CRYOLIFE INC
Form 10-K
February 19, 2010

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, 2009

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, 2009, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $145,618,202, computed using the closing price of $5.54 per share of Common Stock on June 30, 2009, the last trading day of the registrant s most recently completed second fiscal quarter, as reported by the New York Stock Exchange, based on management s belief that Registrant has no affiliates other than its directors and executive officers.

As of February 12, 2010 the number of outstanding shares of Common Stock of the registrant was 28,489,832.

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, 2009.	Part III

PART I

Item 1. Business.

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 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 include surgical adhesives, sealants, and hemostats including BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and HemoStase® (HemoStase), which the Company distributes for Medafor, Inc. (Medafor), as well as other medical devices. The Company s products are often sold in international markets several years before they can be marketed in the U.S. In 2009 international revenues were 16% of total revenues.

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 preserves cardiac and vascular tissue using special 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 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. In 2009 CryoLife used the SynerGraft technology for a portion of its pulmonary valve processing and pulmonary cardiac patch tissue processing. The Company began to phase out the distribution of orthopaedic tissue in 2007 and distributed its last orthopaedic tissue in fourth quarter of 2009.

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

CryoLife distributes HemoStase under a private label agreement with Medafor. 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 its agreement with Medafor, CryoLife is the exclusive distributor in the U.S. for cardiac and vascular surgery (excluding Department of Defense 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 plans to expand its international distribution of HemoStase in 2010 as the required regulatory approvals are obtained. CryoLife is currently in litigation with Medafor related to the conduct of Medafor pursuant to the distribution agreement between the parties, discussed further below in Part I, Item 3, Legal Proceedings. In addition, CryoLife has proposed to the Medafor board of directors a combination of the two companies as discussed in Recent Events Medafor below.

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. CryoLife has recently received regulatory certifications and approvals for BioFoam discussed further below.

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. 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.

BioGlue is the first product to be developed from the Company s Protein Hydrogel Technology (PHT) and BioFoam is the second product. CryoLife continues to research and develop product line extensions to BioGlue including modifications to the BioGlue delivery system. In addition, CryoLife continues to research and develop additional indications for the use of BioFoam, outside of the currently approved indications.

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

Medafor

During the fourth quarter of 2009 and in January 2010, CryoLife completed the purchase of approximately 2.3 million shares of Medafor common stock for $2 per share. Based on the most recent information available to CryoLife, these shares represent approximately 11% of Medafor s stock. In addition, in January 2010 CryoLife announced that it had contacted Medafor s board and proposed a purchase price of $2.00 per share for the remaining outstanding shares, to be paid in a mixture of cash and CryoLife stock. The parties have exchanged letters regarding CryoLife s proposal**,** but on February 10, Medafor s Board of Directors stated that it would not meet with CryoLife to discuss its offer.

BioFoam

In August of 2009 CryoLife received CE Mark certification for BioFoam in the EEA for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) when cessation of bleeding by ligature or other conventional methods is ineffective or impractical. CryoLife is conducting a controlled clinical launch of BioFoam at four centers in the United Kingdom, Germany, and France. The objectives of this 70-patient controlled launch, in which BioFoam is used as a surgical hemostatic adjunct in the open repair of liver parenchyma following liver resection and/or liver transplant surgery, are to (1) collect additional clinical data supporting the safety and performance of BioFoam and (2) further refine the optimal application technique.

In October of 2009 CryoLife was granted approval by the FDA for an Investigational Device Exemption (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.

CryoPatch SG Pulmonary Cardiac Patch

In August of 2009 the Company received a 510(k) clearance from the FDA for its CryoPatch SG. CryoPatch SG is indicated for the repair or reconstruction of the right ventricular outflow tract, which is a surgery commonly performed in children with congenital heart defects, such as tetralogy of Fallot, truncus arteriosus, and pulmonary atresia. CryoPatch SG is distributed in three anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch.

CryoValve SG Aortic Heart Valve

In October of 2009 the Company announced that it received a Humanitarian Use Device (HUD) designation from the FDA for its CryoValve SG aortic heart valve (CryoValve SGAV). The HUD designation is the first step in obtaining a Humanitarian Device Exemption (HDE) which would allow the company to market the CryoValve SGAV in the U.S. An HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the U.S. per year, provided that no comparable device with the same intended use is marketed with other FDA approvals.

The Company believes that its patented SynerGraft technology serves as the foundation for CryoLife s next generation of implantable biological tissues. This technology is designed to remove allogeneic donor cells and cellular remnants from tissue without compromising the integrity of the underlying collagen matrix. The CryoValve SGAV is intended to be used for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic aortic valves in children from birth to 21 years of age. The Company estimates that up to 1,500 children per year could benefit from this technology if the Company is successful in obtaining an HDE.

Strategy

The key elements of the Company s strategy related to growing its business and leveraging its strengths and expertise in its core marketplaces to generate revenue and earnings growth are:

Expand Core Business. Expand the Company s core business in cardiac and vascular medical specialties by expanding the market penetration of BioGlue and related products, heart valves, cardiac patch tissues, and vascular tissue.

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.

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, distribution, or licensing of additional technologies that complement existing services and products.

License Company Technology to Third Parties for Non-Competing Uses. Leverage the Company s current technology platforms, including its 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, the timely and controlled delivery of such tissue to the Company, the screening, dissection, disinfection, 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 procurement organizations 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 medical 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 organ procurement agencies and tissue banks 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 reconstructive heart valve replacement surgery. CryoLife shipped approximately 71,500 heart valves and cardiac patch tissues from 1984 through 2009, including approximately 3,000 shipments in 2009. Revenues from cardiac tissue preservation services accounted for 24%, 24%, and 23% of total Company revenues in 2009, 2008, and 2007, 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 medical relations and education staff, clinical research staff, customer service department, and field representatives. Management believes the Company offers advantages in the areas of clinical data and field services as compared to other human tissue processors and that the Company s tissues offer advantages in certain areas over mechanical, porcine, and bovine heart valve alternatives. The Company currently preserves human aortic and pulmonary heart valves for implantation by cardiac surgeons. In addition, the Company preserves human cardiac patch tissue for surgeons who wish to perform certain specialized cardiac repair procedures. 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 has begun using the SynerGraft technology for a portion of its pulmonary valve and cardiac patch processing. In 2009 45% of pulmonary valves and 6% of cardiac patch tissues shipped by CryoLife were processed with the SynerGraft technology.

The Company estimates that in 2009 the total annual heart valve replacement and cardiac patch market in the U.S. was approximately $675 million. Management believes that of the $675 million, approximately $445 million or 66% 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 93,000 aortic, pulmonary, and tricuspid valve replacement or repair surgeries were conducted in the U.S. in 2009. Of these 93,000 procedures approximately 90% were for aortic valve replacement.

Management believes preserved human heart valves and cardiac patch tissues have characteristics that make them the preferred replacement option for many patients. Specifically, human heart valves, such as those preserved by the Company, allow for more normal blood flow and provide higher cardiac output than stented porcine, bovine, and mechanical heart valves. Human heart valves are not as susceptible to progressive calcification, or hardening, as are traditional glutaraldehyde-fixed porcine and bovine heart valves, and do not require anti-coagulation drug therapy, as do mechanical valves. The synthetic sewing rings contained in mechanical and stented porcine and bovine valves may harbor bacteria and lead to endocarditis. Furthermore, prosthetic valve endocarditis can be difficult to treat with antibiotics, and this usually necessitates the surgical removal of these valves at considerable cost, morbidity, and risk of mortality. Consequently, for many physicians, human heart valves are the preferred alternative to mechanical and animal derived tissue valves for patients who have or are at risk to contract endocarditis.

The following table sets forth the characteristics of alternative heart valve implants that management believes make preserved human heart valves the preferred replacement for certain patient populations:

	Cryopreserved Human	Porcine		Mechanical	Bovine Pericardial
		Stented	Stentless		
Materials:	human tissue	glutaraldehyde-fixed pig tissue and synthetic sewing ring	glutaraldehyde-fixed pig tissue	pyrolitic carbon bi-leaflet and synthetic sewing ring	glutaraldehyde-fixed cow tissue and synthetic sewing ring
Pressure Gradients:	normal	moderate elevation	nearly normal	moderate to high elevation	moderate elevation
Mode of Failure:	gradual	gradual	expected to be gradual	catastrophic	gradual
Longevity in Related Age Groups:	15-20 years	10-15 years	expected to exceed stented porcine valves	15-20 years	10-15 years
Increased Risk of Bleeding or Thromboembolic Events (strokes or other clotting):	no	occasional	occasional	yes	occasional
Anti-Coagulation Drug Therapy Required:	none	short-term	short-term	chronic	short-term
Effectiveness in the Treatment of Endocarditis:	high	low	moderate	low	low

While the clinical benefits of preserved human heart valves discussed above are relevant to all patients, they are particularly important for (i) pediatric patients who are prone to calcification of porcine and bovine tissue, (ii) young or otherwise active patients who face an increased risk of severe blood loss or even death due to side effects associated with the anti-coagulation drug therapy required with mechanical valves, and (iii) women in their childbearing years for whom anti-coagulation drug therapy is contraindicated.

Vascular Tissue. The Company preserves human saphenous veins for use in vascular surgeries that require small diameter conduits (3mm to 6mm), such as peripheral vascular reconstructions and coronary bypass surgery. Failure to bypass or revascularize an obstruction in such cases may result in death or the loss of a limb. The Company also preserves femoral veins and arteries for use in infected areas and aortoiliac arteries for use as vascular grafts. The Company shipped approximately 57,100 human vascular tissues from 1986 through 2009, including approximately 4,300 shipments in 2009. Revenues from vascular preservation services accounted for 27%, 26%, and 24% of total Company revenues in 2009, 2008, and 2007, respectively.

A surgeon s first choice for replacing diseased or damaged vascular tissue is generally the patient s own tissue. However, in cases of advanced vascular disease, the patient s tissue is often unusable and the surgeon may consider using synthetic grafts or preserved human vascular tissue. Small diameter synthetic vascular grafts are generally not suitable 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. Therefore, preserved human vascular tissues are also a preferred graft alternative for patients with previously infected graft sites. The Company s preserved human vascular tissues are used for peripheral vascular reconstruction, coronary artery bypass surgeries, and abdominal aortic reconstruction. In cases of peripheral arteriosclerosis, a preserved saphenous vein can be implanted as a bypass graft for the diseased artery in order to improve blood flow and maintain a functional lower limb. The only alternative for many of these patients is amputation. Preserved vascular tissue can be used in a subset of coronary artery bypass procedures when the patient s own tissue is not available. Preserved aortoiliac arteries can be used in cases of abdominal aortic infection when the use of synthetic graft alternatives is often not an option for placement directly into an infected area.

Orthopaedic Tissue. In the past, the Company preserved human orthopaedic tissue for surgical replacements of the meniscus, the anterior and posterior cruciate ligaments, and osteoarticular cartilage, which are critical to the proper function

of the human knee. In December 2006 CryoLife entered into an exchange and services agreement with Regeneration Technologies, Inc. (RTI) related to cardiac and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife. In accordance with this agreement, on January 1, 2007, CryoLife ceased accepting donated human orthopaedic tissue for processing and RTI ceased accepting donated human cardiac and vascular tissues for processing. Pursuant to this agreement, CryoLife distributed portions of its existing orthopaedic tissue inventory through December 31, 2009 as directed by RTI. Under the RTI Agreement, from July 1, 2008 through December 31, 2016, CryoLife has agreed not to market or solicit orders for orthopaedic tissues, except as directed by RTI. CryoLife notified RTI that starting in 2010, CryoLife will no longer ship orthopaedic tissues from CryoLife for RTI. Revenues from human orthopaedic preservation services accounted for less than 1% of total Company revenues in 2009 and 2008, and 4% of total Company revenues in 2007.

