CRYOLIFE INC
Form 10-K
February 22, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

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

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

(Address of principal executive offices) (zip code)

Registrant s telephone number, including area code (770) 419-3355

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $.01 par value	New York Stock Exchange
Preferred Share Purchase Rights	New York Stock Exchange

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

None

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K Section 229.405 of this chapter is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

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

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

As of June 30, 2010, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $141,686,892, computed using the closing price of $5.39 per share of Common Stock on June 30, 2010, 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 11, 2011 the number of outstanding shares of Common Stock of the registrant was 27,704,394.

Documents Incorporated By Reference

Document	**Parts Into Which Incorporated**
Proxy Statement for the Annual Meeting of Stockholders to be filed within 120 days after December 31, 2010.	Part III

PART I

Item 1. Business.

Overview

CryoLife, Inc. (CryoLife , the Company , we , or us), incorporated in 1984 in Florida, preserves and distributes human tissues and develops, manufactures, and commercializes medical devices for cardiac and vascular transplant applications. The human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife s proprietary SynerGraft® technology. CryoLife s medical devices consist primarily of surgical adhesives, sealants, and hemostats including BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot®, which the Company began distributing for Starch Medical, Inc. (SMI) in October of 2010, and HemoStase®, which the Company currently distributes for Medafor, Inc. (Medafor), although CryoLife expects to discontinue sales of HemoStase in late March 2011 because Medafor terminated the HemoStase distribution agreement. The Company s international revenues were 17% of total revenues in 2010.

Preservation Services and Products

Tissue Preservation Services. CryoLife distributes preserved human cardiac and vascular tissue to implanting institutions throughout the U.S., Canada, and Europe. CryoLife processes and preserves cardiac and vascular tissue 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 treat 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 received a Section 510(k) (510(k)) clearance from the U.S. Food and Drug Administration (FDA) in February 2008 for its CryoValve SGPV, and in August 2009 the Company 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 pulmonary cardiac patch tissue processing.

Surgical Adhesives, 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 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). In October of 2010 CryoLife announced that BioGlue had received Shonin approval from the Japanese Ministry of Health, Labor, and Welfare (MHLW) 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 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 pores for the blood to enter, leading to cellular aggregation and enhanced hemostasis. BioFoam contains a foaming agent, which 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.

On September 28, 2010 CryoLife entered into a worldwide distribution agreement 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 powder 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, spinal, 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 2011 with the FDA to begin clinical trials for the purpose of obtaining Premarket Approval (PMA) to distribute PerClot in the U.S.

CryoLife has been distributing HemoStase under a private label exclusive distribution agreement with Medafor, (EDA) since 2008. On September 27 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful. CryoLife expects to continue to ship HemoStase through late March 2011. HemoStase is a microporous polysaccharide hemostatic agent (coagulant). The product is a plant-based, flowable powder engineered to rapidly dehydrate blood, enhancing clotting on contact. Pursuant to the EDA with Medafor, CryoLife was the exclusive distributor in the U.S. for cardiac and vascular surgery (excluding Department of Defense (DOD) hospitals) and the exclusive distributor internationally (excluding China and Japan) for cardiac, vascular, and general surgery subject to certain exclusions. Distribution of HemoStase began in the U.S., Canada, United Kingdom, Germany, and France in 2008. CryoLife began distribution in other international markets in 2009. CryoLife is currently in litigation with Medafor related to the EDA, discussed further below in Part I, Item 3, Legal Proceedings.

Research and Development

Through its continuing research and development activities, CryoLife uses its expertise in protein chemistry, biochemistry, and cell biology, 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 preserved tissues, medical devices, and other related technologies, to develop innovative techniques and products within these areas, to secure their commercial protection, to establish their efficacy, and then to market these techniques and products. In order to expand CryoLife s service and product offerings, the Company is in the process of developing or investigating several technologies and products. 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 generally 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.

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.

Recent Events

BioGlue Japan

In October of 2010 CryoLife announced that BioGlue Surgical Adhesive had received Shonin approval from the Japanese MHLW for use in the repair of aortic dissections. CryoLife s partner, Century Medical, Inc. (CMI), will distribute BioGlue in Japan for use in this subset of cardiac surgery. Prior to distribution, MHLW will need to complete certain additional steps, most notably review of CryoLife s quality management system and product reimbursement paperwork for Japanese authorities. As a result, the Company estimates that distribution in Japan will begin in the first half of 2011. CryoLife is the exclusive supplier of BioGlue to CMI. The Company estimates that the annual Japanese market for the use of surgical adhesives in the repair of aortic dissection is approximately $10 million, and the total annual market for the use of adhesives and sealants in Japan is approximately $150 million.

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 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.

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, and BioFoam.

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.

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, the storage and shipment of the preserved tissue, and the controlled thawing of the tissue. 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 tissue 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. CryoLife shipped approximately 74,600 heart valves and cardiac patch tissues from 1984 through 2010, including approximately 3,100 shipments in 2010. Revenues from cardiac tissue preservation services accounted for 24%, 23%, and 24% of total Company revenues in 2010, 2009, and 2008, respectively. 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

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offer advantages in certain areas over mechanical, porcine, and bovine heart valve alternatives. 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 more closely 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 June and August 2010 CryoLife received 510(k) clearance from the FDA for a five-year shelf-life on its CryoValve SGPV and its CryoPatch SG, respectively. In 2010 56% of pulmonary valves and 19% of cardiac patch tissues shipped by CryoLife were processed with the SynerGraft technology.

The Company estimates that in 2010 the total annual heart valve replacement and cardiac patch market in the U.S. was approximately $700 million. Management believes that of the $700 million, approximately $525 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 89,000 aortic, pulmonary, and tricuspid valve replacement surgeries were conducted in the U.S. in 2010.

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.

Vascular Tissue. The Company preserves small diameter human saphenous vein conduits (3mm to 6mm) for use in peripheral vascular reconstructions and coronary bypass surgery. 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 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 are ideal grafts for patients with previously infected graft sites. The Company also preserves femoral veins and arteries and aortoiliac arteries for bypass or reconstruction within infected surgical areas.

The Company shipped approximately 61,500 human vascular tissues from 1986 through 2010, including approximately 4,400 shipments in 2010. Revenues from vascular preservation services accounted for 27%, 27%, and 26% of total Company revenues in 2010, 2009, and 2008, respectively. The Company estimates the aggregate U.S. vascular surgical graft market was approximately $142 million in 2010. Management believes that of the $142 million, approximately $100 million or 88,000 procedures were for peripheral vascular reconstruction, coronary artery bypass surgeries, and abdominal aortic reconstruction for which the Company s tissues can be used. The Company also believes the lower limb bypass market was approximately 42,000 procedures in 2010 and of these 15,000 were below-the-knee bypasses.

Surgical Adhesives, Sealants, and Hemostats

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 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). BioGlue is pre-filled in 2ml, 5ml, and 10ml volumes.

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 $260 million in 2010.

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 and Australia. As discussed in Recent Events above, CryoLife received approval in October 2010 to distribute 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.

Revenues from BioGlue represented 41%, 43%, and 46% of total Company revenues in 2010, 2009, and 2008, 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 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 and 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. Since receiving initial FDA approval, 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 Internal 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 enrollment was initiated in October 2010.

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. 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. This feasibility trial will involve 20 patients at two 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 expects that this clinical trial will be funded by grants from the U.S. DOD. The Company estimates that the aggregate European market opportunity for BioFoam is approximately $30 million and approximately $100 million worldwide. Revenues from BioFoam represented less than 1% of total Company revenues in 2010.

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 from pad or sponge form to liquids and powders.

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 and 3 gram sizes with a 100mm or 200mm applicator tip and is expected to be available in a 5 gram size in the first quarter of 2011. PerClot Laparoscopic is available in 1 gram and 3 gram sizes with a 380mm applicator tip.

On September 28, 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, spinal, 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 with the FDA in early 2011 to begin clinical trials for the purpose of obtaining PMA to distribute PerClot in the U.S. The Company estimates that aggregate U.S. sales for hemostatic agents were approximately $730 million in 2010.

CryoLife began distributing PerClot in Europe in the fourth quarter of 2010. Revenues for PerClot represented less than 1% of total Company revenues in 2010. CryoLife plans to begin distribution of PerClot in other international markets as required regulatory approvals are obtained.

HemoStase. HemoStase is a plant-based, flowable powder engineered to rapidly dehydrate blood, enhancing clotting on contact. The Company was the exclusive distributor of Medafor s microporous polysaccharide hemostatic agent under the private label HemoStase for cardiac and vascular surgeries in the U.S. and for cardiac, vascular, and general surgeries in the rest of the world (excluding Japan and China) subject to certain exclusions. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful. CryoLife expects to continue to ship HemoStase through late March 2011. HemoStase is currently available in 1 gram, 3 gram, and 5 gram sizes. Revenues for HemoStase represented 8%, 5%, and 1% of total Company revenues in 2010, 2009, and 2008, respectively. See Part I, Item 3, Legal Proceedings.

Other Medical Devices

ProPatch Soft Tissue Repair Matrix (ProPatch). ProPatch, manufactured from bovine pericardial tissue and treated with the SynerGraft decellularization technology 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, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement, and reconstructive procedures.

In late 2006 CryoLife received 510(k) clearance from the FDA for its ProPatch. CryoLife is planning the first in human implants in early 2011. Additionally, CryoLife is implementing modifications to the manufacturing process that will streamline the process but will not result in any change to the product s effectiveness or indications for use. These modifications will result in a submission of a new 510(k), which is expected to occur in 2011. 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 16 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 110,000 donors. The Company has active relationships with approximately 50 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 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 the tissue is moved to an implantable status, the tissue is stored by the Company or is delivered directly 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 according to 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 290 of these freezers installed at hospitals throughout the U.S. Participating hospitals generally pay the cost of liquid nitrogen and routine maintenance. 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.

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 2010. The Company works to maintain relationships with and market to surgeons within these medical specialties. 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. In the U.S., the Company has 12 cardiac specialists who focus primarily on cardiac surgeons, approximately 30 field service representatives who focus primarily on vascular surgeons, and six region managers. A small number of these positions are open, and the Company is actively recruiting for these positions.

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 coordinates laboratory sessions to demonstrate surgical techniques. Management believes that these activities improve the medical community s acceptance of the tissue preserved by the Company and help to differentiate the Company from other allograft processors. In October 2010 CryoLife hosted the third annual Ross Summit at CryoLife s Corporate Headquarters with 88 cardiac surgeons and cardiologists from 21 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.

Surgical Adhesives, Sealants, and Hemostats

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 direct field representatives employed by the Company s wholly owned European subsidiary, CryoLife Europa, Ltd.

(Europa), and other independent distributors. Through its field representatives and distributors, the Company conducts field training for implanting surgeons regarding the application of its products.

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, and Austria and 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 of donated tissue, primarily for tissues used in pediatric surgeries, that are available for preservation 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 HemoStase.

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 affect 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 cardiac tissue 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. Avoiding elevated PRA is important for patients receiving SynerGraft cardiac tissues as some of these patients may ultimately require a heart transplant. 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. 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. 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, and that these tissues are the preferred repair and reconstruction alternative with respect to processing for defects such as Tetralogy of Fallot, Truncus Arteriosis, Pulmonary Atresia, and more. 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. 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.

Surgical Adhesives, Sealants, and Hemostats

The Company faces competition from several domestic and international medical device, pharmaceutical, and biopharmaceutical companies in its surgical adhesives, sealants, and hemostats product lines. Many of the Company s current and potential competitors for surgical adhesives, sealants, and hemostats 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 affect the Company.

BioGlue. The Company s BioGlue products compete primarily with Baxter International, Inc. s Tisseel, CoSeal, and Tachosil; Ethicon, Inc. s (a Johnson & Johnson Company) Evicel and Omnex; 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. 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 and HemoStase. The Company s PerClot and HemoStase products compete 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, which CryoLife currently distributes under private label as HemoStase. 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. The Company s HemoStase products, which the Company will discontinue selling at the end of March 2011, compete on the basis of safety profile, clinical efficacy, and ease of use.

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 affected. 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, engineering, and cell biology, 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 PhDs 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, 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 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 2010, 2009, and 2008 the Company spent approximately $5.9 million, $5.2 million, and $5.3 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 5% of the Company s revenues for each of the years 2010, 2009, and 2008. Of these amounts spent on research and development activities, $490,000, $799,000, and $411,000 was funded by the DOD in 2010, 2009, and 2008, 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.

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 the second half of 2011. If approval is obtained, the CryoValve SGAV will be shipped to IRB sites approved to receive this tissue. Additional jurisdictions for potential shipments of CryoValve SGAV also include Austria, United Kingdom, and Israel.

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, 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. This feasibility trial will involve 20 patients at two 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 $5.4 million in funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008 for the continued development of PHT for use on the battlefield. The Company anticipates applying for additional funding under this bill for the 2010 allocation. The Company expects that this clinical trial will be funded by grants from the DOD. The Company continues to conduct preclinical research with BioFoam for use in wound sealing in trauma surgery and other potential indications.

PerClot. On September 28, 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 dependant 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 expects to file an IDE with the FDA in the first quarter of 2011 to begin clinical trials for the purpose of obtaining PMA to distribute PerClot in the U.S.

ProPatch. In late 2006 CryoLife received 510(k) clearance from the FDA for its ProPatch. CryoLife is planning the first in human implants in early 2011. Additionally, CryoLife is implementing modifications to the manufacturing process that will streamline the process but will not result in any change to the product s effectiveness or indications for use. These modifications will result in a submission of a new 510(k), which is expected to occur in 2011. 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.

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 7,600 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 surgery 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 tissue for transplant. This laboratory contains approximately 15,600 square feet with a suite of seven clean rooms dedicated to processing. Currently, there are approximately 53 technicians employed in this area, and the laboratory is staffed 24 hours per day, 365 days per year. In 2010 the laboratory packaged approximately 11,300 tissues. The current processing level is estimated to be at about 25% 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 need to increase the number of employees or increase the number of hours worked by its 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.

Other Medical Devices

The Company s headquarters has additional laboratory space consisting of approximately 20,000 square feet with a suite of six clean rooms. This laboratory space is expected to house the manufacturing of PerClot and ProPatch surgical mesh.

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.

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 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.

Medical Device Manufacturing

The Company employs a comprehensive quality assurance program in all of its manufacturing activities. The Company is subject to 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.

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 32 U.S. patents and 119 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, and PHT manufacturing. The Company has approximately 12 pending U.S. patent applications and 17 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 1 month to 13 years. The main patent for BioGlue expires in 2012 in the U.S. and in 2013 in the rest of the world. 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. The Company has an agreement with a third party for calls for the payment of royalties based on revenues from SynerGraft processing. Once the Company begins to manufacture PerClot, it will also be required to pay royalties based on revenues of PerClot manufactured by the Company. In addition, the Company has distribution agreements with third parties for the distribution of PerClot and HemoStase, although the EDA for HemoStase was terminated. 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 affected. Under current law, patent applications in the U.S. and patent applications in foreign countries are maintained in secrecy for a period after filing. The right to a patent in the U.S. is attributable to the first to invent, not the first to file a patent application. 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 filed suit in Germany against Tenaxis because it believes Tenaxis is infringing its main BioGlue patent in Germany. Tenaxis filed a separate nullity suit against this same BioGlue patent in Germany and the lower court ruled that the Company s BioGlue patent was nullified. The Company appealed this ruling and the nullification was stayed pending resolution of the nullification case by the German Supreme Court, which will not likely occur until 2012. 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. 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.

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 was to cease producing devices for it for other than a short period of time, this would have a material adverse affect on our ability to manufacture BioGlue and would materially adversely affect 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, 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 affect the Company s ability to sell PerClot and obtain revenue growth from the product.

The Company has been distributing HemoStase under the EDA with Medafor. As of September 27, 2010 the EDA was terminated by Medafor and CryoLife has ceased receiving product from Medafor. The Company expects to continue to ship HemoStase through late March 2011. The termination of the Medafor EDA is expected to have a material adverse affect on the Company s revenues in 2011 compared to revenues achieved in 2010. See Part I, Item 3, Legal Proceedings.

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) 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 the FDCA and implementing regulations to have an approved PMA.

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). 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.

