CRYOLIFE INC
Form 10-K
February 19, 2009

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, 2008

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 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, 2008, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $297,350,356, computed using the closing price of $11.44 per share of Common Stock on June 30, 2008, 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 13, 2009 the number of outstanding shares of Common Stock of the registrant was 28,160,834.

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, 2008.	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 for cardia and vascular transplant applications and develops and commercializes medical devices. The human tissue distributed by the Company includes the CryoValve® SG pulmonary human heart valve (CryoValve SG), processed using CryoLife s proprietary SynerGraft® technology. The Company s medical devices include BioGlue® Surgical Adhesive (BioGlue) and 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 2008 international revenues were 15% 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 human 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, these advantages include more natural blood flow properties for its preserved human heart valves, 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. On February 7, 2008 the Company received a Section 510(k) (510(k)) clearance from the U.S. Food and Drug Administration (FDA) for its CryoValve SG processed with the Company s proprietary SynerGraft technology. In 2008 CryoLife used the SynerGraft technology for a portion of its pulmonary valve processing. The Company phased out the distribution of orthopaedic tissue in 2007 and 2008 pursuant to an agreement it reached with a third party.

BioGlue. 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 70 other countries for designated applications. In the U.S., BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue under Conformité Européene (CE) Mark product certification in the European Economic Area (EEA) for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). 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 in Central and South America and Asia.

Hemostase. In May of 2008 CryoLife began distributing 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. Distribution of Hemostase began in the U.S., Canada, United Kingdom, Germany, and France in 2008. CryoLife began distribution in other markets in Europe in 2009. CryoLife plans to expand its international distribution of Hemostase as the required regulatory approvals are obtained.

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 products and technologies. 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 product 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). CryoLife continues to research and develop product line extensions to BioGlue including modifications to the BioGlue delivery system. The PHT platform is also the base for several potential products in development. CryoLife is researching the use of derivatives of PHT for use in organ sealing through a product called BioFoam® and has undertaken preliminary clinical evaluations to determine its utility as a nucleus pulposus replacement in spinal disc repair through a product called BioDisc®.

Risk Factors

CryoLife s business is subject to a number of risks, including the possibility of FDA actions, additional expenses and losses from product recalls, possible losses from tissue processing and product liability, securities actions, and other litigation, other regulatory actions, adverse publicity, and lower demand for CryoLife products resulting from product recalls and other FDA activity, the possible inability to obtain sufficient insurance coverage, the possible inability to protect the Company s intellectual property rights, the possible inability to obtain necessary regulatory approvals, dependence on key suppliers, and possible future lack of adequate capital. See Part I, Item 1A, Risk Factors below for a discussion of these and other risk factors.

Recent Events

SynerGraft Processed Human Pulmonary Heart Valve 510(k) Clearance

On February 7, 2008 CryoLife received 510(k) clearance from the FDA for its CryoValve SG pulmonary human heart valve processed with the Company s proprietary SynerGraft technology. CryoLife s proprietary SynerGraft process removes donor cells and cellular remnants from the tissue using a gentle washing step, thereby, creating a decellularized collagen matrix that has fewer antigens than standard processed allograft tissues. The CryoValve SG is indicated for the replacement of diseased, damaged, malformed, or malfunctioning native pulmonary valves. The valve can be used in conjunction with right ventricular outflow tract reconstruction procedures (RVOT), commonly performed in children with congenital heart defects. In addition, the valve can be used for pulmonary valve replacement during the Ross Procedure, an operation in which a patient s defective aortic valve is removed and replaced with the patient s own pulmonary valve. The CryoValve SG is then surgically implanted to replace the removed native pulmonary valve. CryoLife began using the SynerGraft technology for a portion of its pulmonary valve processing in February 2008 and began shipments of the CryoValve SG in March 2008.

At the FDA s request, CryoLife has committed to conducting a post-clearance study to collect long-term clinical data for the CryoValve SG valve. CryoLife submitted a proposed study to the FDA in December 2008 which is discussed further in Research and Development and Clinical Research below. Data collected in this study will be compared to data from a defined control group implanted with a standard processed pulmonary human heart valve. CryoLife believes the information may help ascertain whether the SynerGraft process impacts the long-term durability of the valve. Explant analyses may help determine if the collagen matrix recellularizes with the recipient s own cells.

On February 16, 2009, the Company announced that the FDA had cleared a new labeling claim for the CryoValve SG Pulmonary Human Heart Valve. The labeling claim relates to reducing a component of the immune response in recipients of the CryoValve SG. The new claim relates to data from three company-sponsored clinical studies and a comprehensive review of the scientific literature that shows that implantation of the CryoValve SG reduces the risk inducing what are called HLA class I and class II alloantibodies, based on Panel Reactive Antibody, compared to the standard-processed pulmonary human heart valve. The effect of reduced alloantibodies, however, on the long-term durability or long-term resistance to rejection by the patient of the CryoValve SG has not been clinically proven. An elevated PRA level may increase the possibility that a patient will reject a future whole organ transplant. High and sustained PRA levels may also delay transplantation until a compatible donor can be identified. CryoLife believes this new claim is important to patient management issues for whole organ transplant recipients.

Medafor License Agreement

On April 17, 2008 CryoLife signed an exclusive three-year agreement with Medafor. Under terms of the agreement CryoLife distributes Medafor s microporous polysaccharide hemostatic agent for use in cardiac and vascular surgery in the U.S. (excluding Department of Defense hospitals) and for cardiac, vascular, and general surgery, other than orthopaedic and

ear, nose and throat surgery, internationally, with the exception of China and Japan. This product is a plant-based, flowable powder engineered to rapidly dehydrate blood, enhancing clotting on contact. The unique, absorbable powder hemostat, which received CE Mark approval in 2003 and FDA pre-market approval in September 2006, is distributed by CryoLife under the private label name Hemostase. The agreement automatically renews for an additional three-year period if CryoLife makes minimum purchases as designated under this agreement; however, there is no contractual obligation for CryoLife to make minimum purchases.

CryoLife began distributing Hemostase in the U.S. during the second quarter of 2008. Pursuant to the terms of the agreement, Medafor retained distribution rights to approximately 41 hospitals until no later than December 31, 2008. Medafor also retained the exclusive rights to distribute to U.S. Department of Defense hospitals. Outside of the U.S., CryoLife began distributing Hemostase in the United Kingdom and Germany during the second quarter of 2008 and to France and Canada in the third quarter of 2008. Medafor retained distribution rights to the rest of the world until December 31, 2008. CryoLife began distribution in other markets in Europe in early 2009 and expects to begin distribution of Hemostase in other countries in the rest of the world as soon as the required regulatory approvals are obtained.

BioGlue Brow Lift Approval

On June 10, 2008 CryoLife and BioForm Medical, Inc. (BioForm) announced that they received a CE Mark for the use of BioGlue for fixation following endoscopic browplasty, commonly called brow lift, a reconstructive plastic surgery procedure. The CE Mark approval allows the product to be marketed in the EEA. BioGlue will be distributed by BioForm, for use in approved cosmetic and reconstructive plastic surgery in the EU, under the name BioGlue Aesthetic Medical Adhesive. Under the terms of the agreement, CryoLife is the exclusive supplier of BioGlue to BioForm for all cosmetic and plastic surgery applications. BioForm is responsible for all clinical trials, CE marking of the BioGlue Aesthetic branded product, and for sales and marketing of BioGlue in these applications in 12 EU countries. In addition, regulatory filings for BioGlue Aesthetic are in progress in Canada. BioForm is responsible for these filings, and for sales and marketing of BioGlue Aesthetic branded products in Canada.

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 preserved heart valves, non-valved cardiac tissues and vascular tissues. The Company has continued to expand market penetration of BioGlue both in the U.S. and internationally. In addition, the Company has continued to expand preserved heart valves, non-valved cardiac tissues, and vascular tissues.

Develop the Company s Pipeline of Services and Products. Develop the Company s technologies and intellectual property for additional product and service offerings and commercialization of new products and services. In 2008 the Company received 510(k) clearance from the FDA for its CryoValve SG. Additionally, the Company has continued to develop additional products as discussed further in Research and Development and Clinical Research below for introduction as commercialized 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. In April 2008 the Company entered into an exclusive agreement to distribute Hemostase, a hemostatic agent used to encourage clotting of the blood and reduce bleeding complications in surgery.

License Company Technology to Third Parties For Non-Competing Uses. Leverage the Company s current technology platforms, including its PHT platform and SynerGraft technologies, 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. As part of this strategy, in October 2006, the Company signed the licensing and distribution agreement with BioForm. Additionally, in September 2007, the

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Company signed a distribution agreement allowing Proxy Biomedical Limited (Proxy Biomedical) to include BioGlue in a hernia repair kit in international markets.

Analyze And Identify Underperforming Assets For Potential Sale Or Disposal. Continue to analyze and identify underperforming assets not complementary to the strategies identified above for potential sale or disposal. As a part of this strategy, the Company entered into an exchange and service agreement with Regeneration Technologies, Inc. (RTI Agreement) in December 2006 as discussed below in Services and Products *Human Orthopaedic Tissue* . In addition, the Company decided in early 2009 to de-emphasize its sales efforts related to the CryoLife-O Brien Stentless Porcine Aortic Bioprosthesis.

Services and Products

Tissue 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 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 human heart valves, non-valved cardiac tissues, and vascular tissues.

CryoLife maintains and collects 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, as well as its programs, whereby, 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 and grants to improve their tissue recovery techniques and, thereby, increase the yield of usable tissue.

Human Cardiac Tissue. The human heart valves and cardiac tissues preserved by the Company are used in reconstructive heart valve replacement surgery. CryoLife shipped approximately 68,500 preserved human heart valves and cardiac tissues from 1984 through 2008, including approximately 3,000 shipments in 2008. Revenues from human heart valve and conduit preservation services accounted for 24%, 23%, and 20% of total revenues in 2008, 2007, and 2006, respectively. Based on CryoLife s records of documented implants, management believes that the acceptance of the Company s preserved human heart valve is due in part to physicians recognition of the longevity and natural functionality of the Company s preserved human tissues, the Company s documented clinical data, and the support of the Company s medical relations and education staff, clinical research staff, and field representatives, including its direct field service representatives and customer service department. Management believes the Company offers advantages in the areas of clinical data and field service 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 provides preserved human non-valved cardiac and patch tissue to surgeons who wish to perform certain specialized cardiac repair procedures. Each of these preserved human heart valves, non-valved cardiac tissues, and patches maintains a tissue structure which more closely resembles and more closely simulates the performance of the patient s own tissue than non-human tissue alternatives.

As discussed above at Recent Events , on February 7, 2008 CryoLife received 510(k) clearance from the FDA for its CryoValve SG pulmonary human heart valve processed with the Company s proprietary SynerGraft technology. CryoLife has begun using the SynerGraft technology for a portion of its pulmonary valve processing. In 2008 33% of human pulmonary valves shipped by CryoLife were processed with the SynerGraft technology.

The Company estimates that in 2008 the total annual heart valve and non-valved cardiac replacement market in the U.S. was approximately $660 million. Management believes that of the $660 million, approximately $375 million or 57% of the procedures were for aortic, pulmonary, and tricuspid valve replacements for which the Company s tissues can be used. The Company believes that approximately 89,000 aortic, pulmonary, and tricuspid valve replacement or repair surgeries were conducted in the U.S. in 2008. Of these 89,000 procedures approximately 90% were for aortic valve replacement.

Management believes preserved human heart valves and non-valved cardiac 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**			**Bovine**
		Stented	**Stentless**	**Mechanical**	**Pericardial**
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 (newborn to 17 years) 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.

Human 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 52,800 human vascular tissues from 1986 through 2008, including approximately 3,900 shipments in 2008. Revenues from human vascular preservation services accounted for 26%, 24%, and 21% of total revenues in 2008, 2007, and 2006, respectively.

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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 aorta reconstruction. In cases of peripheral artherosclerosis, 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 field.

Human Orthopaedic Tissue. The Company historically 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 operation of the human knee. In December 2006 CryoLife entered into an exchange and services agreement with RTI respecting procurement, processing, and distribution activities for cardiac and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife. In accordance with the RTI Agreement, CryoLife ceased accepting donated human orthopaedic tissue for processing on January 1, 2007 and began work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise, on January 1, 2007 RTI ceased accepting donated human cardiac and vascular tissues for processing and began work to transition its arrangements for recovery of these tissues to CryoLife. CryoLife continued to distribute its existing orthopaedic tissue inventory through June 30, 2008. From July 1, 2008 through December 31, 2008 CryoLife was entitled to distribute RTI s remaining cardiac and vascular tissue inventory for a commission, and RTI was entitled to distribute CryoLife s remaining orthopaedic tissue inventory for a commission. CryoLife has not received any commissions under this provision. Under the RTI Agreement, from July 1, 2008 through December 31, 2016, except as set forth above, CryoLife has agreed not to market or solicit orders for certain human orthopaedic tissues and RTI has agreed not to market or solicit orders for human cardiac and vascular tissues. The agreement also provides for a non-exclusive license of technology from CryoLife to RTI, and contains customary provisions regarding indemnification and confidentiality. Revenues from human orthopaedic preservation services accounted for 1%, 4%, and 9% of total revenues in 2008, 2007, and 2006, respectively.

Medical Devices

BioGlue and PHT Products. 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 air in lung surgeries, cerebral spinal fluid in neurosurgeries, blood in cardiac surgeries, 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 the lobes of the lung, the dural membrane surrounding the brain and spinal cord, blood vessels, and the gastrointestinal tract. 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 70 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 $209 million in 2008. CryoLife distributes BioGlue under CE Mark product certification in Europe, the Middle East, and Africa (EMEA) 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 in Central and South America and Asia. Revenues from BioGlue represented 46%, 46%, and 49% of total revenues in 2008, 2007, and 2006, respectively.

BioGlue is the first product to be developed from the Company s Protein Hydrogel Technology 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 body tissue.

As a part of the Company s development of other products from its PHT platform, the Company has received conditional approval for BioFoam from the FDA for the feasibility phase of the Company s IDE submission for use to seal abdominal organs. In addition the Company has submitted an application for a CE Mark with its European Notified Body to use BioFoam as an adjunct when bleeding control by conventional methods is ineffective or impractical on organ sealing.

Hemostase. As discussed above at Recent Events *Medafor License Agreement* , in May 2008 the Company began distributing Medafor s microporous polysaccharide hemostatic agent under the private label Hemostase. 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 a 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. Hemostase is currently available in 1, 3, and 5 gram units. Revenues for Hemostase represented 1% of total revenues in 2008. The Company estimates that aggregate U.S. sales for hemostatic agents were approximately $608 million in 2008.

ProPatch Soft Tissue Repair Matrix. 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 pre-clinical animal data are 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 third parties as well as obtaining clinical data to support applications to be marketed directly.

Other Medical Devices. During 2008 the Company had revenues related to the CryoLife-O Brien 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 2008, 2007, and 2006. The Company expects minimal revenues during 2009 for these products. In early 2009 the Company decided to de-emphasize sales efforts related to the CryoLife-O Brien Aortic Bioprosthesis.

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 Note 16 of the Notes to Consolidated Financial Statements regarding segment and geographic information.

Procurement, Distribution, and Marketing

Tissue 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 and 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 100,000 donors. The Company has developed relationships with approximately 70 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 250 of these freezers. Participating hospitals generally pay the cost of liquid nitrogen and regular maintenance. The availability of on-site freezers makes it easier for a hospital s physicians to utilize the Company s preservation services by making the cryopreserved 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 1,200 cardiac and vascular surgeons who have implanted tissues preserved by the Company during 2008. 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. The Company is targeting approximately 34 persons as field service representatives who focus primarily on vascular surgeons, 10 cardiac specialists who focus primarily on cardiac surgeons, and five region managers. A small number of these positions are open, and the Company is actively recruiting for these positions.

The Company sponsors physician 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 preserved human tissue processed by the Company and help to differentiate the Company from other allograft processors. On October 10 and 11, 2008 CryoLife hosted the Ross Summit at CryoLife Corporate Headquarters with 61 cardiac surgeons from nine 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 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 in-house technical specialists that provide technical information and assistance and maintains a staff 24 hours per day, 365 days per year for customer support.

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, the Company conducts field training for implanting surgeons with respect to 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 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.

European Operations

The Company markets its products in the EMEA region through its European subsidiary, Europa based in Guildford, England. Europa, with its team of approximately 21 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 through its direct sales representatives in Great Britain 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 in the Company s human tissue business, 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 or Hemostase.