Surgical Adhesives, Sealants, and Hemostats

BioGlue. 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 BioGlue product. 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 sealants and adhesives were approximately $230 million in 2009. 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. Additional marketing approvals have been granted for specified applications in several other countries throughout the world. Revenues from BioGlue represented 43%, 46%, and 46% of total Company revenues in 2009, 2008, and 2007, respectively.

BioGlue is the first product to be developed from the Company s PHT platform. 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.

HemoStase. The Company exclusively distributes 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. This product is a plant-based, flowable powder engineered to rapidly dehydrate blood, enhancing clotting on contact. Easy to apply, HemoStase does not require additional operating room preparation or special storage conditions and absorbs significantly faster than other surgical hemostats. When applied directly to an actively bleeding wound, each HemoStase particle acts as a molecular sieve to instantly remove fluids from blood. This action causes the particle to expand and concentrates blood proteins, platelets, and other formed elements

on its surface. The particles and their coating of compacted cells create scaffolding for the formation of a clot within minutes of application. The HemoStase particles are fully absorbed and enzymatically cleared from the wound site in less than 48 hours after application. HemoStase is currently available in 1 gram, 3 gram, and 5 gram units. Revenues for HemoStase represented 5% and 2% of total Company revenues in 2009 and 2008, respectively. The Company estimates that aggregate U.S. sales for hemostatic agents were approximately $665 million in 2009.

BioFoam. As discussed above at Recent Events BioFoam , the Company received CE Mark certification and approval by the FDA 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. 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 reoperations in liver resections.

CryoLife began a controlled launch of BioFoam at four clinical centers in Europe in 2009. CryoLife plans to begin distribution of BioFoam in 2010 in Europe. CryoLife plans to begin distribution of BioFoam in other international markets as required regulatory approvals are obtained. The Company estimates that the aggregate European market opportunity in the near term for BioFoam is approximately $30 million and approximately $100 million worldwide.

Other Medical Devices

ProPatch Soft Tissue Repair Matrix (ProPatch). In late 2006 CryoLife received 510(k) clearance from the FDA for its 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. Additional preclinical animal data is being collected with respect to the use of ProPatch in hernia repair as a standard surgical patch for soft tissue reinforcement where weakness exists. 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.

Other. During 2009 the Company had revenues related to the CryoLife-O Brien Stentless Aortic Bioprosthesis, a stentless porcine valve, and CardioWrap®, a resorbable protective plastic sheet used to replace the pericardium in cardiac reconstruction. Revenues for these products represented less than one percent of total revenues in 2009, 2008, and 2007. The Company has decided to de-emphasize its sales efforts related to the CryoLife-O Brien Stentless Aortic Bioprosthesis and CardioWrap; therefore, the Company expects minimal revenues for the CryoLife-O Brien Stentless Aortic Bioprosthesis and CardioWrap in 2010.

See Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations Seasonality , regarding seasonality of the Company s human tissue preservation services and products.

See Part II, Item 8, Note 15 of the Notes to Consolidated Financial Statements regarding segment and geographic information.

Procurement, Distribution, and Marketing

Preservation Services

CryoLife markets its preservation services to tissue procurement agencies, implanting physicians, and prospective tissue recipients. The Company works with tissue banks and organ procurement organizations 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 tissue banks and organ procurement organizations. 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 procurement agency is reimbursed by the Company for costs associated with these procurement services. The procurement

fee, which includes related shipping costs, together with the charges for the preservation and processing services of the Company, are 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 105,000 donors. The Company has developed relationships with approximately 60 tissue banks and organ procurement organizations 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 tissue banks and organ procurement organizations. This includes four account managers who are stationed throughout the country to work directly with the tissue banks and organ procurement organizations. 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 procurement agency 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. At the hospital the tissue is 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. After the Company transports the tissue to the hospital, the Company invoices the institution for its services, which include procurement, processing, and transportation.

The Company provides Company-owned liquid nitrogen freezers to certain client hospitals. The Company has currently installed approximately 270 of these freezers. 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 1,250 cardiac and vascular surgeons who implanted tissues preserved by the Company during 2009. 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 30 field service representatives who focus primarily on vascular surgeons, 12 cardiac specialists who focus primarily on cardiac 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 processed by the Company and help to differentiate the Company from other allograft processors. On September 25 and 26, 2009 CryoLife hosted the second annual Ross Summit at CryoLife s Corporate Headquarters with 80 cardiac surgeons from

18 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 human pulmonary valve from a donor is typically surgically implanted to replace the removed native pulmonary valve.

To assist tissue banks and organ procurement organizations, 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 procurement agency 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 procurement organization support.

Surgical Adhesives, Sealants, and Hemostats

BioGlue. In the U.S. the Company markets BioGlue to physicians and distributes it through its field service representatives and cardiac specialists. The Company markets and distributes BioGlue 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 BioGlue.

During 1998 the Company signed an exclusive agreement with Century Medical, Inc. (Century Medical) for the introduction and distribution of BioGlue in Japan. Under the terms of the agreement, Century Medical is responsible for applications and clearances with the Japanese Ministry of Health and Welfare for the use of BioGlue in Japan. Century Medical has submitted the application to the Japanese Ministry of Health and Welfare, and the review process is ongoing.

HemoStase. In the U.S. the Company markets and distributes HemoStase for use in cardiac and vascular surgery through its field representatives and cardiac specialists. The Company markets and distributes HemoStase for cardiac, vascular, and general surgery in international markets (except China and Japan) through direct field representatives employed by Europa and other independent distributors.

BioFoam. The Company markets and distributes BioFoam in international markets through direct field representatives employed by Europa, its European subsidiary, and other independent distributors.

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 23 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 and Germany and a network of independent distributors in the EMEA region. Europa also distributes tissue to certain hospitals in the EMEA region.

Backlog

The limited supply of tissue that is donated and available for processing can result in a backlog of orders for the tissues the Company preserves, primarily for those tissues used in pediatric surgeries. 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, HemoStase, or BioFoam.

Competition

Preservation Services

The Company currently faces competition from at least two non-profit tissue banks that preserve and distribute human cardiac and vascular tissue, 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

10

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. 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 mechanical valves, porcine valves, valves constructed from bovine pericardium, and valve repair. St. Jude Medical, Inc. is the leading supplier of mechanical heart valves. Medtronic, Inc. is the leading supplier of porcine heart valves. Edwards LifeSciences, 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 preservation services for 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 SGAV is important to patient management issues for potential whole organ transplant recipients, as the Company s heart valves offer better opportunities for patients requiring re-operation.

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 the 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. Companies offering either synthetic or allograft products may enter this market in the future.

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 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. 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.

BioGlue. The Company s BioGlue product competes primarily with Baxter International, Inc. s Tisseel and CoSeal; Ethicon, Inc. s (a Johnson & Johnson Company) Evicel; Covidien Ltd s U.S. Surgical Division s Duraseal product; Tenaxis, Inc. s (Tenaxis) ArterX; and NeoMend, Inc. s ProGEL. The Company currently competes with these products based on BioGlue s benefits and features, such as strength and ease of use. Competitive products may also be under development by other large medical device, pharmaceutical, and biopharmaceutical companies.

HemoStase. The Company s HemoStase product competes with thrombin products, including King Pharmaceuticals, Inc. s Thrombin JMI, ZymoGenetics, Inc. s Recothrom, and Omrix Biopharmaceuticals, Inc. s (a Johnson & Johnson Company) Evithrom; and surgical hemostats, including Pfizer, Inc. s Gelfoam, C.R. Bard, Inc. s Avitene, Baxter International, Inc. s FloSeal, Ethicon, Inc. s Surgicel, Surgiflo, and Surgifoam products, and Starch Medical Inc. s PerClot. Other competitive products may include argon beam coagulators to 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 HemoStase product competes on the basis of its safety profile, its clinical efficacy, and ease of use.

BioFoam. The Company s BioFoam product competes with other surgical hemostatic agents that include Pfizer, Inc. s Gelfoam, Baxter International, Inc. 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.

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 27 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 developing or investigating several technologies and products, including technologies related to human tissue preservation, its PHT product platform used in BioGlue, BioFoam, and other PHT derivatives, and additional applications of its SynerGraft technology.

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 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 the valve. Additionally, explant analyses may help determine if the collagen matrix recellularizes with the recipient s own cells.

In 2009, as discussed above in Recent Events BioFoam , the Company received CE Mark certification and 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. 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 protein hydrogel technology for use on the battlefield. The Company anticipates applying for additional funding under this bill for the 2010 allocation. Before the Company can begin the feasibility arm of the IDE, the Company must receive an additional approval from the U.S. Department of Defense (DOD) as a condition of its award. The Company is in the final review process with the DOD to begin clinical implants of BioFoam in the U.S. 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. The Company is currently involved in follow-up animal trials related to this grant. The Company continues to conduct preclinical research with BioFoam for use in wound sealing in trauma surgery and other potential indications.

In October 2006 the Company signed a licensing and distribution agreement with BioForm for the development and commercialization of BioGlue for use in cosmetic and plastic surgery indications under the name BIOGLUE *Aesthetic*® Medical Adhesive (BioGlue Aesthetic). The agreement calls for BioForm to fund the clinical development and regulatory approval process for commercializing BioGlue Aesthetic for use in cosmetic and plastic surgery indications in the U.S.,

Canada, and various countries in Europe. In addition, BioForm will oversee all aspects of the marketing, sales, and distribution of BioGlue Aesthetic in the U.S., Canada, and various countries in Europe for these indications. The Company will remain the exclusive supplier of BioGlue for all applications. Under the terms of the agreement, the Company received an initial fee from BioForm and will receive a milestone payment upon the first FDA approval for use in cosmetic and plastic surgery indications. BioForm has completed a feasibility study under an IDE from the FDA and is currently under discussions with the FDA regarding the requirements of the pivotal study, the initial study necessary before submission of a premarket approval (PMA) to the FDA. BioForm s strategy is to determine compelling aesthetic applications for BioGlue, demonstrate safety and effectiveness of this material in aesthetic applications, and launch BioGlue Aesthetic as an alternative fixation methodology to improve browplasty and certain other surgical and minimally invasive aesthetic procedures. BioForm received a CE Mark in June 2008 for the use of BioGlue for fixation following endoscopic browplasty, commonly called brow lift, a reconstructive plastic surgery procedure. BioForm had a limited introduction of this product in Europe in 2009. Due to general economic constraints causing a decrease in elective plastic surgery and procedures, revenues were minimal in 2009.

The Company completed a clinical feasibility evaluation of BioDisc®, a product in the PHT platform, to determine its utility as a nucleus pulposus replacement in spinal disc repair. The nucleus pulposus is surrounded by fibrous tissue (annulus fibrosis) and is located in the center of the vertebral disc. The nucleus pulposus is composed of a gelatinous-like material that in conjunction with the annulus fibrosis acts as a cushion or shock absorber to the spinal column. If the nucleus pulposus herniates through the annulus, it may be removed in a procedure known as a discectomy. BioDisc is designed to fill the area where the nucleus pulposus was removed and is intended to preserve disc height, reduce lumbar motion segment instability, and reduce recurrent disc herniation. A ten patient study with a two-year follow-up has been completed. The Company filed a CE Mark submission in February 2007 and received notices from its Notified Body of non-conformities requiring additional data. Management believes that additional human implants and clinical follow-up will be necessary to obtain a CE Mark. The Company will seek a partner to assist in the development prior to investing additional material funds in BioDisc.