Heart Valves. On May 25, 2005, with the promulgation of the final rule for cGTPs, the FDA reclassified human heart valves preserved on or after May 25, 2005 from medical devices to human tissue which is subject to that rule. However, human tissues must meet certain criteria to be solely regulated as human tissue. These criteria include being processed in a manner that is considered not to involve more than minimal manipulation of the tissue and being promoted for a clinical use that is consistent with the same basic function that the tissue served in the donor. SynerGraft processing of cardiovascular tissue was evaluated by the FDA to be more than minimal manipulation; therefore, the CryoValve SGPV falls under the medical device regulations and has been deemed to be subject to the 510(k) process.

BioGlue. The FDA regulates BioGlue as a Class III medical device. In December 2001 the Company received an IDE-PMA approval from the FDA for BioGlue as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. Prior to this approval, the Company received an HDE in December 1999 for BioGlue for use as an adjunct in repair of acute thoracic aortic dissections. BioGlue is Health Canada, Australia, and CE Mark approved for additional soft tissue repair.

BioFoam. In October 2009 CryoLife was initially granted approval by the FDA for an IDE to conduct a human clinical trial with BioFoam 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, CryoLife continued to work with the FDA to make additional protocol refinements. As a requirement of the grant funding the Company received from the DOD, the Company is required to have the DOD review and approve the BioFoam clinical trial prior to implementation. 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. If the Company receives PMA approval of BioFoam, it will be regulated by the FDA as a Class III medical device. BioFoam currently has CE mark approval.

HemoStase. The FDA regulates HemoStase as a Class III medical device. In 2006 the manufacturer of HemoStase received a PMA from the FDA for the product s use in surgical procedures (except neurological, ophthalmic, and urological) as an adjunctive hemostatic device to assist when control of capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is ineffective or impractical. In addition, HemoStase has CE Mark approval and is Health Canada approved for similar clinical uses.

PerClot. CryoLife plans to file an IDE in early 2011 with the FDA to begin clinical trials for the purpose of obtaining a PMA to distribute PerClot in the U.S. PerClot would be regulated by the FDA as a Class III medical device. PerClot currently has CE Mark approval.

ProPatch. The FDA regulates ProPatch as a Class II medical device. In late 2006 CryoLife received 510(k) clearance from the FDA for its ProPatch. ProPatch is indicated for implantation to reinforce soft tissues where weakness exists including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement, and reconstructive procedures. ProPatch is also indicated for the reinforcement of soft tissues repaired by sutures or by suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

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 human cells, tissue, and cellular and tissue-based products establishments 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. It became effective for all other HCT/Ps when the remaining parts of 21 C.F.R. Part 1271 were finalized.

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 affect on the Company. For example, on January 16, 2009 the FDA issued draft guidance for cGTPs and Additional Requirements for Manufacturers of HCT/Ps. This guidance is subject to comment and change before being formally issued by the FDA.

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 and BioFoam, and has CE approval for the distribution of PerClot and HemoStase.

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 EU 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-Erlich-Institute (PEI), which enforces various regulations passed by the regulatory authorities in Germany. Europa has a provisional license in Germany and is awaiting PEI s final approval of its license. In addition, Europa ships tissue into Austria, which currently has no Competent Authority. Other countries in the EEA are in the process of implementing the EUTCD, and if CryoLife chooses to ship tissues into these countries, it will likely need to obtain licenses to do so. 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 affect on the Company s business.

Employees

As of December 31, 2010 CryoLife and its subsidiaries had approximately 393 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 SEC, including, without limitation, its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the Exchange Act), available free of charge on the Company s website, *www.cryolife.com*, on the day of filing. All of such filings made on or after November 15, 2002 have been made available on the 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 the product be the subject of adverse developments with regard to its safety, efficacy, or reimbursement practices, or 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. In 2009 and 2010 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 revenue, financial condition, profitability, and cash flow.

We have only two suppliers of bovine serum albumin, which is necessary for the manufacture of BioGlue. Furthermore, we presently have only one supplier for our BioGlue syringe. 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.

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 or our notified body. For discussion of the validity of our German patent see Uncertainties Related To Patents And Protection Of Proprietary Technology May Adversely Affect The Value Of Our Intellectual Property, below. For a further discussion of the German patent nullity action, see Part I, Item 3, Legal Proceedings.

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

The processing, preservation, and distribution of human tissue, and the manufacture and sale of medical devices entail inherent risks, including the possibility of medical complications for patients, and have resulted and may 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 been and may be inadequate. Adverse judgments and settlements in excess of our available insurance coverage could materially adversely impact our financial position, 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, 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 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 or recalled, and in the future may have to suspend the distribution of or recall particular types of tissues as a result of reported adverse events in connection with our tissues. 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.

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. We believe that our tissues and products will continue to be in demand for the foreseeable future. However, if the economic crisis 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. In addition, 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. This could materially adversely impact our financial condition and profitability.

We Expect Our HemoStase Sales To Cease In Late March 2011. Our Remaining Sales of HemoStase Will Likely Be At A Discount From Our List Price And We May Be Required To Write-Down Our Remaining HemoStase Inventory, Which May Have A Material Adverse Impact On Our Revenues And Profitability.

On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. We believe this termination was wrongful. We believe that we are entitled pursuant to the terms of the EDA to continue selling our remaining HemoStase inventory through late March 2011, and we began selling HemoStase at a discount to our list price in the fourth quarter of 2010 in order to expedite HemoStase sales. We will likely continue to sell our HemoStase inventory at a discount, which may have a material adverse impact on our revenues and profitability in 2011. Also, while we believe that we are entitled to distribute our remaining inventory through late March 2011, Medafor may file for an injunction in court to challenge our ability to continue to distribute the remaining inventory or otherwise attempt to prevent further sales of HemoStase, even though they have not yet done so. Medafor may also attempt to sell HemoStase in direct competition with us while we attempt to sell our remaining HemoStase inventory, which could further materially adversely impact our ability to sell our remaining HemoStase inventory. Medafor s actions have and will likely continue to confuse the marketplace with respect to our rights to sell HemoStase, which could materially adversely impact our revenues, financial condition, profitability, and cash flows.

In 2010 we wrote down $1.6 million of HemoStase inventory. As of December 31, 2010 we had approximately $559,000 of HemoStase inventory for sale that had not been written-down. If we are not able to sell our remaining inventory of HemoStase, we may be forced to write down our remaining HemoStase inventory in 2011.

Revenues from HemoStase were approximately $2.7 million and $8.8 million for the three months and year ended December 31, 2010, respectively. We will not have any revenues from HemoStase after the first quarter of 2011, and our anticipated 2011 revenues from HemoStase will be materially lower than our 2010 HemoStase revenues. The reduction in HemoStase revenues is expected to materially adversely impact our revenues, financial condition, profitability, and cash flows.

See Part I, Item 1, Business, for further information regarding the termination of the EDA with Medafor and Part I, Item 3, Legal Proceedings, for further information regarding our litigation with Medafor.

We Are Currently Involved In Significant Litigation With Medafor And That Litigation Cost May 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. Written discovery is ongoing and depositions have not started. The parties have numerous motions in front of the Court. No trial date has been set by the Court, but is likely that any trial would not occur until 2012. The parties have been involved in other lawsuits in other venues. We spent approximately $1.4 million in 2010 on these lawsuits. We expect that our costs in 2011 will materially adversely impact our financial condition, profitability, and cash flows.

Our Investment In Medafor May Have Been Impaired Due To Medafor s Termination Of The EDA , Which Could Have A Material Adverse Impact On Our Financial Condition And Profitability.

In 2009 and in 2010, we purchased approximately 2.4 million shares of Medafor common stock. We were Medafor s largest distributor in 2009 and 2008, accounting for 19% and 15%, respectively, of Medafor s total revenues. We do not know what percentage of Medafor s total revenues we generated in 2010. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. We believe this termination was wrongful.

Medafor s decision to terminate the EDA may negatively impact Medafor s revenues, profitability, and cash flows. In accordance with accounting principles generally accepted in the U.S. (GAAP), we reviewed available information and determined that as of September 30, 2010, factors were present, including Medafor s termination of the EDA, indicating that we should evaluate our investment in Medafor common stock for impairment. We recorded an impairment of $3.6 million in the third quarter of 2010 to write-down our investment in Medafor common stock. The carrying value of our 2.4 million shares of Medafor common stock after this write-down was $2.6 million as of December 31, 2010.

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. 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. Also, Medafor could take future actions beyond our control that could further impair the value of our investment. For example, on March 12, 2010, Medafor announced that they had entered into a transaction with Magle Life Sciences in exchange for an undisclosed amount of cash and 1.8 million shares of Medafor common stock. We believe Medafor s transaction with Magle diluted our investment. Medafor could in the future issue additional shares or take other actions which could further dilute our investment.

See Part I, Item 3, Legal Proceedings, for further information regarding our litigation with Medafor.

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 asked the Court to dismiss all of their counter-claims, except the breach of contract claims, and intend to continue 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.

See Part I, Item 3, Legal Proceedings, for further information regarding our litigation with Medafor.

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 regulations 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 the Company s 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. The failure to comply with regulatory standards or the discovery of previously unknown problems with a tissues or products could result in fines, delays or suspensions of regulatory clearances, seizures or recalls of tissues or products (with the attendant expenses), the banning of a particular device, operating restrictions and criminal prosecution, as well as decreased revenues as a result of negative publicity and legal claims, and could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

For example, in 2002 the FDA issued an order regarding our non-valved cardiac, vascular, and orthopaedic tissues processed by the Company from October 3, 2001 until August 13, 2002 (the FDA Order). Pursuant to the FDA Order, we recalled these tissues or placed them on quarantine hold. In addition to these recall related costs, the FDA Order subjected us to intense FDA scrutiny and regulatory requirements. These challenges reduced our revenues, increased our costs to process tissues and our operating costs, and strained management resources and available cash. We incurred losses and did not produce cash from operations for many years.

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

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 proposed technologies could infringe patents or other rights owned by others, or others could infringe our patents.

For example, we filed suit in Germany against Tenaxis, Inc. 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, and

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

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. 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.

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 money 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 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. The Company s 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.,
- ProPatch,
- New indications for BioGlue, and
- SynerGraft processed tissues.

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.

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 tissue and our manufacturing processes products from single sources due to quality considerations, costs, or constraints resulting from regulatory requirements. 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 flow.

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. 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.

Also, some level of confusion in the international marketplace may exist in the short-term as we transition to selling both HemoStase and PerClot, and then to selling only PerClot. Any such confusion among our customers may lead to lower than anticipated sales of PerClot in 2011. Further, Medafor may attempt to compete directly with us with respect to our current HemoStase customers and convince them to purchase Medafor s hemostatic agent instead of purchasing PerClot from us.

Our Short-Term Liquidity And Earnings In 2011 Will Be Impacted By Our Substantial Investment In Our Distribution And License And Manufacturing Agreements With SMI, And We Will Not Fully Realize The Benefit Of Our Investment In Future Years 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 will pay up to an additional $2.75 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. 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 will be incurred in 2011 and 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.

Our investment in our agreements with SMI will materially impact our short-term liquidity and earnings in 2011, and we will not be able to fully realize the benefit of our investment in future years unless we are able to obtain the necessary regulatory approvals in the U.S. to distribute PerClot, within the timetable anticipated or at all, and this failure would materially adversely impact our anticipated future revenues and profitability. There is no guarantee that we will obtain this approval when anticipated or at all.

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 complementary product lines and companies,

Expand core business,

Develop our pipeline of services and products,

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

Analyze and identify underperforming assets for potential sale or disposal.

Although management has been 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, or purchasing initial inventory. Inability to recover our initial investment may materially adversely impact our financial condition and profitability.

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 stockholder s value;

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

Incur debt that could have terms unfavorable to us or that we might be unable to repay.

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 Find It Difficult To Integrate Recent Acquisitions Of Technology And Potential Future Acquisitions Of Technology Or Business Combinations, Which Could Disrupt Our Business, Dilute Stockholder Value, And Adversely Impact Our Operating Results.

In connection with possible future acquisitions, we may need to integrate operations that have different and unfamiliar corporate cultures. Likewise, we may need to integrate disparate technologies and product offerings, as well as multiple direct and indirect sales channels. These 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 May Not Realize The Anticipated Benefits From An Acquisition.

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 revenue, cost savings, and other financial and operating benefits. We cannot be certain, however, that we will be able to realize increased revenue, 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.

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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, 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 and PerClot. Revenue from international tissue preservation services was approximately $2.3 million, $1.6 million, and $1.2 million for the years ended December 31, 2010, 2009, and 2008, respectively. International revenue from product sales, which includes international BioGlue revenue, was approximately $17.3 million, $16.0 million, and $14.6 million for the years ended December 31, 2010, 2009, and 2008, 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.

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

Government regulation in the U.S., Europe, 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 and those of our competitors, if successfully developed, will require regulatory approvals from the FDA and perhaps other regulatory authorities before they may be commercially distributed. The process of obtaining a PMA from the FDA normally involves clinical trials as well as an extensive premarket approval application and often takes many years. In addition, 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 or our competitors, 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 tissues and 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 or one of our competitors 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 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 (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 tissue 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 the Company 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.

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 position, profitability, and cash flows.

On March 23, 2010 President Obama signed the Patient Protection and Affordable Care Act. This legislation imposes significant new taxes on medical device makers starting in 2013. Under this legislation, the total cost to the medical device industry would be approximately $20 billion in additional taxes over ten years. These taxes will result in a significant increase in the tax burden on us and our industry, which could have a material adverse impact on our financial position, profitability, and cash flows.

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

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators, and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry as well as among our customers, including healthcare providers. This in turn has resulted in greater pricing pressures and limitations on our ability to sell to important market segments, as group purchasing organizations, independent

delivery networks, and large single accounts continue to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the fees charged for our tissues and prices for our products, which could materially adversely impact our revenues, financial condition, profitability, and cash flows.

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

If we fail to maintain our working relationships with physicians, many of our tissues and products may not be developed and marketed in line with 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 is 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 as public speakers.

Certain states have begun to regulate interactions with physicians and other healthcare professionals. There is existing legislation and regulation that govern interaction with physicians and healthcare professionals, and there is proposed legislation and regulations that govern interactions with physicians and other healthcare professionals that is currently before state legislatures and the U.S. Congress. These existing and proposed regulations and legislation currently impact our ability to maintain strong relationships with physicians, and the proposed regulations and legislation, if passed, 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 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.

See Part I, Item 1, Research and Development for further information regarding our past CryoValve SGPV study.

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, 2010 Consolidated Balance Sheet reflects a $2.6 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 $4.7 million, after including a reasonable margin for statistical fluctuations. Based on an actuarial valuation, we estimated that as of December 31, 2010, $1.1 million 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, 2010. 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 in 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 position, 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 position, 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 an eight-year claims-made policy covering claims incurred during the period April 1, 2003 through March 31, 2011 and reported during the period April 1, 2010 through March 31, 2011. Claims incurred prior to April 1, 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 natural disaster and business interruption 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 March Of 2011 Limits Our Ability To Pursue Significant Acquisitions.

Our credit facility, which expires in March of 2011, 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 Which Expires In March 2011 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 increasing 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.

We May Not Be Able To Enter Into A New Credit Facility After Our Current Credit Facility Expires In March 2011.

Our credit facility expires in March of 2011. Although we anticipate entering into a new credit facility, we may not be able to do so. The inability to enter into a new credit facility may restrict our ability to fund acquisitions of new products or technologies, or to enter into new licenses to further our strategy of growing our business if we cannot fund these activities with existing cash. Any new credit facility may also have restrictions on our ability to merge or acquire companies that may be as restrictive on even more restrictive than our current credit facility. Any new credit facility may also have any number of covenants that restrict our ability to borrow, which could be as restrictive or more restrictive than our current 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 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 2011 product revenue or could result in a material decrease in future revenues as compared to the comparable prior periods. Should this occur, it could have a material adverse impact on our revenues, financial condition, profitability, and cash flows.

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

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

We Are Dependent On Our Key Personnel.

Our business and future operating results depend in significant part upon the continued contributions of our key field personnel and senior management, many of whom would be difficult to replace, including our CEO, 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,

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 $2.99 in the period from January 1, 2006 to December 31, 2010.