Competition

Preserved Human Tissues and Bioprosthetic Cardiac and Vascular Devices

The Company currently faces competition from at least two non-profit tissue banks that cryopreserve 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 resources greater than those of the Company, are engaged in manufacturing, marketing, and selling alternatives to preserved human tissue. Management believes that it competes with other entities that cryopreserve human tissue on the basis of technology, customer service, and quality assurance.

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 SG 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 believes that the CryoValve SG is important to patient management issues of whole organ transplant recipients, as discussed in Recent Events.

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.

Human Heart Valves. Alternatives to human heart valves preserved by the Company include mechanical valves, porcine valves, and valves constructed from bovine pericardium. St. Jude Medical, Inc. is the leading supplier of mechanical heart valves. Medtronic, Inc. is the leading supplier of porcine heart valves. Edwards Life Sciences, Inc. is the leading supplier of bovine pericardial heart valves. The Company is aware of at least six companies that offer porcine, bovine, and mechanical heart valves. In addition, management believes that at least two domestic tissue banks offer preservation services for human heart valves in competition with the Company.

Human 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.

BioGlue

The Company competes with many domestic and international medical device and pharmaceutical companies. In the surgical adhesive and surgical sealant area, the Company 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; and Tenaxis, Inc. s (Tenaxis) ArterX. The Company currently competes with these products based on the products 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. Many of the Company s current and potential competitors have substantially greater financial and personnel resources than the Company. These competitors may also have greater experience in developing products, conducting clinical trials, and obtaining regulatory approvals. Certain of these competitors may obtain patent protection, approval, or clearance by the FDA or foreign countries, or product commercialization 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.

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, and Ethicon, Inc. s Surgicel, Surgiflo, and Surgifoam products. In addition, Starch Medical Inc. has a hemostatic product that has CE approval and that will compete in the future outside of the U.S. 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. Many of the Company s current and potential competitors have substantially greater financial and personnel resources than the Company. These competitors may also have greater experience in developing products, conducting clinical trials, and obtaining regulatory approvals. Certain of these competitors may obtain patent protection, approval, or clearance by the FDA or foreign countries, or product commercialization 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.

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, and results of operations 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, and cell biology, and its understanding of the needs of the cardiac and vascular surgery medical specialties to attempt to expand its surgical adhesive and preservation businesses and to develop or acquire products and technologies for these specialties. The Company identifies market areas that can benefit from preserved living 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 31 people in its research and development and clinical research departments, including six PhDs with specialties in the fields of molecular biology, protein chemistry, vascular physiology, 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, BioDisc, and other PHT derivatives, additional applications of its SynerGraft technology, and organ transplant solutions.

At the FDA s request, the Company has committed to conducting a post-clearance study to collect long-term clinical data for the CryoValve SG. The Company submitted a proposed study to the FDA in December 2008. Data collected in this study will be compared to data from a defined control group implanted with a standard processed pulmonary human 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 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. The agreement calls for BioForm to fund the clinical development and regulatory approval process for commercializing BioGlue 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 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 investigational device exemption, or 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 an IDE. BioForm s strategy is to

determine compelling aesthetic applications for BioGlue, demonstrate safety and effectiveness of this material in aesthetic applications, and launch BioGlue 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 plans to introduce this product in Europe in early 2009.

BioFoam, a product in the PHT platform, contains a foaming agent, which has the potential to rapidly seal organs, such as the liver and spleen, and may provide hemostasis in penetrating wounds and trauma. Under the 2005, 2006, and 2007, U.S. Congress Defense Appropriations Conference Reports the Company was awarded $930,000, $1.9 million, and $848,000, respectively, for the continued development of protein hydrogel technology for use on the battlefield. The 2008 U.S. Congress Defense Appropriations Conference Report included $1.7 million for the continued development of protein hydrogel technology. The Company anticipates applying for additional funding under this bill in 2009. The Company is currently involved in initial animal trials related to this grant. In December 2008 The Company received conditional approval for BioFoam from the FDA for the feasibility phase of the Company s IDE submission for abdominal organ sealing. Before the Company can begin the feasibility study, the Company must receive an additional approval from the U.S. Department of Defense as a condition of its award. The Company is in the final review process with the Department of Defense. In addition, in December the Company filed a CE Mark submission with its Notified Body for BioFoam as an adjunct to conventional methods to control organ bleeding when bleeding control by conventional methods is ineffective or impractical. The Company continues to conduct preclinical research with BioFoam for use in wound sealing in trauma surgery.

BioDisc, a product in the PHT platform, is undergoing clinical evaluation 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 enrollment and a two-year follow-up have been completed. The Company filed a CE Mark submission in February 2007 and received a response from its Notified Body in the fourth quarter of 2008. The Company is currently formulating its response to questions raised by its Notified Body on its CE Mark submission. Management believes that the Notified Body may require additional human implants and clinical follow-up prior to granting a CE Mark. If additional human implants are required, the Company will likely 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 2008, 2007, and 2006 the Company spent approximately $5.3 million, $4.5 million, and $3.5 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 5%, 5%, and 4% of the Company s revenues for the years 2008, 2007, and 2006, respectively.

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 66 technicians employed in this area, and the laboratory is staffed 24 hours per day, 365 days per year. In 2008 the laboratory packaged approximately 13,900 human 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 increasing the number of relationships with tissue banks and organ procurement organizations, or working to increase donor awareness to increase tissue donation. The 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 and add equipment.

BioGlue

BioGlue is presently manufactured at the Company s headquarters facility. The laboratory contains approximately 13,500 square feet, including a suite of six clean rooms. Currently, there are approximately 19 technicians employed in this area. The laboratory has a potential annual capacity of approximately 2 million cartridges or syringes of BioGlue. 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.

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 or 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 or 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.

Tissue Preservation Services

The Company employs a comprehensive quality assurance program in all of its tissue processing activities. The Company is subject to human cells and tissue regulations, including Donor Eligibility and Good Tissue Practice regulations, as well as other FDA Quality System Regulations, and ISO 13485 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, dissected 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 and ISO 13485 and Medical Device Directive requirements.

All materials and components utilized in the production of the Company s products 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 manufactured 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 37 U.S. patents and 91 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 10 pending U.S. patent applications and 25 pending foreign applications that relate to the Company s cryopreservation, PHT, and other areas. There can be no assurance that any patents pending will result in issued patents. 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 patents license rights and trade secrets that provide competitive advantages.

There can be no assurance that the claims allowed in any of the Company s existing or future patents will provide competitive advantages for the Company s products, processes, 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, and results of operations could be materially adversely affected. Under current law, patent applications in the U.S. and patent applications in foreign countries are maintained in secrecy for a period after filing. The right to a patent in the U.S. is attributable to the first to invent, not the first to file a patent application. The Company cannot be sure that products manufactured or distributed by it, or the technologies developed by it, do not infringe patents that may be granted in the future pursuant to pending patent applications or that they do not infringe any patents 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. 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 products or services to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be on terms acceptable to the Company or that the Company would be successful in any attempt to redesign its products or services to avoid infringement. The Company s failure to obtain licenses or to redesign its products or services could have a material adverse effect on the Company s business, financial condition, and results of operations. 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

Our tissue processing and preservation services and our ability to supply needed tissues is dependent upon donation of tissues from human donors. We must rely on the tissue banks and organ procurement organizations that we work with to educate the public on the need for donation and to foster a willingness to donate tissue. We must also maintain good relationships with our tissue procurement organizations and tissue banks to ensure that we will receive donated tissue. In addition, regulations could reduce the availability of tissue available for implantation.

Our BioGlue product is comprised of bovine protein and a cross linker that is delivered to the site through a delivery device. The delivery devices are manufactured by a single supplier. Although we maintain an inventory of devices, if the single supplier was to cease producing devices for us 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 our 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.

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 premarket approval (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.

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.

Human 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 SG pulmonary human heart valve falls under the medical device regulations. On February 7, 2008 the Company received 510(k) clearance from the FDA for its CryoValve SG pulmonary human heart valve processed with the Company s proprietary SynerGraft technology, as discussed in Recent Events .

Porcine Heart Valves. 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 porcine heart 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.

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 Approval from the FDA for use its 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.

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 Current Good Tissue Practice and Additional Requirements for Manufactures of HCT/Ps. This guidance is subject to comment and change before 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 licensed as a clinical laboratory or tissue bank under California, Delaware, Florida, Georgia, Illinois, Maryland, New York, and Oregon law. The Company has such licenses, 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 biological products 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 prior to commercial distribution of the product 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 (30 member state countries - 27 European Union (EU) countries, and 3 European Free Trade Association (EFTA) countries) without additional general applications in each country. However, individual EEA members reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third parties called Notified Bodies award the CE Mark. These Notified Bodies are approved and subject to review by the competent authorities of their respective countries. A number of countries outside of the EEA accept the CE Mark in lieu of marketing submissions as an addendum to that country s application process. The Company has been issued CE Marks for BioGlue and the CryoLife-O Brien stentless porcine aortic bioprosthesis and has CE approval for the distribution of Hemostase. BioGlue may be exported to more than 70 countries outside the U.S. and the Hemostase and CryoLife-O Brien aortic bioprosthesis products may be exported to the EEA and Canada.

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, Austria, and Israel. 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, 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, 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. Austria has not implemented any additional requirements under the EUTCD, but could and will likely do so in the future. 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, 2008 the Company had approximately 435 employees. These employees included six 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. 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 May Receive A Form 483 Notice Of Observations, A Warning Letter, Or Other Similar Communication From The FDA And We May Be Unable To Address The Concerns Raised By The FDA In Such Correspondence or Communication, Or Addressing The Concerns May Be Costly Or Could Materially and Adversely Affect Our Operations.

The FDA has issued Form 483 Notices of Observations and Warning Letters to us in the past that have noted deficiencies in our operations, including process validation, complaint handling and reporting, and analysis of certain testing results, among other items. Although we have had positive FDA inspections recently, we could still be subject to an FDA inspection that results in a Form 483. If the FDA deems our responses to a Form 483 unsatisfactory, it could take further action, such as issuing us a Warning Letter, or in the alternative even before issuing a Form 483, the FDA could issue a Warning Letter or other similar communication directly to us. Corrective actions taken by us to address these regulatory actions could materially and adversely affect our revenues, financial position, profitability, or cash flows. If we are unable to implement adequate corrective actions required by a Warning Letter or similar request made by the FDA, the FDA could do the following:

Institute additional recalls of tissues or products,

Require us to perform additional tests,

Begin to require prescriptions for tissues or products where they are not currently required,

Halt the shipping or processing of tissues or products,

Require additional approvals for marketing our tissue services or products or assess civil penalties.

All of these could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

SynerGraft Processed Human Pulmonary Heart Valves and Other SynerGraft Products May Not Be Accepted By The Marketplace.

CryoValve SG pulmonary human heart valves may not perform as well as expected or provide all of the benefits anticipated by the marketplace and, as a result, the Company may not be able to continue to process a portion of its human pulmonary valves with its SynerGraft technology. If such an event were to occur, the Company would need to return to processing most or all of its pulmonary human heart valves without the SynerGraft technology, which could significantly reduce the expected benefits of the SynerGraft technology. In addition other products being developed for commercialization by CryoLife that utilize the SynerGraft process, such as ProPatch, CryoLife s soft tissue repair matrix for use in hernia repair and certain orthopaedic related conditions, may not provide the anticipated benefits or otherwise achieve marketplace acceptance.

SynerGraft Processed Human Pulmonary Heart Valves Have A One Year Shelf Life.

We are currently using the SynerGraft technology for a portion of our human pulmonary heart valve processing pursuant to the 510(k) clearance we have received for the SynerGraft treated valves. Our SynerGraft pulmonary human heart valves currently have a one year shelf life, whereas our non-SynerGraft processed pulmonary human heart valves have a five year

shelf life. We are currently in discussions with the FDA to extend the shelf life of our SynerGraft pulmonary human heart valves. We do not know when the shelf life of the SynerGraft pulmonary human heart valves may be extended, if at all. Accordingly, if we do not implant our SynerGraft pulmonary human heart valves within one year of cryopreservation, we may be required to discard these valves, and as a result we may lose more tissues than before we started processing pulmonary human heart valves with the SynerGraft technology, which 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 SG Pulmonary Human Heart Valve 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 SG. 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.

The FDA Has Previously Issued A Recall Of Certain Of Our Products And Has The Ability To Inspect Our Facilities, Suspend Our Operations, And Issue A Recall Of Our Products In The Future.

On August 13, 2002 we received an order from the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001, referred to as the FDA Order. Pursuant to the FDA Order, we placed non-valve cardiac, vascular, and orthopaedic tissue processed since October 3, 2001 on quality assurance quarantine and recalled the portion of those tissues that had been distributed but not implanted. In addition we ceased processing non-valved cardiac and vascular tissues until mid-September 2002 and ceased processing orthopaedic tissues until 2003. The FDA Order resulted in the destruction of much of our tissue, required that we adjust revenue for tissue recall returns, curtailed our processing activities, and subjected us to intense FDA scrutiny and additional regulatory requirements that increased costs. We also suffered decreased revenues due to lack of processing ability, decreased market demand for our services, and were faced with liability lawsuits. These challenges reduced our revenues, increased our costs to process tissues and our operating expenses, and strained management resources and available cash. Although we resumed processing and distribution of the types of tissues subject to the FDA Order and resolved many of the product liability suits pending against us, we incurred losses and did not produce cash from operations for many years. Any future recalls or other regulatory action by the FDA could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

The FDA can inspect our facilities, review complaints against us, monitor the efficacy of our products and the claims we make regarding our products benefits, and issue reports to us on areas that require improvement. If the FDA believes that we are not responsive to their requests for any suggested improvement or that our products are not in compliance with regulatory norms, the FDA has the ability to suspend our operations and issue an order for the recall of any or all of our products. If the FDA issues such an order, our revenues, financial condition, profitability, and cash flows could be materially and adversely affected.

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

The processing, preservation, and distribution of human tissue, bovine tissue products, porcine tissue products, and the manufacture and sale of medical devices entail inherent risks of medical complications for patients and have resulted and may result in product liability claims against us and adverse publicity. From time to time various plaintiffs have asserted that our tissue 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 tissue 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 tissue or medical devices, we have been and may be subject to additional FDA and other regulatory scrutiny and 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 preservation services. As a result, some surgeons and hospitals decided not to use our heart valves. Cautionary statements from the FDA or other regulators regarding our tissue services or products, adverse publicity, changes to our labeling, or required prominent warnings or negative reviews from the FDA or regulators of our processing and manufacturing facilities have decreased and may in the future decrease demand for our tissue services 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 services or products could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

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. 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 potential infringements of our U.S. 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 products and services 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 two products, Hemostase and CardioWrap, which are manufactured by third parties. These third parties have patents, licenses, and proprietary technologies that give their products competitive advantages. Others may challenge the validity or enforceability of these patents. Our contracts require that these third parties pursue infringements of patents owned or licensed by them for the products that we distribute. We may choose to assist our third party manufacturers 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 these third parties 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, these third parties technologies could infringe patents or other rights owned by others, or others could infringe these third parties patents or use their proprietary rights inappropriately.

We believe that an entity may be infringing the patent licensed by the company that supplies Hemostase to us. We have notified the supplier of Hemostase about this potential infringement. We are not able to predict what actions the supplier will take. If the supplier does not take any action or if they are ultimately unsuccessful in their attempt to halt the infringement or in prohibiting other infringements of their patents or inappropriate uses of their company s proprietary technology, or should the validity of their licensed patents be successfully challenged, our revenues, financial condition, profitability, and cash flows could be materially and adversely affected.

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

Our products and the tissues we process allegedly have caused and may in the future cause injury to patients using our products or tissues, and we have been and may be exposed to product liability claims.

Following the FDA Order, lawsuits related to our tissue preservation services increased to unprecedented numbers for us. These claims involved assertions that infections and related morbidity, including death, were the result of inadequacies in our procedures. We maintain claims-made insurance policies to mitigate our financial exposure to 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.

As of December 31, 2008, we know of one pending lawsuit against us arising out of our allograft orthopaedic tissue preservation services. We believe that our product liability insurance covers this lawsuit. In addition other parties have made complaints against us that may result in lawsuits in future periods. We ceased accepting orthopaedic tissue for processing in January 2007.

Our December 31, 2008 Consolidated Balance Sheet reflects a liability of approximately $330,000 for the estimated cost of resolving this claim. The amount recorded is an estimate and does not reflect actual settlement arrangements or final judgments, the latter of which could include punitive damages, nor does it represent cash set aside for the purpose of making payments. This balance sheet also reflects a $4.4 million liability which is included as a component of accrued expenses of $2.2 million and other long-term liabilities of $2.2 million for the estimated cost of resolving unreported product liability claims. We believe that the liability could be estimated to be as high as $9.0 million, after including a reasonable margin for statistical fluctuations. Based on an actuarial valuation, we estimated that as of December 31, 2008, $1.5 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, 2008. Actual results may differ from this estimate. Our product liability insurance policies do not include coverage for any punitive damages.