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 preservation services and medical devices, 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 2009, 2008, and 2007 the Company spent approximately $5.2 million, $5.3 million, and $4.5 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 2009, 2008, and 2007.

Processing, 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 dissection and processing, manufacturing, and packaging. Approximately 55 liquid nitrogen storage units 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 Processing

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 58 technicians employed in this area, and the laboratory is staffed 24 hours per day, 365 days per year. In 2009 the laboratory packaged approximately 11,600 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 tissue banks and organ procurement organizations, 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 additional donated tissues were obtained, the Company would need to increase the number of 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 16 technicians employed in this area. The laboratory has a potential annual capacity of approximately 2 million syringes of BioGlue and related products. The current processing level is about 6% 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 bioprosthesis laboratory at the Company s headquarters facility is responsible for the expected manufacturing of the ProPatch surgical mesh. This laboratory is approximately 20,000 square feet with a suite of six clean rooms for tissue processing.

Europa

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

Quality Assurance

The Company s operations encompass the processing 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 EU to perform assessments of compliance with ISO 13485 and the Medical Device Directive. The Medical Device Directive is the governing document for the EU 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 processing 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 procurement agencies. To assure uniformity of procurement practices among the tissue recovery teams, the Company

provides procurement protocols, transport packages, and tissue transport liquids to the procurement organizations. The Company periodically audits procurement organizations 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 processing and 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 processing tissue must meet the Company s quality standards and be approved by quality assurance personnel for use in processing. Throughout tissue processing, detailed records of the tissues, materials, and processes used are maintained and reviewed by quality assurance personnel.

The FDA periodically audits the Company s processing facilities for compliance with its requirements. The States of California, Delaware, Florida, Georgia, Illinois, Maryland, New York, and Oregon license or register the Company s tissue processing facilities as facilities that process, store, and distribute human tissue for implantation. The regulatory bodies of these states may perform inspections of the 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.

All materials, components, and resulting sub-assemblies are documented throughout the manufacturing process to assure traceability. All processes in manufacturing are validated by quality engineers 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, processing 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 110 foreign patents, including patents relating to its technology for human cardiac and vascular tissue preservation, tissue revitalization prior to freezing, tissue transport, tissue packing, BioGlue manufacturing, and PHT manufacturing. The Company has approximately 6 pending U.S. patent applications and 17 pending foreign applications that relate to the Company s preserved 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 to 17 years. The main patent for BioGlue expires in 2012 in the U.S. and in 2013 in the rest of the world. In addition, the Company has distribution agreements with third parties for the distribution of HemoStase. This product has 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 processes, 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

15

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 currently existing or proprietary rights of third parties. For example, we have filed suit in Germany against Tenaxis because we believe Tenaxis is infringing our main BioGlue patent in Germany. This company has filed a separate nullity suit against this same BioGlue patent in Germany and we are awaiting the court s ruling. Should we be unsuccessful in our lawsuit regarding infringement of our BioGlue patent in Germany or should this nullity lawsuit filed by Tenaxis be successful, our revenues and profitability could be materially adversely affected. 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 effect on the Company s business, financial condition, profitability, and cash flows. The Company has agreements with third parties for certain technologies related to its BioGlue and SynerGraft technologies that call for the payment of royalties based on the revenues of such products.

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 tissue banks and organ procurement organizations 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 tissue procurement organizations and tissue banks 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 surgery 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, it would have a material adverse effect on our ability to manufacture BioGlue and would materially adversely affect the Company s revenues.

HemoStase is produced by Medafor for us pursuant to our distribution agreement. If Medafor was unable to obtain the appropriate raw materials for HemoStase in order to manufacture it for the Company, it would materially adversely affect our ability to sell HemoStase and could therefore have a material adverse effect on our revenues. In addition, if Medafor breached its distribution agreement or attempted to terminate the distribution agreement, which it has attempted to do twice previously in connection with our lawsuit against Medafor, it would materially adversely affect our ability to sell HemoStase and would have a material adverse effect on our revenues. 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) procedure, in which the manufacturer provides a premarket notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed 510(k) product (i.e., that it has the same intended use, it is as safe and effective as a legally marketed 510(k) device, and it does not raise different questions of safety and effectiveness than does a legally marketed device). In some cases the submission must include data from clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence.

If the product does not qualify for the 510(k) procedure (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 application for PMA), the FDA must approve a PMA application before marketing can begin. PMA applications must demonstrate, among other matters, that the medical device is safe and effective. 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.

The FDCA also provides for an investigational device exemption (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 Institutional Review Board is needed. The device must be labeled that it is for investigational use and may not be advertised or otherwise promoted and the price charged for the device may be limited. Unexpected adverse events must be reported to the FDA.

Under certain circumstances, the FDA may grant a Humanitarian Device Exemption (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. 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 noncomplying 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. The Company s human heart valves became subject to regulation by the FDA in June 1991, when the FDA published a notice stating that human heart valves were Class III medical devices under the FDCA. The June 1991 notice provided that distribution of human heart valves for transplantation would violate the FDCA unless they were the subject of an approved PMA or IDE on or before August 26, 1991.

On October 14, 1994, however, the FDA announced in the Federal Register that neither an approved application for PMA nor an IDE is required for processors and distributors who had marketed heart valve allografts before June 26, 1991. This action by the FDA resulted in the Company s allograft heart valves being classified as Class II Medical Devices and removed them from clinical trial status. It also allowed the Company to distribute such valves to cardiac surgeons throughout the U.S.

On May 25, 2005, with the promulgation of the final rule for cGTPs, the FDA reclassified human heart valves, processed on or after May 25, 2005, as 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. In 2008 the Company received 510(k) clearance from the FDA for its CryoValve SGPV processed with the Company s proprietary SynerGraft technology, and in 2009 the Company received 510(k) clearance for the FDA for its CryoPatch SG, as discussed in Overview Tissue Preservation Services .

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. The product is Health Canada, Australia, and CE Mark approved for additional soft tissue repair.

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.

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.

BioFoam. In October of 2009 CryoLife was 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. If the Company receives PMA approval of its BioFoam, it will be regulated by the FDA as a Class III medical device.

Other. Porcine heart valves are Class III medical devices and FDA approval of a PMA is required prior to commercial distribution of such valves in the U.S. The CryoLife-O Brien Stentless Aortic Bioprosthesis porcine valves currently marketed by the Company have not been approved by the FDA for commercial distribution in the U.S., but may be manufactured in the U.S. and exported to foreign countries if the valves meet the specifications of the foreign purchaser and do not conflict with the laws of, and are approved by, the country to which they will be exported.

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. Concerns with the transmission of HIV and Hepatitis B led the FDA to issue an Interim Rule in December 1993 as an emergency measure to protect the public from any human tissue that had incomplete or no documentation ascertaining its freedom from communicable diseases. The FDA modified the regulation and reissued it as a new rule (21 C.F.R. Part 1270), effective January 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 rule set minimal requirements to prevent the transmission of communicable diseases from human tissue used for transplantation. The rule defines 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, processed, 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 processed on or after May 25, 2005 as human tissue rather than medical devices.

It is likely that the FDA s regulation of processed 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 effect on the Company. For example, on January 16, 2009 the FDA issued draft guidance for cGTPs and Additional Requirements for Manufactures of HCT/Ps. This guidance is subject to comment and change before being formally issued by the FDA.

Possible Other FDA Regulation

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

NOTA Regulation

The Company s activities in processing 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 processing, 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, and Oregon 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, process, and distribute human tissue designed to be used for medical purposes in human beings. There can be no assurance, however, that more restrictive state laws or regulations will not be adopted in the future that could materially adversely affect the Company s operations. Certain employees of the Company have obtained other required state licenses.

International Approval Requirements

Sales of medical devices and shipments of preserved human tissues outside the U.S. are subject to international regulatory requirements that vary widely from country to country. Approval of a product by comparable regulatory authorities of other countries must be obtained or compliance with applicable regulations for tissues must be met prior to commercial distribution of the product or preserved human tissues in those countries. The time required to obtain these approvals may be longer or shorter than that required for FDA approval.

The EEA recognizes a single medical device approval, called a CE Mark, which allows for distribution of an approved product throughout the EEA (32 member state countries - 27 European Union (EU) countries, 4 European Free Trade Association (EFTA) countries, and Turkey) without additional general applications in each country. However, individual EEA members reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third parties called Notified Bodies award the CE Mark. These Notified Bodies are approved and subject to review by the competent authorities of their respective countries. A number of countries outside of the EEA accept

the CE Mark in lieu of marketing submissions as an addendum to that country s application process. The Company has been issued CE Marks for BioGlue, BioFoam, and the CryoLife-O Brien Stentless Aortic Bioprosthesis and has CE approval for the distribution of HemoStase.

In addition, the distribution of CryoLife s processed 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 or directions, which could impact our ability to send processed tissues into Europe.

Environmental Matters

The Company s tissue processing 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 effect on the Company s business.

Employees

As of December 31, 2009 CryoLife and its subsidiaries had approximately 415 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 if a competitor s product obtains greater acceptance, or our rights to manufacture and market this product are challenged, the result could have a material adverse effect on our revenues, financial condition, profitability, and cash flows. Also, we have only two suppliers of bovine serum albumen, 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. In addition, our U.S. patent for BioGlue expires in 2012 and our patents in the rest of the world for BioGlue expire in 2013. Our main BioGlue patent was the subject of an action to nullify it in Germany and could be nullified in the future. 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. See Uncertainties Related To Patents And Protection of Proprietary Technology May Adversely Affect The Value Of Our Intellectual Property, below.

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 products and processed tissues, development activities, and manufacturing processing 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, manufacturers of medical devices and processors of human tissue must comply with certain regulations that cover the composition, labeling testing, clinical study, manufacturing packaging and distribution of products and tissues. In addition, medical devices must receive FDA clearance or approval before the 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. Furthermore, most major markets for preserved tissues and products outside of the U.S. require clearance, approval or compliance with certain standards before preserved tissues and products can be commercially available. The process of obtaining marketing approval or clearance, or standards compliance from the FDA and foreign regulatory agencies for preserved tissues and products or with respect to enhancements or modification to existing preserved tissues or products can take a significant period of time, require expenditure of substantial resources, involve rigorous preclinical testing and clinical testing, and result in limitations on the indicated uses of the preserved tissues and products. We cannot be certain that we will receive these required approvals or clearances from the FDA and foreign regulatory agencies on a timely basis. The failure to receive approval or clearance for significant new products and preserved tissues on a timely basis could have a material adverse effect 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 marketed preserved tissues and products. Product 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 preserved 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 effect on our revenues financial condition, profitability, and cash flows.

For example, the FDA on August 13, 2002 issued an order regarding our non-valved cardiac, vascular and orthopedic tissues processed by the Company since October 3, 2001, (the FDA Order). Pursuant to the FDA Order, we recalled these tissues or placed them on quarantine hold. In addition to these 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.

CryoLife s Proposed Acquisition Of Medafor Poses A Number Of Risks.