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 position, 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 Legal Or Contractual Restrictions.

We have not paid cash dividends on our common stock. In addition, our credit agreement prohibits us from paying cash dividends, and under Florida law we may not be able to pay cash dividends on our capital stock. Under Florida law, no distribution may be paid on our capital stock, if after giving it effect:

We would not be able to pay our debts as they become due in the usual course of business, or

Our total assets would be less than the sum of our total liabilities plus the amount that would be needed, if we were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of any preferred shareholders whose preferential rights are superior to those receiving the distribution.

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

All statements, other than statements of historical facts, included herein that address activities, events or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

The Company s belief that the current balance of its deferred preservation costs along with its ongoing preservation service activities is sufficient to support its current and projected revenues;

The timing of the discontinuance of HemoStase sales and shipments;

The expected impact of the termination of the Medafor EDA;

Plans and costs related to regulatory approval for the distribution of PerClot in the U.S. and international markets;

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

Plans regarding the distribution of BioGlue in Japan, and our estimates regarding the Japanese market for related products and uses;

Strategies to pursue potential acquisition, licensing, or distribution rights of additional technologies that complement our existing services and products;

Plans to expand our core business, develop our pipeline of services and products, and license our technology;

Plans to begin distribution of BioFoam in other international markets, estimates of the aggregate European market opportunity for BioFoam, and expectations regarding clinical trials for BioFoam;

Expected results of the CryoValve SGPV post-clearance study;

Expectations regarding regulatory approval and subsequent shipments of the CryoValve SGAV;

The Company s plans to apply for further federal funding for the development of BioFoam;

The Company s expectations regarding the timing of court rulings in its legal proceedings;

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

Expected benefits of acquisitions;

Anticipated future demand for our tissues and products;

Expectations regarding the impact of healthcare legislation;

The Company s estimated future liability for existing tissue processing and product liability lawsuits and for claims incurred but not yet reported;

Expectations regarding a new credit facility;

Beliefs regarding growth of BioGlue revenues and the factors affecting such growth;

Expectations regarding revenues from PerClot and HemoStase;

Expectations regarding minimum purchase requirements related to PerClot;

The impact of additional HemoStase write-downs or discounts on HemoStase sales;

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

Management s beliefs that current cardiac and vascular procurement levels are sufficient to support future demand;

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

The Company s beliefs regarding the rate of decrease of its deferred preservation cost balances;

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;

The Company s expectations regarding the renewal of certain contracts;

Expectations regarding the impact of new accounting pronouncements;

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, 2010 (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 7,600 square feet of off-site warehouse space. Approximately 26,000 square feet are dedicated to clean room work areas. The primary facility has six main laboratory facilities: human tissue preservation, BioGlue manufacturing, bioprosthesis manufacturing, research and development, microbiology, and pathology. Each of these areas consists of a general technician work area and adjoining clean rooms for work with human tissue and for aseptic processing. 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 25% 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 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 bioprosthesis manufacturing laboratory contains approximately 20,000 square feet with a suite of six clean rooms. 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 Europa facility located in Guildford, United Kingdom 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

Overview of CryoLife s Claims

On April 29, 2009 the Company filed a lawsuit against Medafor in the U.S. District Court for the Northern District of Georgia (the Court) alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia s Racketeer Influenced and Corrupt Organizations Act (Georgia RICO). The claims arise out of the Company s exclusive distribution agreement with Medafor (the EDA), pursuant to which the Company had the right to distribute a product manufactured by Medafor (the Product) under the name HemoStase. The EDA gave the Company 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 sent the Company a letter stating that it was terminating the EDA based on an allegation that CryoLife had repudiated the agreement. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful.

There have been a number of motions filed with the Court by both parties. On March 8, 2010 the Company filed its Third Amended Complaint, and on August 9, 2010, the Court dismissed the Company s Georgia RICO claim. On October 20, 2010 after Medafor had terminated the EDA the Company filed supplemental claims in the lawsuit against Medafor for additional breaches of the EDA, including claims that Medafor s termination of that contract was wrongful. On November 10, 2010 Medafor filed its First Amended Answer and Counterclaim, discussed more fully below. On December 6, 2010 the Company filed a motion to dismiss most of Medafor s counterclaim. Medafor filed a response to the Company s motion to dismiss on December 23, 2010, and the Company filed a reply brief in support of the motion on January 10, 2011. On December 21, 2010 the Company filed a motion for partial summary judgment based on its contention that Medafor s termination of the EDA was wrongful, and Medafor filed a response brief on January 19, 2011. The Company s reply brief in support of the motion was filed on February 7, 2011. On February 4, 2011 Medafor filed a motion for partial summary

judgment based on its contention that CryoLife had failed to pay Medafor approximately $1.3 million plus prejudgment interest for product Medafor shipped to CryoLife. CryoLife will file a response brief opposing Medafor s motion. The Court has not set a date for a hearing on any of these motions and will likely rule on each of these motions without a hearing. The Court may rule at any time in the future.

The Company s lawsuit alleges that Medafor unlawfully terminated the EDA, and that contrary to Medafor s representations in the EDA, it 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 territory and field given exclusively to the Company. Medafor is alleged to have knowingly and purposefully withheld from the Company disclosure that these competing agreements existed at the time the EDA became operational and to have intentionally misrepresented to the Company that no such contracts existed, or that their termination had been arranged. The lawsuit also alleges that Medafor failed to take reasonable steps to prevent other distributors from distributing the Product in the Company 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.

The Company 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 the Company of significant sales volume and to have impaired and delayed the Company s development of relationships with customers in its exclusive field and territory. Medafor denies these allegations.

Potential Damages

The Company seeks to recover its damages from Medafor, punitive damages, and reimbursement of its attorneys fees. In addition, the Company is seeking damages related to Medafor s wrongful termination of the EDA, which will be based upon the Company 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. No trial date has been set, although CryoLife believes that a trial is not likely until 2012.

Medafor s Termination of the EDA

As referenced above, on March 18, 2010 Medafor notified the Company of its contention that the Company had repudiated the EDA, thereby entitling Medafor 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 Court to enjoin Medafor from proceeding with its termination of the EDA. After two hearings, the 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 Court stated that it viewed this question as more appropriately addressed at summary judgment. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful.

Medafor s Counterclaims

As discussed above, on November 10, 2010 Medafor filed its First Amended Answer and Counterclaim, alleging claims for, among other things, breach of contract, breach of the implied duty of good faith and fair dealing, 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 requested that the Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Georgia Uniform Commercial Code. On December 6, 2010 CryoLife filed a Motion to Dismiss and for More Definite Statement, seeking dismissal of all of Medafor s claims except for its breach of contract claim and its request for declaratory judgment. Medafor filed a response brief opposing the motion on December 23, 2010. On January 10, 2011 CryoLife filed a reply brief in support of its motion. The Court has not ruled on CryoLife s Motion to Dismiss and for More Definitive Statement. As discussed above, Medafor filed a motion for partial summary judgment requesting that the Court order

CryoLife to pay approximately $1.3 million plus prejudgment interest that CryoLife withheld for product sold to CryoLife that CryoLife believes it may not be able to sell.

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 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. No trial date has been set, although a trial is not likely until 2012. CryoLife intends to vigorously prosecute the case, defend itself, and contest the matter.

Written Discovery Has Commenced

Written discovery began on October 8, 2010. The parties have not exchanged any documents other than responses to written discovery. No depositions have been set. The Court has set an eight month discovery period.

Tenaxis

On October 1, 2008 Tenaxis, Inc. 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 on the appeal, the patent formally remains in force. It is likely that the appeal will not be heard until 2012.

On October 30, 2008 the Company 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 the Company s main BioGlue patent by selling a surgical adhesive made up of a mixture of among other things, bovine serum albumin, and glutaraldehyde. The Company 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. Removed and Reserved.

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	72	President, Chief Executive Officer, and Chairman
Jeffrey W. Burris	Since 2010	39	Vice President and General Counsel
Scott B. Capps	Since 2007	44	Vice President, Clinical Research
David M. Fronk	Since 1998	47	Vice President, Regulatory Affairs and Quality Assurance
Albert E. Heacox, Ph.D.	Since 1989	60	Senior Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	46	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Gerald B. Seery	Since 2005	54	Senior Vice President Sales and Marketing

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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 35 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 responsible attorney 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 in 1985 and his M.S. in Biomedical Engineering from the Ohio State University in 1986.

Albert E. Heacox, Ph.D., was appointed to the position of Senior Vice President of Research and Development in December 2004. Dr. Heacox has been with the Company since June 1985 and served as Vice President of Laboratory Operations from June 1989 to December 2004. Dr. Heacox was promoted to Senior Vice President in December of 2000. Dr. Heacox has been responsible for developing protocols and procedures for cardiac, vascular, and connective tissues, implementing upgrades in procedures in conjunction with the Company s quality assurance programs, and overseeing all processing and production activities of the Company s laboratories. Dr. Heacox is now responsible for the continued development of the Company s current products as well as the evaluation of new technologies. Prior to joining the Company, Dr. Heacox worked as a researcher with the U.S. Department of Agriculture and North Dakota State University, developing methods for the preservation of cells and animal germ plasma storage. Dr. Heacox received his B.A. and M.S. in Biology from Adelphi University, received his Ph.D. in Zoology from Washington State University, and completed his post-doctorate training in cell biology at the University of Cologne, West Germany.

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. in 1978 and completed his M.B.A. at Columbia University in New York in 1980.

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.

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

2009	High	Low
First quarter	$ 9.79	$ 3.93
Second quarter	6.21	4.50
Third quarter	8.87	4.95
Fourth quarter	8.25	5.52

As of February 11, 2011 the Company had 414 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 of equity securities by the Company during the quarter ended December 31, 2010 that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934.

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
10/01/10 10/31/10	40,854	$ 6.26	40,854	10,493,156
11/01/10 11/30/10	94,650	5.84	87,000	9,989,903
12/01/10 12/31/10	135,597	5.53	135,597	9,239,905
Total	271,101	5.75	263,451	9,239,905

On June 1, 2010 the Company publicly announced that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. 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 dependant upon various factors, including price, regulatory requirements, and other market conditions. As of December 31, 2010 the Company has purchased 1.0 million shares of its common stock for an aggregate purchase price of $5.8 million.

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Item 6. Selected Financial Data.

The following Selected Financial Data should be read in conjunction with the Company s consolidated financial statements and notes thereto, Management s Discussion and Analysis of Financial Condition and Results of Operations, and other financial information included elsewhere in this report.

Selected Financial Data

(in thousands, except percentages, current ratio, and per share data)

	December 31,				
	2010	**2009**	**2008**	**2007**	**2006**
Operations					
Revenues	$ 116,645	$ 111,685	$ 105,059	$ 94,763	$ 81,311
Operating income	9,868	14,496	13,654	8,299	1,418
Net income	3,944	8,679	31,950	7,201	365
Net income (loss) applicable to common shareholders	3,944	8,679	31,950	6,958	(608)
Research and development expense as a percentage of revenues	5.1%	4.7%	5.1%	4.7%	4.4%
Income (Loss) Per Common Share					
Basic	$ 0.14	$ 0.31	$ 1.15	$ 0.26	$ (0.02)
Diluted	$ 0.14	$ 0.31	$ 1.13	$ 0.26	$ (0.02)
Year-End Financial Position					
Total assets	$ 137,438	$ 133,859	$ 125,037	$ 92,684	$ 79,865
Working capital	82,162	76,312	59,370	40,750	26,472
Long-term liabilities	4,168	4,197	5,672	5,355	4,864
Convertible preferred stock					3
Shareholders equity	113,942	110,446	98,368	62,627	52,088
Current ratio[1]	5:1	5:1	4:1	3:1	2:1
Shareholders equity per diluted common share	$ 4.03	$ 3.90	$ 3.47	$ 2.32	$ 2.10

[1] Current assets divided by current liabilities.

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

Overview

CryoLife, Inc. (CryoLife , the Company , we , or us), incorporated January 19, 1984 in Florida, preserves and distributes human tissues and develops, manufactures, and commercializes medical devices for cardiac and vascular transplant applications. The human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife s proprietary SynerGraft® technology. CryoLife s medical devices consist primarily of surgical adhesives, sealants, and hemostats including BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot®, which the Company began distributing for Starch Medical, Inc. (SMI) in October of 2010, and HemoStase®, which the Company currently distributes for Medafor, Inc. (Medafor), although CryoLife expects to discontinue sales of HemoStase in late March 2011 because Medafor terminated the HemoStase distribution agreement.

For the year ended December 31, 2010 CryoLife achieved record revenues, surpassing $116.0 million in revenues. In addition, CryoLife generated $20.8 million in cash from operations, the largest yearly inflow of cash from operations in Company history. CryoLife used a portion of this cash to purchase assets from SMI, common stock of Medafor, and to repurchase CryoLife common stock.

As a result of the transaction with SMI, CryoLife recorded $4.5 million for prepaid royalties and intangible assets, and expensed $3.5 million allocated to acquired in-process research and development. CryoLife s operating income and net income for the year ended December 31, 2010 was negatively impacted by the expense of the SMI acquired in-process research and development as well as a write-down of HemoStase inventory and legal expenses related to its lawsuit and other dealings with Medafor. CryoLife s net income for the year ended December 31, 2010 was also negatively impacted by the

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write-down of the Company s investment in Medafor common stock. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2010 results. See Part I, Item 1, Business, for further discussion of the Company s business and activities during 2010.

Recent Events

On September 28, 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI of San Jose, California for PerClot, a polysaccharide hemostatic agent used in surgery. In October 2010 CryoLife announced that it had begun European distribution of PerClot. CryoLife plans to file an Investigational Device Exemption in 2011 with the U.S. Food and Drug Administration (FDA) to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S.

On October 7, 2010 CryoLife announced that BioGlue had received Shonin approval from the Japanese Ministry of Health, Labor, and Welfare (MHLW) for use in the repair of aortic dissections. CryoLife s partner, Century Medical, Inc., (CMI) will distribute BioGlue in Japan. Management estimates that distribution in Japan will begin in the first half of 2011.

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 impact 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 during the write-down period that exceed the estimated market value of the tissue, 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 tissues increase or when tissues are shipped or become available for shipment.

The Company recorded write-downs to its deferred preservation costs totaling $187,000, $91,000, and $276,000 for the twelve months ended December 31, 2010, 2009, and 2008, respectively.

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. As of December 31, 2009 deferred preservation costs consisted of $13.8 million for heart valves, $2.6 million for cardiac patch tissues, and $20.0 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 generated deferred tax assets primarily as a result of write-downs of deferred preservation costs, accruals for tissue processing and product liability claims, and operating losses.

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. During the period from 2003 through the third quarter of 2008, CryoLife maintained a valuation allowance on the majority of its deferred tax assets. At each quarterly period during this time, the Company concluded that, based on its analysis, a valuation allowance was needed on its deferred tax assets.

The Company reassessed its determination of the recoverability of its deferred tax assets and the appropriate levels of the valuation allowance as of December 31, 2008. In conducting this assessment, management considered a variety of factors including the Company s operating profits for the years ended December 31, 2008 and 2007, the reasons for the Company s operating losses in prior years, management s judgment as to the likelihood of continued profitability and expectations of future performance, and other factors. Based on this analysis, as of December 31, 2008 the Company determined that maintaining a full valuation on its deferred tax assets was no longer appropriate. As a result, on December 31, 2008 the Company recorded a tax benefit of $19.1 million on its Consolidated Statement of Operations to reverse substantially all of the valuation allowance on its deferred tax assets. The Company continued to maintain valuation allowances on a portion of its deferred tax assets, primarily related to state tax net operating loss carryforwards that the Company does not believe it will be able to utilize based on its projections of profitability in certain states and state carryforward rules and limitations. In future periods the Company will 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.

As of December 31, 2010 the Company had 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. As of December 31, 2009 the Company had a total of $1.8 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax asset of $13.8 million.

The tax years 2007 through 2010 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2007 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 unreported claims included with respect to accident years 2001 through 2010 would be lower than the Company s experience in the 2002/2003 policy year, during which the Company experienced unusually high claim volumes, but higher than the Company s historical claim frequency prior to the 2002/2003 policy year,

The average cost per claim would be lower than the Company s experience since the 2002/2003 policy year, during which the Company experienced an unusually high average cost per claim, but higher than the Company s historical cost per claim prior to the 2002/2003 policy year,

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

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.

