credit facility. The Company cannot currently anticipate if or when ValveXchange may draw funding from this credit facility.

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 clinical trials, including the PerClot and Cardiogenesis clinical trials, to fund other business development activities, to purchase license agreements, for general working capital needs, to fund the Medafor litigation and other litigation, to fund the ValveXchange revolving credit facility, to repurchase the Company's common stock, and for other corporate purposes. These items may have a significant impact on its cash flows during 2012. The Company may seek additional borrowing capacity to fund additional business development activities or other future cash requirements, and will be required to obtain such funding to finance significant future business development activities.

The Company acquired net operating loss carryforwards from its acquisition of Cardiogenesis and the Company has tax credit carryforwards from prior year income tax returns. The Company believes that the utilization of these tax carryforwards will reduce required cash payments for federal income taxes by approximately \$1.8 million for the 2012 tax year.

#### ***Net Cash from Operating Activities***

Net cash provided by operating activities was \$16.8 million for the twelve months ended December 31, 2011 as compared to \$20.8 million for the twelve months ended December 31, 2010. The current year cash provided was primarily due to net income generated by the Company during the period and non-cash expenses, partially offset by increases in working capital needs, primarily due to the Company's acquisition of Cardiogenesis in May 2011.

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, 2011 these non-cash items included a favorable \$5.0 million in depreciation and amortization expense, \$2.8 million in non-cash stock based compensation, and \$1.8 million in deferred income taxes.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the twelve months ended December 31, 2011 these changes included an unfavorable \$2.2 million due to the timing difference between recording receivables and the receipt of cash, an unfavorable \$772,000 due to the timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the actual payment of cash and an unfavorable \$617,000 due to the timing difference between making cash payments and the expensing of assets, including prepaid insurance policy premiums, partially offset by a favorable \$2.4 million due to decreases in deferred preservation costs and inventory balances.

**Net Cash from Investing Activities**

Net cash used in investing activities was \$27.7 million for the twelve months ended December 31, 2011 as compared to \$10.7 million for the twelve months ended December 31, 2010. The current year cash used was primarily due to the payment of \$21.1 million for the acquisition of Cardiogenesis, net of cash acquired, the investment of \$3.6 million for ValveXchange preferred stock, and \$2.5 million in capital expenditures.

**Net Cash from Financing Activities**

Net cash used in financing activities was \$2.8 million for the twelve months ended December 31, 2011 as compared to \$4.7 million for the twelve months ended December 31, 2010. The current year cash used was primarily due to \$3.1 million in purchases of treasury stock, largely related to the Company's publicly announced stock repurchase plan.

**Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of December 31, 2011 are as follows (in thousands):

	<b>Total</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>Thereafter</b>
Operating leases	\$ 26,848	\$ 2,452	\$ 2,611	\$ 2,598	\$ 2,589	\$ 2,633	\$ 13,965
Purchase commitments	8,761	3,216	3,580	1,965			
Research obligations	4,606	2,443	1,189	972	2		
PerClot contingent payments	2,000	500		1,500			
Compensation payments	1,985		992	993			
<b>Total contractual obligations</b>	<b>\$ 44,200</b>	<b>\$ 8,611</b>	<b>\$ 8,372</b>	<b>\$ 8,028</b>	<b>\$ 2,591</b>	<b>\$ 2,633</b>	<b>\$ 13,965</b>

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

The Company's purchase commitments include minimum purchase requirements for PerClot related to the Company's transaction with SMI. These minimum purchases are included through 2014, as the Company expects to receive FDA approval for PerClot no later than 2014. 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 from 2015 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 Company's research obligations represent commitments for ongoing studies and payments to support research and development activities, which will be partially funded by the advances received under the DOD Grants.

The obligation for PerClot contingent payments represents the contingent milestone payments that the Company will pay 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 estimated payments for post-employment benefits for the Company's Chief Executive Officer (CEO). The timing of the CEO's post-employment benefits is based on the December 2012 expiration date of the CEO's employment agreement. Payment of this benefit may be accelerated by a change in control or by the voluntary retirement of the CEO.

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a pending settlement agreement or other contractual obligation and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$1.9 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made for specific litigation or by any taxing authorities.



---

**Capital Expenditures**

Capital expenditures for the twelve months ended December 31, 2011 were \$2.5 million compared to \$2.1 million for the twelve months ended December 31, 2010. Capital expenditures in the twelve months ended December 31, 2011 were primarily related to the routine purchases of tissue processing, manufacturing, computer, and office equipment; computer software; and renovations to the Company's corporate headquarters 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 \$21.7 million and restricted securities of \$5.0 million and interest paid on the Company's variable rate line of credit as of December 31, 2011. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the twelve months ended December 31, 2011, 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, 2011 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, 2011 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, 2011 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 Cardiogenesis Corporation ( Cardiogenesis ) during the second quarter of 2011. Management s assessment and conclusion on the effectiveness of the Company s disclosure controls and procedures as of December 31, 2011 excludes an assessment of the internal control over financial reporting of Cardiogenesis.

During the quarter ended December 31, 2011 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, 2011, 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, 2011.

**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, 2011.

**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, 2011.

**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, 2011.

---

**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.)
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007.)
3.2	Reserved.
3.3	Reserved.
3.4	Reserved.
3.5	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed July 27, 2011.)
4.1	Reserved.
4.2	Form of Certificate for the Company's Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
4.3	Reserved.
4.4	Reserved.
4.5	Reserved.
4.6	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.)
10.1	Reserved.
10.2+	Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc. as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.)
10.2(a)	First Amendment, dated May 7, 2009, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc. as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.9(a) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.)



Exhibit	Number	Description
	10.2(b)+	Second Amendment, dated November 9, 2009, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc. as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.9(a) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.)
	10.2(c)+	Third Amendment, dated January 12, 2010, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)
	10.2(d)	Fourth Amendment, dated May 28, 2010, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.)
	10.2(e)	Fifth Amendment, dated March 2, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)
	10.2(f)	Sixth Amendment, dated June 30, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)
	10.2(g)	Seventh Amendment, dated August 30, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.)
	10.2(h)*+	Amended and Restated Credit Agreement, dated October 28, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner.
	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.)
	10.4	CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Appendix 1 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
	10.5	Reserved.
	10.6+	Agreement between CryoLife, Inc. and Medafor, Inc. dated April 18, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.)
	10.7	Form of 2009 Grant Agreement to Executive Officers pursuant to the 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, 2009.)
	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.)

Exhibit Number	Description
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	Second Amended and Restated Employment Agreement by and between the Company and Steven G. Anderson dated as of November 4, 2008, as amended December 31, 2009. (Incorporated herein by reference to Exhibit 10.9(b) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.)
10.9(a)	Change of Control Agreement, by and between the Company and Albert E. Heacox, Ph.D., dated May 5, 2009. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed May 8, 2009.)
10.9(b)*	Change of Control Agreement, by and between the Company and Jeffrey W. Burris, dated February 5, 2010.
10.9(c)	Change of Control Agreement, by and between the Company and D. Ashley Lee, dated October 24, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed October 28, 2008.)
10.9(d)	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)*	Summary of Modifications to Compensation Arrangements with Albert E. Heacox, Ph.D.
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 Aml 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 Aml 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 Aml Land Development I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(b) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.16(c)	Amended and Restated Lease Agreement between the Company and Aml 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.)

Exhibit Number	Description
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.)
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.)

## Edgar Filing: CRYOLIFE INC - Form 10-K

Exhibit Number	Description
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 2010 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)
10.48	Correction of Form of 2010 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.48 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010.)
10.49	Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)
10.50+	Distribution Agreement between the Company and Starch Medical, Inc., dated September 28, 2010. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed January 18, 2012.)





Edgar Filing: CRYOLIFE INC - Form 10-K

Exhibit Number	Description
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.
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.)
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. Second Amended and Restated Employment Agreement by and between the Company and Steven G. Anderson dated as of November 4, 2008, as amended December 31, 2009. (Incorporated herein by reference to Exhibit 10.9(b) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.)
3. Change of Control Agreement, by and between the Company and Albert E. Heacox, Ph.D., dated May 5, 2009. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed May 8, 2009.)
4. \*Change of Control Agreement, by and between the Company and Jeffrey W. Burris, dated February 5, 2010.
5. Change of Control Agreement, by and between the Company and D. Ashley Lee, dated October 24, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed October 28, 2008.)
6. 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.)
7. Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
8. Form of Key Employee Secrecy and Noncompete Agreement, by and between the Company and its Officers and Key Employees. (Incorporated herein by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
9. CryoLife, Inc. 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. 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.)
11. 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.)
12. 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.)
13. 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.)

Edgar Filing: CRYOLIFE INC - Form 10-K

14. 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.)
  
15. 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.)
  
16. 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.)

## Edgar Filing: CRYOLIFE INC - Form 10-K

---

17. 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.)
18. 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.)
19. 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.)
20. 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.)
21. 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.)
22. \*Summary of Salaries for Named Executive Officers.
23. 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.)
24. 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.)
25. 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.)
26. 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.)
27. 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.)
28. 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.)
29. 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.)

## Edgar Filing: CRYOLIFE INC - Form 10-K

30. 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.)
31. 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.)
32. 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.)

33. Form of 2009 Grant Agreement to Executive Officers pursuant to the 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, 2009.)
34. 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.)
35. 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.)
36. 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.)
37. \*Summary of Compensation Arrangements with Non-Employee Directors.
38. 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.)
39. 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.)
40. 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.)
41. 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.)
42. 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.)
43. 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.)
44. Form of 2010 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)
45. Correction of Form of 2010 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.48 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010.)
- 46.

## Edgar Filing: CRYOLIFE INC - Form 10-K

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.)

47. 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.)
48. 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.)



49. 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.)
50. 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.)
51. \*Summary of Modifications to Compensation Arrangements with Albert E. Heacox, Ph.D.
52. 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.)
53. 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.)
54. 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.)
55. 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.)

\* Filed herewith.

**SIGNATURES**

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

February 17, 2012

CRYOLIFE, INC.

By /s/ STEVEN G. ANDERSON

**Steven G. Anderson**  
 President, Chief Executive Officer, and  
 Chairman of the Board of Directors

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

Signature	Title	Date
<i>/s/ STEVEN G. ANDERSON</i>	President, Chief Executive Officer, and Chairman of the Board of Directors	February 17, 2012
<b>Steven G. Anderson</b>	(Principal Executive Officer) Executive Vice President,	February 17, 2012
<i>/s/ D. ASHLEY LEE</i>	Chief Operating Officer, and Chief Financial Officer	
<b>D. Ashley Lee</b>		
<i>/s/ AMY D. HORTON</i>	(Principal Financial Officer) Chief Accounting Officer	February 17, 2012
<b>Amy D. Horton</b>	(Principal Accounting Officer)	
<i>/s/ THOMAS F. ACKERMAN</i>	Director	February 17, 2012
<b>Thomas F. Ackerman</b>		
<i>/s/ JAMES S. BENSON</i>	Director	February 17, 2012
<b>James S. Benson</b>		
<i>/s/ DANIEL J. BEVEVINO</i>	Director	February 17, 2012
<b>Daniel J. Bebevino</b>		
<i>/s/ RONALD C. ELKINS, M.D.</i>	Director	February 17, 2012
<b>Ronald C. Elkins, M.D.</b>		

Edgar Filing: CRYOLIFE INC - Form 10-K

/s/ RONALD D. McCALL

Director

February 17, 2012

**Ronald D. McCall**

/s/ HARVEY MORGAN

Director

February 17, 2012

**Harvey Morgan**

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

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

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

CryoLife management assessed the effectiveness of CryoLife's internal control over financial reporting as of December 31, 2011. In making this assessment, we used the criteria set forth in the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment, we believe that, as of December 31, 2011, the company's internal control over financial reporting was effective based on those criteria.