CryoLife announced its acquisition of approximately 11% of the stock of Medafor and its desire to acquire the remaining outstanding shares of Medafor. Although we are pursuing a negotiated transaction, the Medafor board has to date not shown any inclination to meet with us and there can be no assurance that our efforts to negotiate an acquisition of Medafor will be successful. If we do not succeed in negotiating an acquisition of Medafor, we may elect to pursue other alternatives, which could include an acquisition of Medafor without its current Board s consent. However, there can be no assurance that we will acquire Medafor or, if we do, on what terms. Our pursuit of such an acquisition will entail certain risks and costs, including, for example, but not limited to, the following:

- It will require the expenditure of time and energy by CryoLife board members and management that might otherwise be dedicated to the conduct of everyday business;
- It may require us to incur significant legal and investment banking fees, and may involve protracted litigation;
- An acquisition could cause us to assume all liabilities of Medafor, including liabilities due to infractions of governmental regulations, although we are not currently aware of any such material violations;
- An acquisition attempted without Medafor s consent would prevent us from being able to conduct the level of diligence we might otherwise conduct regarding Medafor s business and potential liabilities;
- If we use stock to purchase Medafor, current CryoLife shareholdings may be diluted;
- Our pursuit of the acquisition and/or any actual acquisition and attendant market reaction thereto may cause fluctuations and increased volatility in the market price for our common stock;
- Our pursuit of Medafor could impact customer relationships;
- We may seek alternate financing, which could require us to negotiate new terms for our credit facility or pay off our current credit facility;
- Any pursuit of a hostile acquisition may make it less likely that we will be able to renew our contract with Medafor in the future; and
- Any acquisition of Medafor will require us to integrate our businesses, which will in turn entail all the risks and costs customarily attendant on such acquisitions.

The Lawsuit We Filed Against Medafor Regarding Our Distribution Agreement With Medafor May Adversely Impact Our Relationship With Medafor And Could Hinder Our Distribution Of HemoStase Or Prevent Us From Distributing HemoStase.

Our lawsuit against Medafor, the manufacturer of the HemoStase product, could strain our relations with Medafor. This could hinder our distribution of HemoStase or prevent us from distributing HemoStase, which would adversely impact our revenues and profitability. Revenues from HemoStase were approximately $6.0 million during the year ended December 31, 2009. As an example of our strained relationship, Medafor has previously attempted and is currently attempting to terminate our exclusive agreement to distribute HemoStase due to what they claimed were alleged material breaches of the contract, both of which we disputed. If Medafor is successful in any current or future attempt to terminate the agreement, we would no longer be able to distribute HemoStase and our revenues would be adversely impacted. Also, Medafor s attempts to terminate the agreement, even though currently unsuccessful, may signal future attempts to terminate the agreement over other issues and our relationship with Medafor may become further strained, potentially hindering our ability to effectively distribute HemoStase or prevent

us from distributing HemoStase. See Part I, Item 1, Business , for further information regarding our distribution agreement with Medafor and see Part I, Item 3, Legal Proceedings , for further information regarding our litigation with Medafor.

Healthcare Policy Changes, Including Pending Proposals To Reform The U.S. Healthcare System, May Have A Material Adverse Effect On Us.

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators, and third-party payors to keep these costs down. Certain proposals, if passed or implemented, would impose limitations on the fees we will be able to charge for our services and prices for our products, or the amounts of reimbursement available for our services and products from governmental agencies or third-party payors. These limitations could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

Both the U.S. Senate and House of Representatives have passed versions of bills that would significantly reform the U.S. healthcare system. In the Obama administration s fiscal year 2010 federal budget proposal, the administration emphasized maintaining patient choice, reducing inefficiencies and costs, increasing prevention programs, increasing coverage portability and universality, improving quality of care, and maintaining fiscal sustainability. The proposals before Congress and the versions of the bills passed by both houses of Congress contain limits on Medicare payments and increases in taxes, including increasing taxes on medical device manufacturers such as CryoLife. In addition, members of Congress have proposed a single-payer healthcare system, a government health insurance option to compete with private plans, and other expanded public healthcare measures. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our services and products, increase or add taxes to our services and medical devices, reduce medical procedure volumes, and, therefore, may adversely affect our revenues, financial condition, profitability, and cash flows, possibly materially.

Uncertainties Related To Patents And Protection Of Proprietary Technology May Adversely Affect 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.

We have filed suit in Germany against Tenaxis, Inc. because we believe that Tenaxis is infringing our main BioGlue patent in Germany. This company has filed a separate suit to nullify this same BioGlue patent in Germany and both parties are awaiting the Court s decision on this matter. Should we be unsuccessful in our lawsuit regarding infringement of our BioGlue patent or in prohibiting any other infringements of our patents, or should this nullity lawsuit filed by Tenaxis be successful, or the validity of our patents be successfully challenged by a third party, our revenues, financial condition, profitability, and cash flows could be materially and adversely affected. We continue to investigate other potential infringements of our BioGlue patents.

We protect our proprietary technologies and processes in part by confidentiality agreements with our collaborative partners, employees, and consultants. We cannot be sure that these entities and persons will not breach these agreements, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently discovered by competitors. If any of these events occur, they could result in our loss of the economic benefits associated with our key services and products and could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

Uncertainties Related To Patents And Protection Of Proprietary Technology For Products Distributed By CryoLife May Adversely Affect The Ability Of CryoLife To Distribute Those Products.

We distribute HemoStase, which is manufactured by a third party. This third party has patents, licenses, and proprietary technologies and agreements that may provide them competitive advantage. Others may challenge the validity or enforceability of this intellectual property. Our contract requires that this third party pursue infringements of patents owned or licensed by them for the product that we distribute. We may choose to assist our third party manufacturer and may incur substantial costs in any efforts to uphold the validity and prevent infringement of a patent or to protect proprietary technologies and methods. We cannot be certain that if anyone does make such a challenge, that this third party will be able to successfully defend that challenge, with or without our assistance. Furthermore, competitors could independently develop similar technologies, duplicate technologies, design around the patented aspects of such technologies, or attempt to duplicate proprietary technologies that have no patent protection. In addition, this third party s intellectual property could infringe patents or other rights owned by others, or others could infringe this third party s patents or use their intellectual property rights inappropriately.

The Tissues We Process And Our 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 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. When patients are injured, die, or have other adverse results following procedures using our tissues or medical devices, 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 and adversely affect our financial position, profitability, and cash flows.

As a result of medical complications that are alleged to have been caused by or occur in connection with medical procedures involving our tissues or medical devices, 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 effect 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 tissue or products could have a material adverse effect 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 effect 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. We expect the data to be collected to include long-term safety and 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.

Demand For Our Tissues And Products Could Decrease In The Future, Which Could Have A Material Adverse Effect 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 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 affect our margins, and therefore our results of operations, 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 and adversely affect our financial condition and profitability.

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 tissue 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 proposed legislation regarding interactions with physicians and other healthcare professionals that is currently before other state legislatures and the U.S. Congress. These regulations and proposed legislation, if passed, may affect our ability to maintain strong relationships with physicians. If we are unable to maintain our strong relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our revenues, financial condition, profitability, cash flows.

Consolidation In The Healthcare Industry Could Lead To Demands For Price Concessions Or Limits 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 and adversely impact our business, financial condition, and profitability.

Our Existing Insurance Policies May Not Be Sufficient To Cover Our Actual Claims Liability.

The tissues we process and our 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, 2009 Consolidated Balance Sheet reflects a $3.7 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 $7.9 million, after including a reasonable margin for statistical fluctuations. Based on an actuarial valuation, we estimated that as of December 31, 2009, $1.3 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, 2009. 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, 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 the outstanding or any future claims, this will materially and adversely affect 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 and adversely affected. If we do not have sufficient resources to pay the claims 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 adversely impact our financial condition, profitability, and cash flows. In addition, should we be subject to liability, whether imposed by a court or due to a settlement that results in a large insurance claim, our insurance rates could increase significantly. Our current tissue processing and product liability insurance policy is a seven-year claims-made policy covering claims incurred during the period April 1, 2003 through March 31, 2010 and reported during the period April 1, 2008 through March 31, 2010. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

The Loss Of Any Of Our Sole-Source Suppliers Could Have An Adverse Effect On Our Revenues, Financial Condition, Profitability, And Cash Flows.

We purchase certain supplies used in our manufacturing processes 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 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 adversely affect our revenues, financial condition profitability, and cash flow.

Intense Competition May Affect Our Ability To Operate Profitably.

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

- The processing of human tissue,
- The marketing of mechanical valves and synthetic and animal tissue for implantation, and
- The marketing of surgical adhesives, surgical sealants, and hemostatic agents.

Management believes that at least two domestic tissue banks offer preservation services for human heart valves and many companies offer processed porcine heart valves 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 and CoSeal; Ethicon, Inc. s, a Johnson & Johnson Company, Evicel; 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 HemoStase product competes with thrombin products, including King Pharmaceuticals, Inc. s Thrombin JMI, ZymoGenetics, Inc. s Recothrom, and Omrix Biopharmaceuticals, Inc. s, a Johnson and 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 Starch Medical, Inc s Perclot. 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 HemoStase product competes on the basis of its safety profile, clinical efficacy, and ease of use.

Our 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. Our BioFoam product competes on the basis of its clinical efficacy and ease of use.

26

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 a number of our services and products since January 1, 2010. 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 adversely affected.

We cannot give assurance that our products and services 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 effect on our revenues, financial condition, profitability, and cash flows.

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. Revenue from international tissue preservation services was approximately $1.6 million, $1.2 million, and $896,000 for the years ended December 31, 2009, 2008, and 2007, respectively. International revenue from product sales, which includes international BioGlue revenue, was approximately $16.0 million, $14.6 million, and $12.8 million for the years ended December 31, 2009, 2008, and 2007, respectively. Loss of all or a material portion of our international revenues would have a material adverse effect 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 effect on our revenues, financial condition, profitability, and cash flows.

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

The majority of our foreign BioGlue 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 BioGlue sales are made to customers in other countries who must convert local currencies into U.S. dollars in order to purchase BioGlue. 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 2010 BioGlue revenue growth 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 effect on our revenues, financial condition, profitability, and cash flows.

Our Credit Facility Limits Our Ability To Pursue Significant Acquisitions.

Our credit facility 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 a specified aggregate amount. As a result, our ability to consummate acquisitions and fully realize our growth strategy may be materially and adversely affected.

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:

Expand core business,

Develop our pipeline of services and products,

Identify and evaluate acquisition opportunities of complementary product lines and companies,

License company technology to third parties for non-competing uses.

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.

There Are Limitations On The Use Of Our Net Operating Loss Carryforwards.

We estimate that as of December 31, 2009, we had approximately $1.9 million in U.S. Federal net operating loss carryforwards which could be used to offset future taxable income. These carryforwards begin to expire in the 2023 tax year. We may be unable to generate enough profits prior to their expiration to utilize our net operating loss carryforwards.

In addition, the amount of net operating loss carryforwards that we can utilize on an annual basis is capped after an ownership change within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended. Accordingly, a change in control of our Company within the meaning of Section 382 could substantially reduce the annual benefit of our net operating loss carryforwards and could, thereby, result in a portion of our net operating loss carryforwards expiring unused.

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

Our credit facility contains a number of affirmative covenants that we must satisfy before we can borrow. For example, we must satisfy specified leverage ratios, and there are also increasing levels of adjusted earnings before interest, taxes, depreciation, and amortization (EBITDA) 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 and adversely affect our liquidity.