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 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.

At December 31, 2010 and 2009 the short-term and long-term portions of the unreported loss liability and any related recoverable insurance amounts are as follows (in thousands):

	2010	2009
Short-term liability	$ 1,310	$ 1,890
Long-term liability	1,310	1,790
Total liability	2,620	3,680

Short-term recoverable	500	660
Long-term recoverable	550	680
Total recoverable	1,050	1,340
Total net unreported loss liability	$ 1,570	$ 2,340

Further analysis indicated that the liability as of December 31, 2010 could be estimated to be as high as $4.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

On March 31, 2010 the Company bound liability coverage for the 2010/2011 insurance policy year. This policy is an eight-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2011 and

reported during the period April 1, 2010 through March 31, 2011 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

As of February 11, 2011 there were no pending tissue processing or product liability lawsuits filed against the Company.

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.

New Accounting Pronouncements

The Company is required to adopt FASB Accounting Standards Update 2010-6 (ASU 2010-6), Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements effective for interim and annual reporting periods beginning after December 15, 2010. ASU 2010-6 requires reporting entities to make new disclosures about recurring or non-recurring fair value measurements including (i) significant transfers into and out of Level 1 and Level 2 fair value measurements and (ii) information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. ASU 2010-6 will not have an effect on the Company s financial position, profitability, or cash flows upon adoption.

Results of Operations

(In thousands)

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
Preservation services:				
Cardiac tissue	$ 27,997	$ 26,074	24%	24%
Vascular tissue	31,727	30,201	27%	27%
Orthopaedic tissue		181	%	%
Total preservation services	59,724	56,456	51%	51%
Products:				
BioGlue and BioFoam	47,383	47,906	41%	43%
PerClot	264		%	%
HemoStase	8,793	6,008	8%	5%
Other medical devices	(70)	248	%	%
Total products	56,370	54,162	49%	48%
Other	551	1,067	%	1%
Total	$ 116,645	$ 111,685	100%	100%

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, 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, 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 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. The Company does not expect to see a similar level of benefit from price increases in 2011 as it did in 2010.

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.

BioGlue has reached a level of market maturity in the U.S. and is experiencing increasing competitive pressures while continuing to achieve higher levels of growth and penetration in international markets due to its expanded clinical indications. Management believes that as economic conditions begin to improve, growth of BioGlue revenues in future periods would most likely be due to price increases and smaller volume increases or expansions into new markets. The Company expects a decrease in usage of BioGlue in the U.S. in those clinical applications for which new sealant products have FDA approval, partially offset by volume growth of BioGlue due to increases in cardiac and vascular surgical procedure volumes where BioGlue is used. The Company anticipates that it will begin shipping BioGlue to Japan in the first half of 2011, as BioGlue was recently approved in Japan for use in the repair of aortic dissections.

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 (EDA).

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.

As discussed in Recent Events above, on September 28, 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI for PerClot, an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. As discussed in Part II, Item 8, Note 4 of the Notes to Consolidated Financial Statements, CryoLife expects to continue to sell HemoStase until late March 2011, six months from the date Medafor sent the September 27, 2010 notice of termination of the EDA between the companies.

As a result of the items discussed above, CryoLife expects that revenues from the distribution of PerClot will increase in 2011 as the Company transitions its international customers to PerClot and expands distribution into additional international territories. CryoLife expects HemoStase revenues during the first quarter of 2011 to decline from the level of revenues experienced for the three months ended December 31, 2010 and that no HemoStase revenues will be recorded after first quarter 2011. Although it is difficult to determine, CryoLife s HemoStase revenues could be significantly negatively impacted during the first quarter of 2011 by confusion in the marketplace, continued competition from Medafor and other Medafor distributors selling into the Company s markets, and by discounts that the Company has offered and expects to continue to offer to its existing HemoStase customers during the period. The Company s anticipated discontinuation of sales of HemoStase in late March 2011 will materially and adversely decrease revenues in 2011 as compared to 2010. See also Cost of Products below, Part I, Item 1A, Risk Factors, and Part I, Item 3, Legal Proceedings.

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 (PHT), 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 is 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. Per the Company s review of the EDA, the Company expects to continue to sell HemoStase through late March 2011. Based on this review, 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. 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 cost of products in future periods may be favorably impacted if the Company is able to sell more HemoStase than the amounts estimated as discussed above.

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

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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.

The Company believes that cost of products and cost of products as a percentage of product revenues will be negatively impacted in the first quarter of 2011 by discounts on sales of HemoStase that the Company has offered and expects to continue to offer, and may be impacted by additional write-downs of HemoStase inventory. At December 31, 2010 the Company had a remaining balance of $559,000 in HemoStase inventory that had not previously been written down. The Company does not expect that any additional write-downs of HemoStase inventory recorded in the first quarter of 2011 would be material.

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.

The Company believes that expenses associated with lawsuits, including lawsuits with Medafor, and business development opportunities, including costs associated with potential acquisitions, may materially impact the Company s general, administrative, and marketing expenses during 2011.

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 revenue	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, which is expected to increase in 2011.

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 dependant 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.

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 common shares outstanding	28,030	28,473	28,274	28,310
Diluted income per common share	$ 0.08	$ 0.08	$ 0.14	$ 0.31

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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. Basic and diluted income per common share will be impacted in future periods unfavorably by the issuance of common stock to SMI 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, 2009 Compared to Year Ended December 31, 2008

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2009	2008	2009	2008
Preservation services:				
Cardiac tissue	$ 6,697	$ 5,894	23%	23%
Vascular tissue	7,054	6,362	25%	25%
Orthopaedic tissue	33	63	%	%
Total preservation services	13,784	12,319	48%	48%
Products:				
BioGlue and related products	12,583	12,088	44%	48%
HemoStase	1,869	806	7%	3%
Other medical devices	41	100	%	%
Total products	14,493	12,994	51%	51%
Other	338	219	1%	1%
Total	$ 28,615	$ 25,532	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2009	2008	2009	2008
Preservation services:				
Cardiac tissue	$ 26,074	$ 25,514	24%	24%
Vascular tissue	30,201	27,417	27%	26%
Orthopaedic tissue	181	725	%	1%
Total preservation services	56,456	53,656	51%	51%

Products:				
BioGlue and related products	47,906	48,570	43%	46%
HemoStase	6,008	1,532	5%	2%
Other medical devices	248	391	%	%
Total products	54,162	50,493	48%	48%
Other	1,067	910	1%	1%
Total	$ 111,685	$ 105,059	100%	100%

Revenues increased 12% for the three months and 6% for the twelve months ended December 31, 2009 as compared to the three and twelve months ended December 31, 2008, 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, 2009 is presented below.

Cardiac Preservation Services

Revenues from cardiac preservation services increased 14% for the three months ended December 31, 2009 as compared to the three months ended December 31, 2008. This increase was primarily due to the aggregate impact of volume and tissue mix, which together increased revenues by 12%, an increase in average service fees, which increased revenues by 1%, and the favorable impact of foreign exchange, which increased revenues by 1%.

Revenues from cardiac preservation services increased 2% for the twelve months ended December 31, 2009 as compared to the twelve months ended December 31, 2008. This increase was primarily due to the aggregate impact of volume and tissue mix, which increased revenues by 2%.

The Company s cardiac revenues consist of revenues from the distribution of heart valves, cardiac patch tissues, and minimally processed tissues that are distributed to a third party tissue processor.

The 12% increase in revenues from the net effect of volume and tissue mix for the three months ended December 31, 2009 was primarily due to a 10% increase in shipments of heart valves and cardiac patch tissues. The revenue increase was primarily in CryoPatch SG, CryoValve SGPV, and standard processed pulmonary valves. The Company believes that the increase in shipments of cardiac tissues in the three months ended December 31, 2009 was primarily due to increased demand in part due to a return to more normal purchasing patterns as compared to the prior year period when hospitals were cutting purchasing and reducing the level of tissues kept on hand as a result of the deteriorating economic conditions. This increase was also due to the Company s physician training efforts, including the Ross Summit and monthly Aortic Allograft Workshops, which have resulted in additional physicians implanting the Company s tissues, and the efforts of the Company s new cardiac tissue focused sales force, the cardiac specialist program, which was implemented throughout the second half of 2008 and the beginning of 2009.

The 2% increase in revenues from the net effect of volume and tissue mix for the twelve months ended December 31, 2009 was primarily due to favorable tissue mix due to sales of SynerGraft processed cardiac tissues, partially offset by a 1% decrease in shipments of heart valves and cardiac patch tissues. Revenues increased due to shipments of the CryoPatch SG, CryoValve SGPV, and aortic valves. These increases were largely offset by decreases in standard processed pulmonary heart valves and standard processed cardiac patch tissues. The Company believes that the decrease in shipments was primarily due to the first quarter impact of hospitals decreasing the number of heart valves they keep on hand for urgent procedures as a result of the deteriorating economic conditions and their constraining effect on hospital budgets, largely offset by increases in second, third, and fourth quarter 2009 cardiac tissue shipments when compared to the corresponding periods in 2008.

The Company s procurement of cardiac tissues decreased 8% for the three months and 13% for the twelve months ended December 31, 2009 as compared to the three and twelve months ended December 31, 2008, respectively. As a part of the normal course of business, CryoLife routinely adjusts its criteria for accepting incoming tissue based on certain variables. These variables include changes in demand for certain types of tissues processed by the Company, the level of tissues currently available for shipment, changes in incoming tissue availability, and the likelihood that certain tissues will pass the Company s quality controls and testing processes. The decrease in cardiac procurement for the three and twelve months ended December 31, 2009 was primarily the result of changes in tissue acceptance criteria made during 2009 and 2008. The Company may continue to make changes in incoming tissue acceptance criteria, and as a result, the Company s level of procurement may continue to vary from quarter-to-quarter and year-to-year.

Vascular Preservation Services

Revenues from vascular preservation services increased 11% for the three months ended December 31, 2009 as compared to the three months ended December 31, 2008, primarily due to a 9% increase in unit shipments of vascular tissues, which increased revenues by 9% and an increase in average service fees, which increased revenues by 2%. Revenues from vascular preservation services increased 10% for the twelve months ended December 31, 2009 as compared to the twelve months ended December 31, 2008, primarily due to a 10% increase in unit shipments of vascular tissues, which increased revenues by 9% and an increase in average service fees, which increased revenues by 1%.

The increase in vascular volume for the three months ended December 31, 2009 was primarily due to increases in shipments of saphenous veins and to a lesser extent an increase in femoral veins. The increase in vascular volume for the twelve months ended December 31, 2009 was primarily due to increases in shipments of each type of vascular tissue processed by the Company. The largest volume increases were in saphenous veins, which increased due to the strong demand for these tissues, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations.

The Company s procurement of vascular tissues decreased 20% for the three months and 21% for the twelve months ended December 31, 2009 as compared to the three and twelve months ended December 31, 2008, respectively. As a part of the normal course of business, CryoLife routinely adjusts its criteria for accepting incoming tissue based on certain variables. These variables include changes in demand for certain types of tissues processed by the Company, the level of tissues currently available for shipment, changes in incoming tissue availability, and the likelihood that certain tissues will pass the Company s quality controls and testing processes. The decrease in vascular procurement for the three and twelve months ended December 31, 2009 was primarily the result of changes in tissue acceptance criteria made during 2009 and 2008. The Company may continue to make changes in incoming tissue acceptance criteria, and as a result, the Company s level of procurement may continue to vary from quarter-to-quarter and year-to-year.

BioGlue and Related Products

Revenues from the sale of BioGlue and related products increased 4% for the three months ended December 31, 2009 as compared to the three months ended December 31, 2008. This increase was primarily due to an increase in average selling prices, which increased revenues by 4% and the favorable impact of foreign exchange, which increased revenues by 1%, partially offset by a 1% decrease in the volume of milliliters sold, which decreased revenues by 1%.

Revenues from the sale of BioGlue and related products decreased 1% for the twelve months ended December 31, 2009 as compared to the twelve months ended December 31, 2008. This decrease was primarily due to a 2% decrease in the volume of milliliters sold, which decreased revenues by 4%, and the unfavorable impact of foreign exchange, which reduced revenues by 1%, partially offset by an increase in average selling prices, which increased revenues by 4%.

Sales of BioGlue and related products for the three and twelve months ended December 31, 2009 included international sales of BioFoam Surgical Matrix following receipt of the CE Mark approval during the third quarter of 2009. BioFoam sales accounted for less than 1% of total BioGlue and related product sales during 2009.

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

The decrease in sales volume for BioGlue and related products for the three and twelve months ended December 31, 2009 was primarily due to a decrease in shipments of BioGlue in domestic markets, as a result of the deteriorating economic conditions and their constraining effect on hospital budgets. Management believes that hospitals are attempting to control costs by reducing spending on items, such as BioGlue, that are consumed during surgical procedures. The Company has also seen some of its large competitors attempting to enforce purchasing requirements in their contracts, to the detriment of BioGlue. In addition, management believes that BioGlue sales were negatively impacted as a result of changes to the alignment of the Company s sales force during 2009, including the introduction of the cardiac specialist program.

The impact of foreign exchange for the three and twelve months ended December 31, 2009 was due to changes in the exchange rates between the U.S. Dollar and both the British Pound and the Euro in the three and twelve months ended December 31, 2009 as compared to the respective periods in 2008. The Company s sales of BioGlue and related products 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.

Domestic revenues accounted for 69% and 71% of total BioGlue revenues in the three months ended December 31, 2009 and 2008, respectively. Domestic revenues accounted for 70% and 71% of total BioGlue revenues in the twelve months ended December 31, 2009 and 2008, respectively.

HemoStase

Revenues from the sale of HemoStase increased 132% for the three months and 292% for the twelve months ended December 31, 2009 as compared to the three and twelve months ended December 31, 2008, respectively. HemoStase

revenues for the three and twelve months ended December 31, 2009 increased in both domestic and international markets. CryoLife began marketing and distribution of HemoStase under the EDA with Medafor in the second quarter of 2008.

Other Revenues

Other revenues for the three and twelve months ended December 31, 2009 and 2008 included revenues from research grants. Other revenues for the twelve months ended December 31, 2008 included revenues related to the licensing of the Company s technology to a third party.

As of December 31, 2009 CryoLife has been awarded a total of $5.4 million in funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the (DOD Grants), which includes $1.7 million awarded in March of 2009. The DOD Grants were awarded to CryoLife for the development of PHT, which the Company is currently developing for use in organ sealing. Grant revenues in 2009 and 2008 are related to funding under the DOD Grants.

Through December 31, 2009 CryoLife has received a total $5.4 million, representing all awarded funds under the DOD Grants. 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,	
	2009	2008	2009	2008
Cost of preservation services	$ 8,346	$ 6,730	$ 32,767	$ 29,112
Cost of preservation services as a percentage of preservation services revenues	61%	55%	58%	54%

Cost of preservation services increased 24% for the three months and 13% for the twelve months ended December 31, 2009, as compared to the three and twelve months ended December 31, 2008, respectively.

The increase in cost of preservation services in the three months ended December 31, 2009 was primarily due to an increase in the per unit costs of processing tissues and an increase in cardiac and vascular tissues shipped, as discussed above. The increase in cost of preservation services in the twelve months ended December 31, 2009 was primarily due to an increase in the per unit costs of processing tissues and to a lesser extent, an increase in vascular tissues shipped, as discussed above. The increase in the per unit costs of processing tissues in 2009 was largely a result of decreased processing and packaging throughput.

The increase in cost of preservation services as a percentage of preservation services revenues for the three and twelve months ended December 31, 2009 was primarily due to the increase in the per unit costs of processing tissues, partially offset by an increase in average service fees, which has had a small favorable effect on margins.

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
Cost of products	$ 2,672	$ 2,293	$ 9,150	$ 8,153
Cost of products as a percentage of product revenues	18%	18%	17%	16%

Cost of products increased 17% for the three months and 12% for the twelve months ended December 31, 2009, as compared to the three and twelve months ended December 31, 2008, respectively.