CryoLife's independent registered public accounting firm, Deloitte and Touche LLP, has issued an audit report on the effectiveness of CryoLife's internal control over financial reporting as of December 31, 2011.

CryoLife, Inc.

February 17, 2012

---

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of

CryoLife, Inc.

Kennesaw, Georgia

We have audited the internal control over financial reporting of CryoLife, Inc. and subsidiaries (the Company) as of December 31, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting under Sarbanes-Oxley Section 404. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2011 of the Company and our report dated February 17, 2012 expressed an unqualified opinion on those financial statements.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 17, 2012

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of

CryoLife, Inc.

Kennesaw, Georgia

We have audited the accompanying consolidated balance sheets of CryoLife, Inc. and subsidiaries (the Company) as of December 31, 2011 and 2010, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2011 based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 17, 2012 expressed an unqualified opinion on the Company's internal control over financial reporting.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 17, 2012

**CRYOLIFE, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(in thousands)**

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 21,705	\$ 35,497
Restricted securities	312	5,309
<b>Receivables:</b>		
Trade accounts, net	15,767	13,724
Other	1,738	589
<b>Total receivables</b>	<b>17,505</b>	<b>14,313</b>
Deferred preservation costs	29,039	31,570
Inventories	7,320	6,429
Deferred income taxes	5,247	6,096
Prepaid expenses and other assets	2,742	2,276
<b>Total current assets</b>	<b>83,870</b>	<b>101,490</b>
<b>Property and equipment:</b>		
Equipment and software	21,664	20,622
Furniture and fixtures	4,163	3,837
Leasehold improvements	29,348	29,111
Total property and equipment	55,175	53,570
Less accumulated depreciation and amortization	42,867	40,484
<b>Net property and equipment</b>	<b>12,308</b>	<b>13,086</b>
<b>Other assets:</b>		
Investment in equity securities	6,248	2,594
Restricted securities	5,000	
Goodwill	4,220	
Patents, less accumulated amortization of \$2,871 in 2011 and \$2,603 in 2010	2,739	3,282
Trademarks and other intangibles, less accumulated amortization of \$1,300 in 2011 and \$397 in 2010	17,656	5,601
Deferred income taxes	13,265	9,182
Other	2,558	2,203
<b>Total assets</b>	<b>\$ 147,864</b>	<b>\$ 137,438</b>

See accompanying Notes to Consolidated Financial Statements.

**CRYOLIFE, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(in thousands, except per share data)**

	December 31,	
	2011	2010
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 4,370	\$ 4,243
Accrued compensation	3,946	3,357
Accrued procurement fees	3,982	3,081
Accrued expenses	5,131	4,434
Deferred income	1,890	2,095
Other	2,138	2,118
<b>Total current liabilities</b>	<b>21,457</b>	<b>19,328</b>
Other	4,869	4,168
<b>Total liabilities</b>	<b>26,326</b>	<b>23,496</b>
<b>Commitments and contingencies</b>		
<b>Shareholders equity:</b>		
Preferred stock \$0.01 par value per share, 5,000 shares authorized, no shares issued:		
Series A Junior Participating Preferred Stock, 2,000 shares authorized, no shares issued		
Convertible preferred stock, 460 shares authorized, no shares issued		
Common stock \$0.01 par value per share, 75,000 shares authorized, 30,067 shares issued in 2011 and 29,950 shares issued in 2010	301	300
Additional paid-in capital	135,003	133,845
Retained deficit	(1,037)	(8,408)
Accumulated other comprehensive loss	(6)	(32)
Treasury stock at cost, 2,265 shares in 2011 and 2,049 shares in 2010	(12,723)	(11,763)
<b>Total shareholders equity</b>	<b>121,538</b>	<b>113,942</b>
<b>Total liabilities and shareholders equity</b>	<b>\$ 147,864</b>	<b>\$ 137,438</b>

See accompanying Notes to Consolidated Financial Statements.



**CRYOLIFE, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF OPERATIONS**  
(in thousands, except per share data)

	Year Ended December 31,		
	2011	2010	2009
<b>Revenues:</b>			
Preservation services	\$ 59,793	\$ 59,724	\$ 56,456
Products	59,387	56,370	54,162
Other	446	551	1,067
<b>Total revenues</b>	<b>119,626</b>	<b>116,645</b>	<b>111,685</b>
<b>Cost of preservation services and products:</b>			
Preservation services	34,340	35,868	32,767
Products	9,442	12,409	9,150
<b>Total cost of preservation services and products</b>	<b>43,782</b>	<b>48,277</b>	<b>41,917</b>
<b>Gross margin</b>	<b>75,844</b>	<b>68,368</b>	<b>69,768</b>
<b>Operating expenses:</b>			
General, administrative, and marketing	57,302	49,064	50,025
Research and development	6,899	5,923	5,247
Acquired in-process research and development		3,513	
<b>Total operating expenses</b>	<b>64,201</b>	<b>58,500</b>	<b>55,272</b>
<b>Operating income</b>	<b>11,643</b>	<b>9,868</b>	<b>14,496</b>
Interest expense	142	180	83
Interest income	(14)	(23)	(76)
Gain on valuation of derivative		(1,345)	(24)
Other than temporary investment impairment		3,638	
Other expense, net	49	141	159
<b>Income before income taxes</b>	<b>11,466</b>	<b>7,277</b>	<b>14,354</b>
Income tax expense	4,095	3,333	5,675
<b>Net income</b>	<b>\$ 7,371</b>	<b>\$ 3,944</b>	<b>\$ 8,679</b>
<b>Income per common share:</b>			
Basic	<b>\$ 0.26</b>	<b>\$ 0.14</b>	<b>\$ 0.31</b>
Diluted	<b>\$ 0.26</b>	<b>\$ 0.14</b>	<b>\$ 0.30</b>

Edgar Filing: CRYOLIFE INC - Form 10-K

**Weighted-average common shares outstanding:**

Basic	27,441	27,987	28,106
Diluted	27,759	28,274	28,310

See accompanying Notes to Consolidated Financial Statements.

F-6

## CRYOLIFE, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENT OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2011	2010	2009
<b>Net cash flows from operating activities:</b>			
Net income	\$ 7,371	\$ 3,944	\$ 8,679
Adjustments to reconcile net income to net cash from operating activities:	4,960	3,937	4,263
Depreciation and amortization			
Non-cash compensation	2,790	2,621	2,429
Deferred income taxes	1,767	(1,509)	5,254
Excess tax shortfall (benefit) from stock based compensation	445	(1,275)	
Write down of deferred preservation costs and inventories	270	2,093	489
Write-down of intangible asset	255	921	
Other than temporary investment impairment		3,638	
Acquired in-process research and development expense		3,513	
Gain on valuation of derivative		(1,345)	(24)
Other non-cash adjustments to income	67	185	187
Changes in operating assets and liabilities:			
Receivables	(2,230)	179	(745)
Deferred preservation costs and inventories	2,445	3,098	(1,140)
Prepaid expenses and other assets	(617)	(1,539)	(353)
Accounts payable, accrued expenses, and other liabilities	(772)	2,376	(2,467)
<b>Net cash flows provided by operating activities</b>	<b>16,751</b>	<b>20,837</b>	<b>16,572</b>
<b>Net cash flows from investing activities:</b>			
Acquisition of Cardiogenesis, net of cash acquired	(21,062)		
Acquisition of PerClot intangible assets		(5,411)	
Capital expenditures	(2,538)	(2,121)	(1,690)
Purchases of restricted securities and investments	(3,569)	(2,705)	(3,036)
Sales and maturities of marketable securities			1,130
Other	(547)	(497)	(783)
<b>Net cash flows used in investing activities</b>	<b>(27,716)</b>	<b>(10,734)</b>	<b>(4,379)</b>
<b>Net cash flows from financing activities:</b>			
Proceeds from financing of insurance policies		1,179	1,272
Principal payments on debt, capital leases, and short-term notes payable	(31)	(1,537)	(1,328)
Proceeds from exercise of stock options and issuance of common stock	694	239	1,093
Repurchase of common stock	(3,064)	(5,877)	(330)
Excess tax (shortfall) benefit from stock based compensation	(445)	1,275	
<b>Net cash flows (used in) provided by financing activities</b>	<b>(2,846)</b>	<b>(4,721)</b>	<b>707</b>
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(13,811)</b>	<b>5,382</b>	<b>12,900</b>
Effect of exchange rate changes on cash	19	(6)	20
Cash and cash equivalents, beginning of year	35,497	30,121	17,201

<b>Cash and cash equivalents, end of year</b>	<b>\$ 21,705</b>	<b>\$ 35,497</b>	<b>\$ 30,121</b>
---	------------------	------------------	------------------

See accompanying Notes to Consolidated Financial Statements.

F-7

**CRYOLIFE, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT OF SHAREHOLDERS EQUITY**

(in thousands)

	Common Stock		Additional Paid In Capital	Retained Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Shareholders Equity
	Shares	Amount				Shares	Amount	
<b>Balance at December 31, 2008</b>	<b>29,102</b>	<b>\$ 291</b>	<b>\$ 124,744</b>	<b>\$ (21,031)</b>	<b>\$ (80)</b>	<b>(955)</b>	<b>\$ (5,556)</b>	<b>\$ 98,368</b>
Net income				8,679				8,679
Other comprehensive income					42			42
Comprehensive income								8,721
Equity compensation	160	2	2,677					2,679
Exercise of options	134	1	678			(45)	(330)	349
Employee stock purchase plan	79	1	413					414
Excess tax shortfall			(85)					(85)
<b>Balance at December 31, 2009</b>	<b>29,475</b>	<b>\$ 295</b>	<b>\$ 128,427</b>	<b>\$ (12,352)</b>	<b>\$ (38)</b>	<b>(1,000)</b>	<b>\$ (5,886)</b>	<b>\$ 110,446</b>
Net income				3,944				3,944
Other comprehensive income					6			6
Comprehensive income								3,950
Equity compensation	219	2	2,918			(18)	(117)	2,803
Exercise of options	4		18					18
Employee stock purchase plan	43	1	220					221
Excess tax benefit			1,275					1,275
Repurchase of common stock						(1,031)	(5,760)	(5,760)
Stock issued for SMI transaction	209	2	987					989
<b>Balance at December 31, 2010</b>	<b>29,950</b>	<b>\$ 300</b>	<b>\$ 133,845</b>	<b>\$ (8,408)</b>	<b>\$ (32)</b>	<b>(2,049)</b>	<b>\$ (11,763)</b>	<b>\$ 113,942</b>
Net income				7,371				7,371
Other comprehensive income					26			26
Comprehensive income								7,397
Equity compensation	(31)		937			360	2,077	3,014
Exercise of options	84	1	380			37	27	408
Employee stock purchase plan	64		286					286
Excess tax shortfall			(445)					(445)
Repurchase of common stock						(613)	(3,064)	(3,064)
<b>Balance at December 31, 2011</b>	<b>30,067</b>	<b>\$ 301</b>	<b>\$ 135,003</b>	<b>\$ (1,037)</b>	<b>\$ (6)</b>	<b>(2,265)</b>	<b>\$ (12,723)</b>	<b>\$ 121,538</b>

See accompanying Notes to Consolidated Financial Statements.



---

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies**

*Nature of Business*

CryoLife, Inc. (CryoLife, the Company, we, or us) 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<sup>®</sup> SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch<sup>®</sup> SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife's proprietary SynerGraft<sup>®</sup> technology. CryoLife's surgical sealants and hemostats include BioGlue<sup>®</sup> Surgical Adhesive (BioGlue), BioFoam<sup>®</sup> Surgical Matrix (BioFoam), and PerClot<sup>®</sup> 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 that are used to treat patients with severe angina.