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, manufacturing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Consequently, we may not be able to

successfully develop our services or manufacture our products which are under development. If we do develop these services or manufacture these products, 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 of any service, product, or

application, particularly in instances when we have expended significant capital, this could have a material adverse effect 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. New services or products could include the following:

CryoValve SGAV,

New indications for our BioGlue products,

BioGlue Aesthetic,

New products based on our Protein Hydrogel Technology, including BioFoam and BioDisc,

ProPatch, and

SynerGraft processed animal heart valves and vascular tissue.

Extensive Government Regulation May Adversely Affect 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 premarket approvals 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 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 for processing or manufacturing and marketing.

Delays in obtaining U.S. or foreign approvals could result in substantial additional cost and adversely affect 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 or if problems occur following initial marketing. Delays imposed by the governmental 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 affect 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 effect 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 European Union has three separate directives called the European Union Tissue and Cells Directives, (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, CryoLife s 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 CryoLife and Europa of distribution, or modify or eliminate the ability of the Company and Europa 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 effect on our revenues, financial condition, profitability, and cash flows.

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 adversely impact our profitability.

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 effect on our revenues, financial condition, profitability, and cash flows.

We Are Not Insured Against All Potential Losses. Natural Disasters Or Other Catastrophes Could Adversely Affect 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 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 effect 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 effect 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, 2005 to December 31, 2009.

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 and adversely affect our revenues, financial position, profitability, and cash flows.

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

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 Capital 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 expected benefits of surgical adhesives and sealants;

Expected benefits from the SynerGraft SGAV if the Company is successful in obtaining an HDE;

The potential of materials and implantable replacement devices created with PHT to provide certain benefits;

Beliefs regarding the uses and benefits of the post-clearance study to collect long-term clinical data for the CryoValve SGPV;

The Company s expectations regarding regulatory approval and further development of BioDisc;

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

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

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

Anticipated future demand for cardiac and vascular tissues;

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

The Company s expectations regarding any future changes to its incoming tissue acceptance criteria and resultant variances in the Company s level of tissue procurement;

The Company s plans to license its products or obtain additional licenses from third parties;

The Company s plans to seek funding from outside sources to continue commercial development of certain technologies;

The amount and type of future research and development expenses;

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

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

Potential uses of BioFoam;

The Company s plans for distribution of BioFoam in Europe and in other international markets;

Expectations for revenues from the CryoLife-O Brien Stentless Aortic Bioprosthesis and CardioWrap;

The adequacy of the Company s financial resources;

Current intentions to retain future earnings for funding its capital requirements, including potential acquisitions;

Expectations regarding the ability of the Company to distribute HemoStase;

The Company s belief that HemoStase revenues will increase in 2010 as compared to 2009;

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

Commercialization plans for ProPatch, which may include partnering with third parties as well as obtaining clinical data to support applications to be marketed directly;

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 renewal of certain contracts;

The Company s expectations regarding its borrowing capacity under the GE Credit Agreement;

The planned expansion of the Company s international distribution of HemoStase; 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, 2009 (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 processing, 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 processing 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 6% 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.

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. The Federal Patent Court did not rule at the end of the hearing and instead informed the parties that it would issue a ruling in 2010. No ruling has been issued as of February 19, 2010. The Company expects a ruling in the first quarter of 2010.

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, Inc. is infringing the Company s BioGlue patent No. EP 0 650 512 in Germany by selling a surgical adhesive. 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 Court set the patent infringement hearing date for March 30, 2010.

Medafor

Overview

On April 29, 2009 the Company filed a lawsuit against Medafor, Inc. in the U.S. District Court for the Northern District of Georgia alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia Racketeer Influenced and Corrupt Organizations Act (Georgia RICO). On July 30, 2009, the Company filed an amended complaint to further clarify its claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia RICO. The lawsuit arises out of a distribution agreement between the parties (Agreement), pursuant to which the Company has the right to distribute a product manufactured by Medafor (the Product) under the name HemoStase. The Agreement gives 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.

The Company s lawsuit alleges that Medafor, contrary to its representations in the agreement, had numerous exclusive distribution agreements regarding the Product with other distributors in the U.S. and internationally, allowing them 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 of these competing agreements 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 has failed to take reasonable steps to prevent other distributors from distributing the Product in the Company s exclusive field and territory, and that Medafor breached its contractual obligation to prevent competing products from violating Medafor s intellectual property rights in the Product, thereby impairing the value of the Company s exclusive distributorship.

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 was unable to get Medafor to follow the terms of the Agreement. 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 territory.

Potential Damages

The Company seeks to recover its damages from Medafor, accompanied by preliminary and permanent injunctive relief, punitive damages, treble damages for violation of Georgia RICO, and reimbursement of its attorneys fees. The scope of the Company s actual damages will be based on, among other things, the value of sales by other distributors to customers who belonged exclusively to the Company, as well as lost sales opportunities due to confusion in the market caused by Medafor, and costs incurred by the Company in enforcing its rights under its contract with Medafor. The amount of these damages will be determined through discovery in the lawsuit. No trial date has been set.

Procedural History

On December 9, 2009 the Court issued an Order dismissing the Company s fraud and negligent misrepresentations claims, ordering the Company to file a recast complaint regarding the Company s Georgia RICO claim, and ordering the Company to cure any shotgun pleadings in the remainder of its complaint. On December 18, 2009 the Company filed a motion for partial reconsideration, requesting that the Court reconsider its dismissal of the Company s fraud and negligent misrepresentations claims based on Medafor s alleged misrepresentations to CryoLife in the Agreement and after the Agreement was executed. On December 28, 2009 pursuant to the Court s Order, the Company filed a Second Amended Complaint, recasting its Georgia RICO claim and reasserting its remaining claims for, among other things, breach of contract. On January 11, 2010 Medafor filed a motion to dismiss the Second Amended Complaint, asking the Court to dismiss the Georgia RICO claim, and to dismiss the rest of the claims for failure to cure the alleged shotgun pleadings. On January 19, 2010 the Company filed a motion for leave to file an amended complaint to clarify those claims described as shotgun pleadings.

On February 18, 2010, the Court issued an Order granting the Company s motion for partial reconsideration and reinstating the Company s fraud and negligent misrepresentation claims against Medafor based on Medafor s alleged misrepresentations to CryoLife in the Agreement and after the Agreement was executed. The Court also dismissed as moot Medafor s motion to dismiss and denied the Company s motion for leave, ordering instead that the Company file a recast complaint within twenty days to incorporate those parts of the fraud and negligent misrepresentation claims that had been reinstated and to cure any remaining shotgun pleading problems. Finally, the Court told Medafor that it was free to file another motion to dismiss in response to the Company s recast compliant in accordance with the Federal Rules of Civil Procedure.

Medafor s Notices of Termination

On September 18, 2009 Medafor informed CryoLife by letter of its belief that CryoLife materially breached its duties and obligations under the distribution agreement between the parties by distributing HemoStase into Hong Kong and gave CryoLife notice of its intent to terminate the distribution agreement if the breach was not cured within 30 days. While Medafor contended that there was a material breach because CryoLife pursued regulatory approval to distribute HemoStase in Hong Kong, CryoLife s belief was that a court would find that a material breach had not occurred and that in the event a breach had occurred, CryoLife would cure it within thirty days. On October 12, 2009 the Company filed a motion for temporary restraining order and preliminary injunction, requesting that the Court enjoin Medafor from terminating the agreement pursuant to Medafor s September 18, 2009 letter. On October 14, 2009 the court granted the parties Consent Temporary Restraining Order, preventing Medafor from terminating the distribution agreement pending a hearing and ruling from the Court on the Company s request for an entry of preliminary injunction. On October 21, 2009 Medafor informed

CryoLife that it would not terminate the distribution agreement based on the activities described in CryoLife s motion for temporary restraining order and preliminary injunction or set forth in Medafor s September 18, 2009 letter. On October 22, 2009 CryoLife notified the court that it was withdrawing its motion for temporary restraining order and preliminary injunction.

On December 2, 2009 Medafor informed the Company of its belief that the Company had materially breached its duties and obligations under the Agreement and gave the Company notice of its intent to terminate the Agreement if the alleged material breach was not cured by January 8, 2010. Medafor contended that the alleged material breach occurred because the Company allegedly pursued sales of HemoStase in Spain with respect to certain uses that are not permitted by the Agreement. The Company responded to Medafor s allegations in a January 5, 2010 letter, in which the Company explained its contention that it did not materially breach the Agreement, and its contention that it did not pursue improper or prohibited sales of HemoStase in Spain. The Company did not receive a response from Medafor during the next month, so on February 5, 2010 the Company sent a letter to Medafor demanding that Medafor formally retract its termination notice on the grounds that, according to the Company, the allegations in the notice are false and no basis exists to terminate the Agreement. On February 10, 2010 Medafor sent a letter to the Company reiterating its belief that the Company had materially breached the Agreement and demanding additional information regarding the Company s activities in Spain and elsewhere.

Medafor and the Company agreed in December 2009 that if Medafor decides after January 8, 2010 that a material breach has occurred, and that the Company has failed to cure the breach, Medafor will not terminate the Agreement for at least three weeks from the date on which Medafor informs the Company of its decision. In exchange, the Company has agreed that it will not, prior to being informed of Medafor s decision, petition a court to enjoin termination of the Agreement. On February 12, 2010 Medafor and the Company agreed that the three week period had not started and would not start unless and until one party notified the other that it was starting.

Item 4. Submission of Matters to Vote of Security Holders.

Inapplicable.

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	71	President, Chief Executive Officer, and Chairman
Jeffrey W. Burris	Since 2010	38	Vice President and General Counsel
Scott B. Capps	Since 2007	43	Vice President, Clinical Research
David M. Fronk	Since 1998	46	Vice President, Regulatory Affairs and Quality Assurance
Albert E. Heacox, Ph.D.	Since 1989	59	Senior Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	45	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Gerald B. Seery	Since 2005	53	Senior Vice President Sales and Marketing

Steven G. Anderson, a founder of CryoLife, has served as CryoLife s President, Chief Executive Officer, and Chairman of the Board of Directors since its inception. Mr. Anderson has more than 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 a B.A. and an M.S. in Biology from Adelphi University, received his Ph.D. in Biology 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.

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

2008	High	Low
First quarter	$ 10.10	$ 6.65
Second quarter	12.07	8.94
Third quarter	16.64	9.61
Fourth quarter	15.27	7.01

As of February 12, 2010 the Company had 433 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, 2009 that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934.

Period		Total Number of Common Shares Purchased	Average Price Paid per Common Share	Common Stock Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Common Shares That May Yet Be Purchased Under the Plans or Programs
10/01/09	10/31/09	550	$ 8.04		
11/01/09	11/30/09				
12/01/09	12/31/09	6,771	6.49		
Total		7,321	$ 6.61		

The Company currently has no stock repurchase program, publicly announced or otherwise. The common shares shown were tendered to the Company in payment of the exercise price of outstanding options.

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,				
	2009	**2008**	**2007**	**2006**	**2005**
Operations					
Revenues	$ 111,685	$ 105,059	$ 94,763	$ 81,311	$ 69,282
Operating income	14,496	13,654	8,299	1,418	(20,089)
Net income (loss)	8,679	31,950	7,201	365	(19,535)
Net income (loss) applicable to common shareholders	8,679	31,950	6,958	(608)	(20,312)
Research and development expense as a percentage of revenues	4.7%	5.1%	4.7%	4.4%	5.4%
Income (loss) Per Common Share					
Basic	$ 0.31	$ 1.15	$ 0.26	$ (0.02)	$ (0.85)
Diluted	$ 0.31	$ 1.13	$ 0.26	$ (0.02)	$ (0.85)
Year-End Financial Position					
Total assets	$ 133,859	$ 125,037	$ 92,684	$ 79,865	$ 76,809
Working capital	76,312	59,370	40,750	26,472	23,922
Long term liabilities	4,197	5,672	5,355	4,864	4,909
Convertible preferred stock				3	3
Shareholders equity	110,446	98,368	62,627	52,088	50,621
Current ratio[1]	5:1	4:1	3:1	2:1	2:1
Shareholders equity per diluted common share	$ 3.90	$ 3.47	$ 2.32	$ 2.10	$ 2.11

[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 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 include surgical adhesives, sealants, and hemostats including BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and HemoStase® (HemoStase), which the Company distributes for Medafor, Inc. (Medafor), as well as other medical devices.