If we are unsuccessful in arranging acceptable settlements of current or future 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 are a defendant, whether now pending or hereafter arising, 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 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 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 the result of a settlement that results in a large insurance claim, our insurance rates could increase significantly. Our current product liability insurance policy is a six-year claims-made policy covering claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

We May Be Unable To Successfully Market Hemostase.

Part of our plans for future growth involves anticipated revenues from the sale of Hemostase, a private label hemostatic agent. We currently market Hemostase pursuant to a distribution agreement for use in cardiac and vascular surgery in the U.S. and for cardiac, vascular, and general surgery, other than orthopaedic and ear, nose and throat surgery, in certain international markets, subject to certain exclusions. Our ability to successfully market Hemostase is subject to a number of risks, including:

- The possibility that surgeons may not accept Hemostase,
- We may be unable to effectively leverage our existing sales force to market Hemostase,
- Hemostase may not perform as expected or provide all expected benefits,
- Other distributors of the Hemostase product may interfere with or otherwise impede our ability to market the product to new or existing customers, and
- Potential third party infringement of the patent under which Hemostase in produced.

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 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.

Our Failure To Adequately Comply With Government Regulations Could Result In Loss Of Revenues And Customers As Well As Additional Compliance Expense.

The FDA, certain international governments, and some states regulate the facilities and processes that we use. For example, the FDA, pursuant to regulations it promulgated under the Public Health Service Act, currently regulates human tissue. These regulations establish requirements for donor testing and screening of human tissue and record keeping relating to these activities and impose certain registration and product listing requirements on establishments that process or distribute human tissue or cellular-based products. The FDA has also implemented good tissue practice regulations akin to good manufacturing practices, which must be followed by tissue banks and processors of human tissue. These regulations increase regulatory oversight of CryoLife and other processors of human tissue. The FDA also regulates BioGlue through its medical device regulations. These medical device regulations include the establishment of requirements for manufacturer registration, good manufacturing practices through the Quality System Regulations, premarket approval, and medical device reporting.

Our facilities are subject to periodic inspection by the FDA, and state and international regulatory authorities to ensure our compliance with applicable laws and regulations. Certain of our facilities and processes are subject to international standards set by the International Organization for Standardization with respect to which our compliance is reviewed by our Notified Body. If we fail to comply with these laws and regulations, we can be subject to sanctions, such as written observations of deficiencies made following inspections, warning letters, product recalls, fines, product seizures and consent decrees, all of which would be made available to the public. Such actions and publicity could affect our ability to market our products and services. In the past, the FDA has sent us notifications and warning letters relating to deficiencies in our compliance with FDA requirements. We were required to take measures to respond, including labeling our processed tissue with a warning. We also were subject to the FDA Order, which decreased our revenues, increased our processing costs, and materially and adversely affected our revenues, financial position, profitability, and cash flows. We cannot be certain that the FDA, or state or international regulatory authorities will not request that we take additional steps to correct deficiencies that may be raised in the future. Correcting any such deficiencies could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

Continued Deflation 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. The recent devaluation of British Pounds and Euros in relation to the U.S. dollar, should it continue or accelerate, or deflation of other currencies which affect our customers could materially reduce our 2009 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.

The Financial and Credit Liquidity Crisis May Adversely Affect Our Ability To Borrow Money Or Raise Capital.

If the financial and credit liquidity crisis were to continue or become more severe it may impact our ability to obtain money under our credit facility. If the current financial and credit liquidity crisis continues or worsens, our lender may be unable or unwilling to lend money pursuant to our line of credit. In addition, if we determined that it was appropriate or necessary to raise funds in the future, the financial and credit liquidity crisis, if it continues or worsens, may make the future cost of raising funds through the debt or equity markets more expensive or make those markets unavailable. If we were unable to use our line of credit or raise funds through debt or equity markets it could materially and adversely affect our liquidity or our ability to follow our key growth strategies outlined by our Board of Directors.

Current Economic Conditions May Impact Demand For Our Products and Tissues.

Our products and tissue services are purchased by hospitals for use in surgeries. We believe these hospitals have been negatively affected by the deterioration in the U.S. and global economies in several ways. For instance, hospitals are facing increased pressure from reduction in donations that support their operations. In addition, hospitals face increased costs associated with patients being unable to pay their portion of their insurance and from having no insurance. Finally, hospitals have seen decreases in their profitable elective surgeries, further creating economic pressure. The Company believes that because of the deterioration in the U.S. and global economies, hospitals have delayed replenishment of inventories or are carrying inventories at reduced levels, both of which reduce current purchases of CryoLife s products and services. Although the Company believes that hospitals will find it necessary to replenish their inventories in the future, there is no guarantee as to when or if they will do so, and if the economic crisis continues or worsens, they may further reduce their inventories or choose to use alternative or cheaper products or services.

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; and Tenaxis s ArterX. 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, and Ethicon, Inc. s Surgicel, Surgiflo, and Surgifoam products. In addition, Starch Medical, Inc. has a hemostatic product that has CE approval and that will compete in the future outside of the U.S. We are also aware that a few companies have surgical hemostat products under development. For example, Omrix Biopharmaceuticals, Inc. is currently developing a hemostatic patch for control of surgical bleeding that could compete with Hemostase in certain applications. Other medical device, pharmaceutical, and biopharmaceutical companies may also be developing competitive products. Our Hemostase product competes on the basis of its safety profile and ease of use.

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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, 2008. 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.

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

We estimate that as of our last measurement date, December 31, 2008, we had approximately $19.9 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, if any, 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.

Key Growth Strategies Identified As A Result Of Our Strategic Review May Not Generate The Anticipated Benefits.

In January 2006 we engaged a financial advisor to assist our management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. As a result of this review, the Board of Directors has directed management to actively pursue three key strategies to generate revenue and earnings growth in addition to continuing to focus on growing our business and leveraging our strengths and expertise in our core marketplaces. These three strategies are:

- Identifying and evaluating acquisition opportunities of complementary product lines and companies,
- Licensing our technology to third parties for non-competing uses, and
- Analyzing and identifying underperforming assets for possible sale or other disposition.

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

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. See Financial and Credit Crisis May Adversely Affect Our Ability to Borrow Money or Raise Capital above.

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

Our growth and profitability will depend, in part, upon our ability to complete development of and successfully introduce new products and services. We are uncertain whether we can develop commercially acceptable new products and services. We must also expend much time and money to obtain the required regulatory approvals. Although we have conducted preclinical studies on certain products under development which indicate that such 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 products. We also cannot give assurance that the regulatory agencies will clear or approve these or any new products on a

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timely basis, if ever, or that the new products will adequately meet the requirements of the applicable market or achieve market acceptance.

Our ability to complete the development of any of our products is subject to all of the risks associated with the commercialization of new 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 or manufacture our products which are under development. If we do develop or manufacture these products, we may not do so on a timely basis. These products may not meet price or performance objectives, and may not prove to be as effective as competing products.

If we are unable to successfully complete the development of a product, application, or service, or if we determine for financial, technical, or other reasons not to complete development or obtain regulatory approval of any product, application, or service, 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 products or services. 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 products or services 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 products or services could include the following:

New indications for our BioGlue products,

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

BioGlue Aesthetic,

CryoValve SG aortic human heart valve,

ProPatch, and

SynerGraft processed animal heart valves and vascular tissue.

Regulatory Action Outside Of The U.S. Has Affected Our Business In The Past And May Also 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 other products we market internationally, including BioGlue. Revenue from international human tissue preservation services was approximately $1.2 million, $896,000, and $572,000 for the years ended December 31, 2008, 2007, and 2006, respectively. International revenue from product sales, which includes international BioGlue revenue, was approximately $14.5 million, $12.8 million, and $11.3 million for the years ended December 31, 2008, 2007, and 2006, 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.

Physicians Have Been And May Continue To Be Reluctant To Implant Our Preserved Tissues Or Use Our Other Products.

Some physicians or implanting institutions have been reluctant to choose our preserved tissues for use in implantation, due to a perception that the tissue may not be safe or a belief that the implanting physician or hospital may be subject to a heightened liability risk if our tissues are used. In addition, for similar reasons, some hospital risk managers have not allowed implanting surgeons to utilize our tissues when alternatives are available. Several risk managers and physicians have refused to use our products due to these concerns. These conditions have materially and adversely affected demand for our preserved human tissues. If these conditions recur, our results of operations and cash flows will be adversely affected. If implanting hospitals or physicians representing significant revenues refuse to use tissues that we preserve or our other products, including BioGlue, and we are unable to replace the revenues lost, our revenues, financial condition, profitability, and cash flows would be materially and adversely affected.

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In The Past, We Have Experienced Operating Losses And Negative Cash Flows, And We Must Continue To Address The Underlying Causes In Order To Continue To Operate Profitably And Generate Positive Cash Flows.

Due principally to factors mentioned above, we suffered net losses in the years ended December 31, 2002 through 2005 and generated negative operating cash flow each year in the five year period ended December 31, 2006. There is no guarantee that we can continue to address the causes of our previous losses.

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 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 Will 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:

- Unexpected changes in regulatory requirements and tariffs;
- 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;
- Adverse economic or political changes;
- More limited protection for intellectual property in some countries;
- Changes in currency exchange rates;
- 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.

Future Health Care Reimbursement Methods And Policies May Affect The Availability, Amount, And Timing Of Our Revenues.

Even though we do not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand for our preserved tissue and other services and products. Our preservation services with respect to the cardiac and vascular tissues we preserve may be particularly susceptible to third-party cost containment measures. For example, the initial cost of a preserved human heart valve generally exceeds the cost of a mechanical, synthetic, or animal-derived valve. We are unable to predict what changes will be made in the reimbursement methods and policies utilized by third-party health care payors or their effect on us.

If third-party health care payors, including Medicare, change their reimbursement methods and policies with respect to preserved tissues provided for implant by us and other services and products that we offer, this could have a material and adverse effect on us. Significant

uncertainty exists as to the reimbursement status of newly approved health care products and services, and there can be no assurance that adequate third-party coverage will be available for us to maintain price levels sufficient to realize an appropriate return on our investment in developing new products.

If government-mandated health insurance is adopted, the demand for and prices obtained for our services and products could be negatively impacted because government-mandated health insurance could result in higher cost surgeries not being approved or could limit the level of reimbursement for new products, such as the CryoValve SG pulmonary human heart valve.

Government, hospitals, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products approved for marketing by the FDA. In some cases, these entities refuse to provide any coverage for uses of approved products for indications for which the FDA has not granted

marketing approval. If government and other third-party payors do not provide adequate coverage and reimbursement levels for uses of our new products and services, market acceptance of these products would be adversely affected, which could 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 products and services are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop products or processes with significant advantages over the 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.

Extensive Government Regulation May Adversely Affect Our Ability To Develop And Sell Products And Services.

Government regulation in the U.S., Europe, the Middle East, and Africa, and other jurisdictions can determine the success of our and our competitors efforts to market and develop services and products. Most of our products and services 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 SG pulmonary human heart valve 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 products developed by us or our competitors, independently or in collaboration with others, will receive the required approvals for 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 product approvals that could restrict commercial applications of our products. The FDA may withdraw 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 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 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,

Inability to locate, recruit, and qualify sufficient numbers of patients,

Lack of funding,

The inability to locate or recruit clinical investigators,

The redesign of clinical trial programs,

The inability to manufacture or acquire sufficient quantities of the particular 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 products or services offered, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. The unapproved use of our products or our preserved tissues could adversely affect the reputation of our company and our products or services. Products or services 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, or NOTA, prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs. Congress could adopt more restrictive interpretations of NOTA in the future that challenge one or more aspects of industry methods of charging for preservation services. Our laboratory operations and those of our competitors are subject to the U.S. Department of Labor, Occupational Safety and Health Administration, and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations which govern the processing, transportation, and storage of human organs and tissue.

The 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, 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.

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 2010. Our business and future operating results also depend in significant part upon our ability to attract and retain qualified management, processing, field, 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:

Variations in operating results,

Regulatory actions such as the adverse FDA activity,

Product liability claims,

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

Governmental regulatory acts,

Developments with respect to patents or proprietary rights,

General conditions in the medical device or service industries,

Actions taken by government regulators, 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, 2008.

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 Are Not Likely To Pay Common Stock Dividends In The Foreseeable Future, And We May Not Be Able To Pay Cash Dividends On Our Capital Stock Due To Legal or Contractual Restrictions.

We have not paid, and do not presently intend to pay, 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 ability to increase, and methods for increasing, BioGlue, Hemostase, and preserved tissue market penetration;

Potential BioGlue product line extensions;

The expected benefits of surgical adhesives and sealants;

The planned distribution of BioGlue by BioForm for use in approved cosmetic and reconstructive plastic surgery in the EU;

Expected usage of SynerGraft technology;

The anticipated competitive advantages and potential impact on revenues of SynerGraft;

Expectations that CryoValve SG will continue to command premium fees over the standard processed CryoValve;

Expected continued increase in 2009 of cardiac preservation service revenues as a result of shipments of CryoValve SG;

Expectations regarding the impact of CryoValve SG pulmonary heart valve on cost of preservation services as a percentage of preservation services revenues;

Information regarding the expected SynerGraft post-clearance study;

Future increases and decreases in cardiac valve shipments by the Company in 2009 and future periods;

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

The expected outcome of lawsuits filed by or against the Company and the adequacy of insurance coverage;

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

Expectations regarding, and possible increases in the cost and retention of, future insurance coverage;

Anticipated future demand for cardiac and vascular tissues;

Anticipated long-term advantages of the Company s preserved human tissues as compared to other alternatives;

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

Anticipated levels of tissue procurement in 2009 and future periods;

The Company s competitive position, including the impact of price increases;

Competitive advantages offered by the Company s patents, trade secrets, trademarks, and technology licensing rights;

The anticipated impact of the Company s strategic plans and its ability to implement them;

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;

Commercialization plans and potential benefits of our products in development;

Expectations regarding capital expenditures;

The amount and type of future research and development expenses;

The ability to expand the Company s service and product offerings;

Expected seasonality trends;

Expected impact of adoption of new accounting pronouncements;

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

Expected decreases in revenues from the distribution of orthopaedic tissue;

Expected increases in grant revenues;

The receipt of governmental grants for BioFoam development;

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

The adequacy of the Company s financial resources;

Current intentions not to pay cash dividends on our common stock;

Current intentions to retain future earnings for capital requirements;

Expectations regarding the use of net operating loss carryforwards;

Expectations regarding the ability of the Company to distribute Hemostase;

Expectations regarding the impact of the reversal of the valuation allowances on the Company s deferred tax assets and on our effective income tax rate;

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 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 under 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 the risk factors discussed in Item 1.A 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, 2008 (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. The volume of tissue processed is currently constrained by the availability of tissue. To increase the current processing levels, the Company could increase the number of employees, expand its second and third shift, and add equipment. 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.

Item 3. Legal Proceedings.

On January 18, 2008, the Company was served with a lawsuit filed in the State Court of Cobb County, Georgia, by Michael Hohenbery, an individual who underwent surgery in December 2006 for implantation of a meniscal allograft tissue preserved by the Company. The plaintiff alleges that such tissue was contaminated and resulted in an infection in his knee. The plaintiff seeks $10 million in compensatory damages and $100 million in punitive damages against the Company. The plaintiff s complaint alleged that the Company was strictly liable because it manufactured a product, that the Company was negligent, that the Company was professionally negligent and that the Company breached both express and implied warranties. On July 17, 2008 the Court dismissed the claims of strict liability, professional negligence and breach of express and implied warranties. Discovery in the case is still ongoing. The plaintiff has filed its expert reports and the Company is in the process of deposing these experts. Based on the Court s current scheduling order, the plaintiff s experts are to be deposed by April 15, 2009 and the Company s experts are to be disclosed to the Plaintiff by May 29, 2009. A trial date has not been set. The Company intends to continue to defend itself in the lawsuit. The Company believes that it has adequate insurance coverage for this particular case. The Company s insurance coverage will not pay any punitive damage award.

On October 1, 2008, Tenaxis, Inc. filed a nullity action against one of CryoLife s BioGlue patents in Federal Patent Court in the State of Bavaria in the Federal Republic of Germany that seeks to invalidate CryoLife s patent No. EP 0 650 512, which is our main European patent for BioGlue. The Company filed a response to the lawsuit denying the nullity action and intends to defend itself against the nullity action. The Patent Court has indicated that trial in the nullity action could proceed as early as November of 2009.