*Principles of Consolidation*

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

*Translation of Foreign Currencies*

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

*Use of Estimates*

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

*Revenue Recognition*

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

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





The Company assesses the likelihood of collection based on a number of factors, including past transaction history with the customer and the credit worthiness of the customer.

### ***Shipping and Handling Charges***

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

### ***Advertising Costs***

The costs to develop, produce, and communicate the Company's advertising are expensed as incurred and are classified as general, administrative, and marketing expenses. The Company records the cost to print or copy certain sales materials as a prepaid expense and amortizes these costs as an advertising expense over the period they are expected to be used, typically six months to one year. The total amount of advertising expense included in the Company's Consolidated Statements of Operations was \$948,000, \$846,000, and \$1.4 million for the years ended December 31, 2011, 2010, and 2009, respectively.

### ***Stock-Based Compensation***

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

The Company recognizes the cost of all share-based payments in the financial statements using a fair-value based measurement method. The Company values its RSAs and RSUs based on the stock price on the date of grant and expenses the related compensation cost using the straight-line method over the vesting period. The Company uses a Black-Scholes model to value its stock option grants, including the Company's ESPP options, and expenses the related compensation cost using the straight-line method over the vesting period.

The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, volatility, dividend yield, and the risk-free interest rate. The expected term is primarily based on the contractual term of the option and Company data related to historic exercise and post-vesting forfeiture patterns, which is adjusted based on management's expectations of future results. The expected term is determined separately for options issued to the Company's directors and to employees. The Company's anticipated volatility level is primarily based on the historic volatility of the Company's common stock, adjusted to remove the effects of certain periods of unusual volatility not expected to recur, and adjusted based on management's expectations of future volatility, for the life of the option or option group. The Company's model includes a zero dividend yield assumption in all periods, as the Company has not historically paid, nor does it anticipate paying, dividends on its common stock. The risk-free interest rate is based on recent U.S. Treasury note auction results with a similar life to that of the option. The Company's model does not include a discount for post-vesting restrictions, as the Company has not issued awards with such restrictions. The period expense is then determined based on this valuation and, at that time, an estimated forfeiture rate is used to reduce the expense recorded. The Company's estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company and is adjusted to reflect actual forfeitures at each vesting date.

### ***Income Per Common Share***

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

Under the two class method, net income is allocated to the weighted-average number of common shares outstanding during the period and the weighted average participating securities outstanding during the period. The portion of net income that is allocated to the participating securities is excluded from basic and dilutive net income per common share. Diluted net

income per share is computed using the weighted-average number of common shares outstanding plus the dilutive effects of outstanding stock options and awards and other dilutive instruments as appropriate.

### **Financial Instruments**

The Company's financial instruments include cash equivalents, marketable securities, restricted securities, accounts receivable, and accounts payable. The Company typically values financial assets and liabilities such as receivables, accounts payable, and debt obligations at their carrying values, which approximate fair value due to their generally short-term duration.

The Company records certain financial instruments at fair value, including: cash equivalents, certain marketable securities, and certain restricted securities. These financial instruments are discussed in further detail in the notes below. 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, 2011 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the 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 require judgment. 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.

The Company also measures certain non-financial assets at fair value on a non-recurring basis when applying accounting for business combinations or when asset impairments are recorded. The Company uses the fair value hierarchy above to value these assets and reports these fair values in the periods in which they are recorded or written down.

A summary of financial instruments measured at fair value as of December 31, 2011 and 2010 is as follows (in thousands):

<b>December 31, 2011</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Cash equivalents:</b>				
Money market funds	\$	\$ 7,334	\$	\$ 7,334
<b>Restricted securities:</b>				
Money market funds		5,312		5,312
<b>Total assets</b>	<b>\$</b>	<b>\$ 12,646</b>	<b>\$</b>	<b>\$ 12,646</b>

<b>December 31, 2010</b>				
<b>Cash equivalents:</b>				
Money market funds	\$	\$ 2,056	\$	\$ 2,056
U.S. Treasury debt securities	14,099			14,099
<b>Restricted securities:</b>				
Money market funds		309		309
U.S. Treasury debt securities	5,000			5,000
<b>Total assets</b>	<b>\$ 19,099</b>	<b>\$ 2,365</b>	<b>\$</b>	<b>\$ 21,464</b>

During the years ended December 31, 2011 and 2010 the Company initially recorded certain non-financial assets at fair value related to the acquisition of Cardiogenesis and the acquisition of the PerClot assets from SMI. Disclosures of these initial fair value determinations are included in Note 4 and Note 5 below.

## Edgar Filing: CRYOLIFE INC - Form 10-K

No non-financial assets were measured at fair value on a non-recurring basis after initial recognition in the Company's Consolidated Balance Sheets as of December 31, 2011. A summary of the non-financial assets measured at fair value on a non-recurring basis after initial recognition in the Company's Consolidated Balance Sheets as of December 31, 2010 follows (in thousands):

F-11

<b>December 31, 2010</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Investment in equity securities	\$	\$	\$ 2,594	\$ 2,594

See Note 6 for further discussion of the investment in equity securities of Medafor common stock. The Company uses prices quoted from its investment management companies to determine the level 2 valuation of its investments in money market funds and securities. Refer to the discussion of the inputs and methods used in the non-recurring valuation of the Company's assets acquired from Cardiogenesis in Note 4 and SMI in Note 5 below.

### ***Cash and Cash Equivalents***

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

The Company's cash equivalents include advance funding received under the U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the ( DOD Grants ), for the continued development of protein hydrogel technology. The advance funding is accounted for as deferred income on the Consolidated Balance Sheets. Such revenue is recognized as expenses are incurred related to these grants. As of December 31, 2011 and 2010 \$1.2 million and \$1.7 million, respectively, of cash equivalents were related to these grants. These funds must be used for the specified purposes.

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

	<b>2011</b>	<b>2010</b>	<b>2009</b>
Cash paid during the year for:			
Interest	\$ 89	\$ 143	\$ 25
Income taxes	3,564	2,502	540

Non-cash investing and financing activities:

Issuance of common stock for acquisition of PerClot intangible assets	\$	\$ 989	\$
Initial value of derivative issued		620	749

### ***Marketable Securities and Other Investments***

The Company typically invests in large, well-capitalized financial institutions, and the Company's policy excludes investment in any securities rated less than investment-grade by national rating services, unless specifically approved by the board of directors.

The Company determines the classification of its investments as trading, available-for-sale, or held-to-maturity at the time of purchase and reevaluates such designations quarterly. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Debt securities are classified as held-to-maturity when the Company has the intent and ability to hold the securities to maturity. Any securities not designated as trading or held-to-maturity are considered available-for-sale.

The Company typically states its investments at their fair values; however, for held-to-maturity securities or when current fair value information is not readily available, investments are recorded using the cost method. The cost of securities sold is based on the specific identification method.

Under the fair value method, the Company uses quoted prices in active markets for each security. The Company adjusts each investment to its quoted price and records the unrealized gains or losses in other income (expense), net for trading securities, or accumulated other comprehensive income (loss), for available-for-sale securities. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in other income (expense), net.

Under the cost method, each investment is recorded at cost. Subsequent dividends received are recognized as income, and the investment is reviewed for impairment if factors indicate that a decrease in the value of the investment has occurred. The Company's total cost method investments were \$6.2 million and \$2.6 million, as of December 31, 2011 and 2010, respectively. See Notes 3 and 6 for further discussion of the Company's cost method investments and the evaluation of these investments for impairment.



---

***Deferred Preservation Costs***

By federal law, human tissues cannot be bought or sold. Therefore, the tissues the Company preserves and processes are not held as inventory. Donated human tissues are procured from deceased human donors by tissue banks and organ procurement organizations ( OTPOs ), which consign the tissues to the Company for processing, preservation, and distribution. Although the Company cannot own human tissues, the preservation process is a manufacturing process that is accounted for using the same principles as inventory costing. Preservation costs consist primarily of direct labor and materials (including salary and fringe benefits, laboratory expenses, tissue procurement fees, and freight-in charges) and indirect costs (including allocations of costs from departments that support processing and preservation activities and facility allocations).

Preservation costs are stated at the lower of cost or market value on a first-in, first-out basis and are deferred until recognized in cost of preservation upon shipment of the tissue to an implanting facility. The allocation of fixed production overhead costs is based on actual production levels, to the extent that they are within the range of the facility's normal capacity. Cost of preservation services also includes, as incurred, idle facility expense, excessive spoilage, extra freight, and rehandling costs.

The calculation of deferred preservation costs involves a high degree of judgment and complexity. The costs included in deferred preservation costs contain several estimates due to the timing differences between the occurrence of the cost and receipt of final bills for services. Costs that contain estimates include tissue procurement fees, which are estimated based on the Company's contracts with independent OTPOs, and freight-in charges, which are estimated based on the Company's prior experiences with these charges. These costs are adjusted for differences between estimated and actual fees when invoices for these services are received. Management believes that its estimates approximate the actual costs of these services, but estimates could differ from actual costs. Total deferred preservation costs are then allocated among the different tissues processed during the period based on specific cost drivers such as the number of donors and the 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 determines this estimate of quarantine yields based on its experience in prior periods and reevaluates this estimate periodically. Due to the nature of this estimate and the length of the processing times experienced by the Company, actual yields could differ from the Company's estimates. A significant change in quarantine yields could result in an adjustment to or write-down of deferred preservation costs and, therefore, materially affect the amount of deferred preservation costs on the Company's Consolidated Balance Sheets and the cost of preservation services on the Company's Consolidated Statements of Operations.

As a part of the normal course of business, the Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value or if there is any impairment to the costs for tissues not expected to ship prior to the expiration date of its packaging. The Company records a charge to cost of preservation services to write down the amount of deferred preservation costs not deemed to be recoverable. Typically, lower of cost or market value write-downs are primarily due to excess tissue processing costs incurred that exceed the estimated market value of the tissue services, based on then recent average service fees. Impairment write-downs are recorded based on the book value of the impaired tissues. Actual results may differ from these estimates. These write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if the market value of tissue services increase or when tissues are shipped or become available for shipment.

The Company recorded write-downs to its deferred preservation costs totaling \$270,000, \$187,000, and \$91,000 for the years ended December 31, 2011, 2010, and 2009, respectively.

As of December 31, 2011 deferred preservation costs consisted of \$10.2 million for heart valves, \$2.4 million for cardiac patch tissues, and \$16.4 million for vascular tissues. As of December 31, 2010 deferred preservation costs consisted of \$12.0 million for heart valves, \$2.5 million for cardiac patch tissues, and \$17.1 million for vascular tissues.

***Inventories***

Inventories are comprised of BioGlue; BioFoam; PerClot; revascularization technologies lasers, handpieces, and accessories; other medical devices; supplies; and raw materials. Inventory costs for manufactured products consist primarily of direct labor and materials (including salary and fringe benefits, raw materials, and supplies) and indirect costs (including allocations of costs from departments that support manufacturing activities and facility allocations). Inventory costs for products purchased for resale or contract manufactured consist primarily of the purchase cost, freight-in charges, and indirect costs as appropriate.

Inventories are valued at the lower of cost or market on a first-in, first-out basis and the costs are recognized as cost of products upon shipment of the product. The allocation of fixed production overhead costs is based on actual production levels, to the extent that they are within the range of the facility's normal capacity. Cost of products also includes, as incurred, idle facility expense, excessive spoilage, extra freight, and rehandling costs.