For the year ended December 31, 2009 CryoLife achieved record revenues and operating income, surpassing $111 million in revenues and reaching $14.5 million in operating income. In addition, CryoLife generated $12.9 million in cash during 2009, including $16.6 million in cash from operations, the largest inflow of cash from operations in Company history. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2009 results. See Part I, Item 1, Business, for further discussion of the Company s business and activities during 2009.

Recent Events

During the fourth quarter of 2009 and in January 2010, CryoLife completed the purchase of approximately 2.3 million shares of Medafor common stock for $2 per share. Based on the most recent information available to CryoLife, these shares represent approximately 11% of Medafor s stock. The stock purchase agreements contain terms that could require the Company to make an additional make whole payment if CryoLife acquires more than 50% of the diluted outstanding stock of Medafor or merges with Medafor within a 3 year period for a share price in excess of the price initially paid. The Company accounted for these contract provisions as an embedded derivative (the Medafor Derivative). The estimated value of the Medafor Derivative was approximately $725,000 at December 31, 2009.

In January 2010 CryoLife announced that it had contacted Medafor s board and proposed a purchase price of $2.00 per share for the remaining outstanding shares, to be paid in a mixture of cash and CryoLife stock. The parties have exchanged

40

letters regarding CryoLife s proposal, but on February 10, Medafor s Board of Directors stated that it would not meet with CryoLife to discuss its offer.

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, 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 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. Allocation of fixed production overheads 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 idle facility expense, excessive spoilage, extra freight, and rehandling costs, as applicable.

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 procurement agencies, 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 believes that this estimate is an appropriate approximation of the tissue 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 effect 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 their packaging. CryoLife records a charge to cost of preservation services to write down the amount of deferred preservation costs not deemed to be recoverable. Lower of cost or market value write-downs are typically 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 increases or when tissues are shipped or become available for shipment.

The Company recorded write-downs to its deferred preservation costs totaling $91,000, $276,000, and $819,000 for the twelve months ended December 31, 2009, 2008, and 2007, respectively.

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. As of December 31, 2008 deferred preservation costs consisted of $12.2 million for heart valves, $1.7 million for cardiac patch tissues, and $21.0 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, and 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, 2009 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 $13.8 million. As of December 31, 2008 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 $19.1 million.

The realizability of the Company s deferred tax assets could be limited in future periods following a change in control as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, which relates to certain specified changes in control of taxpayers. The tax years 2006 through 2009 remain open to examination by the major taxing jurisdictions to which the Company is subject.

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 evaluates 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 CryoLife will write down the value of the asset or asset group. For the years ended December 31, 2009, 2008, and 2007 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, 2009 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, 2009, 2008, and 2007 and determined that the fair value of the assets exceeded their carrying value. Based on the results of its analysis, the Company does not believe that the value of its non-amortizing intangible assets was impaired as of December 31, 2009, 2008, or 2007. Management will continue to evaluate the recoverability of these non-amortizing intangible assets on an annual basis.

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 2009 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.

43

At December 31, 2009 and 2008 the short term and long term portions of the unreported loss liability and any related recoverable are as follows (in thousands):

	2009	2008
Short term liability	$ 1,890	$ 2,230
Long term liability	1,790	2,180
Total liability	3,680	4,410
Short term recoverable	660	720
Long term recoverable	680	780
Total recoverable	1,340	1,500
Total net unreported loss liability	$ 2,340	$ 2,910

Further analysis indicated that the liability as of December 31, 2009 could be estimated to be as high as $7.9 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

On April 1, 2009 the Company bound liability coverage for the 2009/2010 insurance policy year. This policy is a seven-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2010 and reported during the period April 1, 2009 through March 31, 2010 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

As of February 12, 2010 there were no pending tissue processing or product liability lawsuits filed against the Company.

New Accounting Pronouncements

In June 2009 the FASB issued the FASB Accounting Standards Codification (the Codification) for financial statements issued for interim and annual periods ending after September 15, 2009, which was effective for the Company beginning in the third quarter of 2009. The Codification became the single authoritative source for GAAP. Accordingly, previous references to GAAP accounting standards are no longer used in our disclosures, including the Notes to the Consolidated Financial Statements.

The Company was required to adopt new accounting guidance related to subsequent events as of June 30, 2009. This guidance establishes general standards of accounting for and the disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued.

The Company was required to adopt new accounting guidance related to business combinations on January 1, 2009. The new guidance establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The adoption of the new guidance did not have an effect on the financial position, profitability, or cash flows of the Company upon adoption, but will affect the accounting for any future business combination.

Results of Operations

(In thousands)

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. The Company believes that its existing cardiac tissues available for shipment and current procurement levels are sufficient to support anticipated future demand for cardiac tissues for the reasonably foreseeable future.

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. The Company believes that its existing vascular

tissues available for shipment and current procurement levels are sufficient to support anticipated future demand for vascular tissues for the reasonably foreseeable future.

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. Management has implemented initiatives that they believe will address these issues in 2010.

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 a multinational distribution agreement with Medafor, Inc. (Medafor) in the second quarter of 2008.

The Company believes that HemoStase revenues will increase in 2010 as compared to 2009, as this product is still in a high growth phase, due to its limited penetration in the Company s existing customer base. The Company s revenues from its sale of HemoStase could be materially adversely impacted, however, by the Company s recent unsolicited offer to purchase Medafor, CryoLife s lawsuit with Medafor, or any current or future attempts by Medafor to terminate the Company s distribution agreement. See Part I, Item 3, Legal Proceedings.

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 protein hydrogel technology, 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 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

48

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.

Expenses associated with business development opportunities, including costs associated with acquisitions and attempted acquisitions, may materially impact the Company s general, administrative, and marketing expenses in 2010.

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 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. See Part II, Item 8, Note 13 of the Notes to Consolidated Financial Statements for further discussion of the Company s income taxes.

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.

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2008	2007	2008	2007
Preservation services:				
Cardiac tissue	$ 5,894	$ 6,511	23%	26%
Vascular tissue	6,362	5,920	25%	24%
Orthopaedic tissue	63	552	%	2%
Total preservation services	12,319	12,983	48%	52%
Products:				
BioGlue	12,088	11,511	48%	46%
HemoStase	806		3%	%
Other medical devices	100	105	%	%
Total products	12,994	11,616	51%	46%
Other	219	469	1%	2%
Total	$ 25,532	$ 25,068	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2008	2007	2008	2007
Preservation services:				
Cardiac tissue	$ 25,514	$ 22,098	24%	23%
Vascular tissue	27,417	22,702	26%	24%
Orthopaedic tissue	725	4,202	1%	5%
Total preservation services	53,656	49,002	51%	52%
Products:				
BioGlue	48,570	43,884	46%	46%
HemoStase	1,532		2%	%
Other medical devices	391	828	%	1%
Total products	50,493	44,712	48%	47%
Other	910	1,049	1%	1%
Total	$ 105,059	$ 94,763	100%	100%

Revenues increased 2% for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007. Revenues increased 11% for the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007.

A detailed discussion of the change in preservation services revenues for each of the three major tissue types distributed by the Company and the change in BioGlue revenues for the three and twelve months ended December 31, 2008 is presented below.

Cardiac Preservation Services

Revenues from cardiac preservation services decreased 9% for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007. This decrease was primarily due to the aggregate impact of a 22% decrease in unit shipments of cardiac tissues partially offset by the favorable effect of tissue mix, which together decreased revenues by 12%, and an increase in average service fees, which increased revenues by 3%.

Revenues from cardiac preservation services increased 15% for the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007. This increase was primarily due to the aggregate impact of

favorable tissue mix and a 2% increase in unit shipments of cardiac tissues, which together increased revenues by 9%, and an increase in average service fees, which increased revenues by 6%.

The decrease in revenues from the net effect of volume and tissue mix for the three months ended December 31, 2008 was primarily due to a decrease in shipments of standard processed pulmonary valves. This decrease was largely offset by an increase in shipments of the CryoValve SGPV. The net decrease in aggregate pulmonary valve shipments (which includes both standard processed pulmonary valves and CryoValve SGPVs) had a minimal effect on revenues, due to favorable tissue mix, as the CryoValve SGPV demands premium fees over standard processed pulmonary valves. The remaining cardiac volume decrease was primarily due to a decrease in shipments of cardiac patches and aortic valves.

Management believes that there has not been a corresponding decrease in the number of procedures in which the Company s aortic and pulmonary valves are utilized. However, management believes that due to the current economic conditions and its constraining effect on hospital budgets, that hospitals are decreasing the number of heart valves they keep on-hand for urgent procedures. The decrease in shipments of cardiac patches was primarily due to the timing of releases of these tissues, which are in high demand for pediatric surgeries.

The favorable tissue mix and volume increase for the twelve months ended December 31, 2008 was primarily due to the impact of CryoValve SGPV shipments and to a lesser extent due to the increase in shipments of aortic valves. On February 7, 2008 the FDA cleared the Company s 510(k) premarket notification for the CryoValve SGPV and as a result, the Company reintroduced the CryoValve SGPV in March of 2008. Due to the reintroduction of the CryoValve SGPV, shipments of standard processed pulmonary valves decreased. The net effect of this change in tissue mix was favorable, despite a similar number of units shipped, as the CryoValve SGPV demands premium fees over standard processed pulmonary valves. For the three and twelve months ended December 31, 2008, CryoValve SGPV revenues accounted for 29% and 20%, respectively, of the Company s total cardiac preservation service revenues.

The increases in average service fees for the three and twelve months ended December 31, 2008 was primarily due to the fee increases that went into effect in January 2008 on most standard processed cardiac tissues and due to the routine expiration or renegotiation of pricing contracts with certain customers.

The Company s procurement of cardiac tissues, from which heart valves and cardiac patches are processed, decreased 19% for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007. The Company s procurement of cardiac tissues for the twelve months ended December 31, 2008 was consistent with procurement for the twelve months ended December 31, 2007. 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 in the three months ended December 31, 2008 as compared to the three months ended December 31, 2007 was primarily the result of changes in tissue acceptance criteria made during 2008.

Vascular Preservation Services

Revenues from vascular preservation services increased 7% for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007. This increase was primarily due to an 8% increase in unit shipments of vascular tissues.

Revenues from vascular preservation services increased 21% for the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007. This increase was primarily due to an 18% increase in unit shipments of vascular tissues, which increased revenues by 17%, and an increase in average service fees, which increased revenues by 4%.

The increase in vascular volume for the three and twelve months ended December 31, 2008 was primarily due to increases in shipments of each of the types of vascular tissues 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 increase in average service fees for the twelve months ended December 31, 2008 was primarily due to the fee increases that went into effect in January 2008 on most vascular tissues and due to the routine expiration or renegotiation of pricing contracts with certain customers.