The increase in cost of products in the three and twelve months ended December 31, 2009 was primarily due to the increase in shipments of HemoStase, which the Company began distributing in the second quarter of 2008. To a lesser extent, the increase in cost of products was due to a slight increase in the per unit cost of BioGlue, largely offset by a

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decrease in the per unit cost of HemoStase. The per unit cost of HemoStase decreased due to increased distribution of HemoStase internationally, as international product has a reduced cost. Cost of products for the three and twelve months ended December 31, 2008 was negatively impacted by the write-down of $277,000 and $1.5 million, respectively, in other medical device inventory.

Cost of products as a percentage of product revenues for the three and twelve months ended December 31, 2009 was comparable to the three and twelve months ended December 31, 2008, respectively. During these periods cost of products as a percentage of product revenues increased due to increasing revenues from HemoStase, which has a lower profit margin than BioGlue, as well as an increase in the per unit cost of BioGlue, largely offset by the favorable effect of the absence in the current year of the product write-downs recorded during 2008 and an increase in BioGlue average selling prices, as discussed above.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
General, administrative, and marketing expenses	$ 12,585	$ 12,334	$ 50,025	$ 48,831
General, administrative, and marketing expenses as a percentage of total revenues	44%	48%	45%	46%

General, administrative, and marketing expenses increased 2% for both the three and twelve months ended December 31, 2009, as compared to the three and twelve months ended December 31, 2008, respectively.

The increase in general, administrative, and marketing expenses for the three months ended December 31, 2009 was primarily due to $377,000 in costs related to a reduction in workforce implemented during the quarter, the effect of a smaller reduction in tissue processing and product liability accruals, and increased professional fees, partially offset by a decrease in marketing expenses related to the Ross Summit, which took place in the third quarter of 2009 versus the fourth quarter of 2008. The reduction in workforce was part of a Company initiative to increase efficiencies and reduce costs through manufacturing process improvements, expense control, and cost cutting measures.

The increase in general, administrative, and marketing expenses for the twelve months ended December 31, 2009 was primarily due to increases in marketing expenses, including increased personnel costs, partially related to an increase in the sales force, and other marketing expenses to support current revenue growth and the Company s efforts to increase its preservation service and product offerings. The increase was also due to the effect of a smaller reduction in tissue processing and product liability accruals and an increase in stock based compensation over the prior year period.

The Company s expenses related to the grant of stock options and restricted stock awards were $566,000 and $547,000 for the three months ended December 31, 2009 and 2008, respectively, and $2.2 million and $1.8 million for the twelve months ended December 31, 2009 and 2008, respectively. The Company s general, administrative, and marketing expenses included a benefit for the reduction in tissue processing and product liability accruals of $165,000 and $530,000 for the three months ended December 31, 2009 and 2008, respectively, and $570,000 and $980,000 for the twelve months ended December 31, 2009 and 2008, respectively.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
Research and development expenses	$ 1,393	$ 1,371	$ 5,247	$ 5,309
Research and development expenses as a percentage of total revenue	5%	5%	5%	5%

Research and development spending in 2009 and 2008 was primarily focused on the Company s tissue preservation, SynerGraft products and tissues, and BioGlue and related products. SynerGraft products and tissues include the Company s

CryoValve SGPV and CryoValve SG aortic heart valves, CryoPatch SG, and xenograft SynerGraft tissue products. BioGlue related products include BioGlue, BioGlue Aesthetic, BioFoam, and BioDisc®.

Other Income and Expenses

Interest expense was ($85,000) and $62,000 for the three months ended December 31, 2009 and 2008, respectively, and $83,000 and $263,000 for the twelve months ended December 31, 2009 and 2008, respectively. Interest expense for the three and twelve months ended December 31, 2009 and 2008 included interest incurred related to the Company s debt, capital leases, 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 $3,000 and $96,000 for the three months ended December 31, 2009 and 2008, respectively, and $76,000 and $381,000 for the twelve months ended December 31, 2009 and 2008, respectively. Interest income for the three and twelve months ended December 31, 2009 and 2008 was primarily due to interest earned on the Company s cash, cash equivalents, and restricted securities. The decrease in interest income in 2009 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.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2009	2008	2009	2008
Income before income taxes	$ 3,672	$ 2,717	$ 14,354	$ 13,536
Income tax expense (benefit)	1,306	(19,024)	5,675	(18,414)
Net income	$ 2,366	$ 21,741	$ 8,679	$ 31,950
Diluted common shares outstanding	28,473	28,478	28,310	28,351
Diluted income per common share	$ 0.08	$ 0.76	$ 0.31	$ 1.13

Income before income taxes increased 35% for the three months and 6% for the twelve months ended December 31, 2009 as compared to the three and twelve months ended December 31, 2008, respectively. Income before income taxes for the three and twelve months ended December 31, 2009 increased primarily due to an increase in revenues and other factors as discussed above.

The Company s effective income tax rate was 36% and 40% for the three and twelve months ended December 31, 2009, respectively, which included the effect of the Company s federal, state, and foreign tax obligations. The Company s income tax benefit for the three and twelve months ended December 31, 2008 included $19.1 million in reversals of the Company s valuation allowance on its deferred tax assets. This reversal was partially offset by current tax expense including alternative minimum tax on the Company s taxable income that could not be offset by the Company s net operating loss carryforwards, state tax obligations, and foreign taxes on income of the Company s wholly owned European subsidiary.

Net income and diluted earnings per common share decreased for the three and twelve months ended December 31, 2009 as compared to the corresponding periods in 2008 despite an increase in income before income taxes. This decrease was due to income tax expense recorded in the 2009 periods as compared to the income tax benefit recorded in the corresponding periods in 2008, as discussed above.

Seasonality

The Company believes the demand for its cardiac preservation services is 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, who drive the demand for a large percentage of cardiac tissues processed by CryoLife.

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

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

the summer holiday season in Europe and fewer surgeries being performed on adult patients in the summer months in the U.S.

The Company is uncertain whether 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.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2010 net working capital (current assets of $101.5 million less current liabilities of $19.3 million) was $82.2 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $76.3 million, with a current ratio of 5 to 1 at December 31, 2009.

Overall Liquidity and Capital Resources

The Company s primary cash requirements for the twelve months ended December 31, 2010 arose out of general working capital needs, consideration paid for the transaction with SMI, the acquisition of Medafor common stock, repurchases of the Company s common stock, and the payment of legal and professional fees. Legal and professional fees during the twelve months ended December 31, 2010 included costs associated with the Company s litigation with Medafor and business development costs, including costs for SMI, the Company s attempt to purchase Medafor, and other business development activities. The Company funded its cash requirements primarily through its operating activities, which generated cash during the period.

During 2009 the Company analyzed its deferred preservation cost balances and their recent growth and began a series of initiatives to reduce the growth of deferred preservation costs. As a result of these initiatives, the growth rate of the Company s deferred preservation costs slowed during 2009, and the balance of the Company s deferred preservation costs decreased by $4.9 million during the twelve months ended December 31, 2010. The Company believes that the rate of decrease of its deferred preservation cost balances may slow in future months. The Company will continue to manage its incoming tissue procurement and other costs in an effort to manage its deferred preservation cost balances. However, the Company cannot predict its specific deferred preservation cost balances in the future with certainty. The Company believes that the current balance of its deferred preservation costs along with its ongoing preservation service activities is sufficient to support its current and projected revenues.

CryoLife entered into a credit facility with GE Capital in March of 2008, as amended (the GE Credit Agreement) which provides for up to $15.0 million in revolving credit for working capital, acquisitions, and other corporate purposes, of which $14.8 million was available for borrowing as of December 31, 2010. As of December 31, 2010 the outstanding balance under this agreement was zero. 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 in restricted securities on the Company s Consolidated Balance Sheet. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined, of at least $20.0 million. The GE Credit Agreement will expire in late March 2011. CryoLife is currently reviewing its options on whether to extend the GE Credit Agreement or enter into a new credit agreement or loan with GE Capital or another lender. CryoLife is also considering possibly expanding its line of credit capacity to provide liquidity for growth, including potential acquisitions, although there is no guarantee that a new or extended line of credit can be obtained.

The Company s cash equivalents include advance funding received under the DOD Grants for the continued development of PHT. As of December 31, 2010 $1.7 million of the cash equivalents recorded on the Company s Consolidated Balance Sheet were related to the DOD Grants. These funds must be used for the specified purposes.

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 for general working capital needs, to fund business development activities, including acquisitions and attempted acquisitions, to purchase license agreements, to repurchase the Company s common stock, to fund the Medafor litigation, to fund clinical trials, and for other corporate purposes. The Company expects that these items will have a significant affect on its cash flows in 2011. In addition, the Company believes that the anticipated material decrease in HemoStase revenues in 2011 will have a material, adverse impact on the Company s liquidity as compared to 2010. The

Company may seek additional borrowing capacity to fund these future cash requirements. The Company had net operating loss carryforwards that it has been using to reduce otherwise required cash payments for federal and state income taxes for the 2010 tax year. Cash payments for taxes will increase in 2011 as the Company s federal net operating loss carryforwards will be fully utilized in the 2010 tax year.

Liability Claims

As of December 31, 2010 the Company had accrued a total $2.6 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to December 31, 2010 and had recorded a receivable of $1.1 million representing estimated amounts to be recoverable from the Company s insurance carriers with respect to such accrued liability. Further analysis indicated that the liability could be estimated to be as high as $4.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The $2.6 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.

Net Cash from Operating Activities

Net cash provided by operating activities was $20.8 million for the twelve months ended December 31, 2010 as compared to $16.6 million for the twelve months ended December 31, 2009.

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, 2010 these non-cash items included a favorable $3.5 million for acquired in-process research and development expense as a result of the transaction with SMI, $3.6 million in other than temporary investment impairment, $3.9 million in depreciation and amortization expense, $2.6 million in non-cash stock based compensation, and $2.1 million in write-downs of deferred preservation costs and inventory, primarily HemoStase, partially offset by $1.5 million in deferred income taxes, $1.3 million in excess tax benefits related to stock compensation, and $1.3 million in non-cash gain on valuation of derivative.

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, 2010 these changes included a favorable $4.9 million due to decreases in deferred preservation costs and a favorable $2.4 million due to the timing differences between the recording of accounts payable, accrued expenses, and other current liabilities and the actual payment of cash, partially offset by an unfavorable $1.8 million increase in inventory balances, primarily HemoStase purchases prior to the non-cash write-down discussed above, and an unfavorable $1.5 million due to the timing difference between making cash payments and the expensing of assets, primarily prepaid royalties from the transaction with SMI.

Net Cash from Investing Activities

Net cash used in investing activities was $10.7 million for the twelve months ended December 31, 2010 as compared to $4.4 million for the twelve months ended December 31, 2009. The current year cash used was primarily due to $5.4 million in payments related to the transaction with SMI, $2.7 million in purchases of marketable securities and investments, largely related to the purchase of Medafor common stock, and $2.1 million in capital expenditures.

Net Cash from Financing Activities

Net cash used in financing activities was $4.7 million for the twelve months ended December 31, 2010 as compared to net cash provided of $707,000 for the twelve months ended December 31, 2009. The current year cash used was primarily due to $5.9 million in purchases of treasury stock, related to the Company s publicly announced stock repurchase plan, and $1.2 million in principal payments on capital leases and short-term notes payable, partially offset by $1.2 million in proceeds from the financing of insurance policies and a $1.3 million excess tax benefit related to stock compensation.

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, 2010 are as follows (in thousands):

	Total	2011	2012	2013	2014	2015	Thereafter
Operating leases	$ 28,584	$ 2,388	$ 2,550	$ 2,477	$ 2,482	$ 2,519	$ 16,168
Purchase commitments	8,747	2,264	2,583	3,500	400		
Research obligations	3,740	2,049	337	651	703		
SMI contingent payments	2,250	750		500	1,000		
Compensation payments	1,985			993	992		
Total contractual obligations	$ 45,306	$ 7,451	$ 5,470	$ 8,121	$ 5,577	$ 2,519	$ 16,168

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 2013, as that is when the Company expects to receive FDA approval for PerClot. Upon FDA approval, the Company may terminate its minimum purchase requirements, which it expects to do, but if the Company does not terminate this provision, it will have minimum purchases obligations in 2014 and through the end of the contract term. The Company s purchase commitments also include obligations from agreements with suppliers to stock certain custom raw materials needed for the Company s processing and production and contractual payments for licensing computer software and telecommunication services, and other items as appropriate.

The Company s research obligations represent commitments for ongoing studies and payments to support research and development activities, a large portion of which will be funded by the advances received under the DOD Grants.

The obligation for SMI contingent payments represents the contingent milestone payments that the Company will pay if certain FDA regulatory approvals and other commercial milestones are achieved, as discussed in Recent Events above. 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 tissue processing and product 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 $1.4 million, because the Company can not 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, 2010 were $2.1 million compared to $1.7 million for the twelve months ended December 31, 2009. Capital expenditures in the twelve months ended December 31, 2010 were primarily related to 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 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 $35.5 million and restricted money market funds of $5.0 million and interest paid on the Company s variable rate line of credit as of December 31, 2010. A 10% adverse change in interest rates as

compared to the rates experienced by the Company in the

three months ended December 31, 2010, affecting the Company s cash and cash equivalents, restricted money market funds, 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.

Changes in exchange rates which occurred during the twelve months ended December 31, 2010 as well as any future material adverse fluctuations in exchange rates could have a material and adverse impact on the Company s revenues, profitability, and cash flows. An additional 10% adverse change in exchange rates from the exchange rates in effect on December 31, 2010 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 exchange rates in effect on December 31, 2010 as compared to the weighted average exchange rates experienced by the Company for the twelve months ended December 31, 2010 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. Because of 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.

Based upon the most recent Disclosure Controls evaluation, conducted by management with the participation of the CEO and CFO, as of December 31, 2010 the CEO and CFO have concluded that the Company s Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission s rules and forms.

During the quarter ended December 31, 2010, there were no changes in the Company s internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company s internal control over financial reporting.

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

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

Item 9B. Other Information.

None.

PART III

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

The response to Item 10 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission not later than April 30, 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 not later than April 30, 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 not later than April 30, 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 not later than April 30, 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 not later than April 30, 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	Reserved.
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 January 6, 2010.)
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.)
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.)

Exhibit Number	Description
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.)
10.3	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+	Exchange and Service Agreement, dated December 15, 2006, by and between CryoLife, Inc. and Regeneration Technologies, Inc. and its affiliates RTI Donor Services, Inc. and Regeneration Technologies, Inc. Cardiovascular. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
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.)
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(a)	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(b)	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(c)	Change of Control Agreement, by and between the Company and David M. Fronk, dated May 5, 2009. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed May 8, 2009.)
10.9(d)	Change of Control Agreement, by and between the Company and D. Ashley Lee, dated October 24, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed October 28, 2008.)
10.9(e)	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.).

Exhibit Number	Description
10.12*	Summary of Salaries for Named Executive Officers.
10.13	Form of Non-Qualified Stock Option Grant Agreement under 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.14	Amended and Restated Technology Acquisition Agreement between the Company and Nicholas Kowanko, Ph.D., dated March 14, 1996. (Incorporated herein by reference to Exhibit 10.14 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2004.)
10.15	CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated herein by reference to Appendix 2 to the Registrant s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.16	Lease Agreement between the Company and Amli Land Development I Limited Partnership, dated April 18, 1995. (Incorporated herein by reference to Exhibit 10.16 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007.)
10.16(a)	First Amendment to Lease Agreement, dated April 18, 1995, between the Company and Amli Land Development I Limited Partnership dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)
10.16(b)	Restatement and Amendment to Funding Agreement between the Company and Amli Land Development I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(b) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.16(c)	Amended and Restated Lease Agreement between the Company and Amli Land Development I Limited Partnership, dated May 10, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.)
10.17	CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.)
10.17(a)	Form of Non-Employee Director Stock Grant Agreement pursuant to the CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.)
10.18	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.19	CryoLife, Inc. 2004 Employee Stock Incentive Plan, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.20	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.)