As a part of the normal course of business, the Company regularly evaluates its inventory to determine if the costs are appropriately recorded at the lower of cost or market value or if there is any impairment to inventory for products not expected to ship prior to their expiration. The Company records a charge to cost of products to write down the amount of inventory not deemed to be recoverable. Actual results may differ from these estimates. These write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if these estimates change or if the inventory is sold.

The Company recorded write-downs to its inventory totaling zero, \$1.9 million, and \$25,000 for the years ended December 31, 2011, 2010, and 2009, respectively. The 2010 amount was primarily due to a \$1.6 million write-down of HemoStase inventory as discussed in Note 6.

### **Property and Equipment**

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

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

	<b>2011</b>	<b>2010</b>	<b>2009</b>
Depreciation expense	\$ 3,590	\$ 3,366	\$ 3,711

### **Goodwill and Other Intangible Assets**

The Company's intangible assets consist of goodwill, patents, trademarks, and other intangible assets, as discussed further below. These assets include intangible assets from the acquisition of Cardiogenesis, as discussed in Note 4, and PerClot distribution and manufacturing rights acquired from SMI, as discussed in Note 5.

The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. As of December 31, 2011 and 2010 gross carrying values, accumulated amortization, and approximate amortization periods of the Company's definite lived intangible assets are as follows (dollars in thousands):

	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Amortization Period</b>
<b>December 31, 2011</b>			
Acquired technology	\$ 9,230	\$ 524	11 Years
Patents	5,610	2,871	17 Years
Distribution and manufacturing rights and know-how	3,559	231	15 Years
Customer lists and relationships	2,370	114	13 Years
Non-compete agreement	381	191	10 Years
Other	114	48	2-3 Years

### **December 31, 2010**

Patents	\$ 5,885	\$ 2,603	17 Years
Distribution and manufacturing rights	2,559	43	15 Years
Non-compete agreement	381	152	10 Years
Customer lists	64	11	3 Years

During the year ended December 31, 2010 CryoLife wrote off approximately \$729,000 in previously capitalized legal fees associated with BioGlue patent litigation in Germany, as the Company determined that it was no longer probable that it would prevail in this patent defense litigation.





Edgar Filing: CRYOLIFE INC - Form 10-K

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

	2011	2010	2009
Amortization expense	\$ 1,370	\$ 571	\$ 552

As of December 31, 2011 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2012	2013	2014	2015	2016	Total
Amortization expense	\$ 1,797	\$ 1,692	\$ 1,594	\$ 1,567	\$ 1,554	\$ 8,204

The Company's indefinite lived intangible assets do not amortize, but are instead subject to periodic impairment testing as discussed in *Impairments of Long-Lived Assets and Non-Amortizing Intangible Assets* below. Based on its prior experience with similar agreements, the Company believes that its acquired contracts and procurement agreements have an indefinite useful life, as the Company expects to continue to renew these contracts for the foreseeable future. The Company believes that its trademarks and other acquired technology have an indefinite useful life as the Company currently anticipates that these trademarks and other acquired technology will contribute cash flows to the Company indefinitely.

As of December 31, 2011 and 2010 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	2011	2010
Goodwill	\$ 4,220	\$
Procurement contracts and agreements	2,013	2,013
Trademarks	847	790
Other	250	

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

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

Significant underperformance relative to expected historical or projected future operating results,

Significant negative industry or economic trends,

Significant decline in the Company's stock price for a sustained period, or

Significant decline in the Company's market capitalization relative to net book value.

If CryoLife determines that an impairment review is necessary, the Company will evaluate its assets or asset groups by comparing their carrying values to the sum of the undiscounted future cash flows expected to result from their use and eventual disposition. If the carrying values exceed the future cash flows, then the asset or asset group is considered impaired, and the Company will write down the value of the asset or asset group. For the years ended December 31, 2011, 2010, and 2009 the Company did not experience any factors that indicated that an impairment review of its long-lived assets was warranted.

CryoLife evaluates its goodwill and other non-amortizing intangible assets for impairment on an annual basis as of October 31 and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of December 31, 2011 the Company's non-amortizing intangible assets consisted of acquired procurement contracts and agreements, trademarks, and other acquired technology. The Company performed an analysis of its non-amortizing intangible assets as of December 31, 2011 and 2010, and determined that the fair value of the assets exceeded their carrying value and were, therefore, not impaired. Management will continue to evaluate the recoverability of these

non-amortizing intangible assets on an annual basis.

***Accrued Procurement Fees***

Tissue is procured from deceased human donors by OTPOs, which consign the tissue to the Company for processing, preservation, and distribution. The Company reimburses the OTPOs for their costs to recover the tissue and passes these costs on to the customer when the tissue is shipped and the performance of the service is complete. The Company accrues estimated

procurement fees due to the OTPOs at the time tissues are received based on contractual agreements between the Company and the OTPOs.

### ***Liability Claims***

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

The Company estimates its liability and any related recoverable under the Company's insurance policies as of each balance sheet date. The Company uses a frequency-severity approach to estimate its unreported tissue processing and product liability claims, whereby, projected losses are calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims are determined based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim is calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The Company uses a number of assumptions in order to estimate the unreported loss liability including:

A ceiling of \$5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5.0 million,

The future claim reporting lag time would be a blend of the Company's experiences and industry data,

The frequency of reported claims would be based on the Company's past experience for policy years 1993/1994 through the present with consideration given to the frequency spike experienced in policy year 2002/2003,

The average cost per claim would be consistent with the Company's historical experience, adjusted to current cost levels,

The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on these product lines,

The number of BioGlue claims per million dollars of BioGlue revenue would be 60% lower than non-BioGlue claims per million dollars of revenue. The 60% factor was selected based on BioGlue claims experience to date and consultation with the actuary, and

The number of Cardiogenesis claims per million dollars of Cardiogenesis revenue would be 85% lower than non-Cardiogenesis claims per million dollars of revenue. The 85% factor was selected based on Cardiogenesis claims experience to date and consultation with the actuary.

The Company believes that the assumptions it uses to determine its unreported loss liability provide a reasonable basis for its calculation. However, the accuracy of the estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors, actual results may differ significantly from the assumptions used and amounts accrued.

The analysis performed generates a range of estimates of the Company's unreported loss liability. The Company records its determination of the most likely estimate. The Company accrues its estimate of unreported tissue processing and product liability claims as components of accrued expenses and other long-term liabilities and records the related recoverable insurance amounts as a component of receivables and other long-term assets. The amounts recorded represent management's estimate of the probable losses and anticipated recoveries for unreported claims

related to services performed and products sold prior to the balance sheet date.

***Legal Contingencies***

The Company accrues losses from a legal contingency when the loss is both probable and reasonably estimable. The accuracy of the Company's estimates of losses for legal contingencies is limited by uncertainties surrounding litigation. Therefore, actual results may differ significantly from the amounts accrued, if any. The Company accrues for legal

contingencies as a component of accrued expenses and other long-term liabilities. Gains from legal contingencies are recorded when the contingency is resolved and the Company is reasonably certain of collectability.

#### ***Legal Fees***

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

#### ***Uncertain Tax Positions***

The Company periodically assesses its uncertain tax positions and recognizes tax benefits if they are more-likely-than-not to be upheld upon review by the appropriate taxing authority. The Company measures the tax benefit by determining the maximum amount that has a greater than 50 percent likelihood of ultimately being realized. The Company reverses previously accrued liabilities for uncertain tax positions when audits are concluded, statutes expire, administrative practices dictate that a liability is no longer warranted, or in other circumstances as deemed necessary. These assessments can be complex and the Company often obtains assistance from external advisors to make these assessments. The Company recognizes interest and penalties related to uncertain tax positions in other (expense) income, net on its Consolidated Statement of Operations. See Note 14 for further discussion of the Company's liabilities for uncertain tax positions.

#### ***Deferred Income Taxes***

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company periodically assesses the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance against 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 a high degree of 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 deferred tax assets will be limited in future periods due to a change in control of its subsidiary Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, as a result of the Company's acquisition of

## Edgar Filing: CRYOLIFE INC - Form 10-K

Cardiogenesis in the second quarter of 2011. 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 this change in control.

The Company's tax years 2008 through 2011 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2008, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

F-17

---

### ***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.

### ***Derivative Instruments***

The Company determines the fair value of its stand-alone and embedded derivative instruments at issuance and records any resulting asset or liability on the Company's Consolidated Balance Sheets. Changes in the fair value of the derivative instruments are recognized in the line item change in valuation of derivative on the Company's Consolidated Statements of Operations.

### ***New Accounting Pronouncements***

In May 2011 the Financial Accounting Standard Board (FASB) issued 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. ASU 2011-04 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-04 to have a material effect on its financial condition, profitability, and cash flows.

In June 2011 the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income* which requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income, or in two separate but consecutive statements and eliminates the option to present components of other comprehensive income as part of the statement of equity. In December 2011 the FASB issued ASU 2011-12, which deferred the guidance on whether to require entities to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement where net income is presented and the statement where other comprehensive income is presented for both interim and annual financial statements. ASU 2011-12 reinstated the requirements for the presentation of reclassifications that were in place prior to the issuance of ASU 2011-05 and did not change the effective date for ASU 2011-05. ASU 2011-05 and ASU 2011-12 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-05 and ASU 2011-12 to have a material effect on its financial condition, profitability, and cash flows.

In September 2011 the FASB issued 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. If the qualitative assessment indicates that the fair value of a reporting unit is more likely than not less than the carrying amount, the two-step impairment test would be required. Otherwise, further testing would not be needed. ASU 2011-08 will be effective for the Company beginning January 1, 2012, and the Company does not expect the adoption of ASU 2011-08 to have a material effect on its financial condition, profitability, and cash flows.

## 2. Cash Equivalents and Marketable Securities

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

	Cost Basis	Unrealized Holding Gains	Estimated Market Value
<b>December 31, 2011</b>			
Cash equivalents:			
Money market funds	\$ 7,334	\$	\$ 7,334
Restricted securities:			
Money market funds	5,312		5,312
<b>December 31, 2010</b>			
Cash equivalents:			
Money market funds	\$ 2,056	\$	\$ 2,056
U.S. Treasury debt securities	14,099		14,099
Restricted securities:			
Money market funds	309		309
U.S. Treasury debt securities	5,000		5,000

As of December 31, 2011 and 2010 \$312,000 and \$309,000, respectively, of the Company's money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating to international tax obligations. As of December 31, 2011 \$5.0 million of the Company's money market funds and as of December 31, 2010 \$5.0 million of the Company's U.S. Treasury debt securities were designated as restricted securities due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation (GE Capital). The Company amended and restated the credit agreement with GE Capital in the fourth quarter of 2011 as discussed in Note 8. As of December 31, 2011 the restriction on the Company's money market funds lapses when then credit agreement with GE Capital expires.

There were no gross realized gains or losses on cash equivalents or restricted securities for the years ended December 31, 2011, 2010, and 2009. At December 31, 2011 \$5.0 million of the Company's restricted securities had no maturity date and \$312,000 of the Company's restricted securities had a maturity date within three months. At December 31, 2010 \$5.3 million of the Company's restricted securities had a maturity date within three months.

## 3. Investment in ValveXchange

### *Investment*

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. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. The Company's carrying value of this investment includes the purchase price and certain transaction costs and CryoLife's investment represents an approximate 19% equity ownership in ValveXchange. As ValveXchange's stock is not actively traded on any public stock exchange and as the Company's investment is in preferred stock, the Company accounted for this investment using the cost method. The Company recorded its investment as a long-term asset, investment in equity securities, on the Company's Consolidated Balance Sheet.