The Company s procurement of vascular tissues decreased 4% for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007. The Company s procurement of vascular tissues decreased 5% for

the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007. 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 in the three and twelve months ended December 31, 2008 as compared to the three and twelve months ended December 31, 2007, respectively, was primarily the result of changes in tissue acceptance criteria made during 2008.

Orthopaedic Preservation Services

Revenues from orthopaedic preservation services decreased 89% and 83% for the three and twelve months ended December 31, 2008, as compared to the three and twelve months ended December 31, 2007, respectively. This decrease was primarily due to significant decreases in unit shipments of orthopaedic tissues, due to the cessation of the Company s orthopaedic marketing efforts as of June 30, 2008, pursuant to its agreement with Regeneration Technologies, Inc. (RTI). The decrease was also due to the limited supply of orthopaedic tissues available for shipment, resulting from the Company s cessation of procuring and processing these tissues on January 1, 2007, and declining demand for the Company s orthopaedic tissues. For a commission, RTI was able to market and direct CryoLife to ship the Company s remaining orthopaedic tissues from July 1, 2008 through December 31, 2008. These marketing efforts by RTI generated minimal revenues during the three months ended December 31, 2008.

BioGlue

Revenues from the sale of BioGlue increased 5% for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007. This increase was primarily due to an increase in average selling prices, which increased revenues by 5%, and a 3% increase in the number of BioGlue milliliters shipped, which increased revenues by 2%, partially offset by the unfavorable impact of foreign exchange, which reduced revenues by 2%.

Revenues from the sale of BioGlue increased 11% for the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007. This increase was primarily due to an increase in average selling prices, which increased revenues by 6%, and a 5% increase in the number of BioGlue milliliters shipped, which increased revenues by 5%.

The increase in average selling prices for the three and twelve months ended December 31, 2008 were primarily due to domestic list price increases that went into effect in January 2008 and the routine expiration or renegotiation of pricing contracts with certain customers. The volume increase for the three and twelve months ended December 31, 2008 was primarily due to an increase in sales of BioGlue syringes in domestic and international markets, partially offset by a related decrease in BioGlue cartridge sales. The unfavorable impact of foreign exchange for the three months ended December 31, 2008 was due to changes in the exchange rates between the U.S. Dollar and the British Pound and the Euro from the prior year period.

Domestic revenues accounted for 71% of total BioGlue revenues in both of the three month periods ended December 31, 2008 and 2007. Domestic revenues accounted for 71% and 72% of total BioGlue revenues for the twelve months ended December 31, 2008 and 2007, respectively.

Other Revenues

Other revenues for the three months ended December 31, 2008 included revenues from research grants. Other revenues for the three months ended December 31, 2007 included revenues from research grants and revenues related to the licensing of the Company s technology to a third party.

Other revenues for the twelve months ended December 31, 2008 and 2007 included revenues from research grants and revenues related to the licensing of the Company s technology to a third party.

In 2008, 2007, and 2005 CryoLife was awarded $848,000, $1.9 million, and $930,000, respectively, in funding allocated from 2005 through 2007 U.S. Congress Defense Appropriations Conference Reports, collectively the (DOD Grants). These grants were awarded for the development of protein hydrogel technology, which the Company is currently developing for use in organ sealing. Grant revenues in 2008 and 2007 are related to funding under the DOD Grants for the development of BioFoam.

Through December 31, 2008 CryoLife had received cash payments for a portion of the DOD Grants, for a total of $3.3 million. As of December 31, 2008 CryoLife had $1.6 million in unspent cash advances under the grants recorded as cash and deferred revenues 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,	
	2008	2007	2008	2007
Cost of preservation services	$ 6,730	$ 7,250	$ 29,112	$ 28,433
Cost of preservation services as a percentage of total preservation services revenue	55%	56%	54%	58%

Cost of preservation services decreased 7% for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007. Cost of preservation services increased 2% for the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007.

The decrease in cost of preservation services for the three months ended December 31, 2008 was primarily due to a decrease in the volume of cardiac and orthopaedic tissues shipments, partially offset by an increase in vascular tissue shipments and an increase in the per unit cost of cardiac tissues. The increase in cost of preservation services for the twelve months ended December 31, 2008 was primarily due to an increase in vascular tissue shipments and an increase in the per unit cost of cardiac tissues, partially offset by the favorable effect of lower write-downs recorded in the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007 and decreases in the volume of orthopaedic tissue shipments.

Cost of preservation services as a percentage of preservation services revenues for the three months ended December 31, 2008 was comparable to the three months ended December 31, 2007. Cost of preservation services as a percentage of preservation services revenues decreased for the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007. This decrease was primarily due to a decrease in write-downs recorded in the twelve months ended December 31, 2008 as compared to the twelve months ended December 31, 2007 and due to the increases in average service fees and the premium related to the Company s SynerGraft processed tissues.

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Cost of products	$ 2,293	$ 1,664	$ 8,153	$ 7,108
Cost of products as a percentage of total product revenue	18%	14%	16%	16%

Cost of products increased 38% and 15% for the three and twelve months ended December 31, 2008 as compared to the three and twelve months ended December 31, 2007, respectively.

The increase in cost of products for the three months ended December 31, 2008 was primarily due to HemoStase sales, as a result of the Company s launch of that product in the second quarter of 2008, and to a lesser extent an increase in the volume of BioGlue sales and an increase in the cost of bioprosthetic devices.

The increase in cost of products for the twelve months ended December 31, 2008 was primarily due to HemoStase sales and to a lesser extent an increase in the cost of bioprosthetic devices, including $1.5 million in write-downs of bioprosthesis inventory. These write-downs were primarily due to impairments in the value of inventory for products that are not expected to ship prior to their expiration date. These write-downs were a result of changes in sales estimates for these products or delays in the expected launch of a new product.

Cost of products as a percentage of product revenues increased for the three months ended December 31, 2008 as compared to the three months ended December 31, 2007, primarily due to a change in product mix as the Company launched the lower margin product HemoStase during 2008 and due to an increase in the per unit cost of BioGlue.

Cost of products as a percentage of product revenues for the twelve months ended December 31, 2008 was comparable to the twelve months ended December 31, 2007, as the favorable effect of the decrease in sales volume for lower margin bioprosthetic devices and a decrease in the per unit cost of BioGlue was largely offset by the unfavorable effect of the bioprosthetic write-downs discussed above and the unfavorable effect of sales of lower margin HemoStase products.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
General, administrative, and marketing expenses	$ 12,334	$ 12,053	$ 48,831	$ 46,470
General, administrative, and marketing expenses as a percentage of total revenue	48%	48%	46%	49%

The increase in general, administrative, and marketing expenses for the three months ended December 31, 2008 was primarily due to increases in marketing expenses, largely offset by the favorable effect of a $530,000 reversal of tissue processing and product liability accruals. In addition, a decrease in bonus accruals for the three months ended December 31, 2008 was largely offset by an increase in expenses related to the grant of stock options and restricted stock awards.

The increase in general, administrative, and marketing expenses for the twelve months ended December 31, 2008 was primarily due to increases in marketing expenses, and to a lesser extent increases in expenses related to the grant of stock options and restricted stock awards, partially offset by the favorable effect of a $980,000 reversal of tissue processing and product liability accruals and a $786,000 decrease in post employment benefit expenses, as this 2007 expense did not recur in 2008.

The increases in marketing expenses described above included increased commissions and personnel costs, partially related to an increase in sales force, corporate advertising, and promotional materials, including spending on the 2008 Ross Summit and other physician training events to support the Company s expanding tissue service and product offerings and revenue growth. The Company s expenses related to the grant of stock options and restricted stock awards was $547,000 and $1.8 million for the three and twelve months ended December 31, 2008, respectively, and $352,000 and $1.3 million for the three and twelve months ended December 31, 2007, respectively.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Research and development expenses	$ 1,371	$ 1,319	$ 5,309	$ 4,453
Research and development expenses as a percentage of total revenue	5%	5%	5%	5%

Research and development expenses for the three months ended December 31, 2008 was comparable to the three months ended December 31, 2007. The increase in research and development expenses for the twelve months ended December 31, 2008 was primarily due to spending on BioFoam research, including research funded under the 2005 and 2006 DOD Grants discussed in Revenues Other Revenues above and spending on organ transport solutions. Research and development spending in 2008 and 2007 was primarily focused on the Company s tissue preservation, SynerGraft products and tissues, and Protein Hydrogel Technologies (PHT). SynerGraft products and tissues include the Company s CryoValve SGPV and xenograft tissue products. PHT includes BioGlue, BioFoam, BioDisc, and related products.

Other Income and Expenses

Interest expense was $62,000 for the three months ended December 31, 2008, compared to $159,000 for the three months ended December 31, 2007. Interest expense was $263,000 for the twelve months ended December 31, 2008, compared to $677,000 for the twelve months ended December 31, 2007. Interest expense for the three and twelve months ended December 31, 2008 decreased primarily due to a decrease in line of credit borrowings as a result of the February 8, 2008 expiration and pay off of the balance due on the Company s prior credit agreement with Wells Fargo Foothill, Inc. and to a lesser extent due to lower interest rates. In addition, the Company has maintained lower balances on its new line of credit with GE Capital entered into in March of 2008, as the Company s cash generated by operations has been sufficient to support its operating needs.

Interest income was $96,000 for the three months ended December 31, 2008, compared to $167,000 for the three months ended December 31, 2007. Interest income was $381,000 for the twelve months ended December 31, 2008, compared to $527,000 for the twelve months ended December 31, 2007. Interest income for the three and twelve months ended December 31, 2008 and 2007 was primarily due to interest earned on the Company s cash, cash equivalents, marketable securities and restricted cash and investments. Interest income has decreased due to lower interest rates earned during 2008 as compared to 2007 despite an increase in cash and investment balances.

The change in valuation of the embedded derivative feature of the Company s preferred stock was zero for both the three and twelve months ended December 31, 2008 as compared to an expense of zero and $821,000 for the three and twelve months ended December 31, 2007, respectively. The change in valuation of the Derivative for the twelve months ended December 31, 2007 was primarily due to conversions of the Company s preferred stock during the second quarter of 2007 in excess of amounts previously accrued.

The Company s income tax benefit was $19.0 million and $18.4 million for the three and twelve months ended December 31, 2008, respectively. Income tax benefit in 2008 includes $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. The Company s income tax expense was $134,000 and $368,000 for the three and twelve months ended December 31, 2007, respectively. Income tax expense in the prior year periods was primarily due to alternative minimum tax on the Company s taxable income in each period 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. See Part II, Item 8, Note 13 of the Notes to Consolidated Financial Statements for further discussion of the Company s income taxes.

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 demand for the Company s vascular preservation services does not appear to be seasonal.

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

The Company is uncertain whether demand for HemoStase will be seasonal. As HemoStase 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 HemoStase sales may be obscured.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2009 net working capital (current assets of $95.5 million less current liabilities of $19.2 million) was $76.3 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $59.4 million, with a current ratio of 4 to 1 at December 31, 2008.

Overall Liquidity and Capital Resources

The Company s primary cash requirements for the twelve months ended December 31, 2009 arose out of general working capital needs and the acquisition of Medafor common stock. The Company funded its cash requirements primarily through its operating activities, which generated cash during the period.

During 2007 and 2008, the Company used a portion of its working capital to increase the balance of its deferred preservation costs and inventories, as indicated on the Company s Statements of Cash Flows. During 2009 the Company 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 the first half of 2009, and the balance of the Company s deferred preservation costs decreased slightly during the second half of 2009. 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.