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Exhibit Number	Description
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.)
10.28	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.29 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.29	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.30(a) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.30	Form of Director Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.30(b) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.31	Form of Non-Employee Directors Stock Option Agreement and Grant pursuant to the Amended and Restated Non-Employee Directors Stock Option Plan. (Incorporated herein by reference to Exhibit 10.31 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.32	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.33	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.33 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.34	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.34 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.35	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.35 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.36	Form of Grant of Non-Qualified Stock Option to Directors. (Incorporated herein by reference to Exhibit 10.36 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.37	Grant of Incentive Stock Option to Steven G. Anderson, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
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.

Exhibit Number	Description
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	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.)
10.47	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.
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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.)
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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.)
10.52*	CryoLife, Inc. Executive Deferred Compensation Plan.
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.

* Filed herewith.

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

3. B. Executive Compensation Plans and Arrangements.

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

2. 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 David M. Fronk, dated May 5, 2009. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed May 8, 2009.)

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.)

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.)

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.* Summary of Salaries for Named Executive Officers.

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

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

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

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

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

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

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

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

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

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

32. Form of 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.)

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

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

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

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

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

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

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

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

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

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

43. Form of 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.)

44.* 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.

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

46.* CryoLife, Inc. Executive Deferred Compensation Plan.

* Filed herewith.

SIGNATURES

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

CRYOLIFE, INC.

February 22, 2011 By /s/ Steven G. Anderson
Steven G. Anderson

President, Chief Executive Officer, and

Chairman of the Board of Directors

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

Signature	Title	Date
/s/ Steven G. Anderson **Steven G. Anderson**	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	February 22, 2011
/s/ D. Ashley Lee **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 22, 2011
/s/ Amy D. Horton **Amy D. Horton**	Chief Accounting Officer (Principal Accounting Officer)	February 22, 2011
/s/ Thomas F. Ackerman **Thomas F. Ackerman**	Director	February 22, 2011
/s/ James S. Benson **James S. Benson**	Director	February 22, 2011
/s/ Daniel J. Bevevino **Daniel J. Bevevino**	Director	February 22, 2011
/s/ Ronald C. Elkins, M.D. **Ronald C. Elkins, M.D.**	Director	February 22, 2011
/s/ Ronald D. McCall	Director	February 22, 2011

Ronald D. McCall

/s/ Harvey Morgan | Director | February 22, 2011

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, 2010. 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, 2010, 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, 2010.

CryoLife, Inc.

February 22, 2011

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, 2010, 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, 2010, 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, 2010 of the Company and our report dated February 22, 2011 expressed an unqualified opinion on those financial statements.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 22, 2011

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, 2010 and 2009, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, 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, 2010 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 22, 2011 expressed an unqualified opinion on the Company s internal control over financial reporting.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 22, 2011

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,497	$ 30,121
Restricted securities	5,309	
Receivables:		
Trade accounts, net	13,724	13,709
Other	589	927
Total receivables	**14,313**	**14,636**
Deferred preservation costs	31,570	36,445
Inventories	6,429	6,446
Deferred income taxes	6,096	5,694
Prepaid expenses and other assets	2,276	2,186
Total current assets	**101,490**	**95,528**
Property and equipment:		
Equipment and software	20,622	19,722
Furniture and fixtures	3,837	3,735
Leasehold improvements	29,111	29,000
Total property and equipment	53,570	52,457
Less accumulated depreciation and amortization	40,484	38,148
Net property and equipment	**13,086**	**14,309**
Other assets:		
Investment in equity securities	2,594	3,221
Restricted money market funds		5,000
Patents, less accumulated amortization of $2,603 in 2010 and $2,155 in 2009	3,282	4,248
Trademarks and other intangibles, less accumulated amortization of $397 in 2010 and $871 in 2009	5,601	2,724
Deferred income taxes	9,182	8,075
Other	2,203	754
Total assets	**$ 137,438**	**$ 133,859**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands except per share amounts)

	December 31, 2010	2009
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,243	$ 2,954
Accrued compensation	3,357	3,361
Accrued procurement fees	3,081	3,228
Accrued expenses	4,434	4,182
Deferred income	2,095	2,646
Derivative liability		725
Other current liabilities	2,118	2,120
Total current liabilities	**19,328**	**19,216**
Line of credit		315
Other	4,168	3,882
Total liabilities	**23,496**	**23,413**
Commitments and contingencies		
Shareholders equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued:		
Series A Junior Participating Preferred Stock, 2,000 shares authorized, no shares issued		
Convertible preferred stock, 460 shares authorized, no shares issued		
Common stock $0.01 par value per share, 75,000 shares authorized, 29,950 shares issued in 2010 and 29,475 shares issued in 2009	300	295
Additional paid-in capital	133,845	128,427
Retained deficit	(8,408)	(12,352)
Accumulated other comprehensive loss	(32)	(38)
Treasury stock at cost, 2,049 shares in 2010 and 1,000 shares in 2009	(11,763)	(5,886)
Total shareholders equity	**113,942**	**110,446**
Total liabilities and shareholders equity	**$ 137,438**	**$ 133,859**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2010	**2009**	**2008**
Revenues:			
Preservation services	$ 59,724	$ 56,456	$ 53,656
Products	56,370	54,162	50,493
Other	551	1,067	910
Total revenues	**116,645**	**111,685**	**105,059**
Cost of preservation services and products:			
Preservation services	35,868	32,767	29,112
Products	12,409	9,150	8,153
Total cost of preservation services and products	**48,277**	**41,917**	**37,265**
Gross margin	**68,368**	**69,768**	**67,794**
Operating expenses:			
General, administrative, and marketing	49,064	50,025	48,831
Research and development	5,923	5,247	5,309
Acquired in-process research and development	3,513		
Total operating expenses	**58,500**	**55,272**	**54,140**
Operating income	**9,868**	**14,496**	**13,654**
Interest expense	180	83	263
Interest income	(23)	(76)	(381)
Gain on valuation of derivative	(1,345)	(24)	
Other than temporary investment impairment	3,638		
Other expense, net	141	159	236
Income before income taxes	**7,277**	**14,354**	**13,536**
Income tax expense (benefit)	3,333	5,675	(18,414)
Net income	**$ 3,944**	**$ 8,679**	**$ 31,950**
Income per common share:			
Basic	**$ 0.14**	**$ 0.31**	**$ 1.15**
Diluted	**$ 0.14**	**$ 0.31**	**$ 1.13**
Weighted-average common shares outstanding:			
Basic	27,987	28,106	27,800

Diluted	28,274	28,310	28,351

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2010	**2009**	**2008**
Net cash flows from operating activities:			
Net income	$ 3,944	$ 8,679	$ 31,950
Adjustments to reconcile net income to net cash from operating activities:			
Depreciation and amortization	3,937	4,263	4,353
Other than temporary investment impairment	3,638		
Acquired in-process research and development expense	3,513		
Non-cash compensation	2,621	2,429	2,099
Write-down of deferred preservation costs and inventories	2,093	489	1,728
Write-down of intangible asset	921		
Reversal of deferred income tax valuation allowance			(19,147)
Deferred income taxes	(1,509)	5,254	(7)
Gain on valuation of derivative	(1,345)	(24)	
Excess tax benefit from stock based compensation	(1,275)		
Other non-cash adjustments to income	185	187	84
Changes in operating assets and liabilities:			
Receivables	179	(745)	(841)
Deferred preservation costs	4,901	(1,839)	(8,286)
Inventories	(1,803)	699	(2,922)
Prepaid expenses and other assets	(1,539)	(353)	(21)
Accounts payable, accrued expenses, and other liabilities	2,376	(2,467)	547
Net cash flows provided by operating activities	**20,837**	**16,572**	**9,537**
Net cash flows from investing activities:			
Acquisition of SMI intangible assets	(5,411)		
Capital expenditures	(2,121)	(1,690)	(1,738)
Purchases of restricted securities	(300)		(5,000)
Purchases of marketable securities and investments	(2,405)	(3,036)	(1,118)
Sales and maturities of marketable securities		1,130	3,565
Other	(497)	(783)	(46)
Net cash flows used in investing activities	**(10,734)**	**(4,379)**	**(4,337)**
Net cash flows from financing activities:			
Principal payments on debt	(315)		(4,588)
Proceeds from financing of insurance policies and debt issuance	1,179	1,272	1,728
Principal payments on capital leases and short-term notes payable	(1,222)	(1,328)	(1,343)
Proceeds from exercise of stock options and issuance of common stock	239	1,093	2,383
Repurchases of common stock	(5,877)	(330)	(611)
Excess tax benefit from stock based compensation	1,275		
Net cash flows (used in) provided by financing activities	**(4,721)**	**707**	**(2,431)**
Increase in cash and cash equivalents	**5,382**	**12,900**	**2,769**

Effect of exchange rate changes on cash	(6)	20	(28)
Cash and cash equivalents, beginning of year	30,121	17,201	14,460
Cash and cash equivalents, end of year	**$ 35,497**	**$ 30,121**	**$ 17,201**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands)

	Common Stock		Additional Paid In Capital	Retained Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Shareholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2007	**28,526**	**$ 285**	**$ 120,562**	**$ (52,981)**	**$**	**(949)**	**$ (5,239)**	**$ 62,627**
Net income				31,950				31,950
Other comprehensive loss					(80)			(80)
Comprehensive income								31,870
Equity compensation	183	2	2,097			(12)	(120)	1,979
Exercise of options	345	3	1,716			6	(197)	1,522
Employee stock purchase plan	48	1	369					370
Balance at December 31, 2008	**29,102**	**$ 291**	**$ 124,744**	**$ (21,031)**	**$ (80)**	**(955)**	**$ (5,556)**	**$ 98,368**
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)
Balance at December 31, 2009	**29,475**	**$ 295**	**$ 128,427**	**$ (12,352)**	**$ (38)**	**(1,000)**	**$ (5,886)**	**$ 110,446**
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
Repurchases of common stock						(1,031)	(5,760)	(5,760)
Stock issued for SMI transaction	209	2	987					989
Balance at December 31, 2010	**29,950**	**$ 300**	**$ 133,845**	**$ (8,408)**	**$ (32)**	**(2,049)**	**$ (11,763)**	**$ 113,942**

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 and develops, manufactures, and commercializes medical devices for cardiac and vascular transplant applications. The human tissue distributed by CryoLife includes the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife s proprietary SynerGraft® technology. CryoLife s medical devices consist primarily of surgical adhesives, sealants, and hemostats including BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot®, which the Company began distributing for Starch Medical, Inc. (SMI) in October of 2010, and HemoStase®, which the Company currently distributes for Medafor, Inc. (Medafor), although CryoLife expects to discontinue sales of HemoStase in late March 2011 because Medafor terminated the HemoStase distribution agreement.

CryoLife distributes preserved human cardiac and vascular tissues to implanting institutions throughout the U.S., Canada, and Europe. The Company received a Section 510(k) (510(k)) clearance from the U.S. Food and Drug Administration (FDA) in February 2008 for its CryoValve SGPV and in August 2009 for its CryoPatch SG, both processed with the Company s proprietary SynerGraft technology. CryoLife distributes 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. CryoLife distributes BioGlue under Conformité Européene (CE) Mark product certification in the European Economic Area (EEA) for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). Additional marketing approvals have been granted for specified applications in several other countries throughout the world, including Canada, Australia, and Japan. CryoLife distributes BioFoam under CE Mark certification and has approval by the FDA for an Investigational Device Exemption (IDE) to conduct a human clinical trial with BioFoam to help seal liver tissues in patients for whom cessation of bleeding by ligature or other conventional methods is ineffective or impractical.

CryoLife distributes PerClot under a worldwide distribution agreement with SMI. PerClot has CE Mark designation allowing commercial distribution into the European Community and other markets. CryoLife plans to file an IDE in early 2011 with the FDA to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S. CryoLife has been distributing HemoStase under a private label exclusive distribution agreement with Medafor (EDA) since 2008. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful. CryoLife expects to continue to ship HemoStase through late March 2011.

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 valuation of investments, allowance for doubtful accounts, deferred preservation costs, valuation and lives of long-lived tangible and intangible assets, deferred income taxes, valuation of 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, and certain accrued liabilities, including accrued procurement fees, income taxes, and financial instruments (including derivatives).

Revenue Recognition

The Company recognizes revenues for preservation services when services are completed and tissue is shipped to the customer. Revenues for products are recognized at the time the product is shipped, at which time title passes to the customer, and there are no further performance obligations. The Company 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. 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.

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 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 of 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 $531,000, $1.2 million, and $1.5 million for the years ended December 31, 2010, 2009, and 2008, respectively.

Stock-Based Compensation

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of restricted stock awards (RSA s), restricted stock units (RSU s), and options to purchase shares of CryoLife common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP) for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period.

The 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 and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company s ESPP options is also determined using a Black-Scholes model and is expensed over the vesting period.

The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, volatility, dividend yield, and the risk-free interest rate. The expected term is primarily based on the contractual term of the option and Company data related to historic exercise and post-vesting forfeiture patterns, which is adjusted based on management s expectations of future results. The 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 on the basis of the weighted-average number of common shares outstanding plus, if applicable, the dilutive effects of equity instruments including the effect of outstanding stock options, convertible preferred stock, restricted stock awards, and restricted stock units.

Financial Instruments

The Company s financial instruments include cash equivalents, marketable securities, restricted securities, accounts receivable, accounts payable, debt obligations, and derivatives. 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, certain restricted securities, and derivatives. These financial instruments are discussed in further detail in the sections 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, 2010 the Company has not chosen to make any such elections. Fair value financial instruments are recorded at fair value 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.

A summary of financial instruments measured at fair value as of December 31, 2010 and 2009 is as follows (in thousands):

	Level 1	Level 2	Level 3	Total
December 31, 2010				
Cash equivalents:				
U.S. Treasury 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
Total assets	**$ 19,099**	**$ 2,365**	**$**	**$ 21,464**
December 31, 2009				
Cash equivalents:				
U.S. Treasury debt securities	$ 8,999	$	$	$ 8,999
U.S. Treasury money market funds		18,754		18,754
Restricted securities		5,000		5,000
Total assets	8,999	23,754		32,753

Derivative liability			(725)	(725)
Total liabilities			(725)	(725)
Net assets (liabilities)	$ 8,999	$ 23,754	$ (725)	$ 32,028

Changes in fair value of level 3 liabilities are listed in the table below (in thousands). Refer to Note 4 for further discussion of the derivative.

	Derivative Liability
Balance as of December 31, 2008	$
Initial value of derivative issued	749
Total gains unrealized included in earnings	(24)
Balance as of December 31, 2009	$ 725
Initial value of derivative issued	620
Total gains unrealized included in earnings	(1,345)
Balance as of December 31, 2010	$

A summary of the non-financial assets measured at fair value on a non-recurring basis in the Company s Consolidated Balance Sheet as of December 31, 2010 follows (in thousands). Refer to Note 3 for further discussion of the assets acquired from SMI and Note 4 for further discussion of the investment in Medafor common stock.

	Level 1	Level 2	Level 3	Total
SMI assets:				
Patent	$	$	$ 327	$ 327
Distribution and manufacturing rights			2,560	2,560
Investment in equity securities			2,594	2,594

In addition, the Company valued an in-process research and development asset acquired from SMI at $3.5 million using level 3 inputs. This asset was expensed and was not included on the Company s Consolidated Balance Sheet as of December 31, 2010.

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. See Note 3 below for a discussion of the inputs and methods used in the non-recurring valuation of the Company s assets acquired from SMI, and see Note 4 below for a discussion of the inputs and methods used in the level 3 valuation of the Company s derivative liability and the non-recurring valuation of the Company s investment in equity securities.

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, 2010 and 2009 $1.7 million and $2.6 million, respectively, of cash equivalents was 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):

	2010	2009	2008
Cash paid during the year for:			
Interest	$ 143	$ 25	$ 225
Income taxes	2,502	540	645
Non-cash investing and financing activities:			
Issuance of common stock for acquisition of SMI 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.

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, 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 tissues increase or when tissues are shipped or become available for shipment.

The Company recorded write-downs to its deferred preservation costs totaling $187,000, $91,000, and $276,000 for the years ended December 31, 2010, 2009, and 2008, respectively.

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. As of December 31, 2009 deferred preservation costs consisted of $13.8 million for heart valves, $2.6 million for cardiac patch tissues, and $20.0 million for vascular tissues.