The Company will evaluate the carrying value of the ValveXchange Preferred Stock investment if factors become known that indicate an impairment review is warranted. If the Company subsequently determines that the value of its ValveXchange





stock has been impaired, or if the Company decides to sell its ValveXchange Preferred Stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in ValveXchange could be material. During the year ended December 31, 2011, the Company reviewed available information and determined that no factors were present indicating that the Company should evaluate its investment in ValveXchange Preferred Stock for impairment.

#### ***Loan Agreement***

In July 2011 the Company entered into an agreement with ValveXchange to make available up to \$2.0 million to ValveXchange in debt financing through a revolving credit facility ( ValveXchange Loan ). The ValveXchange Loan includes various affirmative and negative covenants, including financial covenant requirements, and expires on July 30, 2018, unless terminated earlier. Amounts loaned under the ValveXchange Loan earn interest at an 8% annual rate and are secured by substantially all of the tangible and intangible assets of ValveXchange. The Company incurred loan origination costs, net of fees charged to ValveXchange, of approximately \$117,000, which will be expensed on a straight-line basis over the life of the loan facility. The Company will record advances to ValveXchange as long-term notes receivable. As of December 31, 2011 there were no outstanding receivable balances under the ValveXchange Loan and the remaining availability was \$2.0 million.

#### ***Option Agreement***

Concurrently with the ValveXchange Loan described above, CryoLife entered into an option agreement with ValveXchange through which CryoLife obtained the right of first refusal to acquire ValveXchange during a period that extends through the completion of initial commercialization milestones and the right to negotiate with ValveXchange for European distribution rights.

### **4. Cardiogenesis Acquisition**

#### ***Overview***

On May 17, 2011 CryoLife completed its acquisition of all of the outstanding shares of Cardiogenesis for \$0.457 per share or approximately \$21.7 million. CryoLife used cash on hand to fund the transaction and operates Cardiogenesis as a wholly owned subsidiary.

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 its revascularization technologies, which include the Holmium: YAG laser console and single use, fiber-optic handpieces. The system is FDA approved for performing a surgical procedure known as Transmyocardial Revascularization , used for treating patients with stable angina that is not responsive to conventional therapy.

#### ***Accounting for the Transaction***

The Company has recorded an allocation of the \$21.7 million purchase price to Cardiogenesis' tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of May 17, 2011. The allocation of the purchase price to intangible assets was based on valuations performed to determine the fair value of such assets as of the acquisition date. Goodwill has been recorded based on the amount by which the purchase price exceeds the fair value of the net assets acquired. The liability amounts recorded include the Company's estimate of contingent liabilities assumed. The accuracy of the amounts recorded is based on information available to the Company. If the value of the assets acquired or liabilities assumed by the Company 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.

## Edgar Filing: CRYOLIFE INC - Form 10-K

The purchase price allocation as of December 31, 2011 is as follows (in thousands):

	<b>Opening Balance Sheet</b>
Cash and cash equivalents	\$ 650
Receivables	1,055
Inventory	852
Property and equipment	248
Intangible assets	11,900
Goodwill	4,220
Net deferred tax assets	5,002
Other assets	230
Liabilities assumed	(2,445)
 Total purchase price	 \$ 21,712

CryoLife incurred approximately \$3.0 million in transaction and integration costs related to the acquisition in the year ended December 31, 2011.

### ***Pro Forma***

Cardiogenesis revenues of \$5.7 million from the date of acquisition are included in the Company's Consolidated Statement of Operations for the year ended December 31, 2011. Selected unaudited pro forma results of operations for the years ended December 31, 2011, 2010, and 2009 assuming the Cardiogenesis acquisition had occurred as of January 1, 2009, are presented for comparative purposes below (in thousands, except per share data):

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Total revenues	\$ 123,951	\$ 127,935	\$ 122,039
Net income	7,962	3,176	5,610

Pro forma results for the year ended December 31, 2009 include CryoLife's acquisition and integration related costs of approximately \$3.0 million, on a pre-tax basis, and other costs as appropriate. Pro forma disclosures were calculated using a tax rate of approximately 36%.

### ***Legal Action***

On February 19, 2008 CardioFocus, Inc. ( CardioFocus ) filed a complaint in the U.S. District Court for the District of Massachusetts (the Massachusetts Court ) against Cardiogenesis, CryoLife's wholly owned subsidiary, acquired on May 17, 2011 and a number of other companies. In the complaint CardioFocus alleges that Cardiogenesis and the other defendants had previously violated patent rights allegedly held by CardioFocus directed to the use of holmium-doped YAG lasers in connection with low-hydroxyl content silica fibers for use in performing surgery. All of the asserted patents have now expired and the Company is the sole remaining defendant in the action. CardioFocus seeks a reasonable royalty pursuant to the Georgia Pacific factors for Cardiogenesis' sales of its accused products, namely, the SolarGen, TMR, and New Star lasers and lasers systems, during the period 2002 to 2007.

Since the filing of the lawsuit in February of 2008, Cardiogenesis has filed numerous requests for reexamination of the two patents being asserted against Cardiogenesis with the U.S. Patent and Trademark Office ( USPTO ). Through these reexaminations three asserted claims from two patents have survived. Specifically, Claim 2 of U.S. Patent No. 6,547,780 (the 780 Patent ) and Claims 2 and 7 of U.S. Patent No. 5,843,073 (the 073 Patent ) were confirmed by the USPTO. Notwithstanding the confirmation of the asserted claims, CryoLife and Cardiogenesis believe that significant issues concerning the validity, enforceability, and non-infringement of the asserted patents continue to exist.

On August 15, 2011 at the request of both parties, the Massachusetts Court lifted the stay and entered a Scheduling Order. Pursuant to the Scheduling Order, a claims construction hearing or so-called Markman Hearing occurred on October 21, 2011. On November 3, 2011 the Massachusetts Court issued a claim construction ruling that construed certain claim terms in favor of CardioFocus's position. On November 14,

## Edgar Filing: CRYOLIFE INC - Form 10-K

2011 Cardiogenesis filed a motion for reconsideration of the Massachusetts Court's construction of certain claim terms. In addition, Cardiogenesis has filed additional reexamination requests for the three claims with the USPTO, but the USPTO has denied the reexamination requests. Cardiogenesis has

F-21

filed petitions with the USPTO for reconsideration of those denials. The parties are currently in the expert witness phase of discovery, with trial scheduled for June 18, 2012.

The Company intends to defend itself vigorously in this action. At this time the Company is unable to predict the outcome of this matter and believes that the outcome of this matter will not have a material adverse effect on the Company's results of operations or cash flows as there are still many pre-trial motions to be addressed and expert witness testimony to be analyzed. However, as this matter is ongoing, there is no assurance that this matter will be resolved favorably by the Company or will not result in a material liability to the Company, which could materially affect its results of operations and cash flows.

## 5. PerClot Technology Acquisition

### *Overview*

On September 28, 2010 CryoLife entered into a worldwide distribution agreement (the *Distribution Agreement*) and a license and manufacturing agreement (the *License 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. Under the terms of the agreements, CryoLife received the worldwide rights to commercialize PerClot for all approved surgical indications and a license to manufacture the PerClot product, subject to certain exclusions. CryoLife also received an assignment of the PerClot trademark from SMI as part of the terms of the agreements.

The *Distribution Agreement* contains certain minimum purchase requirements and has a term of 15 years. CryoLife may begin manufacturing PerClot under the terms of the *License Agreement*, which extends for an indefinite period. Upon FDA approval, the Company may terminate such minimum purchase requirements. Following the start of manufacturing and U.S. regulatory approval, CryoLife may terminate the *Distribution Agreement* and sell PerClot pursuant to the *License Agreement*. CryoLife will pay royalties to SMI at stated rates on net revenues of products manufactured under the *License Agreement*. In addition to allowing CryoLife to manufacture PerClot, the *License Agreement* granted CryoLife a three-year option to purchase certain remaining related technology from SMI, which the Company exercised in September 2011.

As part of the initial transaction, CryoLife paid SMI \$6.75 million in cash, which included \$1.5 million in cash for prepaid royalties, and approximately 209,000 shares of restricted CryoLife common stock. CryoLife 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 FDA regulatory and other commercial milestones are achieved.

### *Accounting for the Transaction*

CryoLife accounted for the agreements discussed above as an asset acquisition. The initial consideration aggregated approximately \$8.0 million, including: \$6.75 million in cash, restricted common stock valued at approximately \$1.0 million, and direct transaction costs. CryoLife recorded a non-current asset for the \$1.5 million in prepaid royalties, a deferred tax asset of \$145,000, and allocated the remaining consideration to the individual intangible assets acquired based on their relative fair values as determined by a valuation study. As a result, CryoLife recorded intangible assets of \$327,000 for the PerClot trademark, \$2.6 million for the PerClot distribution and manufacturing rights in certain international countries, and \$3.5 million for the 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 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 in the third quarter of 2010. The PerClot trademark acquired by the Company has an indefinite useful life; therefore, that asset will not be amortized, but will instead be subject to annual impairment testing. The \$2.6 million intangible asset will be amortized over its useful life of 15 years.

CryoLife expects to record future contingent payment amounts of up to \$2.5 million initially as research and development expense or, after FDA approval or issuance of a patent, as acquired intangible assets. As of December 31, 2011 CryoLife recorded research and development expenses of \$250,000 for the contractual milestone payment due to SMI upon filing of the IDE.

The common stock issued to SMI will be held by CryoLife until March 31, 2012, when the restricted provisions of the stock lapse.

### ***Starch Technology Purchase***

On September 2, 2011 CryoLife entered into an additional license agreement with SMI to purchase the technology to produce and use modified starch, the key component for manufacturing PerClot, for \$1.0 million plus transaction related expenses. The Company recorded the technology purchased as an intangible asset which will be amortized over its useful life of 14 years.

## **6. Medafor Matters**

### ***Overview***

CryoLife began distributing HemoStase in 2008 for Medafor under an EDA. In November 2009 and in 2010 the Company executed stock purchase agreements to purchase a total of approximately 2.4 million shares of common stock in Medafor for \$4.9 million. The Company's carrying value of this investment included the purchase price and adjustments to record certain of the stock purchase agreements' embedded derivative liabilities at the fair market value on the purchase date, as discussed further below. As Medafor's common stock is not actively traded on any public stock exchange, as Medafor is a non-reporting company for which financial information is not readily available, and as the Company does not exert significant influence over the operations of Medafor, the Company accounted for this investment using the cost method and recorded it as the long-term asset, investment in equity securities, on the Company's Consolidated Balance Sheets.

### ***HemoStase Inventory***

Based on Medafor's final termination of the EDA in late September 2010, the Company performed a review of its HemoStase inventory to determine if the carrying value of the inventory had been impaired. At the time of the termination, CryoLife expected to continue to sell HemoStase for a six-month period following the final termination of the EDA. As a result, the Company determined that the carrying value of the HemoStase inventory was impaired. The Company wrote down the value of its HemoStase inventory to \$1.7 million and recorded additional cost of products expense of \$1.6 million in the third quarter of 2010. The Company believed that the remaining \$1.7 million inventory balance was a reasonable estimate of the amount of inventory it would be able to distribute during the six-month period. The amount of this write-down reflected management's estimate based on information available at that time. As of December 31, 2011 and 2010 the Company had zero and \$559,000, respectively, in remaining value of HemoStase inventory on its Consolidated Balance Sheets.

The Company was able to sell more HemoStase than it originally estimated and that had previously been written down; therefore, cost of products in the year ended December 31, 2011 was favorably impacted by approximately \$330,000.