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. A trial date in the patent infringement action in Germany has not been set. In connection with the Company s patent infringement action in Germany, the Company on November 10, 2008 filed a so called 28 USC 1782 petition in the United States Northern District of California seeking discovery regarding certain information concerning Tenaxis s surgical adhesive. The U.S. District Court granted the Company s petition on January 13, 2009. Pursuant to the 28 USC 1782 action discovery is still ongoing.

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	70	President, Chief Executive Officer, and Chairman
Scott B. Capps	Since 2007	42	Vice President, Clinical Research
David M. Fronk	Since 1998	45	Vice President, Regulatory Affairs and Quality Assurance
Albert E. Heacox, Ph.D.	Since 1989	58	Senior Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	44	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Gerald B. Seery	Since 2005	52	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.

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.

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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.

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

2007	High	Low
First quarter	$ 9.51	$ 7.00
Second quarter	15.20	8.25
Third quarter	14.34	7.60
Fourth quarter	9.88	6.20

As of February 13, 2009 the Company had 440 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. In addition the Company currently intends to retain any future earnings for funding its capital requirements and, therefore, does not anticipate paying any cash dividends on its common stock in the foreseeable future. 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, 2008 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
10/01/08	10/31/08	118	$ 15.26		
11/01/08	11/30/08				
12/01/08	12/31/08				
Total		118	$ 15.26		

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,				
	2008	**2007**	**2006**	**2005**	**2004**
Operations					
Revenues	$ 105,059	$ 94,763	$ 81,311	$ 69,282	$ 62,384
Net income (loss)	32,908	7,201	365	(19,535)	(18,749)
Net income (loss) applicable to common shareholders	32,908	6,958	(608)	(20,312)	(18,749)
Research and development expense as a percentage of revenues	5.1%	4.7%	4.4%	5.4%	6.3%
Income (loss) Per Common Share					
Basic	$ 1.18	$ 0.26	$ (0.02)	$ (0.85)	$ (0.81)
Diluted	$ 1.16	$ 0.26	$ (0.02)	$ (0.85)	$ (0.81)
Year-End Financial Position					
Total assets	$ 125,995	$ 92,684	$ 79,865	$ 76,809	$ 73,261
Working capital	59,370	40,750	26,472	23,922	19,689
Long term liabilities	5,672	5,355	4,864	4,909	5,629
Convertible preferred stock			3	3	
Shareholders equity	99,326	62,627	52,088	50,621	49,660
Current ratio[1]	4:1	3:1	2:1	2:1	2:1
Shareholders equity per diluted common share	$ 3.50	$ 2.32	$ 2.10	$ 2.11	$ 2.16

[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 for cardia and vascular transplant applications and develops and commercializes medical devices. The human tissue distributed by the Company includes the CryoValve® SG pulmonary human heart valve (CryoValve SG), processed using CryoLife s proprietary SynerGraft® technology. The Company s medical devices include BioGlue® Surgical Adhesive (BioGlue) and Hemostase, which the Company distributes for Medafor, Inc. (Medafor), as well as other medical devices.

For the year ended December 31, 2008 CryoLife reached a milestone by surpassing $100 million in revenue for the first time in Company history, as 2008 revenues totaled $105.1 million. Additionally, in 2008 the Company achieved eight consecutive quarters of profitability for the first time since 2001. The Company s profitability in 2008 was increased by $20.1 million due to the reversal of the valuation allowance on its deferred tax assets. See Deferred Income Taxes and Results of Operations section below for additional analysis of the fourth quarter and full year 2008 results. See Part I, Item 1, Business, for further discussion of the Company s business and activities during 2008.

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.

Liability Claims: In the normal course of business, the Company has tissue processing and product liability complaints filed against it. As of February 13, 2009 one tissue processing liability lawsuit was pending against the Company arising out of the allograft orthopaedic tissue preservation services previously provided by the Company. Management believes this lawsuit is covered by liability insurance. This lawsuit is currently in the discovery stage and expert witnesses are also being deposed. Other parties have made complaints that may result in lawsuits in future periods.

Based on an analysis the Company performed as of December 31, 2008 and 2007, the Company accrued a total of approximately $330,000 for the pending tissue processing liability lawsuit. The $330,000 accrual was included as a component of accrued expenses on the December 31, 2008 and 2007 Consolidated Balance Sheets.

On April 1, 2008 the Company bound liability coverage for the 2008/2009 insurance policy year. This policy is a six-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

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. The Company periodically evaluates its exposure to unreported tissue processing and product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. The Company updated its estimates of the unreported claims as of December 31, 2008. The unreported loss liability was estimated using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated 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 was calculated using a lognormal claims model blending the Company s historical average cost per claim with industry claims data. The Company used 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,

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The frequency of unreported claims included with respect to accident years 2001 through 2008 would be lower than the Company s experience in the 2002/2003 policy year, 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, 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 these assumptions provide a reasonable basis for the calculation of the unreported liability loss, but 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 estimated that its liability for unreported tissue processing and product liability claims was $4.4 million as of December 31, 2008. The $4.4 million balance is included as a component of accrued expenses of $2.2 million and other long-term liabilities of $2.2 million on the December 31, 2008 Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as $9.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The Company estimated that as of December 31, 2008, $1.5 million of the accrual for unreported liability claims would be recoverable under the Company s insurance policies. The $1.5 million insurance recoverable is included as a component of other receivables of $700,000 and other long-term assets of $800,000 on the December 31, 2008 Consolidated Balance Sheet. 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, 2008. Actual results may differ from this estimate.

As of December 31, 2007 the Company accrued $6.3 million for unreported liability claims and recorded a receivable of $2.4 million for unreported liability claims estimated to be recoverable under the Company s insurance policies. This $6.3 million accrual was included as a component of accrued expenses of $3.2 million and other long-term liabilities of $3.1 million on the December 31, 2007 Consolidated Balance Sheet. The $2.4 million insurance recoverable was included as a component of other current receivables of $1.1 million and other long-term assets of $1.3 million on the December 31, 2007 Consolidated Balance Sheet.

Deferred Preservation Costs: By federal law, human tissues cannot be bought or sold. Therefore, the tissues the Company preserves and further processes cannot be 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. 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). Although the Company cannot own human tissue, the preservation process is a manufacturing process that is accounted for in accordance with Accounting Research Bulletin No. 43 Chapter 4 Inventory Pricing . Preservation costs are stated at the lower of cost or market on a first-in, first-out basis and are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities. Cost of preservation services also includes idle facility expense, excessive spoilage, extra freight, and rehandling costs and requires allocation of fixed production overheads to be based on the normal capacity of the production facilities in accordance with Statement of Financial Accounting Standards (SFAS) No. 151 Inventory Costs .

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

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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 materially impact the amount of deferred preservation costs on the Company s Consolidated Balance Sheets and the cost of preservation services, including the lower of cost or market write-down, described below, on the Company s Consolidated Statements of Operations.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value and to determine if there are any impairments to the book value of the Company s deferred preservation costs. CryoLife records a charge to cost of preservation services to write down the amount of deferred preservation costs that are not deemed to be recoverable. These write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels when tissues are shipped or become available for shipment.

The Company recorded write-downs of $172,000 for the twelve months ended December 31, 2008 due to the impairment of certain vascular tissues and $366,000 for the twelve months ended December 31, 2007 due to the impairment of certain vascular and orthopaedic tissues. The tissues were impaired in the period that the Company determined that the tissues were not expected to ship prior to the expiration date of the tissue s packaging. The Company recorded write-downs of $453,000 and $1.2 million for the years ended December 31, 2007, and 2006, respectively, for the value of certain deferred preservation costs that exceeded market value. These write-downs were primarily due to excess tissue processing costs incurred in those periods that exceeded market value based on then recent average service fees. Actual results may differ from these estimates.

As of December 31, 2008 deferred preservation costs consisted of $12.2 million for allograft heart valve tissues, $1.7 million for non-valved cardiac tissues, $21.0 million for vascular tissues and zero for orthopaedic tissues. As of December 31, 2007 deferred preservation costs consisted of $7.6 million for allograft heart valve tissues, $2.1 million for non-valved cardiac tissues, $17.1 million for vascular tissues, and $123,000 for orthopaedic 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 in accordance with SFAS No. 109 Accounting for Income Taxes (SFAS 109), 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.

As of December 31, 2007, the Company performed an analysis in accordance with SFAS 109 of the recoverability of its deferred tax assets. This analysis included consideration of a variety of factors, which included the Company s historical operating results and uncertainties regarding projected future operating results. The Company concluded that a valuation allowance was needed on its deferred tax assets as of December 31, 2007. The Company performed additional assessments as of March 31, 2008, June 30, 2008, and September 30, 2008 and determined at each of these dates that 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 in accordance with SFAS No. 109, 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 $20.1 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, 2008 the Company had a total of $2.8 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax asset of $20.1 million. As of December 31, 2007 the Company had a total of $28.2 million in valuation allowances against deferred tax assets and a net deferred tax liability of $27,000 related to taxes in a foreign jurisdiction.

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 2005 through 2008 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 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.

SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS 144) requires the write down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. For the years ended December 31, 2008 and 2007 the Company did not experience any factors that indicated an SFAS 144 impairment review was warranted. For the year ended December 31, 2006 the Company performed an SFAS 144 impairment analysis, due to a variety of triggering factors, including its operating performance. Per management s analysis, the undiscounted future cash flows of the Company s asset groups exceeded their carrying values as of December 31, 2006. Therefore, management concluded that there was not an impairment of the Company s long-lived tangible and amortizing intangible assets.

SFAS No. 142 Goodwill and Other Intangible Assets (SFAS 142), requires that non-amortizing intangible assets are subjected to impairment testing on an annual basis and, if necessary, during interim periods if factors indicate that an impairment review is warranted. The Company s non-amortizing intangible assets as of December 31, 2008 consisted of trademarks and procurement agreements, including procurement contracts and access to the procurement of cardiac and vascular human tissues received from a third party as a result of an agreement entered into in 2006. In accordance with SFAS 142, the Company performed an analysis of its non-amortizing intangible assets as of December 31, 2008 and 2007. During this analysis, the Company 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 an impairment existed related to its non-amortizing intangible assets as of December 31, 2008 or 2007. Management will continue to evaluate the recoverability of these non-amortizing intangible assets on an annual basis in accordance with SFAS 142.

New Accounting Pronouncements

The Company will be required to adopt SFAS No. 141R Business Combinations (SFAS 141R), for the fiscal year beginning January 1, 2009. SFAS 141R 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 Company does not expect the adoption of SFAS 141R to have a material effect on its financial position, profitability, or cash flows upon adoption. All business combinations consummated after the implementation date will be accounted for under SFAS 141R.

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Results of Operations

(In thousands)

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

Revenues

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Revenues	$ 25,532	$ 25,068	$ 105,059	$ 94,763

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, the change in BioGlue revenues, and the change in other medical device revenues for the three and twelve months ended December 31, 2008 is presented below.

Cardiac Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Revenues	$ 5,894	$ 6,511	$ 25,514	$ 22,098
Cardiac revenues as a percentage of total revenue	23%	26%	24%	23%

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 SG. The net decrease in aggregate pulmonary valve shipments (which includes both standard processed pulmonary valves and CryoValve SGs) had a minimal effect on revenues, due to favorable tissue mix, as the CryoValve SG demands premium fees over standard processed pulmonary valves. The remaining cardiac volume decrease was primarily due to a decrease in shipments of non-valved cardiac tissues 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 valved cardiac tissues they keep on-hand for urgent procedures. The decrease in shipments of non-valved cardiac tissues 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 SG 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 SG and as a result, the Company reintroduced the CryoValve SG in March of 2008. Due to the reintroduction of the CryoValve SG, 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 SG demands premium fees over standard processed pulmonary valves. For the three and

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twelve months ended December 31, 2008, CryoValve SG 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 non-valved cardiac tissues 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, but are not limited to, the likelihood that certain tissues will pass the Company s quality controls and testing processes, changes in demand for certain types of tissues processed by the Company, changes in incoming tissue availability, and the level of tissues currently available for shipment. 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. If these changes remain in effect, the Company believes that cardiac procurement will continue at these reduced levels into 2009 as compared to prior year periods. However, 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.

The Company may continue to experience a decrease in cardiac valve shipments into 2009. The Company believes that the trend of decreasing cardiac valve shipments will reverse sometime during 2009 as hospitals begin to maintain on-hand tissues at reduced levels. However, there can be no assurance that this trend will reverse. The Company believes that cardiac revenues in 2009 will be favorably impacted by shipments of the CryoValve SG, which have a premium fee over the standard processed CryoValve. However, there can be no assurance that the CryoValve SG will continue to command premium fees or that shipments of the CryoValve SG will continue to occur at material levels.

Vascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Revenues	$ 6,362	$ 5,920	$ 27,417	$ 22,702
Vascular revenues as a percentage of total revenue	25%	24%	26%	24%

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, but are not limited to, the likelihood that certain tissues will pass the Company s quality controls and testing processes, changes in demand for certain types of tissues processed by the Company, changes in incoming tissue availability, and the level of tissues currently available for shipment. 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. If these changes remain in effect, the Company believes that vascular procurement will continue at these reduced levels through 2009 as compared to the prior year periods. However, 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.

Orthopaedic Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Revenues	$ 63	$ 552	$ 725	$ 4,202
Orthopaedic revenues as a percentage of total revenue	%	2%	1%	4%

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 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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Revenues	$ 12,088	$ 11,511	$ 48,570	$ 43,884
BioGlue revenues as a percentage of total revenue	47%	46%	46%	46%

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.

The majority of the Company s international BioGlue revenues are denominated in British Pounds and Euros, and as such are sensitive to changes in exchange rates. In addition, a portion of the Company s 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. As a result the Company s revenues in 2009 could be negatively impacted by changes in exchange rates from the weighted average exchange rates experienced by the Company in the prior year periods and by declining demand from foreign customers who may be impacted by changes in exchange rates.

Other Medical Devices

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Revenues	$ 906	$ 105	$ 1,923	$ 828
Other medical devices revenues as a percentage of total revenues	4%	%	2%	1%

Revenues from the sale of other medical devices increased 763% and 132% for the three and twelve months ended December 31, 2008, respectively, as compared to the three and twelve months ended December 31, 2007. The increases in revenues for the three and twelve months ended December 31, 2008 were primarily due to sales of Hemostase, which CryoLife began distributing during the second quarter of 2008. Hemostase revenues for the three and twelve months ended December 31, 2008 were $806,000 and $1.5 million, respectively.

Other medical device revenues in 2008 consisted of sales of Hemostase, CardioWrap, and bioprosthetic devices. Other medical device revenues in 2007 consisted of sales of CardioWrap and bioprosthetic devices.

Other Revenues

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2008	2007	2008	2007
Grant and licensing revenues	$ 219	$ 469	$ 910	$ 1,049
Grant and licensing revenues as a percentage of total revenue	1%	2%	1%	1%

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 U.S. Congress Defense Appropriations Conference Reports, the (2007 DOD Grant , 2006 DOD Grant , and 2005 DOD Grant , respectively). 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 one or more of these grants for the development of BioFoam®. The 2008 Defense Appropriations Conference Report (the 2008 DOD Grant) included $1.7 million for the continued development of protein hydrogel technology. CryoLife anticipates applying for funding under this bill in 2009. The Company does not currently know if it will be approved to receive funding under the 2008 DOD Grant or when decisions concerning the funding will be made.

Through December 31, 2008 CryoLife had received cash payments for all funds awarded under the 2005 and 2006 DOD Grants, and a portion of the 2007 DOD Grant, 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.

Costs and Expenses

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. The write-downs are discussed further in Critical Accounting Policies above.

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.

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 postemployment 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 $605,000 and $2.0 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 SG pulmonary human heart valve and other xenograft tissue products. PHT includes BioGlue, BioFoam, BioDisc®, and related products.

Other Costs 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 payoff 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 $20.0 million and $19.4 million for the three and twelve months ended December 31, 2008, respectively. Income tax benefit in 2008 includes $20.1 million in reversals of the Company s valuation allowance on its deferred tax assets. This reversal was partially offset by 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 14 of the Notes to Consolidated Financial Statements for further discussion of the Company s income taxes.

The Company s income tax expense is expected to increase significantly in 2009 as the Company will begin to record income tax expense based on its estimated combined federal, state, and foreign effective tax rate during 2009. The Company did not record income tax expense based on its effective tax rate in 2008, 2007, and 2006 due to the valuation allowance on the Company s deferred tax assets during those years.

Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

Revenues

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	**2006**	**2007**	**2006**
Revenues	$ 25,068	$ 21,090	$ 94,763	$ 81,311

Revenues increased 19% for the three months ended December 31, 2007 as compared to the three months ended December 31, 2006. Revenues increased 17% for the twelve months ended December 31, 2007 as compared to the twelve months ended December 31, 2006.

The increase in revenues for the three and twelve month periods ended December 31, 2007 was primarily due to an increase in cardiac and vascular preservation services revenues and BioGlue revenues, partially offset by a decrease in orthopaedic preservation services revenues as compared to the prior year periods.

A detailed discussion of the change in preservation services revenues for each of the three major tissue types distributed by the Company, the change in BioGlue revenues, and the change in other medical device revenues for the three and twelve months ended December 31, 2007 is presented below.

Cardiac Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Revenues	$ 6,511	$ 4,438	$ 22,098	$ 15,988
Cardiac revenues as a percentage of total revenue	26%	21%	23%	20%

Revenues from cardiac preservation services increased 47% for the three months ended December 31, 2007 as compared to the three months ended December 31, 2006. This increase was primarily due to a 44% increase in unit shipments of cardiac tissues, which increased revenues by 38%, an increase in average service fees, which increased revenues by 8%, and favorable foreign exchange, which increased revenues by 1%.

Revenues from cardiac preservation services increased 38% for the twelve months ended December 31, 2007 as compared to the twelve months ended December 31, 2006. This increase was primarily due to a 33% increase in unit shipments of cardiac tissues, which increased revenues by 28%, and an increase in average service fees, which increased revenues by 10%.

The increase in cardiac volume for the three and twelve months ended December 31, 2007 was due to increased shipments of all of the cardiac tissues processed by the Company. The increases in cardiac shipments were a result of increased availability of tissues due to improvements in the procurement of cardiac tissues and due to strengthening demand for the Company s tissues. The increase in average service fees for the three and twelve months ended December 31, 2007 was primarily due to fee increases that went into effect in January 2007 and July 2006, particularly the increases related to non-valved conduits, 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 non-valved cardiac tissues are processed, increased 29% for the three and twelve months ended December 31, 2007 as compared to the three and twelve months ended December 31, 2006. The increase in cardiac tissue procurement in 2007 over the prior year periods is primarily due to an increase in the share of the donated tissue supply received by CryoLife in comparison to all other cardiac tissue processors, which was due in part to the RTI Agreement.

Vascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Revenues	$ 5,920	$ 3,890	$ 22,702	$ 16,956
Vascular revenues as a percentage of total revenue	24%	18%	24%	21%

Revenues from vascular preservation services increased 52% for the three months ended December 31, 2007 as compared to the three months ended December 31, 2006. This increase was primarily due to a 38% increase in unit shipments of vascular tissues, which increased revenues by 41%, and an increase in average service fees, which increased revenues by 11%.

Revenues from vascular preservation services increased 34% for the twelve months ended December 31, 2007 as compared to the twelve months ended December 31, 2006. This increase was primarily due to a 19% increase in unit shipments of vascular tissues, which increased revenues by 22%, and an increase in average service fees, which increased revenues by 12%.

The increase in vascular volume for the three and twelve months ended December 31, 2007 was primarily due to increases in shipments of saphenous veins. The increases in vascular shipments were primarily due to strong demand for the Company s tissues, primarily demand for saphenous veins for use in peripheral vascular reconstruction surgeries to avoid limb amputations, and strong procurement of vascular tissues in recent periods. The increase in average service fees for the three and twelve months ended December 31, 2007 was primarily due to fee increases that went into effect in January 2007 and the routine expiration or renegotiation of pricing contracts with certain customers.

The Company s procurement of vascular tissues increased 4% for the three months ended December 31, 2007 as compared to the three months ended December 31, 2006 and increased 10% for the twelve months ended December 31, 2007 as compared to the twelve months ended December 31, 2006. The increase in vascular tissue procurement in 2007 over the prior year periods is primarily due to an increase in the share of the donated tissue supply received by CryoLife in comparison to all other vascular tissue processors, which was due in part to the RTI Agreement.

Orthopaedic Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Revenues	$ 552	$ 1,911	$ 4,202	$ 7,134
Orthopaedic revenues as a percentage of total revenue	2%	9%	4%	9%

Revenues from orthopaedic preservation services decreased 71% and 41% for the three and twelve months ended December 31, 2007 as compared to the three and twelve months ended December 31, 2006, respectively. The decrease in revenues for the three and twelve months ended December 31, 2007 was primarily due to decreases in unit shipments of orthopaedic tissues, as a result of 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 in accordance with the RTI Agreement and, to a lesser extent, due to declining demand for the Company s orthopaedic tissues, as the Company ceased marketing its orthopaedic preservation services.

BioGlue

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Revenues	$ 11,511	$ 10,491	$ 43,884	$ 40,025
BioGlue revenues as a percentage of total revenue	46%	50%	46%	49%

Revenues from the sale of BioGlue increased 10% for the three months ended December 31, 2007 as compared to the three months ended December 31, 2006. This increase was primarily due to an increase in average prices, which increased revenues by 5%, a 4% increase in the number of milliliters of BioGlue shipped, which increased revenues by 4%, and the favorable effect of foreign exchange, which increased revenues by 1%.

Revenues from the sale of BioGlue increased 10% for the twelve months ended December 31, 2007 as compared to the twelve months ended December 31, 2006. This increase was primarily due to an increase in average prices, which increased revenues by 6%, a 3% increase in the number of milliliters of BioGlue shipped, which increased revenues by 3%, and the favorable effect of foreign exchange, which increased revenues by 1%.

The increase in average selling prices for the three and twelve months ended December 31, 2007 was primarily due to price increases that went into effect in January 2007 and July 2006, domestically and in certain international markets, and the routine expiration or renegotiation of pricing contracts with certain customers.

Domestic revenues accounted for 71% and 72% of total BioGlue revenues for the three and twelve months ended December 31, 2007, respectively, and 74% of total BioGlue revenues for both the three and twelve months ended December 31, 2006.

Other Revenues

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Grant and licensing revenues	$ 469	$ 122	$ 1,049	$ 196
Grant and licensing revenues as a percentage of total revenue	2%	1%	1%	%

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Grant and licensing revenues for the three and twelve months ended December 31, 2007 and 2006 included revenues for research grants and revenues related to the licensing of the Company s technology to a third party.

In 2005 CryoLife was awarded $930,000 in funding allocated from the 2005 DOD Grant in connection with the development of BioFoam®. Grant revenues in 2007 and 2006 are related to funding under this grant. In 2007 CryoLife was awarded $1.9 million in funding allocated under the 2006 DOD Grant in connection with further development of BioFoam. The 2007 DOD Grant included $848,000 for the continued development of protein hydrogel technology for use on the battlefield. CryoLife applied for funding under this bill during 2007.

Through December 31, 2007 CryoLife had received a total of $1.9 million in advances on these grants and approximately $1.0 million in advances are yet to be received. As of December 31, 2007 CryoLife had $1.0 million in unspent cash advances under the grants recorded as cash and deferred revenues on the Company s Consolidated Balance Sheet.

Costs and Expenses

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Cost of preservation services	$ 7,250	$ 9,207	$ 28,433	$ 29,958
Cost of preservation services as a percentage of total preservation services revenue	56%	90%	58%	75%

Cost of preservation services for the three and twelve months ended December 31, 2007 included the write-down of $105,000 and $453,000, respectively, of certain deferred preservation costs that exceeded market value. Cost of preservation services for the three and twelve months ended December 31, 2006 included the write-down of $140,000 and $1.2 million, respectively, of certain deferred preservation costs that exceeded market value. The write-down of deferred preservation costs that exceeded market value in both years was primarily related to the Company s non-valved cardiac tissues. The Company implemented fee increases in July 2006 and January 2007, in part to address these tissues, which have had costs in excess of the average service fees. The decrease of the write-down in 2007 as compared to the prior year periods was primarily due to the favorable effect of the fee increases.

Cost of preservation services for the twelve months ended December 31, 2007 included a write-down of $366,000 due to the impairment of certain vascular and orthopaedic tissues. Cost of preservation services for the twelve months ended December 31, 2006 included the write-down of $588,000 due to the impairment of certain orthopaedic tissues. The tissues were considered impaired in the period in which the Company determined that the tissues were not expected to ship prior to the expiration date of the tissue s packaging.

Cost of preservation services for the three and twelve months ended December 31, 2006 includes the write-down of $2.8 million due to the impairment of certain orthopaedic tissues and processing materials as a result of the RTI Agreement. Cost of preservation services was favorably affected for the three and twelve months ended December 31, 2007 by shipments of orthopaedic tissue with a zero cost basis for which revenues were recognized but costs, estimated to be $85,000 and $347,000, respectively, had already been written-down in previous periods.

Cost of preservation services for the three and twelve months ended December 31, 2007 decreased primarily due to the net favorable effect of the decrease in write-downs in 2007 as compared to 2006 as discussed above, partially offset by an increase in the costs resulting from an increase in preservation services volume as compared to the prior year.

Cost of preservation services as a percentage of preservation services revenues for the three and twelve months ended December 31, 2007 decreased primarily due to the net favorable effect of the decrease in the write-downs in 2007 as compared to 2006, as discussed above, and improvements in preservation service margins. Preservation service margins were favorably impacted by increases in average service fees and a favorable mix shift as the less profitable orthopaedic tissues made up a lower percentage of the Company s tissue shipments.

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Cost of products	$ 1,664	$ 1,882	$ 7,108	$ 7,463
Cost of products as a percentage of total product revenue	14%	18%	16%	18%

The decrease in cost of products for the three and twelve months ended December 31, 2007 as compared to the three and twelve months ended December 31, 2006 was primarily due to a decrease in the sales volume of other implantable medical devices, partially offset by an increase in BioGlue sales volume.

The decrease in cost of products as a percentage of total product revenues for the three and twelve months ended December 31, 2007 as compared to the three and twelve months ended December 31, 2006 was primarily due to favorable product mix. The Company experienced favorable product mix as sales of lower margin implantable medical devices made up a smaller percentage of total products sold in 2007 as compared to 2006.

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
General, administrative, and marketing expenses	$ 12,053	$ 11,439	$ 46,470	$ 41,545
Cost of general, administrative, and marketing expenses as a percentage of total revenue	48%	54%	49%	51%

General, administrative, and marketing expenses for the three months ended December 31, 2007 included a charge for stock based compensation expenses of approximately $516,000. General, administrative, and marketing expenses for the three months ended December 31, 2006 included a charge of $751,000 for stock based compensation expenses, and a favorable adjustment of $333,000 to unreported tissue processing and product liability accruals. The increase in general, administrative, and marketing expenses for the three months ended December 31, 2007 was primarily due to an increase in marketing literature, advertising, and personnel costs to support revenue growth and the net unfavorable effect of the change in non-cash charges discussed above partially offset by a decrease in insurance costs.

General, administrative, and marketing expenses for the twelve months ended December 31, 2007 included charges of approximately $2.0 million for stock based compensation expenses and $786,000 for post retirement benefits. General, administrative, and marketing expenses for the twelve months ended December 31, 2006 included a favorable adjustment of $2.0 million related to the settlement of an insurance coverage dispute with an insurance company, net of associated legal fees, a favorable adjustment of $784,000 to reserves for tissue processing and product liability losses, a charge of $1.5 million for stock based compensation expenses, and an accrual of $448,000 for post employment benefits. The increase in general, administrative, and marketing expenses for the twelve months ended December 31, 2007 was primarily due to the net unfavorable effect of the change in the items discussed above, an increase in marketing literature, advertising, and personnel costs to support revenue growth, and an increase in compensation costs for management and administrative employees, partially offset by a decrease in insurance costs.

Gain on Exit Activities

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Gain on exit activities	$	$ 2,620	$	$ 2,620
Gain on exit activities as a percentage of total revenue	%	12%	%	3%

Gain on exit activities in the three and twelve months ended December 31, 2006 represents the gain associated with the RTI Agreement. The gain is primarily due to a gain on the recording of intangible assets received from RTI, partially offset

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by several individually immaterial asset write-downs and expense accruals incurred as a result of the transaction. The intangibles acquired from RTI in the transaction include procurement contracts and access to the procurement of cardiac and vascular human tissues previously received by RTI, customer lists, and a non-compete agreement. This gain was offset by losses due to the impairment of certain orthopaedic tissues and processing materials resulting from the RTI Agreement which have been recorded as part of cost of human tissue preservation services as discussed above. The gain on exit activities and the write-down in cost of human tissue preservation services net to an overall loss of $159,000 related to the transaction in 2006. See Part II, Item 8, Note 2 of the Notes to Consolidated Financial Statements for further discussion of the RTI Agreement and its financial impact.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2007	2006	2007	2006
Research and development expenses	$ 1,319	$ 975	$ 4,453	$ 3,547
Research and development expenses as a percentage of total revenue	5%	5%	5%	4%

The increase in research and development expenses for the three and twelve months ended December 31, 2007 was primarily due to spending on BioFoam research funded under the 2005 DOD Grant discussed in Revenues Other Revenues above. Research and development spending in 2007 and 2006 was primarily focused on the Company s tissue preservation, SynerGraft products and tissues, and PHT. SynerGraft products and tissues include the Company s CryoValve SG pulmonary human heart valve and other xenograft tissue products. PHT includes BioGlue, BioFoam, BioDisc, and related products.

Other Costs and Expenses

Interest expense was $159,000 for the three months ended December 31, 2007, compared to $153,000 for the three months ended December 31, 2006. Interest expense was $677,000 for the twelve months ended December 31, 2007, compared to $657,000 for the twelve months ended December 31, 2006. Interest expense for the three and twelve months ended December 31, 2007 included interest incurred related to the Company s prior credit agreement, notes payable, capital leases and interest related to uncertain tax positions. Interest expense for the three and twelve months ended December 31, 2006 included interest incurred related to the credit agreement, notes payable, and capital leases.

Interest income was $167,000 for the three months ended December 31, 2007, compared to $105,000 for the three months ended December 31, 2006. Interest income was $527,000 for the twelve months ended December 31, 2007, compared to $409,000 for the twelve months ended December 31, 2006. Interest income for the three and twelve months ended December 31, 2007 and 2006 was primarily due to interest earned on the Company s cash, cash equivalents, and marketable securities.

The change in valuation of the embedded derivative feature of the Company s preferred stock (the Derivative) was zero for the three months ended December 31, 2007 as compared to an expense of $10,000 for the three months ended December 31, 2006. The change in valuation of the Derivative was an expense of $821,000 for the twelve months ended December 31, 2007 as compared to $121,000 for the twelve months ended December 31, 2006. The change in valuation of the Derivative for the twelve months ended December 31, 2007 was due to the first quarter revaluation of the Derivative and the second quarter automatic and voluntary conversions of the Company s preferred stock to common stock in excess of the Derivative liability accrued in prior periods. As the preferred stock was fully converted to common stock in the second quarter of 2007, no additional expense was recorded in the three months ended December 31, 2007. The Company will not record additional expenses or income on the change in valuation of the Derivative in the future, as the Derivative was settled.

The Company s income tax expense of $134,000 and $368,000 for the three and twelve months ended December 31, 2007, respectively, was primarily due to estimated alternative minimum tax on the Company s U.S. taxable income for 2007 that could not be offset by the Company s net operating loss carryforwards and estimated foreign taxes on income of the Company s wholly owned European subsidiary.

The Company s income tax expense was $148,000 and $285,000 for the three and twelve months ended December 31, 2006, respectively. The Company s income tax expense for the three months ended December 31, 2006 was primarily due to alternative minimum tax on the Company s U.S. taxable income for 2006 that could not be offset by the Company s net operating loss carryforwards, and foreign taxes on income of the Company s wholly owned European subsidiary. The

Company s income tax expense for the twelve months ended December 31, 2006 was primarily due to the recording of deferred tax liabilities related to a foreign jurisdiction and alternative minimum tax on the Company s U.S. taxable income for 2006 that could not be offset by the Company s net operating loss carryforwards, partially offset by the favorable effect of adjustments to certain state tax obligations and the favorable effect of reductions in the estimated foreign taxes on income of the Company s wholly owned European subsidiary.

Seasonality

The demand for the Company s cardiac preservation services has historically been seasonal, with peak demand generally occurring in the second and third quarters. 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. In recent years the growth rate of CryoLife s cardiac business has obscured the seasonal trend, but the Company believes that this seasonal trend will be more apparent in future years.

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

The demand for BioGlue appears to be seasonal, with a slight 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 will continue to evaluate the seasonal nature of BioGlue sales.