Inventories

Inventories are comprised of BioGlue, BioFoam, PerClot, HemoStase, other medical devices, supplies, and raw materials. Inventories are valued at the lower of cost or market on a first-in, first-out basis. Idle facility expense, excessive spoilage, extra freight, and rehandling costs are expensed when incurred in cost of products and are not capitalized into inventories. Allocation of fixed production overheads is based on the normal capacity of the production facilities.

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 lease term or the estimated useful lives of the assets, whichever is shorter.

Intangible Assets

The Company s intangible assets consist of procurement contracts and agreements, trademarks, patents, customer lists, a non-compete agreement, and distribution and manufacturing rights acquired in the SMI transaction discussed in Note 3.

The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. As of December 31, 2010 and 2009 gross carrying values, accumulated amortization, and approximate amortization periods of the Company s definite lived intangible assets are as follows (dollars in thousands):

	Gross Carrying Value	Accumulated Amortization	Amortization Period
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
December 31, 2009			
Patents	$ 6,403	$ 2,155	17 Years
Customer lists	574	565	3 Years
Non-compete agreement	381	114	10 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.

As of December 31, 2010 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2011	2012	2013	2014	2015	Total
Amortization expense	$ 696	$ 681	$ 594	$ 499	$ 474	$ 2,944

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 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 have an indefinite useful life as the Company currently anticipates that these trademarks will contribute cash flows to the Company indefinitely.

As of December 31, 2010 and 2009 the carrying values of the Company s indefinite lived intangible assets are as follows (in thousands):

	2010	2009
Procurement contracts and agreements	$ 2,013	$ 2,013
Trademarks	790	435

Impairments of Long-Lived 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, 2010, 2009, and 2008 the Company did not experience any factors that indicated that an impairment review of its long-lived assets was warranted.

CryoLife evaluates its non-amortizing intangible assets for impairment on an annual basis and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of December 31, 2010 the Company s non-amortizing intangible assets consisted of trademarks and acquired procurement contracts and agreements. The Company performed an analysis of its non-amortizing intangible assets as of December 31, 2010 and 2009, 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 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 unreported claims included with respect to accident years 2001 through 2010 would be lower than the Company s experience in the 2002/2003 policy year, during which the Company experienced unusually high claim volumes, but higher than the Company s historical claim frequency prior to the 2002/2003 policy year,

The average cost per claim would be lower than the Company s experience since the 2002/2003 policy year, during which the Company experienced an unusually high average cost per claim, but higher than the Company s historical cost per claim prior to the 2002/2003 policy year,

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

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.

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 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.

Uncertain Tax Positions

The Company periodically assesses its uncertain tax positions and recognizes tax benefits if they are more-likely-than-not to be upheld upon review by the appropriate taxing authority. The Company measures the tax benefit by determining the maximum amount that has a greater than 50 percent likelihood of ultimately being realized. The Company reverses previously accrued liabilities for uncertain tax positions when audits are concluded, statutes expire, administrative practices dictate that a liability is no longer warranted, or in other circumstances as deemed necessary. These assessments can be complex and the Company often obtains assistance from external advisors to make these assessments. The Company recognizes interest and penalties related to uncertain tax positions in other income (expense) 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 generated deferred tax assets primarily as a result of write-downs of deferred preservation costs and inventory, accruals for tissue processing and product liability claims, asset impairments, and operating losses.

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. During the period from 2003 through the third quarter of 2008, CryoLife maintained a valuation allowance on the majority of its deferred tax assets.

The Company reassessed its determination of the recoverability of its deferred tax assets and the appropriate levels of the valuation allowance, as of December 31, 2008. In conducting this assessment, management considered a variety of factors, including the Company s operating profits for the years ended December 31, 2008 and 2007, the reasons for the Company s operating losses in prior years, management s judgment as to the likelihood of continued profitability and expectations of future performance, and other factors. Based on this analysis, the Company determined that maintaining a full valuation on its deferred tax assets as of December 31, 2008 was no longer appropriate. As a result, on December 31, 2008 the Company recorded a tax benefit of $19.1 million on its Consolidated Statement of Operations to reverse substantially all of the valuation allowance on its deferred tax assets. The Company continues to maintain valuation allowances on a portion of its deferred tax assets, primarily related to state income tax net operating loss carryforwards that the Company does not believe it will be able to utilize based on its projections of profitability in certain states and state carryforward rules and limitations. The Company assesses the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially affect the recoverability of its deferred tax assets.

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. As of December 31, 2009 the Company had a total of $1.8 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax asset of $13.8 million.

The Company s tax years 2007 through 2010 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns prior to 2007 from years in which net operating losses and tax credits have arisen are still open for examination by the tax authorities.

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

The Company is required to adopt FASB Accounting Standards Update 2010-6 (ASU 2010-6), Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements effective for interim and annual reporting periods beginning after December 15, 2010. ASU 2010-6 requires reporting entities to make new disclosures about recurring or non-recurring fair value measurements including (i) significant transfers into and out of Level 1 and Level 2 fair value measurements and (ii) information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. ASU 2010-6 will not have an effect on the Company s financial position, profitability, or cash flows upon adoption.

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
December 31, 2010			
Cash equivalents:			
U.S. Treasury 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

December 31, 2009			
Cash equivalents:			
U.S. Treasury money market funds	$ 18,754	$	$ 18,754
U.S. Treasury debt securities	8,999		8,999
Restricted securities:			
U.S. Treasury money market funds, long-term	5,000		5,000

As of December 31, 2010 $309,000 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, 2010 $5.0 million of the Company s U.S. Treasury debt securities and as of December 31, 2009 $5.0 million of the Company s U.S. Treasury money market funds were designated as long-term restricted money market funds due to a financial covenant requirement under the Company s credit agreement with General Electric Capital Corporation (GE Capital) as discussed in Note 6.

There were no gross realized gains or losses on cash equivalents for the years ended December 31, 2010, 2009, and 2008. At December 31, 2010 $5.3 million of the Company s restricted securities had a maturity date within three months. At December 31, 2009 none of the Company s restricted securities had a maturity date.

3. SMI Agreements

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 powder 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, spinal, 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, excluding China, Taiwan, Hong Kong, Macau, North Korea, Iran, and Syria, to commercialize PerClot for all approved surgical indications and a license to manufacture the PerClot product, exclusive of rights to sell PerClot with an endoscope. CryoLife also received an assignment of the PerClot trademark from SMI as part of the terms of the agreements. CryoLife plans to file an IDE with the FDA to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S.

The Distribution Agreement contains certain minimum purchase requirements and has a term of 15 years. CryoLife intends to begin manufacturing PerClot from plant starch modified by SMI under the terms of the License Agreement in either late 2011 or 2012. Following the start of manufacturing and receipt of U.S. regulatory approval, CryoLife may terminate the Distribution 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 grants CryoLife a three-year option to purchase certain remaining related technology from SMI.

As part of the transaction, CryoLife paid SMI $6.75 million in cash, which includes $1.5 million in cash for prepaid royalties, and approximately 209,000 shares of restricted CryoLife common stock. The common stock issued to SMI will be held by CryoLife until March 31, 2012, when the restricted provisions of the stock lapse. CryoLife will pay additional contingent amounts of up to $2.75 million to SMI if certain FDA regulatory and other commercial milestones are achieved.

The Company s Distribution Agreement with SMI contains minimum purchase requirements for PerClot through the end of the contract term. Upon FDA approval, the Company may terminate such minimum purchase requirements.

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 and 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 is considered in-process research and development as it is dependant upon regulatory approvals which have not yet been obtained. Therefore, CryoLife expensed the $3.5 million as in-process research and development upon acquisition. 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 periodic impairment testing. The $2.6 million intangible asset will be amortized over its useful life of 15 years. See additional disclosures in Note 1 above.

CryoLife expects to record future contingent payment amounts of up to $2.75 million initially as research and development expense or, after FDA approval or issuance of a patent, as acquired intangible assets.

4. Medafor Matters

Overview

CryoLife began distributing HemoStase in 2008 for Medafor, a company incorporated in Minnesota, under the 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.

Recent Events

On March 18, 2010 Medafor announced that it was treating the EDA as terminated and ceased shipments of HemoStase to CryoLife. CryoLife thereafter moved to the U.S. District Court for the Northern District of Georgia, Atlanta Division (the Court) to preliminarily enjoin Medafor from proceeding with its termination. Shortly thereafter, Medafor informed CryoLife that, although Medafor had terminated the EDA, it would continue to act as if the EDA were in effect for a short period of time. Medafor resumed shipments of HemoStase in late June of 2010. On September 20, 2010 the Court issued an order denying CryoLife s request for the preliminary injunction. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful.

Based on this communication and subsequent communications CryoLife has received from Medafor, CryoLife does not believe that Medafor will make any further inventory shipments to CryoLife. CryoLife was Medafor s largest distributor in 2009 and 2008. CryoLife believes it was Medafor s largest distributor in 2010. See further discussion of these recent events in Legal Action below.

On September 28, 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI for PerClot, a competing hemostatic agent used in surgery, as discussed in Note 3 above.

Investment in Medafor Common Stock

During the quarter ended September 30, 2010 the Company reviewed available information, including the events described in the paragraphs above, 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 effect 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, CryoLife recorded a non-operating expense, other than temporary investment impairment of $3.6 million to write-down its investment in Medafor common stock. The carrying value of the Company s 2.4 million shares of Medafor common stock after this write-down was $2.6 million or $1.09 per share as of December 31, 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), 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 Sheet. 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 Statement of Operations.

As of December 31, 2010 the Company believed that the likelihood of a Triggering Event was zero. As a result, the Company recorded a non-cash gain on the change in the value of derivative on the Consolidated Statement of Operations of $1.3 million for the year ended December 31, 2010. The gain on valuation of the Medafor Derivative was recorded as a decrease in the derivative liability on the Consolidated Balance Sheet. This decrease in the liability was partially offset by an increase of $620,000 related to additional purchases of Medafor common stock during the year ended December 31, 2010. See also the disclosure of the change in fair value of the derivative liability in Note 1. The value of the Medafor Derivative was zero and $725,000 as of December 31, 2010 and 2009, respectively.

HemoStase Inventory

Based on Medafor s termination of the EDA in late September 2010 and the determination that Medafor would no longer be shipping HemoStase to CryoLife, the Company performed a review of its HemoStase inventory to determine if the carrying value of the inventory had been impaired.

Per its review of the EDA, the Company expects to continue to sell HemoStase for a six-month period following the most recent termination of the EDA, which period concludes in late March 2011. As a result, 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 related finished goods inventory in the third quarter of 2010. The Company believed that the remaining value as of September 30, 2010 of $1.7 million of HemoStase inventory after the write-down was recoverable over the six-month selling period following the termination of the EDA. As of December 31, 2010, the remaining HemoStase inventory value was $559,000.

The amount of this write-down reflects management s estimate based on information currently available. Management continues 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 cost of products in future periods may be favorably impacted if the Company is able to sell more HemoStase than the amounts estimated as discussed above.

Legal Action

Overview of CryoLife s Claims

On April 29, 2009 the Company filed a lawsuit against Medafor in the U.S. District Court for the Northern District of Georgia (the Court) alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia s Racketeer Influenced and Corrupt Organizations Act (Georgia RICO). The claims arise out of the Company s EDA with Medafor, pursuant to which the Company had the right to distribute a product manufactured by Medafor (the Product) under the name HemoStase. The EDA gave the Company 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 sent the Company a letter stating that it was terminating the EDA based on an allegation that CryoLife had repudiated the agreement. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful.

There have been a number of motions filed with the Court by both parties. On March 8, 2010 the Company filed its Third Amended Complaint, and on August 9, 2010, the Court dismissed the Company s Georgia RICO claim. On October 20, 2010 after Medafor had terminated the EDA the Company filed supplemental claims in the lawsuit against Medafor for additional breaches of the EDA, including claims that Medafor s termination of that contract was wrongful. On November 10, 2010 Medafor filed its First Amended Answer and Counterclaim, discussed more fully below. On December 6, 2010 the Company filed a motion to dismiss most of Medafor s counterclaim. Medafor filed a response to the Company s motion to dismiss on December 23, 2010, and the Company filed a reply brief in support of the motion on January 10, 2011. On December 21, 2010 the Company filed a motion for partial summary judgment based on its contention that Medafor s termination of the EDA was wrongful, and Medafor filed a response brief on January 19, 2011. The Company s reply brief in support of the motion was filed on February 7, 2011. On February 4, 2011 Medafor filed a motion for partial summary judgment based on its contention that CryoLife had failed to pay Medafor approximately $1.3 million plus prejudgment interest for product Medafor shipped to CryoLife. CryoLife will file a response brief opposing Medafor s motion. The Court has not set a date for a hearing on any of these motions and will likely rule on each of these motions without a hearing. The Court may rule at any time in the future.

The Company s lawsuit alleges that Medafor unlawfully terminated the EDA, and that contrary to Medafor s representations in the EDA, it 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 territory and field given exclusively to the Company. Medafor is alleged to have knowingly and purposefully withheld from the Company disclosure that these competing agreements existed at the time the EDA became operational and to have intentionally misrepresented to the Company that no such contracts existed, or that their termination had been arranged. The lawsuit also alleges that Medafor failed to take reasonable steps to prevent other distributors from distributing the Product in the Company 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.

The Company 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 the Company of significant sales volume and to have impaired and delayed the Company s development of relationships with customers in its exclusive field and territory. Medafor denies these allegations.

Potential Damages

The Company seeks to recover its damages from Medafor, punitive damages, and reimbursement of its attorneys fees. In addition, the Company is seeking damages related to Medafor s wrongful termination of the EDA, which will be based upon the Company 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. No trial date has been set, although CryoLife believes that a trial is not likely until 2012.

Medafor s Termination of the EDA

As referenced above, on March 18, 2010 Medafor notified the Company of its contention that the Company had repudiated the EDA, thereby entitling Medafor 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 Court to enjoin Medafor from proceeding with its termination of the EDA. After two hearings, the 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 Court stated that it viewed this question as more appropriately addressed at summary judgment. On September 27, 2010 Medafor sent the Company a letter stating that Medafor was fully, finally and immediately terminating the EDA. CryoLife believes this termination was wrongful.

Medafor s Counterclaims

As discussed above, on November 10, 2010 Medafor filed its First Amended Answer and Counterclaim, alleging claims for, among other things, breach of contract, breach of the implied duty of good faith and fair dealing, 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 requested that the Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Georgia Uniform Commercial Code. On December 6, 2010 CryoLife filed a Motion to Dismiss and for More Definite Statement, seeking dismissal of all of Medafor s claims except for its breach of contract claim and its request for declaratory judgment. Medafor filed a response brief opposing the motion on December 23, 2010. On January 10, 2011 CryoLife filed a reply brief in support of its motion. The Court has not ruled on CryoLife s Motion to Dismiss and for More Definitive Statement. As discussed above, Medafor filed a motion for partial summary judgment requesting that the Court order CryoLife to pay approximately $1.3 million plus prejudgment interest that CryoLife withheld for product sold to CryoLife that CryoLife believes it may not be able to sell.

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 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. No trial date has been set, although a trial is not likely until 2012. CryoLife intends to vigorously prosecute the case, defend itself, and contest the matter.

Written Discovery Has Commenced

Written discovery began on October 8, 2010. The parties have not exchanged any documents other than responses to written discovery. No depositions have been set. The Court has set an eight month discovery period.

Contingency Related to the Lawsuit and Claims

CryoLife intends to vigorously defend itself and contest the matter. Given the early stage of this case, the Company does not believe at this time that there is a reasonable probability that a loss will occur. Due to the early stage of the case, CryoLife does not currently believe that it is possible to reasonably estimate the amount of loss or a range of losses on the current counter-claims made by Medafor or any future additional counter-claims that may be made by Medafor. The parties have not discussed settlement in any meaningful way.