### ***Investment in Medafor Common Stock***

During the year ended December 31, 2010, the Company reviewed available information to determine if factors indicated that a decrease in value of the investment in Medafor common stock had occurred. CryoLife determined that the available information, particularly Medafor's termination of its largest distributor, indicated that the Company should evaluate its investment in Medafor common stock for impairment.

CryoLife used a market based approach for the valuation, including comparing Medafor to a variety of comparable publicly traded companies, recent merger targets, and company groups. CryoLife considered both qualitative and quantitative factors that could affect the valuation of Medafor's common stock. Based on its analysis, the Company believed that its investment in Medafor was impaired and that this impairment was other than temporary. Therefore, in the third quarter of 2010 CryoLife recorded a non-operating expense, other than temporary investment impairment, of \$3.6 million to write down its investment in Medafor common stock to \$2.6 million. During the year ended December 31, 2011 the Company reviewed available information and determined that no factors were present indicating that the Company should evaluate its investment in Medafor common stock for further impairment. The carrying value of the Company's 2.4 million shares of Medafor common stock was approximately \$2.6 million as of both December 31, 2011 and 2010.

The Company will continue to evaluate the carrying value of this investment if changes to the factors discussed above or additional factors become known that indicate the Company should evaluate its investment in Medafor common stock for

further impairment. If the Company subsequently determines that the value of its Medafor common stock has been impaired further, or if the Company decides to sell its 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.

### *Medafor Derivative*

Per the terms of certain of the stock purchase agreements for the Medafor shares discussed above, in the event that CryoLife acquires more than 50% of the diluted outstanding stock of Medafor or merges with Medafor within a three-year period from each respective agreement date (a Triggering Event), the last of which will expire on June 7, 2013, CryoLife is required to make a future per share payment (the Purchase Price Make-Whole Payment) to such sellers. The payment would be equal to the difference between an amount calculated using the average cost of any subsequent shares purchased, as defined in each respective agreement, and the price of the shares purchased pursuant to each applicable stock purchase agreement. The Company was required to account for these Purchase Price Make-Whole Payment provisions as embedded derivatives (collectively the Medafor Derivative).

CryoLife performed a valuation of the Medafor Derivative using a Black-Scholes model to estimate the future value of the shares on the purchase date. Management's assumptions as to the likelihood of a Triggering Event occurring coupled with the valuation of the Purchase Price Make-Whole Payment were then used to calculate the derivative liability. The fair value of the Medafor Derivative was initially recorded as an increase to the investment in equity securities and a corresponding derivative liability on the Company's Consolidated Balance Sheets. The Medafor Derivative was revalued quarterly, and any change in the value of the derivative subsequent to the purchase date was recorded in the Company's Consolidated Statements of Operations.

During the quarter ended March 31, 2010 the Company's estimate of the likelihood of a Triggering Event decreased significantly, largely due to the Company withdrawing its offer to purchase Medafor. As of December 31, 2011 and 2010 the Company believed that the likelihood of a Triggering Event was remote.

The value of the Medafor Derivative was zero as of both December 31, 2011 and 2010. The change in the value of the derivative recorded on the Consolidated Statements of Operations was zero and a gain of \$1.3 million for the year ended December 31, 2011 and 2010, respectively.

### *Legal Action*

#### *Background of Georgia Lawsuit*

On April 29, 2009 CryoLife filed a lawsuit against Medafor in the U.S. District Court for the Northern District of Georgia (the Georgia Court). The lawsuit arises out of CryoLife's now terminated EDA with Medafor, pursuant to which CryoLife had the right to distribute a product manufactured by Medafor (the Product) under the name HemoStase. The EDA gave CryoLife exclusive rights to market and distribute the Product in all applications in cardiac and vascular surgery in most of the U.S. and for all cardiac and vascular surgeries and most other types of general surgery applications in much of the rest of the world.

On March 18, 2010 Medafor notified CryoLife of its contention that CryoLife had repudiated the EDA, and that Medafor was thereby entitled to terminate the contract. Medafor asserted that it had made a valid statutory demand, in a February 10, 2010 letter to CryoLife, for adequate assurances of CryoLife's future performance under the EDA, and that CryoLife had repudiated the EDA by failing to respond in a timely manner. CryoLife filed a motion for preliminary injunction, on March 29, 2010, asking the Georgia Court to enjoin Medafor from proceeding with its termination of the EDA.

After two hearings, the Georgia Court, on September 20, 2010, issued an order denying CryoLife's request for a preliminary injunction against Medafor. Although the order denied the preliminary injunction, it did not address the merits of the parties' respective positions on the underlying issue of whether Medafor's termination of the EDA was wrongful. The Georgia Court stated that it viewed this question as more appropriately addressed after discovery and at summary judgment. On September 27, 2010 Medafor sent CryoLife a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes Medafor's termination of the EDA was wrongful.

#### *Overview of CryoLife's Claims*

CryoLife's lawsuit, as amended and supplemented, alleges that Medafor unlawfully terminated the EDA. It also asserts claims for breach of the EDA and fraud. CryoLife alleges that contrary to Medafor's representations in the EDA, Medafor

had numerous distribution agreements regarding the Product with other distributors in the U.S. and internationally, allowing these distributors to market and distribute the Product in the medical fields and territories given exclusively to the Company. Medafor is alleged to have knowingly and purposefully withheld from CryoLife disclosure that these competing agreements existed at the time the EDA was executed and to have intentionally misrepresented to CryoLife that no similar contracts existed, or that their timely termination was being arranged. The lawsuit also alleges that Medafor failed to take reasonable steps to prevent other distributors from distributing the Product in CryoLife's exclusive field within its exclusive territory, and that Medafor failed to take necessary actions to ensure the value of CryoLife's distributorship. Medafor denies these allegations.

CryoLife alleges that it brought these transgressions to Medafor's attention on numerous occasions and attempted to work with Medafor to secure its compliance with the terms of the parties' agreement, but Medafor refused to follow the terms of the EDA. Medafor's actions are alleged to have deprived CryoLife of significant sales volume and to have impaired and delayed CryoLife's development of relationships with customers in its exclusive field and territory. Medafor denies these allegations.

#### *CryoLife's Potential Damages*

CryoLife seeks to recover its damages from Medafor, punitive damages, and reimbursement of its attorneys' fees. In addition, CryoLife is seeking damages related to Medafor's wrongful termination of the EDA, which will be based upon CryoLife's lost profits for the period of time during which the EDA would have continued in effect but for Medafor's wrongful termination of it. The amount of these damages will be determined through discovery in the lawsuit. Also, CryoLife has alleged that Medafor has violated the Lanham Act and the Georgia Uniform Deceptive Trade Practices Act. No trial date has been set, although based on the Georgia Court's schedule, trial is not likely until 2013.

#### *Medafor's Counterclaims*

Medafor has asserted counterclaims against CryoLife that allege, among other things, breach of contract, violation of the Georgia Trade Secrets Act, tortious interference with business relationships, libel, violation of the Lanham Act, violation of Georgia's Uniform Deceptive Trade Practices Act, fraud and negligent misrepresentation, and conversion. In addition, Medafor requests that the Georgia Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Georgia Uniform Commercial Code.

#### *Summary of Medafor's Potential Damages Claims*

Pursuant to its counterclaims, Medafor seeks to recover its alleged damages from CryoLife, including from the alleged repudiation of the EDA, injunctive relief, prejudgment interest, punitive damages, and attorneys' fees and expenses. Until such time as the Georgia Court rules on Medafor's counterclaims and discovery in the lawsuit has finished, assessing the potential or likelihood that Medafor could prevail and the amount of damages that could be awarded to Medafor if it were to prevail will be difficult. CryoLife intends to vigorously prosecute the case, defend itself, and contest the matter.

#### *Discovery is Ongoing*

Written discovery began in this case on October 8, 2010. On July 5, 2011 the Georgia Court appointed a Discovery Special Master to manage and supervise discovery pursuant to a Joint Motion for Appointment of Special Master filed by the parties. Pursuant to that appointment, the parties have met repeatedly with the Special Master regarding discovery issues. A few depositions have been taken and depositions will continue through September 15, 2012, the date on which the Georgia Court has ordered that non-expert discovery end. The Georgia Court has scheduled a status conference for parties on April 10, 2012. Expert witness testimony and other pre-trial motions likely will not be concluded until 2013.

Pursuant to the Georgia Court's order, the parties have mediation scheduled for March 22 and March 23, 2012.

#### *Background of Minnesota Lawsuit*

On July 14, 2011 following CryoLife's demand to Medafor's Board of Directors that Medafor register its common stock under Section 12(g) of the Securities Exchange Act of 1934, as amended (the Exchange Act), Medafor filed a lawsuit against CryoLife in the U.S. District Court for the District of Minnesota (Minnesota Court). In that lawsuit, Medafor seeks a declaratory judgment that its December 31, 2010 reverse stock split reduced the number of Medafor shareholders to less than 500 and that, therefore, Medafor is not required to comply with the registration requirements of Section 12(g) of the Exchange Act (*i.e.*, not required to register as a public company with the SEC). Medafor's lawsuit also requests that the



Minnesota Court award Medafor its costs and expenses in the lawsuit. On August 5, 2011 CryoLife filed a Motion to Dismiss Medafor's claims, arguing that there was no subject matter jurisdiction over the claims because there was no private right cause of action under Section 12(g) of the Securities Exchange Act of 1934 and, therefore, Medafor had no right to the relief it sought *vis a vis* CryoLife. The Minnesota Court held a hearing on CryoLife's motion to Dismiss on October 11, 2011, and took the matter under advisement. The Minnesota Court ordered the parties to mediation, but cancelled that mediation in light of the upcoming mediation ordered by the Georgia Court. As of February 15, 2012 the Minnesota Court had not ruled on the Motion to Dismiss. At this time, CryoLife is unable to predict the outcome of this matter. The Company believes that the outcome of this Minnesota Court matter will not have a material adverse effect on its financial position, result of operations, or cash flow. But because this matter is ongoing, it is unclear whether this matter will ultimately be resolved in the Company's favor.

## 7. Inventories

Inventories at December 31 are comprised of the following (in thousands):

	2011	2010
Raw materials and supplies	\$ 4,759	\$ 4,301
Work-in-process	218	349
Finished goods	2,343	1,779
Total inventories	\$ 7,320	\$ 6,429

## 8. Debt

### *GE Credit Agreement*

On October 28, 2011 CryoLife amended and restated its March 26, 2008 credit agreement with GE Capital (the "GE Credit Agreement") which provides revolving credit for working capital, acquisitions, and other corporate purposes. The amendment increased the borrowing capacity under the GE Credit Agreement from \$15.0 million to \$20.0 million (including a letter of credit subfacility) and extended the expiration from October 31, 2011 to October 28, 2014. The initial commitment may continue to be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. Since 2009, as requested by the German courts, the Company has been maintaining a letter of credit relating to the Company's patent infringement legal proceeding against Tenaxis, Inc. in Germany, which reduces the aggregate borrowing capacity. The letter of credit had a one-year initial term and automatically renews for additional one-year periods.

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings subject to defined adjustments as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as restricted securities as of December 31, 2011 and 2010 on the Company's Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined within the agreement, of at least \$20.0 million. The GE Credit Agreement includes customary conditions on incurring new indebtedness and prohibits payments of cash dividends on the Company's common stock. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. As of December 31, 2011 the Company was in compliance with the covenants of the GE Credit Agreement.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest as determined by GE Capital at either LIBOR, with a minimum rate of 4.25%, or GE Capital's base rate, with a minimum rate of 3.25% each, plus the applicable margin. As of December 31, 2011 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate was 6.50%, and the remaining availability was \$19.8 million. As of December 31, 2010 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate was 6.25%, and the remaining availability was \$14.8 million.