In March of 2008 CryoLife entered into a credit facility with GE Capital, which provides for up to $15.0 million in revolving credit for working capital, acquisitions, and other corporate purposes, of which $14.5 million is currently available for borrowing. As of December 31, 2009 the outstanding balance under this agreement was $315,000. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least $5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company s liquidity needs during the term of the GE Credit Agreement, and as such have been recorded as the long-term asset restricted money market funds on the Company s Consolidated Balance Sheet.

The Company s cash equivalents include advance funding received under the DOD Grants for the continued development of protein hydrogel technology. As of December 31, 2009 $2.6 million of cash equivalents were recorded on the Company s Consolidated Balance Sheet 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 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, and for other corporate purposes. The Company has net operating loss carryforwards that will reduce required cash payments for federal and state income taxes for the 2010 tax year.

Liability Claims

As of December 31, 2009 the Company had accrued a total $3.7 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to December 31, 2009 and had recorded a receivable of $1.3 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 $7.9 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The $3.7 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 $16.6 million for the twelve months ended December 31, 2009 as compared to $9.5 million for the twelve months ended December 31, 2008. The current year cash provided was primarily due to net income generated during the period and the net effect of non-cash items, partially offset by increases in working capital needs due to the timing of receipts and payments in the ordinary course of business.

57

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, 2009 these non-cash items included a favorable $4.3 million in depreciation and amortization expense, $5.3 million in deferred income taxes, $2.4 million in non-cash stock based compensation, and $489,000 in write-downs for impairments of deferred preservation costs and inventory.

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, 2009 these changes included an unfavorable $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, $1.1 million due to increases in deferred preservation costs and inventory balances, for which vendors and employees have already been paid, $790,000 due to the increase in receivables, and $353,000 due to the timing difference between making cash payments and the expensing of assets, including prepaid insurance policy premiums.

Net Cash from Investing Activities

Net cash used in investing activities was $4.4 million for the twelve months ended December 31, 2009, as compared to $4.3 million for the twelve months ended December 31, 2008. The current year cash used was primarily due to $1.7 million in capital expenditures and $3.0 million in purchases of marketable securities and investments, primarily the purchase of Medafor common stock, partially offset by $1.1 million in sales and maturities of restricted marketable securities.

Net Cash from Financing Activities

Net cash provided by financing activities was $707,000 for the twelve months ended December 31, 2009, as compared to net cash used of $2.4 million for the twelve months ended December 31, 2008. The current year cash provided was primarily due to $1.3 million in proceeds from the financing of insurance policies and $1.1 million in proceeds from the exercise of options and the issuance of common stock under the Company s employee stock purchase plan, partially offset by $1.3 million in principal payments on capital leases and short-term notes payable.

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, 2009 are as follows (in thousands):

	Total	2010	2011	2012	2013	2014	Thereafter
Operating leases	$ 16,192	$ 2,614	$ 2,570	$ 2,514	$ 2,474	$ 2,509	$ 3,511
Compensation payments	3,516	1,531			993	992	
Research obligations	3,025	1,554	909	562			
Royalty payments	807	807					
Purchase commitments	365	346	19				
Line of credit	315		315				
Other obligations	127	114	10	3			
Total contractual obligations	$ 24,347	$ 6,966	$ 3,823	$ 3,079	$ 3,467	$ 3,501	$ 3,511

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 compensation payment obligations represent estimated cash payments to be made for its 2009 performance-based bonus plans and 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 Company s research obligations represent commitments for ongoing studies and payments to support research and development activities, the majority of which will be funded by the advances received under the DOD Grants.

The Company s purchase commitments include obligations from agreements with suppliers to stock certain custom raw materials needed for the Company s processing and production and contractual payments for telecommunication services. The Company s royalty payments are related to BioGlue revenues.

The line of credit obligation results from the Company s borrowing of funds under the GE Credit Agreement. The timing of this obligation is based on the agreement s March 25, 2011 expiration date, at which time the outstanding principal balance will be due. The table above does not include interest and fees on the line of credit, as these can vary due to changes in the level of borrowings and changes in interest rates.

The Company s other obligations contain various items including advertising commitments, capital lease obligations, and other items as appropriate.

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; (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $825,000, because the Company could 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; (iii) any payments related to the Medafor Derivative, because the Company could not make a reasonably reliable estimate of the amount and period of the future payments that would be required, if at all; and (iv) any specified purchases of HemoStase. The Company s exclusive distribution agreement with Medafor does not require that the Company make minimum purchases. If, however, the Company does not make the minimum purchases as stated in the agreement, the exclusive distribution agreement may by terminated by Medafor.

Capital Expenditures

Capital expenditures were $1.7 million for each of the twelve months ended December 31, 2009 and 2008. Capital expenditures in 2009 were primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment 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 $30.1 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, 2009. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended December 31, 2009, 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 majority 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. In the fourth quarter of 2008 and in the full year of 2009 the Company experienced a decrease in revenues when compared to the respective prior year periods due to changes in exchange rates.

Changes in exchange rates which occurred during the twelve months ended December 31, 2009 as well as any future material adverse fluctuations in exchange rates could have a material and adverse effect on the Company s revenues, profitability, and cash flows for the full year of 2009. An additional 10% adverse change in exchange rates from the exchange rates in effect on December 31, 2009 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, 2009 as compared to the weighted average exchange rates experienced by the Company for the twelve months ended December 31, 2009 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.

Based upon the most recent Disclosure Controls evaluation, conducted by management with the participation of the CEO and CFO, as of December 31, 2009 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, 2009, 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, 2010, 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, 2010.

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, 2010.

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, 2010.

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, 2010.

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 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 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.
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.

10.3 CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s 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.)

Exhibit Number	Description
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 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 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 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 November 2, 2009.
10.9(b)*	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.
10.9(c)	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 Form 8-K filed May 8, 2009.)
10.9(d)	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 Form 8-K filed May 8, 2009.)
10.9(e)	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 Form 8-K filed October 28, 2008.)
10.9(f)	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 Form 8-K filed November 3, 2008.)
10.10	Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated herein by reference to Exhibit 10.9 to the Registrant s Registration Statement on Form S-1 (No. 33-56388).)
10.11	Form of Key Employee Secrecy and Noncompete Agreement, by and between the Company and its Officers and Key Employees (Incorporated herein by reference to Exhibit 10.11 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.).
10.12	Summary of Revised Salaries for Named Executive Officers. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Form 10-Q for the quarter ended March 31, 2008.)
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 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.)

64

Exhibit Number	Description
10.17	CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s 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 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 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 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 Form 8-K filed February 25, 2008.)
10.22	Technology License Agreement between the Company and Colorado State University Research Foundation dated March 28, 1996. (Incorporated herein by reference to Exhibit 10.22 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007.)
10.23	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)
10.24	Form of Incentive Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)
10.25	Form of Section 16 Officer Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)
10.26	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)
10.27	Grant of Incentive Stock Option to D. Ashley Lee, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006.)
10.29	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.)
10.30(a)	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(b)	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.)

Exhibit Number	Description
10.33	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.33 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.34	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.34 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.35	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.35 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.36	Form of Grant of Non-Qualified Stock Option to Directors. (Incorporated herein by reference to Exhibit 10.36 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.37	Grant of Incentive Stock Option to Steven G. Anderson, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.38	International Distribution Agreement, dated September 17, 1998, between the Company and Century Medical, Inc. (Incorporated by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.39	CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan, as amended, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.40	Form of Directors Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)
10.41	CryoLife, Inc. 2002 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.)
10.42	Settlement and Release Agreement, dated August 2, 2002, by and between Colorado State University Research Foundation, the Company, and Dr. E. Christopher Orton. (Incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.43	Settlement Agreement and Release, dated September 25, 2006, by and between CryoLife, Inc. and St. Paul Mercury Insurance Company. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.)
10.44*	Summary of Compensation Arrangements with Non-Employee Directors.
10.45	CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.)
10.46*	First Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated October 27, 2009
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 November 2, 2009.

3.* 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.

4. 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 Form 8-K filed May 8, 2009.)

5. 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 Form 8-K filed May 8, 2009.)

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

7. 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 Form 8-K filed November 3, 2008.)

8. 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).)

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

10. 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.)

11. CryoLife, Inc. 1998 Long-Term Incentive Plan. (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.)

12. 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.)

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

14. 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.)

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

16. 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.)

17. 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.)

18. 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.)

19. 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.)

20. 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.)

21. 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.)

22. Summary of Salaries for Named Executive Officers. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Form 10-Q for the quarter ended March 31, 2008.)

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

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

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

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

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

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

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

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

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

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

33. Form of 2009 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.)

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

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

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

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

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

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

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

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

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

43.* First Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated October 27, 2009.

* 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 19, 2010 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 19, 2010
/s/ D. Ashley Lee **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 19, 2010
/s/ Amy D. Horton **Amy D. Horton**	Chief Accounting Officer (Principal Accounting Officer)	February 19, 2010
/s/ Thomas F. Ackerman **Thomas F. Ackerman**	Director	February 19, 2010
/s/ James S. Benson **James S. Benson**	Director	February 19, 2010
/s/ Daniel J. Bevevino **Daniel J. Bevevino**	Director	February 19, 2010
/s/ John M. Cook **John M. Cook**	Director	February 19, 2010
/s/ Ronald C. Elkins, M.D.	Director	February 19, 2010

Ronald C. Elkins, M.D.		
/s/ Ronald D. McCall	Director	February 19, 2010
Ronald D. McCall		
/s/ Harvey Morgan	Director	February 19, 2010
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, 2009. 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, 2009, 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, 2009.

CryoLife, Inc.

February 19, 2010

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, 2009, 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, 2009, 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, 2009 of the Company and our report dated February 19, 2010 expressed an unqualified opinion on those financial statements.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 19, 2010

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, 2009 and 2008, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009 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 19, 2010 expressed an unqualified opinion on the Company s internal control over financial reporting.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 19, 2010

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,121	$ 17,201
Restricted securities		562
Receivables:		
Trade accounts, less allowance for doubtful accounts of $225 in 2009 and $200 in 2008	13,709	12,824
Other	927	1,175
Total receivables	14,636	13,999
Deferred preservation costs	36,445	34,913
Inventories	6,446	7,077
Deferred income taxes	5,694	4,896
Prepaid expenses and other assets	2,186	1,719
Total current assets	**95,528**	**80,367**
Property and equipment:		
Equipment and software	19,722	19,044
Furniture and fixtures	3,735	5,006
Leasehold improvements	29,000	28,843
Total property and equipment	52,457	52,893
Less accumulated depreciation and amortization	38,148	36,455
Net property and equipment	**14,309**	**16,438**
Other assets:		
Investment in equity securities	3,221	
Restricted money market funds	5,000	5,000
Patents, less accumulated amortization of $2,155 in 2009 and $1,905 in 2008	4,248	3,771
Trademarks and other intangibles, less accumulated amortization of $871 in 2009 and $639 in 2008	2,724	2,952
Deferred income taxes	8,075	15,541
Other	754	968
Total assets	**$ 133,859**	**$ 125,037**

See accompanying notes to consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands except per share amounts)

	December 31, 2009	2008
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,954	$ 3,270
Accrued compensation	3,361	3,850
Accrued procurement fees	3,228	4,473
Accrued expenses	4,182	5,252
Deferred income	2,646	1,592
Deferred income taxes		391
Derivative liability	725	
Other current liabilities	2,120	2,169
Total current liabilities	**19,216**	**20,997**
Deferred income taxes		919
Line of credit	315	