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. The Company will continue to evaluate the seasonal nature of Hemostase sales.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2008 net working capital (current assets of $80.4 million less current liabilities of $21.0 million) was $59.4 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of $40.8 million, with a current ratio of 3 to 1 at December 31, 2007.

Overall Liquidity and Capital Resources

CryoLife is actively pursuing three key strategies designed to generate revenue and earnings growth in addition to continuing to focus on growing its business and leveraging its strengths and expertise in its core marketplaces. These three strategies are: (i) identify and evaluate acquisition opportunities of complementary product lines and companies; (ii) license Company technology to third parties for non-competing uses; and (iii) analyze and identify underperforming assets for potential sale or disposal. Management s actions related to this Board directive are ongoing and any material acquisition of complementary product lines or companies would likely require additional debt or equity financing. In addition the GE Credit Agreement, discussed further below, contains certain restrictions on the Company s ability to effect an acquisition for cash.

The Company s primary cash requirements for the year ended December 31, 2008 arose out of the reclassification of cash equivalents to long-term restricted money market funds as required under the terms of the GE Credit Agreement as discussed below, payment of the balance due under the Company s prior credit agreement which expired in February 2008, and general working capital needs, including annual payments of royalties and bonuses accrued in the prior year, capital expenditures for facilities and equipment, and funding of research and development projects. The Company funded its cash requirements primarily through its operating activities, which generated cash during the period.

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. If the current global financial and credit liquidity crisis continues or worsens, GE may be unable or unwilling to lend money pursuant to this agreement. As of December 31, 2008 the outstanding balance under this agreement was $315,000. As of April 15, 2008, as required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least $5.0 million in accounts in which GE Capital has a first priority perfected lien. 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.

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The Company s cash equivalents include advance funding received under the 2006 and 2007 DOD Grants for the continued development of protein hydrogel technology. As of December 31, 2008 $1.6 million of cash equivalents were recorded on the Company s Consolidated Balance Sheet related to the 2006 and 2007 DOD Grants. These funds must be used for the specified purposes.

The Company believes that its anticipated cash from operations, existing cash, cash equivalents, and marketable securities will enable the Company to meet its operational liquidity needs for at least the next twelve months.

Liability Claims

As discussed in Critical Accounting Policies above, as of December 31, 2008 the Company had a $330,000 accrual for a pending tissue processing liability lawsuit. The timing and amount of actual future payments with respect to tissue processing and product liability claims is dependent on when and if judgments are rendered and/or settlements are reached. Should payments be required, the Company s portion of these monies would have to be paid from liquid assets. The Company continues to attempt to reach resolution of outstanding claims in order to minimize the potential cash payout.

As discussed in Critical Accounting Policies above, at December 31, 2008 the Company had accrued a total $4.4 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to December 31, 2008 and had recorded a receivable of $1.5 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 $9.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The $4.4 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 $9.5 million for the twelve months ended December 31, 2008 as compared to $9.3 million for the twelve months ended December 31, 2007. The current year cash provided was primarily due to net income generated during the period, partially offset by non-cash items, primarily the reversal of the Company s valuation allowance on its deferred tax assets, discussed further below, and, to a lesser extent, increases in working capital needs due to the timing of receipts and payments in the ordinary course of business.

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, 2008 the Company s $32.9 million net income included non-cash items that generated favorable and unfavorable adjustments to net income. The most significant non-cash item was the $20.1 million adjustment to deferred income tax, generated by the December 31, 2008 reversal of the Company s valuation allowance on its deferred tax assets. Other non-cash adjustments included a favorable $3.8 million in depreciation expense, a favorable $2.1 million in non-cash compensation, primarily stock compensation expense, a favorable $1.7 million in write-downs for impairment of deferred preservation costs and inventory, and a favorable $542,000 in amortization expense.

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, 2008 these changes included an unfavorable $8.3 million and $2.9 million due to the buildup of deferred preservation costs and inventories, respectively, for which vendors and employees have already been paid, and an unfavorable $785,000 due to the increase in accounts receivable.

Net Cash from Investing Activities

Net cash used in investing activities was $4.3 million for the twelve months ended December 31, 2008, as compared to net cash provided by investing activities of $446,000 for the twelve months ended December 31, 2007. The current year cash used was primarily due to $5.0 million in cash equivalents that were reclassified as long-term restricted money market funds as required under the terms of the GE Credit Agreement as discussed above, $1.7 million in capital expenditures and $1.1 million in purchases of marketable securities, partially offset by $3.6 million in sales and maturities of marketable securities.

Net Cash from Financing Activities

Net cash used in financing activities was $ 2.4 million for the twelve months ended December 31, 2008, as compared to net cash provided of $743,000 for the twelve months ended December 31, 2007. The current year cash used was primarily due to $4.6 million in principal payments on debt, and $1.3 million in principal payments on notes payable, partially offset by $2.4 million in proceeds from the exercise of options and the issuance of stock under the Company s ESPP, $1.3 million in proceeds from the financing of insurance policies, and $428,000 in proceeds from debt issuance. The principal payments on debt were primarily due to the payoff of the balance due under the Company s prior credit agreement which expired in February 2008.

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, 2008 are as follows (in thousands):

	Total	2009	2010	2011	2012	2013	Thereafter
Operating leases	$ 16,426	$ 2,472	$ 2,353	$ 2,319	$ 2,300	$ 2,344	$ 4,638
Compensation payments	2,927	942		993	992		
Purchase commitments	1,347	1,227	120	1			
Royalty payments	813	813					
Line of credit	315			315			
Capital lease obligations	88	53	35				
Other obligations	364	320	30	10	4		
Total contractual obligations	$ 22,280	$ 5,827	$ 2,538	$ 3,638	$ 3,296	$ 2,344	$ 4,638

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 rented by the Company, leases on Company vehicles, and leases on a variety of office equipment.

The Company s compensation payment obligations represent cash payments for its 2008 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 2010 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 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 licensing computer software. 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 capital lease obligations result from the financing of certain of the Company s equipment. The Company s other obligations contain various items including payments to support research and development activities 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) additional payments of up to $1.2 million related to licensing of technology from a third party which are contingent upon the outcome of the Company s research activities; (iii) $1.6 million in advance funding received under the 2006 and 2007 DOD Grants for which a specific timetable of spending has not been established and for which there are no current agreements or contracts in place; and (iv) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $2.2 million, 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 by any taxing authorities.

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Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2008 were $1.7 million compared to $1.2 million for the twelve months ended December 31, 2007. Planned capital expenditures for 2009 are primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment 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 $17.2 million and restricted money market funds and investments of $5.6 million and interest paid on the Company s variable rate line of credit as of December 31, 2008. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended December 31, 2008, affecting the Company s cash and cash equivalents, restricted money market funds and investments, and line of credit would not have a material impact on the Company s financial position, results of operations, 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 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 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 foreign BioGlue revenues are denominated in British Pounds and Euros and a portion of the Company s general, administrative, and marketing expenses are denominated in British Pounds and Euros. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. dollar equivalent of net income from transactions conducted in other currencies. As a result the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

Changes in exchange rates which occurred during the fourth quarter of 2008 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 during 2009. An additional 10% adverse change in exchange rates from the exchange rates in effect on December 31, 2008 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, 2008 as compared to the weighted average exchange rates experienced by the Company for the twelve months ended December 31, 2008 affecting the Company s revenue and expense transactions denominated in foreign currencies, would have resulted in revenues approximately $1.3 million lower than the revenues reported by the Company for the twelve months ended December 31, 2008. As this reduction in revenues would have been largely offset by lower general, administrative, and marketing expenses denominated in British Pounds and Euros, the net effect of this change in foreign currency exchange rates 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, 2008 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, 2008, 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, 2009, 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, 2009.

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, 2009.

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, 2009.

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, 2009.

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.

2. Financial Statement Schedule

Schedule II Valuation and Qualifying Accounts

All other financial statement schedules not listed above are omitted, as the required information is 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 October 28, 2008.)
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	The Stipulation of Settlement of the shareholder derivative action dated August 1, 2005. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed August 5, 2005.)
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.)

10.3	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 2008 Grant pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Form 10-Q for the quarter ended March 31, 2008.)
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.
10.9(b)*	First Amended and Restated Employment Agreement, by and between the Company and Albert E. Heacox, Ph.D., dated December 9, 2008.
10.9(c)*	First Amended and Restated Employment Agreement, by and between the Company and David M. Fronk, dated December 11, 2008.
10.9(d)	Change of Control Agreement, by and between the Company and D. Ashley Lee, dated October 24, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Form 8-K filed October 28, 2008.)
10.9(e)	Change of Control Agreement, by and between the Company and Gerald B. Seery, dated November 2, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s 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.)
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.)

Exhibit Number	Description
10.18	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s 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.)
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.)

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Exhibit Number	Description
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.
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.

3.* First Amended and Restated Employment Agreement, by and between the Company and Albert E. Heacox, Ph.D., dated December 9, 2008.

4.* First Amended and Restated Employment Agreement, by and between the Company and David M. Fronk, dated December 11, 2008.

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

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

7. Reserved.

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 2008 grant pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Form 10-Q for the quarter ended March 31, 2008.)

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.)

* 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, 2009 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, 2009
/s/ D. Ashley Lee **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 19, 2009
/s/ Amy D. Horton **Amy D. Horton**	Chief Accounting Officer (Principal Accounting Officer)	February 19, 2009
/s/ Thomas F. Ackerman **Thomas F. Ackerman**	Director	February 19, 2009
/s/ James S. Benson **James S. Benson**	Director	February 19, 2009
/s/ Daniel J. Bevevino **Daniel J. Bevevino**	Director	February 19, 2009
/s/ John M. Cook **John M. Cook**	Director	February 19, 2009
/s/ Ronald C. Elkins, M.D.	Director	February 19, 2009

Ronald C. Elkins, M.D.		
/s/ Ronald D. McCall	Director	February 19, 2009
Ronald D. McCall		
/s/ Harvey Morgan	Director	February 19, 2009
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, 2008. 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, 2008, 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, 2008.

CryoLife, Inc.

February 19, 2009

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, 2008, 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, 2008, 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 and financial statement schedule as of and for the year ended December 31, 2008, of the Company and our report dated February 19, 2009, expressed an unqualified opinion on those financial statements and financial statement schedule and included an explanatory paragraph relating to the Company s adoption on January 1, 2007, of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109.*

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 19, 2009

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, 2008 and 2007, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2008. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements and the financial statement schedule 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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 14 to the consolidated financial statements, the Company changed its method of accounting for uncertain tax positions effective January 1, 2007 in accordance with the adoption of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*.

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, 2008, 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, 2009 expressed an unqualified opinion on the Company s internal control over financial reporting.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 19, 2009

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,201	$ 14,460
Marketable securities, at market		2,987
Restricted securities	562	
Receivables:		
Trade accounts, less allowance for doubtful accounts of $200 in 2008 and $180 in 2007	12,824	12,311
Other	1,175	1,373
Total receivables	13,999	13,684
Deferred preservation costs	34,913	26,903
Inventories	7,077	5,607
Deferred income taxes	4,896	
Prepaid expenses and other assets	1,719	1,811
Total current assets	**80,367**	**65,452**
Property and equipment:		
Equipment	18,905	19,472
Furniture and fixtures	5,006	5,295
Leasehold improvements	28,843	28,946
Construction in progress	139	38
Total property and equipment	52,893	53,751
Less accumulated depreciation and amortization	36,455	35,111
Net property and equipment	**16,438**	**18,640**
Other assets:		
Patents, less accumulated amortization of $1,905 in 2008 and $1,648 in 2007	3,771	3,906
Trademarks and other intangibles, less accumulated amortization of $639 in 2008 and $417 in 2007	2,952	3,213
Deferred income taxes	16,499	148
Restricted money market funds	5,000	
Other	968	1,325
Total assets	**$ 125,995**	**$ 92,684**

See accompanying notes to consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2008	2007
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,270	$ 2,956
Accrued compensation	3,850	2,963
Accrued procurement fees	4,473	5,161
Accrued expenses	5,252	5,611
Deferred income	1,592	1,111
Deferred income taxes	391	175
Line of credit		4,506
Other current liabilities	2,169	2,219
Total current liabilities	**20,997**	**24,702**
Deferred income taxes	919	
Line of credit	315	
Other	4,438	5,355
Total liabilities	**26,669**	**30,057**
Shareholders equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized; Series A Junior Participating Preferred Stock, 2,000 shares authorized, no shares issued		
Convertible preferred stock, 460 shares authorized, no shares issued		
Common stock $0.01 par value per share, 75,000 shares authorized, 29,102 shares issued in 2008 and 28,526 shares issued in 2007	291	285
Additional paid-in capital	124,744	120,562
Retained deficit	(20,073)	(52,981)
Accumulated other comprehensive loss	(80)	
Treasury stock at cost, 955 shares in 2008 and 949 shares in 2007	(5,556)	(5,239)
Total shareholders equity	**99,326**	**62,627**
Total liabilities and shareholders equity	**$ 125,995**	**$ 92,684**

See accompanying notes to consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2008	**2007**	**2006**
Revenues:			
Preservation services	$ 53,656	$ 49,002	$ 40,078
Products	50,493	44,712	41,037
Other	910	1,049	196
Total revenues	**105,059**	**94,763**	**81,311**
Cost of preservation services and products:			
Preservation services	29,112	28,433	29,958
Products	8,153	7,108	7,463
Total cost of preservation services and products	**37,265**	**35,541**	**37,421**
Gross margin	**67,794**	**59,222**	**43,890**
Operating expenses:			
General, administrative, and marketing	48,831	46,470	41,545
Gain on exit activities			(2,620)
Research and development	5,309	4,453	3,547
Total operating expenses	**54,140**	**50,923**	**42,472**
Operating income	**13,654**	**8,299**	**1,418**
Interest expense	263	677	657
Interest income	(381)	(527)	(409)
Change in valuation of derivative		821	121
Other expense (income), net	236	(241)	399
Income before income taxes	**13,536**	**7,569**	**650**
Income tax (benefit) expense	(19,372)	368	285
Net income	**$ 32,908**	**$ 7,201**	**$ 365**
Effect of preferred stock dividends		(243)	(973)
Net income (loss) applicable to common shares	**$ 32,908**	**$ 6,958**	**$ (608)**
Income (loss) per common share:			
Basic	$ 1.18	$ 0.26	$ (0.02)
Diluted	$ 1.16	$ 0.26	$ (0.02)
Weighted average common shares outstanding:			
Basic	27,800	26,331	24,829
Diluted	28,351	26,974	24,829

See accompanying notes to consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2008	**2007**	**2006**
Net cash flows from operating activities:			
Net income	$ 32,908	$ 7,201	$ 365
Adjustments to reconcile net income to net cash from operating activities:			
Loss on disposal of assets	21	130	426
Depreciation of property and equipment	3,811	3,929	4,560
Amortization	542	527	284
Provision for doubtful accounts	146	167	65
Write-down of deferred preservation costs and inventories	1,728	819	1,758
Reversal of deferred income tax valuation allowance	(20,105)		
Deferred income taxes	(7)	(961)	226
Non-cash compensation	2,099	2,127	1,620
Change in valuation of derivative		821	121
Other non-cash adjustments to income	(83)	(220)	(213)
Changes in operating assets and liabilities:			
Trade and other receivables	(785)	(23)	(2,431)
Income taxes	8	30	213
Deferred preservation costs	(8,286)	(8,444)	(9,800)
Inventories	(2,922)	(454)	(600)
Prepaid expenses and other assets	(21)	685	397
Accounts payable	267	842	155
Accrued expenses and other liabilities	216	2,116	1,783
Net cash flows provided by (used in) operating activities	**9,537**	**9,292**	**(1,071)**
Net cash flows from investing activities:			
Capital expenditures	(1,738)	(1,207)	(1,642)
Net proceeds from sale of assets	147	19	13
Restricted money market funds, long-term	(5,000)		
Purchases of marketable securities	(1,118)	(12,331)	(17,385)
Sales and maturities of marketable securities	3,565	14,155	18,562
Other	(193)	(190)	(105)
Net cash flows (used in) provided by investing activities	**(4,337)**	**446**	**(557)**
Net cash flows from financing activities:			
Proceeds from debt issuance	428	532	710
Principal payments on debt	(4,588)	(533)	(553)
Principal payments on capital leases	(43)	(40)	(570)
Proceeds from financing of insurance policies	1,300	1,912	2,349
Principal payments on short-term note payable	(1,300)	(1,912)	(2,349)
Proceeds from exercise of options and issuance of stock	2,383	1,748	468
Payment of preferred stock dividend and make whole payments		(486)	(973)
Purchase of treasury stock	(611)	(478)	(50)
Net cash flows (used in) provided by financing activities	**(2,431)**	**743**	**(968)**
Increase (decrease) in cash	**2,769**	**10,481**	**(2,596)**