**Other**

In March 2010 the Company entered into an agreement to finance approximately \$1.2 million in insurance premiums at a 2.707% annual interest rate, which was payable in equal monthly payments over a nine-month period. As of December 31, 2011 and 2010 the aggregate outstanding balances under this agreement were zero.

Total interest expense was \$142,000, \$180,000, and \$83,000 in 2011, 2010, and 2009, respectively, which included interest on debt, uncertain tax positions, and capital leases.

**9. Commitments and Contingencies**

**Leases**

The Company's operating lease obligations result from the lease of land and buildings that comprise the Company's corporate headquarters and manufacturing facilities, leases related to additional office and warehouse space, leases on Company vehicles, and leases on a variety of office equipment. In prior years, the Company's capital lease obligations resulted from the financing of certain of the Company's equipment. As of December 31, 2011 the remaining obligations under the Company's capital leases was zero.

The term of the lease of the land and buildings that comprise the Company's corporate headquarters was originally 15 years. During the second quarter of 2010 the Company signed an amendment to the lease on its corporate headquarters extending the lease until 2022. Certain of the Company's leases contain escalation clauses, rent concessions, and renewal options for additional periods. Rent expense is computed on the straight-line method over the lease term. The Company has a deferred rent accrual of \$1.6 million and \$1.5 million as of December 31, 2011 and 2010, respectively, recorded in other long-term liabilities, primarily related to the lease on its corporate headquarters. Total rental expense for operating leases was \$2.7 million in 2011 and \$2.6 million in both 2010 and 2009.

Future minimum operating lease payments under non-cancelable leases as of December 31, 2011 are as follows (in thousands):

	<b>Operating Leases</b>
2012	\$ 2,452
2013	2,611
2014	2,598
2015	2,588
2016	2,633
Thereafter	13,965
<b>Total minimum lease payments</b>	<b>\$ 26,847</b>

**Liability Claims**

At December 31, 2011 and 2010 the short-term and long-term portions of the unreported loss liability and any related recoverable insurance amounts are as follows (in thousands):

	<b>2011</b>	<b>2010</b>
Short-term liability	\$ 1,030	\$ 1,310
Long-term liability	960	1,310
<b>Total liability</b>	<b>1,990</b>	<b>2,620</b>
Short-term recoverable	350	500
Long-term recoverable	350	550

Edgar Filing: CRYOLIFE INC - Form 10-K

Total recoverable	700	1,050
Total net unreported loss liability	\$ 1,290	\$ 1,570

Further analysis indicated that the liability as of December 31, 2011 could be estimated to be as high as \$3.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

F-27

## 10. Common Stock Repurchase

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. From June 1, 2010 to September 30, 2011 the Company had purchased a total of 1.3 million shares of its common stock for an aggregate purchase price of \$7.3 million. 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 \$15.0 million stock repurchase program and an additional \$7.3 million. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions.

For the year ended December 31, 2011 the Company purchased approximately 593,000 shares of its common stock for an aggregate purchase price of \$2.9 million. For the year ended December 31, 2010 the Company purchased approximately 1.0 million shares of its common stock for an aggregate purchase price of \$5.8 million. These shares were accounted for as part of treasury stock, carried at cost, and reflected as a reduction of shareholders' equity on the Company's Consolidated Balance Sheets.

## 11. Shareholder Rights Plan

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

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

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

## 12. Employee Benefit Plans

### *401(k) Plan*

The Company has a 401(k) savings plan (the Plan) providing retirement benefits to all employees who have completed at least three months of service. In 2011 and 2010 the Company made matching contributions to the plan of 20% of each

participant's contribution for up to 5% of each participant's salary. The Company made matching contributions of 50% of each participant's contribution for up to 4% of each participant's salary in 2009. Total Company contributions approximated \$204,000, for the years ended December 31, 2011 and 2010, and \$456,000 for the year ended December 31, 2009. Additionally, the Company may make discretionary contributions to the Plan that are allocated to each participant's account. No discretionary contributions were made in any of the past three years.

### *Deferred Compensation Plan*

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

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

### *Employment Agreement*

The Company has an employment agreement with its Chief Executive Officer ( *CEO* ), which expires on December 31, 2012, that confers benefits which become payable upon a change in control or upon certain termination events. As of both December 31, 2011 and 2010, the Company has recorded \$2.1 million in other current liabilities on the Consolidated Balance Sheets representing benefits payable upon the CEO's voluntary retirement.

## **13. Stock Compensation**

### *Overview*

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of RSAs, RSUs, and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved ESPP for the benefit of its employees.

Under the Company's plans, the Company is currently authorized to grant the following number of shares and the Company has available for grant up to the following number of shares as of December 31, 2011 and 2010:

<b>Plan</b>	<b>Authorized Shares</b>	<b>Available for Grant</b>	
		<b>2011</b>	<b>2010</b>
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	917,000	981,000
2002 Stock Incentive Plan	974,000	7,000	243,000
2004 Employee Stock Incentive Plan	2,100,000	293,000	26,000
2008 Non-Employee Directors Stock Incentive Plan	300,000	88,000	119,000
2009 Employee Stock Incentive Plan	2,000,000	1,037,000	1,560,000
Total	7,274,000	2,342,000	2,929,000

During 2010 the Company amended the 1996 Discounted Employee Stock Purchase Plan to increase the authorized shares under the plan by 1.0 million shares. Upon the exercise of stock options or grants of RSAs, the Company may issue the required shares out of authorized but unissued common stock or out of treasury stock, at management's discretion.



**RSAs and RSUs**

In 2011 the Compensation Committee of the Company's Board of Directors authorized grants of RSAs and RSUs from approved stock incentive plans to non-employee Directors and certain Company executives, officers, and employees totaling 421,000 shares of common stock, which had an aggregate market value of \$2.2 million.

In 2010 the Compensation Committee of the Company's Board of Directors authorized grants of RSAs and RSUs from approved stock incentive plans to non-employee Directors and certain Company executives, officers, and employees totaling 278,000 shares of common stock, which had an aggregate market value of \$1.7 million.

In 2009 the Compensation Committee of the Company's Board of Directors authorized grants of RSAs from approved stock incentive plans to non-employee Directors and certain Company executives and officers totaling 160,000 shares of common stock, which had an aggregate market value of \$1.1 million.

A summary of stock grant activity for the years ended December 31, 2011, 2010, and 2009 is as follows:

	RSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2008		152,000	\$ 9.50
Granted		160,000	6.77
Vested		(45,000)	10.62
Unvested at December 31, 2009		267,000	7.67
Granted		219,000	5.93
Vested		(122,000)	6.34
Unvested at December 31, 2010		364,000	7.07
Granted		360,000	5.18
Vested		(128,000)	7.28
Forfeited		(44,000)	5.48
Unvested at December 31, 2011		552,000	5.91

	RSUs	Shares	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2009				\$
Granted		58,000		
Outstanding at December 31, 2010		58,000	1.85	313,000
Granted		61,000		
Vested		(19,000)		
Forfeited		(3,000)		

Edgar Filing: CRYOLIFE INC - Form 10-K

Outstanding at December 31, 2011	97,000	1.66	466,000
Vested and expected to vest	90,000	1.66	432,000
<i>Stock Options</i>			

The Compensation Committee of the Company's Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company executives and employees totaling 599,000, 451,000, and 438,000 shares in 2011, 2010, and 2009, respectively, with exercise prices equal to the stock prices on the respective grant dates.



Edgar Filing: CRYOLIFE INC - Form 10-K

A summary of the Company's stock option activity for the years ended December 31, 2011, 2010, and 2009 follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2008	1,773,000	\$ 7.23	3.63	\$ 7,174,000
Granted	438,000	4.83		
Exercised	(134,000)	5.08		
Forfeited	(26,000)	5.62		
Expired	(64,000)	5.50		
Outstanding at December 31, 2009	1,987,000	6.92	3.59	1,731,000
Granted	451,000	6.96		
Exercised	(4,000)	4.49		
Forfeited	(15,000)	6.11		
Expired	(138,000)	10.20		
Outstanding at December 31, 2010	2,281,000	6.74	3.46	603,000
Granted	599,000	5.13		
Exercised	(260,000)	4.53		
Forfeited	(100,000)	5.60		
Expired	(320,000)	5.30		
Outstanding at December 31, 2011	2,200,000	6.83	4.00	
Vested and expected to vest	2,163,000	6.85	3.96	
Exercisable at December 31, 2011	1,249,000	7.72	2.84	

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

	2011	2010	2009
Weighted-average fair value of options granted	\$ 2.54	\$ 3.34	\$ 2.40
Intrinsic value of options exercised	261,000	10,000	274,000

Employees purchased common stock totaling 64,000, 43,000, and 79,000 shares in 2011, 2010, and 2009, respectively, through the Company's ESPP.

**Stock Compensation Expense**

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

	2011		2010		2009	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	4.0 Years	.50 Years	3.8 Years	.38 Years	4.0 Years	.25 Years
Expected stock price volatility	.65	.39	.65	.47	.65	.75
Risk-free interest rate	1.25%	0.14%	1.25%	0.17%	1.51%	0.14%

## Edgar Filing: CRYOLIFE INC - Form 10-K

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

	<b>2011</b>	<b>2010</b>	<b>2009</b>
RSA and RSU expense	\$ 1,408	\$ 970	\$ 899
Stock option and ESPP option expense	1,606	1,950	1,780
<b>Total stock compensation expense</b>	<b>\$ 3,014</b>	<b>\$ 2,920</b>	<b>\$ 2,679</b>

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, and stock options issued in each respective year as well as those issued in prior periods that continue to vest during the period, and compensation related to the Company's ESPP. These amounts were recorded as stock compensation expense and were subject to the Company's normal allocation of expenses to deferred preservation costs and inventory costs. The Company capitalized \$224,000, \$299,000, and \$250,000 in the years ended December 31, 2011, 2010, and 2009,

respectively, of the stock compensation expense included in the table above into its deferred preservation costs and inventory costs.

As of December 31, 2011 the Company had a total of \$2.1 million in total unrecognized compensation costs related to unvested RSAs and RSUs, before considering the effect of expected forfeitures. As of December 31, 2011 this expense is expected to be recognized over a weighted-average period of 1.4 years for RSAs and 2.5 years for RSUs. As of December 31, 2011 there was approximately \$1.7 million in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of December 31, 2011 this expense is expected to be recognized over a weighted-average period of 1.6 years.

#### 14. Income Taxes

##### *Income Tax Expense*

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

	2011	2010	2009
Domestic	\$ 11,238	\$ 6,936	\$ 14,158
Foreign	228	341	196
<b>Income before income taxes</b>	<b>\$ 11,466</b>	<b>\$ 7,277</b>	<b>\$ 14,354</b>

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

	2011	2010	2009
<b>Current:</b>			
Federal	\$ 2,634	\$ 4,415	\$ 225
State	103	255	114
Foreign	84	46	82
	2,821	4,716	421
<b>Deferred:</b>			
Federal	1,087	(1,560)	5,022
State	183	158	255
Foreign	4	19	(23)
	1,274	(1,383)	5,254
<b>Income tax expense</b>	<b>\$ 4,095</b>	<b>\$ 3,333</b>	<b>\$ 5,675</b>

The Company's income tax expense in 2011, 2010, and 2009 included the Company's federal, state, and foreign tax obligations. The Company's effective income tax rate was approximately 36%, 46% and 40% for the years ended December 31, 2011, 2010, and 2009, respectively. The Company's effective income tax rate for the year 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.