5. Inventories

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

	2010	2009
Raw materials and supplies	$ 4,301	$ 4,144
Work-in-process	349	278
Finished goods	1,779	2,024
Total inventories	$ 6,429	$ 6,446

6. Debt

GE Credit Agreement

On March 26, 2008 CryoLife entered into a credit agreement with GE Capital as lender (the GE Credit Agreement). The GE Credit Agreement provides for a revolving credit facility in an aggregate amount not to exceed the initial commitment of $15.0 million (including a letter of credit subfacility). The initial commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. In the second quarter of 2009, as requested by the German courts, the Company obtained a letter of credit relating to the Company s patent infringement legal proceeding against Tenaxis, Inc. in Germany, which reduced the aggregate borrowing capacity to $14.8 million. 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. Further, beginning April 15, 2008 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 and long-term restricted money market funds as of December 31, 2010 and 2009, respectively, 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, 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. The GE Credit Agreement expires on March 25, 2011, at which time any outstanding principal balance will be due. As of December 31, 2010 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 at LIBOR, with a minimum rate of 3%, or GE Capital s base rate, with a minimum rate of 4% each, plus the applicable margin. As of December 31, 2010 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate would have been 6.25%, and the remaining availability was $14.8 million. As of December 31, 2009 the outstanding balance of the GE Credit Agreement was $315,000, the aggregate interest rate was 5.50%, and the remaining availability was $14.5 million.

Wells Fargo Credit Agreement

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. (Wells Fargo) as lender which provided for a revolving credit facility in an aggregate amount equal to the lesser of $15.0 million or a borrowing base determined in accordance with the terms of the credit agreement. The credit agreement with Wells Fargo expired on February 8, 2008 in accordance with its terms, at which time the outstanding principal balance of $4.5 million was paid from cash on hand.

Other

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. 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. In April 2009 the Company entered into an agreement to finance approximately $1.3 million in insurance premiums at a 3.695% annual interest rate, which was payable in equal monthly payments over a nine-month period. As of December 31, 2010 and 2009 the aggregate outstanding balances under these agreements were zero.

Total interest expense was $180,000, $83,000, and $263,000 in 2010, 2009, and 2008, respectively, which included interest on debt, capital leases, and uncertain tax positions.

7. 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, 2010 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 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 $1.5 million and $1.3 million as of December 31, 2010 and 2009, respectively, recorded in other long-term liabilities, primarily related to the lease on its corporate headquarters. Total rental expense for operating leases was $2.6 million for both 2010 and 2009 and $2.5 million for 2008.

Future minimum operating lease payments under non-cancelable leases as of December 31, 2010 are as follows (in thousands):

	Operating Leases
2011	$ 2,388
2012	2,550
2013	2,477
2014	2,482
2015	2,519
Thereafter	16,168
Total minimum lease payments	$ 28,584

Liability Claims

At December 31, 2010 and 2009 the short-term and long-term portions of the unreported loss liability and any related recoverable insurance amounts are as follows (in thousands):

	2010	2009
Short-term liability	$ 1,310	$ 1,890
Long-term liability	1,310	1,790
Total liability	2,620	3,680
Short-term recoverable	500	660
Long-term recoverable	550	680
Total recoverable	1,050	1,340
Total net unreported loss liability	$ 1,570	$ 2,340

Further analysis indicated that the total liability as of December 31, 2010 could be estimated to be as high as $4.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

On March 31, 2010 the Company bound liability coverage for the 2010/2011 insurance policy year. This policy is an eight-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2011 and reported during the period April 1, 2010 through March 31, 2011 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

As of February 11, 2011 there were no pending tissue processing or product liability lawsuits filed against the Company.

Employment Agreement

The Company has an employment agreement with its Chief Executive Officer (CEO) that confers benefits which become payable upon a change in control or upon certain termination events. As of both December 31, 2010 and 2009, 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.

8. Common Stock Repurchase

On June 1, 2010 the Company announced that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions on such terms as management deems appropriate, and will be dependent upon various factors, including price, regulatory requirements, and other market conditions. As of December 31, 2010 the Company had 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 treasury stock, carried at cost, and reflected as a reduction of shareholders equity on the Company s Consolidated Balance Sheet.

9. 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. The Company also maintains an 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, 2010 and 2009:

Plan	Authorized Shares	Available for Grant 2010	Available for Grant 2009
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	981,000	32,000
2002 Stock Incentive Plan	974,000	243,000	219,000
2004 Employee Stock Incentive Plan	2,000,000	26,000	194,000
2008 Non-Employee Directors Stock Incentive Plan	300,000	119,000	182,000
2009 Employee Stock Incentive Plan	2,000,000	1,560,000	2,000,000
Total	7,174,000	2,929,000	2,627,000

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, 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 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.

In 2008 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 managers totaling 183,000 shares of common stock, which had an aggregate market value of $1.8 million. These RSAs included 81,000 shares of common stock valued at $786,000 issued as part of the 2007 performance-based bonus plans for certain Company executives, officers, and managers. The Company recorded the expense related to the 2007

performance-based bonus plans during the year ended December 31, 2007.

A summary of stock grant activity for the years ended December 31, 2010, 2009, and 2008 is as follows:

RSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2007	88,000	$ 10.48
Granted	183,000	9.92
Vested	(119,000)	10.87
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

RSUs	Shares	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2009			
Granted	58,000		
Outstanding at December 31, 2010	58,000	1.85	$ 313,000
Vested and expected to vest	54,000	1.85	$ 291,000

Stock Options

The Compensation Committee of the Company s Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company executives and employees totaling 451,000, 438,000, and 403,000, shares in 2010, 2009, and 2008, respectively, with exercise prices equal to the stock prices on the respective grant dates.

A summary of the Company s stock option activity for the years ended December 31, 2010, 2009, and 2008 follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,859,000	$ 6.31	3.19	$ 3,992,000
Granted	403,000	10.15		
Exercised	(393,000)	5.12		
Forfeited	(16,000)	6.28		

Expired	(80,000)	11.06		
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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Vested and expected to vest	2,254,000	$ 6.75	3.43	$ 600,000
Exercisable at December 31, 2010	1,239,000	$ 6.93	2.40	$ 359,000

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

	2010	2009	2008
Weighted-average fair value of options granted	$ 3.34	$ 2.40	$ 4.52
Intrinsic value of options exercised	$ 10,000	$ 274,000	$ 2,429,000

Employees purchased common stock totaling 43,000, 79,000, and 48,000 shares in 2010, 2009, and 2008, respectively, through the Company s ESPP.

Stock Compensation Expense

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

	2010		2009		2008	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	3.8 Years	.38 Years	4.0 Years	.25 Years	3.5 Years	.25 Years
Expected stock price volatility	.65	.47	.65	.75	.60	.76
Risk-free interest rate	1.25%	0.17%	1.51%	0.14%	2.34%	1.83%

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

	2010	2009	2008
RSA and RSU expense	$ 970	$ 899	$ 788
Stock option expense	1,950	1,780	1,311
Total stock compensation expense	$ 2,920	$ 2,679	$ 2,099

Included in the total stock compensation expense were expenses related to RSAs, RSUs, and stock options issued in the current year as well as those issued in prior years that continue to vest during the period, and compensation related to the Company s ESPP. These amounts were recorded as compensation expense and were subject to the Company s normal allocation of expenses to inventory and deferred preservation costs. The Company capitalized $299,000, $250,000, and $145,000 in the years ended December 31, 2010, 2009, and 2008, respectively, of the stock compensation expense included in the table above into its deferred preservation costs and inventory costs.

As of December 31, 2010 the Company had a total of $1.5 million in total unrecognized compensation costs related to unvested RSAs and RSUs, before considering the effect of expected forfeitures. As of December 31, 2010 this expense is expected to be recognized over a weighted-average period of 1.3 years for RSAs and 2.85 years for RSUs. As of December 31, 2010 there was approximately $1.8 million in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of December 31, 2010 this expense is expected to be recognized over a weighted-average period of 1.3 years.

10. 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).

11. Comprehensive Income

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

	2010	2009	2008
Net income	$ 3,944	$ 8,679	$ 31,950
Change in unrealized loss on investments			(3)
Change in translation adjustment	6	42	(77)
Comprehensive income	$ 3,950	$ 8,721	$ 31,870

The tax effect on the change in unrealized loss on investments and the translation adjustment is zero for each period presented. The accumulated other comprehensive loss of $32,000 and $38,000 as of December 31, 2010 and 2009, respectively, consisted solely of currency translation adjustments.

12. Employee Benefit Plans

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 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 and 2008. Total Company contributions approximated $204,000, $456,000, and $414,000 for the years ended December 31, 2010, 2009, and 2008, respectively. 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.

13. 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):

	2010	2009	2008
Basic income per common share:			
Net income	$ 3,944	$ 8,679	$ 31,950
Basic weighted-average common shares outstanding	27,987	28,106	27,800
Basic income per common share	$ 0.14	$ 0.31	$ 1.15
Diluted income per common share:			
Net income	$ 3,944	$ 8,679	$ 31,950
Basic weighted-average common shares outstanding	27,987	28,106	27,800
Effect of dilutive stock options [a]	133	116	498
Effect of dilutive RSAs and RSUs	154	88	53
Diluted weighted-average common shares outstanding	28,274	28,310	28,351
Diluted income per common share	$ 0.14	$ 0.31	$ 1.13

[a] The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares, because the inclusion of these stock options would be antidilutive to income per common share. Accordingly, stock options to purchase 1.5 million, 1.3 million, and 374,000, shares for the years ended December 31, 2010, 2009, and 2008, 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 8 above.

14. Income Taxes

Income Tax Expense

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

	2010	2009	2008
Domestic	$ 6,936	$ 14,158	$ 13,330
Foreign	341	196	206
Income before income taxes	$ 7,277	$ 14,354	$ 13,536

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

	2010	2009	2008
Current:			
Federal	$ 4,415	$ 225	$ 391

State	255	114	273
Foreign	46	82	69
	4,716	421	733
Deferred:			
Federal	(1,560)	5,022	(16,959)
State	158	255	(2,195)
Foreign	19	(23)	7
	(1,383)	5,254	(19,147)
Income tax expense (benefit)	$ 3,333	$ 5,675	$ (18,414)

The Company s income tax expense in 2010 and 2009 included the Company s federal, state, and foreign tax obligations. The Company s income tax benefit of $18.4 million in 2008 was primarily due to $19.1 million in reversals of

the Company s valuation allowance on its deferred tax assets, partially offset by current tax expense including alternative minimum tax on the Company s taxable income that could not be offset by the Company s net operating loss carryforwards, state tax obligations, and foreign taxes on income of the Company s wholly owned European subsidiary.

The income tax expense (benefit) 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):

	2010	2009	2008
Tax expense at statutory rate	$ 2,547	$ 5,024	$ 4,738
Increase (reduction) in income taxes resulting from:			
State income taxes, net of federal benefit	347	321	592
Equity compensation	334	334	232
Non-deductible entertainment expenses	129	129	134
Foreign income taxes	28	26	52
Reversal of deferred tax valuation allowance			(19,147)
Other changes in deferred tax valuation allowance		(55)	(4,932)
Research and development credit	(187)	(68)	(77)
Other	135	(36)	(6)
	$ 3,333	$ 5,675	$ (18,414)

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):

	2010	2009
Deferred tax assets:		
Allowance for bad debts	$ 110	$ 84
Deferred preservation costs and inventory reserves	1,401	1,434
Investment in equity securities	832	
Property	2,197	2,301
Intangible assets	440	
Accrued expenses	2,812	2,388
Loss carryforwards	2,942	3,945
Credit carryforwards	4,527	5,230
Stock compensation	1,455	1,054
Other	716	508
Less valuation allowance	(1,771)	(1,771)
Total deferred tax assets	15,661	15,173
Deferred tax liabilities:		
Prepaid items	(377)	(364)
Intangible assets		(1,040)
Other	(6)	
Total deferred tax liabilities	(383)	(1,404)
Total net deferred tax assets	$ 15,278	$ 13,769

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. As of December 31, 2009 the Company had a total of $1.8 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax asset of $13.8 million.

As of December 31, 2010 the Company had approximately $2.9 million of tax effected state net operating loss carryforwards that will begin to expire in 2011, $1.3 million 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, 2010 the Company had $3.0 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):

	2010	2009	2008
Beginning balance	$ 1,742	$ 1,799	$ 1,736
Decreases related to prior year tax positions	(19)	(183)	
Increases related to current year tax positions	99	136	63
Settlements		(10)	
Ending balance	$ 1,822	$ 1,742	$ 1,799

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):

	2010	2009	2008
Beginning balance	$ 342	$ 431	$ 347
Accrual of interest and penalties	49	83	84
Decreases related to prior year tax positions		(172)	
Ending balance	$ 391	$ 342	$ 431

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. As of December 31, 2009 the Company s total uncertain tax liability including interest and penalties of $2.1 million was recorded as a reduction to deferred tax assets of $1.3 million and a non current liability of $825,000 on the Company s Consolidated Balance Sheet.

The Company s tax years 2007 through 2010 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2007 in which net operating losses and tax credits have arisen are still open for examination by the tax authorities.

15. Transactions with Related Parties

The Company expensed $22,000, $99,000, and $142,000 in 2010, 2009, and 2008, 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 $5.0 million, $2.6 million, and $1.5 million in 2010, 2009, and 2008, 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 $390,000, $439,000, and $452,000 with the Company in 2010, 2009, and 2008, respectively. Additionally, the son of this member of the Company s Board of Directors is employed by a medical center that generated preservation services and product revenues of $178,000, $231,000, and $258,000 with the Company in 2010, 2009, and 2008, respectively.

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

16. 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 2010 and from shipments of previously preserved orthopaedic tissues during 2009 and 2008. The Medical Devices segment includes external revenues from product sales of BioGlue, BioFoam, PerClot, and HemoStase, 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 preservation services and products, and gross margins for the Company s operating segments (in thousands):

	2010	2009	2008
Revenues:			
Preservation services	$ 59,724	$ 56,456	$ 53,656
Medical devices	56,370	54,162	50,493
Other [a]	551	1,067	910
Total revenues	116,645	111,685	105,059
Cost of preservation services and products:			
Preservation services	35,868	32,767	29,112
Medical devices	12,409	9,150	8,153
Total cost of preservation services and products	48,277	41,917	37,265
Gross margin:			
Preservation services	23,856	23,689	24,544
Medical devices	43,961	45,012	42,340
Other [a]	551	1,067	910
Total gross margin	$ 68,368	$ 69,768	$ 67,794

Net revenues by product for the years ended December 31, 2010, 2009, and 2008 were as follows (in thousands):

	2010	2009	2008
Preservation services:			
Cardiac tissue	$ 27,997	$ 26,074	$ 25,514
Vascular tissue	31,727	30,201	27,417
Orthopaedic tissue		181	725
Total preservation services	59,724	56,456	53,656
Products:			
BioGlue and BioFoam	47,383	47,906	48,570
PerClot	264		
HemoStase	8,793	6,008	1,532
Other medical devices	(70)	248	391
Total products	56,370	54,162	50,493
Other [a]	551	1,067	910
Total revenues	$ 116,645	$ 111,685	$ 105,059

[a] For the year ended December 31, 2010 and 2009 the Other designation includes grant revenue. For the years ended December 31, 2008, the Other designation includes 1) grant revenue and 2) revenues related to the licensing of the Company s technology to a third party.

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2010, 2009, and 2008 were as follows (in thousands):

	2010	2009	2008
U.S.	$ 97,037	$ 94,094	$ 89,297
International	19,608	17,591	15,762
Total	$ 116,645	$ 111,685	$ 105,059

At December 31, 2010, and 2009, 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.

SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE:				
2010	$ 29,717	$ 29,263	$ 28,443	$ 29,222
2009	26,688	28,163	28,219	28,615
2008	25,568	27,155	26,804	25,532
GROSS MARGIN:				
2010	$ 17,792	$ 17,769	$ 15,222*	$ 17,585
2009	17,235	17,895	17,041	17,597
2008	16,258	17,866	17,161	16,509
NET INCOME (LOSS):				
2010	$ 1,934	$ 2,926	$ (3,031)*	$ 2,115
2009	1,949	2,502	1,862	2,366
2008	2,765	3,888	3,556	21,741**
INCOME (LOSS) PER COMMON SHARE DILUTED:				
2010	$ 0.07	$ 0.10	$ (0.11)*	$ 0.08
2009	0.07	0.09	0.07	0.08
2008	0.10	0.14	0.12	0.76**

* 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 net loss and loss per share-diluted 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.

** The fourth quarter 2008 net income and income per common share diluted includes the favorable effect of $19.1 million for the reversal of the Company s valuation allowance on its deferred tax assets.