Effect of exchange rate changes on cash	(28)	(154)	98
Cash and cash equivalents, beginning of year	14,460	4,133	6,631
Cash and cash equivalents, end of year	**$ 17,201**	**$ 14,460**	**$ 4,133**

See accompanying notes to consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands)

	Preferred Stock		Common Stock		Additional Paid In Capital	Retained Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Shareholders Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance at December 31, 2005	**325**	**$ 3**	**25,582**	**$ 256**	**$ 113,507**	**$ (58,569)**	**$ 123**	**(892)**	**$ (4,699)**	**$ 50,621**
Net income						365				365
Other comprehensive income							37			37
Comprehensive income										402
Dividend payments on preferred stock						(973)				(973)
Exercise of options			101	1	227			(2)	(12)	216
Equity compensation			54		1,620			(12)	(50)	1,570
Employee stock purchase plan			76	1	251					252
Balance at December 31, 2006	**325**	**$ 3**	**25,813**	**$ 258**	**$ 115,605**	**$ (59,177)**	**$ 160**	**(906)**	**$ (4,761)**	**$ 52,088**
Cumulative effect of change in accounting for income taxes						(762)				(762)
Net income						7,201				7,201
Other comprehensive loss							(160)			(160)
Comprehensive income										7,041
Conversion of preferred stock and dividend make-whole payments	(325)	(3)	2,100	21	1,038					1,056
Dividend payments on preferred stock						(243)				(243)
Exercise of options			410	4	1,428			(43)	(478)	954
Equity compensation			157	1	2,126					2,127
Excess tax benefits					50					50
Employee stock purchase plan			46	1	315					316
Balance at December 31, 2007			**28,526**	**$ 285**	**$ 120,562**	**$ (52,981)**	**$**	**(949)**	**$ (5,239)**	**$ 62,627**
Net income						32,908				32,908
Other comprehensive loss							(80)			(80)
Comprehensive income										32,828
Exercise of options			345	3	1,716			6	(197)	1,522
Equity compensation			183	2	2,097			(12)	(120)	1,979
Employee stock purchase plan			48	1	369					370
Balance at December 31, 2008		**$**	**29,102**	**$ 291**	**$ 124,744**	**$ (20,073)**	**$ (80)**	**(955)**	**$ (5,556)**	**$ 99,326**

See accompanying notes to consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Nature of Business

CryoLife, Inc. (CryoLife , the Company , we , or us) preserves and distributes human tissues for cardiac and vascular transplant applications and develops and commercializes medical devices. The human tissue distributed by the Company includes the CryoValve® SG pulmonary human heart valve (CryoValve SG), processed using CryoLife s proprietary SynerGraft® technology. The Company s medical devices include BioGlue® Surgical Adhesive (BioGlue) and Hemostase, which the Company distributes for Medafor, Inc. (Medafor), as well as other medical devices.

CryoLife distributes preserved human cardiac and vascular tissue to implanting institutions throughout the U.S., Canada, and Europe. On February 7, 2008 the Company received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its CryoValve SG. CryoLife distributes BioGlue throughout the U.S. and in more than 70 other countries for designated applications. In the U.S. BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue under Conformité Européene (CE) Mark product certification in the European Economic Area (EEA) for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). 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 in Central and South America and Asia. In May of 2008 CryoLife began distributing Hemostase under a private label agreement with Medafor. 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.

Principles of Consolidation

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

Use of Estimates

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

Revenue Recognition

The Company recognizes revenue in accordance with Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition (SAB 104), which provides guidance on applying generally accepted accounting principles to revenue recognition issues. Revenues for preservation services are recognized when services are completed and tissue is shipped to the customer. Revenues for products are recognized at the time the product is shipped, at which time title passes to the customer and there are no further performance obligations. The Company assesses the likelihood of collection based on a number of factors, including past transaction history with the customer and the credit-worthiness of the customer. Revenues from research grants are recognized in the period the associated costs are incurred. Revenues from upfront licensing agreements are recognized ratably over the period the Company expects to fulfill its obligations.

Shipping and Handling Charges

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

Advertising Costs

The costs to produce and communicate the Company s advertising are expensed as incurred and are classified as general, administrative, and marketing expenses. The Company records the cost of certain sales materials as a prepaid expense and amortizes these costs as advertising expense over the period they are expected to be used, typically six months to one year. The total amount of advertising expense included in the Company s Consolidated Statements of Operations was $1.5 million, $944,000, and $796,000 for the years ended December 31, 2008, 2007, and 2006, respectively.

Cash and Cash Equivalents

Cash equivalents consist primarily of highly liquid investments with maturity dates of 90 days or less at the time of acquisition. The carrying value of cash equivalents approximates fair value.

The Company s cash equivalents include advance funding received under the U.S. Congress 2005, 2006, and 2007 Defense Appropriations Conference Reports the (2005 DOD Grant, 2006 DOD Grant, and 2007 DOD Grant, respectively) for the continued development of protein hydrogel technology. The advance funding is accounted for as deferred income on the Consolidated Balance Sheets and is recognized as other revenue as expenses are incurred related to these grants. As of December 31, 2008 and 2007 $1.6 million and $1.0 million, respectively was related to these grants.

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

	2008	2007	2006
Cash paid during the year for:			
Interest	$ 225	$ 691	$ 635
Income taxes	645	416	34
Non-cash investing and financing activities:			
Payment of make whole payments in common stock	$	$ 1,056	$
Non-cash acquisition of intangibles			2,909
Assets acquired under capital leases			180

Marketable Securities

The Company maintains investments in several large, well-capitalized financial institutions, and the Company s policy excludes investment in any securities rated less than investment-grade by national rating services. Management determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designations quarterly.

Debt securities are classified as held-to-maturity when the Company has the intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Trading securities are stated at their fair values, with the realized and unrealized gains and losses, interest, and dividends included in other income. Debt securities not classified as held-to-maturity or marketable equity securities not classified as trading are classified as available-for-sale. Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of applicable income taxes, reported in a separate component of shareholders equity. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in other income. The cost of securities sold is based on the specific identification method.

The Company uses the market approach to measure the fair value of its marketable securities in accordance with Statement of Financial Accounting Standards (SFAS) No. 115 (as amended), Accounting For Certain Investments in Debt and Equity Securities (SFAS 115). The Company s investment broker provides quoted prices in active markets for each available-for-sale security. The Company then adjusts each investment to its quoted price and records the unrealized gains or losses in accumulated other comprehensive income for these securities.

As of December 31, 2008 $5.0 million of the Company s money market funds were designated as long-term restricted money market funds due to a financial covenant requirement under the Company s credit agreement with General Electric Capital Corporation (GE Capital) as discussed in Note 5.

As of December 31, 2008 $562,000 of marketable securities were designated as held-to-maturity. These securities were designated as held-to-maturity due to a contractual commitment to hold the securities as pledged collateral relating to one of the

Company s tissue processing and product liability insurance policies and, therefore, they were reported as restricted securities on the Consolidated Balance Sheet. As of December 31, 2007 $3.0 million of marketable securities were designated as available-for-sale.

Deferred Preservation Costs

By federal law, human tissues cannot be bought or sold. Therefore, the tissues the Company preserves and further processes cannot be 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. 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). Although the Company cannot own human tissue, the preservation process is a manufacturing process that is accounted for in accordance with Accounting Research Bulletin No. 43 Chapter 4, Inventory Pricing. Preservation costs are stated at the lower of cost or market on a first-in, first-out basis and are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities. Cost of preservation services also includes idle facility expense, excessive spoilage, extra freight, and rehandling costs and requires allocation of fixed production overheads to be based on the normal capacity of the production facilities in accordance with SFAS No. 151, Inventory Costs (SFAS 151).

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 materially impact the amount of deferred preservation costs on the Company s Consolidated Balance Sheets and the cost of preservation services, including the lower of cost or market write-down, described below, on the Company s Consolidated Statements of Operations.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value and to determine if there are any impairments to the book value of the Company s deferred preservation costs. CryoLife records a charge to cost of preservation services to write down the amount of deferred preservation costs that are not deemed to be recoverable. These write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels when tissues are shipped or become available for shipment.

The Company recorded write-downs of $172,000 for the year ended December 31, 2008 due to the impairment of certain vascular tissues and $366,000 for the year ended December 31, 2007 due to the impairment of certain vascular and orthopaedic tissues. The tissues were impaired in the period that the Company determined that the tissues were not expected to ship prior to the expiration date of their packaging. In addition the Company recorded write-downs of $453,000 and $1.2 million for the years ended December 31, 2007 and 2006, respectively, for the value of certain deferred preservation costs that exceeded market value. These write-downs were primarily due to excess tissue processing costs incurred in those periods that exceeded market value based on then recent average service fees. Actual results may differ from these estimates.

As of December 31, 2008 deferred preservation costs consisted of $12.2 million for allograft heart valve tissues, $1.7 million for non-valved cardiac tissues, $21.0 million for vascular tissues, and zero for orthopaedic tissues. As of December 31, 2007 deferred preservation costs consisted of $7.6 million for allograft heart valve tissues, $2.1 million for non-valved cardiac tissues, $17.1 million for vascular tissues, and $123,000 for orthopaedic tissues.

Inventories

Inventories are comprised of implantable surgical adhesives and other medical devices and are valued at the lower of cost or market on a first-in, first-out basis. Cost of products also includes idle facility expense, excessive spoilage, extra freight, and rehandling costs, as necessary, and requires allocation of fixed production overheads to be based on the normal capacity of the production facilities in accordance with SFAS 151.

Property and Equipment

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

Intangible Assets

The Company s intangible assets consist of patents, trademarks, customer lists, non-compete agreements, and procurement agreements, including procurement contracts and access to the procurement of cardiac and vascular human tissues received from a third party as a result of an agreement entered into in 2006.

The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. As of December 31, 2008 and 2007 gross carrying values, accumulated amortization, and approximate amortization periods of the Company s definite lived intangible assets are as follows (in thousands):

	Gross Carrying Value	Accumulated Amortization	Amortization Period
December 31, 2008			
Patents	$ 5,676	$ 1,905	17 Years
Customer lists	570	371	3 Years
Non-compete agreement	381	76	10 Years
December 31, 2007			
Patents	$ 5,554	$ 1,648	17 Years
Customer lists	611	187	3 Years
Non-compete agreement	381	38	10 Years

As of December 31, 2008 scheduled amortization of intangible assets for the next five years would be as follows (in thousands):

	2009	2010	2011	2012	2013	Total
Amortization expense	$ 541	$ 354	$ 335	$ 320	$ 316	$ 1,866

The Company s indefinite lived intangible assets do not amortize, but are instead subject to periodic impairment testing in accordance with SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). Based on its prior experience with similar agreements, the Company believes that the procurement agreements received from a third party have an indefinite useful life, as the Company expects to continue to renew these contracts for the foreseeable future. As of December 31, 2008 and 2007 the carrying values of the Company s indefinite lived intangible assets are as follows (in thousands):

	2008	2007
Trademarks	$ 435	$ 433
Procurement agreements	2,013	2,013

Impairments of Long-Lived Assets

The Company assesses the potential impairment of its long-lived assets 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.

SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS 144) requires the write down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. For the years ended December 31, 2008 and 2007 the Company did not experience any factors that indicated an SFAS 144 impairment review was warranted. For the year ended December 31, 2006 the Company performed an SFAS 144 impairment analysis, due to a variety of triggering factors, including its operating performance. Per management s analysis, the undiscounted future cash flows of the Company s asset groups exceeded their carrying values as of December 31, 2006. Therefore, management concluded that there was not an impairment of the Company s long-lived tangible and amortizing intangible assets.

SFAS 142 requires that non-amortizing intangible assets are subjected to impairment testing on an annual basis and, if necessary, during interim periods if factors indicate that an impairment review is warranted. The Company s non-amortizing intangible assets as of December 31, 2008 consisted of trademarks and procurement agreements, including procurement contracts and access to the procurement of cardiac and vascular human tissues received from a third party as a result of an agreement entered into in 2006 as discussed Note 2 below. In accordance with SFAS 142, the Company performed an analysis of its non-amortizing intangible assets as of December 31, 2008 and 2007. During this analysis, the Company determined that the fair value of the assets exceeded their carrying value. Based of the results of its analysis, the Company does not believe that an impairment existed related to its non-amortizing intangible assets as of December 31, 2008 or 2007. Management will continue to evaluate the recoverability of these non-amortizing intangible assets on an annual basis in accordance with SFAS 142.

Accrued Procurement Fees

Tissue is procured from deceased human donors by organ and tissue procurement agencies (Agencies), which consign the tissue to the Company for processing, preservation, and distribution. The Company reimburses the Agencies for their costs to recover the tissue and passes on these costs to the customer when the tissue is shipped and the service is complete. The Company accrues the estimated procurement fees due to the Agencies at the time the tissue is received based on contractual agreements between the Company and the Agencies.

Liability Claims

In the normal course of business, the Company has tissue processing and product liability complaints filed against it. 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. The Company periodically evaluates its exposure to unreported tissue processing and product liability claims, and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. The Company updated its estimates of the unreported claims as of December 31, 2008. The unreported loss liability was estimated using a frequency-severity approach, whereby, projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated 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 was calculated using a lognormal claims model blending the Company s historical average cost per claim with industry claims data. The Company records accruals for estimated costs for unreported tissue processing and product liability claims based on the information included in the actuarial valuation.

In addition to the Company s evaluation of its exposure related to unreported tissue processing and product liability claims, the Company periodically evaluates its exposure related to settled but unpaid claims and pending claims based on settlement negotiations to date, advice from counsel, and historical claim settlements. The Company then records accruals for settled but unpaid claims and pending claims based on its analysis. The company expenses the costs of legal services as they are incurred.

Uncertain Tax Positions

On January 1, 2007 the Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 (FIN 48). FIN 48 establishes a threshold for recognizing tax

benefits if they are more-likely-than-not to be upheld upon review by the appropriate taxing authority and the requirement that companies recognize the maximum amount of tax benefit that has a greater than 50 percent likelihood of ultimately being realized. See Note 14 for further discussion of the Company s uncertain tax liabilities.

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 in accordance with SFAS No. 109 Accounting for Income Taxes (SFAS 109), 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.

As of December 31, 2007, the Company performed an analysis in accordance with SFAS 109 of the recoverability of its deferred tax assets. This analysis included consideration of a variety of factors, which included the Company s historical operating results and uncertainties regarding projected future operating results. The Company concluded that a valuation allowance was needed on its deferred tax assets as of December 31, 2007. The Company performed additional assessments as of March 31, 2008, June 30, 2008, and September 30, 2008 and determined at each of these dates that 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 in accordance with SFAS No. 109, 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 allowance on its deferred tax assets was no longer appropriate.

As a result, on December 31, 2008 the Company recorded a tax benefit of $20.1 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, 2008 the Company had a total of $2.8 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax asset of $20.1 million. As of December 31, 2007 the Company had a total of $28.2 million in valuation allowances against deferred tax assets and a net deferred tax liability of $27,000 related to taxes in a foreign jurisdiction.

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 2005 through 2008 remain open to examination by the major taxing jurisdictions to which the Company is subject.

Income (Loss) Per Common Share

Income (loss) per common share is computed in accordance with SFAS No. 128, Earnings Per Share (SFAS 128), on the basis of the weighted average number of common shares outstanding plus, if applicable, the dilutive effects of outstanding stock options and contingently returnable shares, computed using the treasury stock method, the dilutive effect of outstanding convertible preferred stock, computed using the if converted method, and the dilutive effect of contingent stock awards.

Stock-Based Compensation

The Company has stock option and stock incentive plans that provide for grants to employees and directors of shares and options to purchase shares of the Company s common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. SFAS No. 123, Revised Share-Based Payment (SFAS 123R), requires companies to recognize the cost of all share-based payments in the financial statements using a fair-value based measurement method. The Company uses the Black-Scholes model to value its stock compensation under SFAS 123R and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the stock compensation is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk free interest rate.

Translation of Foreign Currencies

Assets and liabilities of the Company denominated in foreign currencies are translated at the exchange rate in effect as of the balance sheet date. Translation adjustments are recorded as a separate component of other comprehensive income in the shareholders equity section of the Company s Consolidated Balance Sheets. All revenue and expense accounts are translated as transactions occur at exchange rates in effect at the time of each transaction.