Edgar Filing: CRYOLIFE INC - Form 10-K

The income tax expense amounts differ from the amounts computed by applying the U.S. federal statutory income tax rate of 35% to pretax income as a result of the following (in thousands):

	2011	2010	2009
Tax expense at statutory rate	\$ 4,013	\$ 2,547	\$ 5,024
Increase (reduction) in income taxes resulting from:			
Non-deductible transaction costs	540		
State income taxes, net of federal benefit	250	347	321
Equity compensation	149	334	334
Non-deductible entertainment expenses	142	129	129
Foreign income taxes	3	28	26
Domestic production activities deduction	(727)		
Research and development credit	(314)	(187)	(68)
Other	39	135	(91)
	\$ 4,095	\$ 3,333	\$ 5,675

*Deferred Taxes*

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

	2011	2010
Deferred tax assets:		
Allowance for bad debts	\$ 151	\$ 110
Deferred preservation costs and inventory reserves	699	1,401
Investment in equity securities	802	832
Property	2,380	2,197
Intangible assets		440
Accrued expenses	2,859	2,812
Loss carryforwards	11,842	2,942
Credit carryforwards	4,124	4,527
Stock compensation	1,636	1,455
Other	717	716
Less valuation allowance	(2,395)	(1,771)
Total deferred tax assets	22,815	15,661
Deferred tax liabilities:		
Prepaid items	(348)	(377)
Intangible assets	(3,935)	
Other	(20)	(6)
Total deferred tax liabilities	(4,303)	(383)
Total net deferred tax assets	\$ 18,512	\$ 15,278

As of December 31, 2011 the Company maintained a total of \$2.4 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$18.5 million. As of December 31, 2010 the Company maintained a total of \$1.8 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$15.3 million.

## Edgar Filing: CRYOLIFE INC - Form 10-K

The increase in the Company's net deferred tax assets is primarily due to the acquisition of Cardiogenesis in the second quarter of 2011, as Cardiogenesis had significant deferred tax assets, primarily due to its net operating loss carryforwards. 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 subsidiary Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisition of Cardiogenesis constitutes 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 this change 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 subsidiary Cardiogenesis. Due to Cardiogenesis' history of losses when operated as a stand-alone company, management believes it is more likely than not that these deferred tax assets will not be realized.

F-33

Therefore, the Company recorded a valuation allowance against these state net operating loss carryforwards. See also Note 4 above for a further discussion of the Company's acquisition of Cardiogenesis.

As of December 31, 2011 the Company had approximately \$2.9 million of tax-effected state net operating loss carryforwards that will begin to expire in 2012, \$887,000 in research and development tax credit carryforwards that will begin to expire in 2022, and \$180,000 in credits from the state of Texas that will fully expire by 2027. Additionally, at December 31, 2011 the Company had \$3.1 million in alternative minimum tax credit carryforwards that do not expire.

#### **Uncertain Tax Positions**

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

	2011	2010	2009
Beginning balance	\$ 1,822	\$ 1,742	\$ 1,799
Decreases related to prior year tax positions	(112)	(19)	(183)
Increases related to current year tax positions	78	99	136
Settlements			(10)
Ending balance	\$ 1,788	\$ 1,822	\$ 1,742

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

	2011	2010	2009
Beginning balance	\$ 391	\$ 342	\$ 431
Accrual of interest and penalties	65	49	83
Decreases related to prior year tax positions	(38)		(172)
Ending balance	\$ 418	\$ 391	\$ 342

As of December 31, 2011 the Company's total uncertain tax liability including interest and penalties of \$2.2 million was recorded as a reduction to deferred tax assets of \$309,000 and a non-current liability of \$1.9 million on the Company's Consolidated Balance Sheet. As of December 31, 2010 the Company's total uncertain tax liability including interest and penalties of \$2.2 million was recorded as a reduction to deferred tax assets of \$850,000 and a non-current liability of \$1.4 million on the Company's Consolidated Balance Sheet.

#### **Other**

The Company's tax years 2008 through 2011 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2008 in which net operating losses and tax credits have arisen are still open for examination by the tax authorities.

#### **15. Comprehensive Income**

The following is a summary of comprehensive income (in thousands):

	2011	2010	2009
Net income	\$ 7,371	\$ 3,944	\$ 8,679
Change in cumulative translation adjustment	26	6	42

Edgar Filing: CRYOLIFE INC - Form 10-K

Comprehensive income	\$ 7,397	\$ 3,950	\$ 8,721
----------------------	----------	----------	----------

The accumulated other comprehensive loss of \$6,000 and \$32,000 as of December 31, 2011 and 2010, respectively, consisted solely of currency translation adjustments.

F-34

**16. Income Per Common Share**

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

	2011	2010	2009
<b>Basic income per common share</b>			
Net income	\$ 7,371	\$ 3,944	\$ 8,679
Net income allocated to participating securities	(149)	(51)	(74)
Net income allocated to common shareholders	\$ 7,222	3,893	8,605
Basic weighted-average common shares outstanding	27,441	27,987	28,106
Basic income per common share	\$ 0.26	\$ 0.14	\$ 0.31
<b>Diluted income per common share</b>			
Net income	\$ 7,371	\$ 3,944	\$ 8,679
Net income allocated to participating securities	(147)	(50)	(74)
Net income allocated to common shareholders	\$ 7,224	3,894	8,605
Basic weighted-average common shares outstanding	27,441	27,987	28,106
Effect of dilutive options and awards <sup>a</sup>	318	287	204
Diluted weighted-average common shares outstanding	27,759	28,274	28,310
Diluted income per common share	\$ 0.26	\$ 0.14	\$ 0.30

<sup>a</sup> The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares, because the inclusion of these stock options would be antidilutive to income per common share. Accordingly, stock options to purchase 2.0 million, 1.5 million, and 1.3 million, shares for the years ended December 31, 2011, 2010, and 2009, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

In future periods, basic and diluted income per common share are expected to be affected by the fluctuations in the fair value of the Company's common stock, the exercise and issuance of additional stock options, the issuance of additional RSAs and RSUs, and stock repurchases as discussed in Note 13 above.

**17. Transactions with Related Parties**

The Company expensed \$45,000, \$22,000, and \$100,000 in 2011, 2010, and 2009, respectively, relating to supplies for clinical trials purchased from a company whose Chief Financial Officer is a member of the Company's Board of Directors and a shareholder of the Company. The Company also expensed zero, \$5.0 million, and \$2.6 million in 2011, 2010, and 2009, respectively, relating to purchases of HemoStase finished goods inventory from Medafor.

A member of the Company's Board of Directors and a shareholder of the Company is a current employee of and the former Chief of Thoracic Surgery of a university hospital that generated preservation services and product revenues of \$198,000, \$390,000, and \$439,000 with the Company in 2011, 2010, and 2009, respectively. Additionally, the son of this member of the Company's Board of Directors receives a retainer for performing heart and lung transplants from a medical center that generated preservation services and product revenues of \$219,000, \$189,000, and \$231,000 with the Company in 2011, 2010, and 2009, respectively.



## Edgar Filing: CRYOLIFE INC - Form 10-K

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

### **18. Segment and Geographic Information**

The Company has two reportable segments organized according to its services and products: Preservation Services and Medical Devices. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues during 2011 and 2010 and from shipments of previously preserved orthopaedic tissues during 2009. The

F-35

Edgar Filing: CRYOLIFE INC - Form 10-K

Medical Devices segment includes external revenues from product sales of BioGlue, BioFoam, PerClot, HemoStase, and revascularization technologies, as well as sales of other medical devices. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company's management, is segment gross margin, or net external revenues less cost of preservation services and products. The Company does not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below. The following table summarizes revenues, cost of services and products, and gross margins for the Company's operating segments (in thousands):

	2011	2010	2009
<b>Revenues:</b>			
Preservation services	\$ 59,793	\$ 59,724	\$ 56,456
Medical devices	59,387	56,370	54,162
Other <sup>a</sup>	446	551	1,067
<b>Total revenues</b>	<b>119,626</b>	<b>116,645</b>	<b>111,685</b>
<b>Cost of preservation services and products:</b>			
Preservation services	34,340	35,868	32,767
Medical devices	9,442	12,409	9,150
<b>Total cost of preservation services and products</b>	<b>43,782</b>	<b>48,277</b>	<b>41,917</b>
<b>Gross margin:</b>			
Preservation services	25,453	23,856	23,689
Medical devices	49,945	43,961	45,012
Other <sup>a</sup>	446	551	1,067
<b>Total gross margin</b>	<b>\$ 75,844</b>	<b>\$ 68,368</b>	<b>\$ 69,768</b>

Net revenues by product for the years ended December 31, 2011, 2010, and 2009 were as follows (in thousands):

	2011	2010	2009
<b>Preservation services:</b>			
Cardiac tissue	\$ 26,618	\$ 27,997	\$ 26,074
Vascular tissue	33,175	31,727	30,201
Orthopaedic tissue			181
<b>Total preservation services</b>	<b>59,793</b>	<b>59,724</b>	<b>56,456</b>
<b>Products:</b>			
BioGlue and BioFoam	49,455	47,383	47,906
PerClot	2,528	264	
HemoStase	1,699	8,793	6,008
Revascularization technologies	5,705		
Other medical devices		(70)	248
<b>Total products</b>	<b>59,387</b>	<b>56,370</b>	<b>54,162</b>
Other <sup>a</sup>	446	551	1,067
<b>Total revenues</b>	<b>\$ 119,626</b>	<b>\$ 116,645</b>	<b>\$ 111,685</b>

Edgar Filing: CRYOLIFE INC - Form 10-K

<sup>a</sup> For the years ended December 31, 2011, 2010 and 2009 the Other designation includes grant revenue.

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2011, 2010, and 2009 were as follows (in thousands):

	<b>2011</b>	<b>2010</b>	<b>2009</b>
U.S.	\$ 95,975	\$ 97,037	\$ 94,094
International	23,651	19,608	17,591
<b>Total</b>	<b>\$ 119,626</b>	<b>\$ 116,645</b>	<b>\$ 111,685</b>

At December 31, 2011 and 2010, over 95% of the long-lived assets of the Company were held in the U.S., where all Company manufacturing facilities and the corporate headquarters are located. At December 31, 2011 all of the Company's \$4.2 million in goodwill was allocated to its Medical Devices segment.

**SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

(in thousands, except per share data)

	First	Second	Third	Fourth
	Quarter	Quarter	Quarter	Quarter
<b>REVENUE:</b>				
2011	\$ 30,196	\$ 29,379	\$ 29,654	\$ 30,397
2010	29,717	29,263	28,443	29,222
2009	26,688	28,163	28,219	28,615
<b>GROSS MARGIN:</b>				
2011	\$ 18,504	\$ 19,053	\$ 18,912	\$ 19,375
2010	17,792	17,769	15,222*	17,585
2009	17,235	17,895	17,041	17,597
<b>NET INCOME (LOSS):</b>				
2011	\$ 1,666	\$ 1,820	\$ 2,019	\$ 1,866
2010	1,934	2,926	(3,031)*	2,115
2009	1,949	2,502	1,862	2,366
<b>INCOME (LOSS) PER COMMON SHARE DILUTED:</b>				
2011	\$ 0.06	\$ 0.07	\$ 0.07	\$ 0.07
2010	0.07	0.10	(0.11)*	0.08
2009	0.07	0.09	0.07	0.08

\* The third quarter 2010 gross margin, net loss, and loss per share-diluted includes the unfavorable effect of a \$1.6 million write-down of HemoStase inventory as a result of Medafor, Inc.'s termination of the distribution agreement between the parties. The third quarter 2010 net loss and loss per share-diluted also includes the unfavorable effects of \$3.5 million in acquired in-process research and development expense, as a result of the transaction with Starch Medical, Inc., and \$3.6 million for the other than temporary impairment of the Company's investment in Medafor common stock.