Derivative Instruments

The Company accounts for derivative instruments in accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133). Beginning in 2005 the Company was required to separate and account for the Dividend Make-Whole Payment feature, as defined in Note 6, of its 6% convertible preferred stock as an embedded derivative. At issuance, the Company determined the fair value of its derivative and recorded the value as a current liability on the Company s Consolidated Balance Sheet. Prior to the conversion of the preferred stock in 2007, changes in the fair value of the derivative were recognized as a non-operating income (expense) on the Company s Consolidated Statements of Operations.

Fair Values of Financial Instruments

SFAS No. 107, Disclosures about Fair Value of Financial Instruments (SFAS 107), requires the Company to disclose estimated fair values for its financial instruments. The carrying amounts of receivables and accounts payable approximate their fair values due to the short-term maturity of these instruments. The carrying value of the Company s other financial instruments, including the Company s debt approximated fair value at December 31, 2008 and 2007.

New Accounting Pronouncements

The Company will be required to adopt SFAS No. 141R, Business Combinations (SFAS 141R), for the fiscal year beginning January 1, 2009. SFAS 141R 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 Company does not expect the adoption of SFAS 141R to have a material effect on its financial position, profitability, or cash flows upon adoption. All business combinations consummated after the implementation date will be accounted for under SFAS 141R.

2. Exchange and Service Agreement

In December 2006 the Company announced that it had entered into an exchange and service agreement with RTI and certain of its affiliates, respecting procurement, processing, and distribution activities for cardiac and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife. In accordance with the RTI Agreement, CryoLife ceased accepting donated human orthopaedic tissue for processing commencing January 1, 2007 and began work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise, on January 1, 2007 RTI ceased accepting donated human cardiac and vascular tissues for processing and began work to transition its arrangements for recovery of these tissues to CryoLife. No cash was exchanged in the transaction. CryoLife continued to distribute its existing orthopaedic tissue inventory through June 30, 2008. From July 1, 2008 through December 31, 2008, CryoLife was entitled to distribute RTI s remaining cardiac and vascular tissue inventory for a commission, and RTI was entitled to distribute CryoLife s remaining orthopaedic tissue inventory for a commission. CryoLife has not received any commission under this provision. Under the RTI Agreement, from July 1, 2008 through December 31, 2016,

except as set forth above, CryoLife has agreed not to market or solicit orders for certain human orthopaedic tissues and RTI has agreed not to market or solicit orders for human cardiac and vascular tissues. The agreement also provides for a non-exclusive license of technology from CryoLife to RTI, and contains customary provisions regarding indemnification and confidentiality.

As a result of the RTI Agreement, the Company recorded a net $159,000 loss during the fourth quarter of 2006, which was composed of a write-down of $2.8 million in cost of preservation services and a $2.6 million gain on exit activities on the Company s Consolidated Statement of Operations.

The $2.8 million write-down was due to the impairment of certain orthopaedic tissues and processing materials. The write-down of deferred tissue preservation costs was based on an estimate of the tissues that would be shipped during the 18-month period subsequent to December 31, 2006 in which the Company continued to distribute its existing orthopaedic tissues.

The $2.6 million gain on exit activities was primarily due to a gain on the recording of intangible assets received from RTI, partially offset by several individually immaterial asset write-downs and expense accruals incurred as a result of the transaction. The intangibles acquired from RTI in the transaction included procurement contracts and access to the procurement of cardiac and vascular human tissues previously received by RTI, customer lists, and a non-compete agreement. The assets transferred to RTI were internally developed intangible assets, and as such, had no book value on CryoLife s Consolidated Balance Sheets prior to the transaction. The RTI Agreement was accounted for as a non-monetary exchange in accordance with Accounting Principles Board Opinion No. 29 (As Amended), Accounting for Nonmonetary Transactions , as clarified by Emerging Issues Task Force (EITF) 01-2, Interpretations of APB Opinion No. 29 and SFAS 153 Exchanges of Nonmonetary Assets.

3. Cash Equivalents and Marketable Securities

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

December 31, 2008	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 14,372	$	$ 14,372
Marketable securities:			
Restricted government entity sponsored debt securities	$ 562	$	$ 562
Restricted money market funds, long-term	$ 5,000	$	$ 5,000

December 31, 2007	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 11,724	$	$ 11,724
Marketable securities:			
Government entity sponsored debt securities	$ 2,984	$ 3	$ 2,987

There were no gross realized gains or losses on sales of available-for-sale securities for the years ended December 31, 2008 and 2007. Differences between cost and market listed above, consisting of a net unrealized holding gain of $3,000 at December 31, 2007, are included as a separate component of accumulated other comprehensive income in the shareholders equity section of the Consolidated Balance Sheets.

At December 31, 2008 all of the Company s marketable securities had a maturity date between 90 days and one year. At December 31, 2007 all of the Company s marketable securities had a maturity date within 90 days.

4. Inventories

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

	2008	2007
Raw materials	$ 4,418	$ 2,956
Work-in-process	616	650
Finished goods	2,043	2,001
Total Inventories	$ 7,077	$ 5,607

5. Debt

On March 26, 2008 CryoLife and its subsidiaries entered into a credit agreement with GE Capital as lender (the GE Credit Agreement). The GE Credit Agreement provides for a revolving credit facility in an aggregate amount not to exceed the initial commitment of $15.0 million (including a letter of credit subfacility of up to an aggregate of $1.5 million). The initial commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. While the Company currently expects that its aggregate borrowing capacity under the GE Credit Agreement will equal $15.0 million, there can be no assurance that the borrowing capacity will remain at this level. Also, if the current global financial and credit liquidity crisis continues or worsens, GE may be unable or unwilling to lend money pursuant to this agreement.

The GE Credit Agreement places limitations on the amount that the Company may borrow, and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings before extraordinary gains, interest, taxes, depreciation, and amortization as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. Further, beginning April 15, 2008 as required under the terms of the GE Credit Agreement, the Company must maintain cash and cash equivalents of at least $5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as long-term restricted money market funds on the Company s Consolidated Balance Sheet, as they are restricted for the term of the GE Credit Agreement. The GE Credit Agreement also includes customary conditions on incurring new indebtedness and prohibits payments of cash dividends on the Company s common stock. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The GE Credit Agreement expires on March 25, 2011, at which time the outstanding principal balance will be due. As of December 31, 2008 the Company was in compliance with the covenants of the GE Credit Agreement.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest at either LIBOR plus 3.25% or GE Capital s base rate, as defined, plus 2.25%, as applicable. As of December 31, 2008 the outstanding balance of the GE Credit Agreement was $315,000, the aggregate interest rate was 5.50%, and the remaining availability was $14.7 million.

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. (Wells Fargo) as lender which provided for a revolving credit facility in an aggregate amount equal to the lesser of $15.0 million (including a letter of credit subfacility of up to an aggregate of $2.0 million) or a borrowing base determined in accordance with the terms of the credit agreement. The credit agreement with Wells Fargo expired on February 8, 2008 in accordance with its terms, at which time the outstanding principal balance of $4.5 million was paid from cash on hand.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In April 2008 the Company entered into such an agreement to finance approximately $1.3 million in insurance premiums. The amount financed accrued interest at a 4.632% annual rate and was payable in equal monthly payments over a nine month period. As of December 31, 2008 the aggregate outstanding balance under this agreement was zero. In the second quarter of 2007 the Company entered into two such agreements to finance approximately $1.4 million and $478,000 in insurance premiums. The amounts financed accrued interest at 7.027% and were payable in equal monthly payments over a nine month and an eight month period, respectively. As of December 31, 2008 and 2007 the aggregate outstanding balance under these agreements was zero.

Total interest expense was $263,000, $677,000, and $657,000 in 2008, 2007, and 2006, respectively, which included interest on debt, capital leases, and uncertain tax positions.

The Company has an irrevocable standby letter of credit of $500,000 outstanding as of December 31, 2008. The letter of credit is maintained as collateral for the deductible related to one of the Company s tissue processing and product liability insurance policies and is secured by certain marketable securities as discussed in Note 1.

6. Convertible Preferred Stock

In early 2005 the Company completed a public offering of 417,000 shares of 6% convertible preferred stock (the Preferred Stock) at a price to the public of $50.00 per share. Net proceeds from the offering, after deducting underwriting discounts and offering-related expenses, totaled approximately $19.1 million.

Dividends on the Preferred Stock were cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly. Any dividends were required to be declared by the Company s Board of Directors and to come from funds legally available for dividend payments. In March 2007 the Company declared a dividend of $0.75 per share on its Preferred Stock; the dividend of approximately $243,000 was paid to shareholders in April 2007. No dividends were declared during the remainder of 2007 or 2008. The Company made cash payments of $486,000 and $973,000 in the years ended December 31, 2007 and 2006, respectively, for dividends declared.

The Preferred Stock was convertible at the option of the holder at any time into the Company s common stock at a conversion rate of approximately 6.2189 shares of common stock for each share of Preferred Stock, based on an initial conversion price of $8.04. The Company had reserved 4.6 million shares of common stock for issuance upon conversion. Through June 4, 2007 holders had cumulatively voluntarily converted 139,000 shares of Preferred Stock into 867,000 shares of common stock.

The Preferred Stock contained provisions that allowed the Company to convert its Preferred Stock into common stock if the closing price of the Company s common stock exceeded $12.06, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion. This condition was satisfied on June 4, 2007 and on that day the Company exercised its right to automatically convert the Preferred Stock into common stock. As a result, on June 25, 2007 the Company automatically converted the remaining 278,000 shares of Preferred Stock into 1.7 million shares of common stock at the conversion rate of approximately 6.2189 shares of common stock per share of Preferred Stock.

The Company was required to make additional payments for both the voluntary and automatic conversions of Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock (the Dividend Make-Whole Payment). The Dividend Make-Whole Payment was payable in cash or, at the Company s option, in shares of the Company s common stock, or a combination of cash and shares of common stock. The Dividend Make-Whole Payment is discussed further in Note 7 below.

As of December 31, 2008 and 2007 there were no outstanding shares of Preferred Stock as a result of the second quarter 2007 automatic conversion of the Preferred Stock to common stock.

7. Derivatives

The Company was required to separate and account for the Dividend Make-Whole Payment feature of its Preferred Stock as an embedded derivative (the Derivative) in accordance with SFAS No. 133. As an embedded derivative instrument, the Dividend Make-Whole Payment feature was measured at fair value and reflected as a current liability on the Company s Consolidated Balance Sheets. Changes in the fair value of the Derivative were recognized in the line item change in valuation of derivative on the Company s Consolidated Statements of Operations.

The Company determined the fair value of the Derivative to be approximately $1.0 million on the 2005 date of issuance. The proceeds from the Preferred Stock recorded on the Consolidated Balance Sheets were reduced by this amount, which was allocated to the derivative liability.

As discussed in Note 6 above, on June 25, 2007 the Company automatically converted the remaining shares of the Preferred Stock into common stock, thereby triggering the payment of the remaining Dividend Make-Whole Payment. Through June 4, 2007 the Company had issued 132,000 shares of common stock to converting holders in satisfaction of the Dividend Make-Whole Payment. The value of voluntary conversions during 2007 was $178,000 based on the share prices on the respective dates of conversion. On June 25, 2007 the Company issued 69,000 shares of common stock to preferred

shareholders to satisfy the Dividend Make-Whole Payment due to the automatic conversion. The value of the Dividend Make-Whole Payment was $878,000 based on the share price of $12.71 on the date of conversion.

The Company recorded other expense totaling $821,000 for the year ended December 31, 2007 related to the first quarter revaluation of the Derivative and the second quarter automatic and voluntary conversions of the Preferred Stock to common stock. The 2007 expenses for the voluntary and automatic conversions represent the value of the Dividend Make-Whole Payments paid by the Company that exceeded the derivative liability accrued in prior periods. The Company recorded other expense of $121,000 for the year ended December 31, 2006 related to the quarterly revaluations of the Derivative.

At December 31, 2008 and 2007 there was no remaining derivative liability as a result of the second quarter 2007 automatic conversion of the Preferred Stock into common stock.

8. Commitments and Contingencies

Leases

The Company s capital lease obligations result from the financing of certain of the Company s equipment. 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 rented by the Company, leases on Company vehicles, and leases on a variety of office equipment.

The term of the lease of the land and buildings that comprise the Company s corporate headquarters was originally 15 years and was later extended to 19 years. This lease expires in 2015. Certain leases contain escalation clauses and renewal options for additional periods. Rent expense is computed on the straight-line method over the lease term with an offsetting accrual of $1.3 million as of December 31, 2008 and 2007, respectively, recorded in other long-term liabilities. Total rental expense for operating leases was $2.3 million for 2008, 2007, and 2006.

Future minimum lease payments under non-cancelable leases as of December 31, 2008 are as follows (in thousands):

	Leases	
	Capital	**Operating**
2009	53	2,472
2010	35	2,353
2011		2,319
2012		2,300
2013		2,344
Thereafter		4,638
Total minimum lease payments	$ 88	$ 16,426
Less amount representing interest at a weighted average 9% interest rate	7	
Present value of net minimum lease payments	81	
Less current maturities	47	
Capital lease obligations, less current maturities	$ 34	

The gross amount of property acquired under capital leases included in the Consolidated Balance Sheets consists of the following (in thousands):

	2008	**2007**
Equipment	$ 937	$ 937
Furniture and fixtures	765	765
Leasehold improvements	1,244	1,244

Total	$ 2,946	$ 2,946

Litigation, Claims, and Assessments

Liability Claims

In the normal course of business, the Company has tissue processing and product liability complaints filed against it. As of February 13, 2009 one tissue processing liability lawsuit was pending against the Company arising out of the allograft orthopaedic tissue preservation services previously provided by the Company. Management believes this lawsuit is covered by liability insurance. This lawsuit is currently in the discovery stage and expert witnesses are also being deposed. Other parties have made complaints that may result in lawsuits in future periods.

Based on an analysis the Company performed as of December 31, 2008 and 2007, the Company accrued a total of approximately $330,000 for the pending tissue processing liability lawsuit. The $330,000 accrual was included as a component of accrued expenses on the December 31, 2008 and 2007 Consolidated Balance Sheets.

On April 1, 2008 the Company bound liability coverage for the 2008/2009 insurance policy year. This policy is a six-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

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. The Company periodically evaluates its exposure to unreported tissue processing and product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. The Company updated its estimates of the unreported claims as of December 31, 2008. The unreported loss liability was estimated using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated 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 was calculated using a lognormal claims model blending the Company s historical average cost per claim with industry claims data. Company used 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 2008 would be lower than the Company s experience in the 2002/2003 policy year, 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, 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 because adequate historical data is not yet 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 these assumptions provide a reasonable basis for the calculation of the unreported liability loss, but 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 estimated that its liability for unreported tissue processing and product liability claims was $4.4 million as of December 31, 2008. The $4.4 million balance is included as a component of accrued expenses of $2.2 million and other long-term liabilities of $2.2 million on the December 31, 2008 Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as $9.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The Company estimated that as of December 31, 2008, $1.5 million of the accrual for unreported liability claims would be recoverable under the Company s insurance policies. The $1.5 million

insurance recoverable is included as a component of other receivables of $700,000 and other long-term assets of $800,000 on the December 31, 2008 Consolidated Balance Sheet. 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, 2008. Actual results may differ from this estimate.

As of December 31, 2007 the Company accrued $6.3 million for unreported liability claims and recorded a receivable of $2.4 million for unreported liability claims estimated to be recoverable under the Company s insurance policies. This $6.3 million accrual was included as a component of accrued expenses of $3.2 million and other long-term liabilities of $3.1 million on the December 31, 2007 Consolidated Balance Sheet. The $2.4 million insurance recoverable was included as a component of other current receivables of $1.1 million and other long-term assets of $1.3 million on the December 31, 2007 Consolidated Balance Sheet.

Insurance Coverage Dispute

In September 2006 the Company favorably settled insurance coverage disputes with former insurance carriers for $2.1 million, net of associated legal fees. The disputes involved losses stemming from approximately $11.3 million paid in 2005 by the Company in settlement of outstanding claims. No party admitted any liability as part of the September 2006 settlement. The net proceeds of $2.1 million were received in October 2006 and are included as a component of general, administrative, and marketing expenses on the Consolidated Statements of Operations for the year ended December 31, 2006.

Employment Agreement

The Company has an employment agreement with its Chief Executive Officer, (CEO), that confers benefits which become payable upon a change in control or upon certain termination events. As of both December 31, 2008 and 2007, the Company has recorded an accrual of $2.1 million in Other Current Liabilities on the Consolidated Balance Sheet representing benefits payable upon the CEO s voluntary retirement.

9. Stock Compensation

Overview

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

Under the Company s plans, the Company is currently authorized to grant the following number of shares and the Company has available for grant up to the following number of shares as of December 31, 2008 and 2007:

Plan	Authorized Shares	Available for Grant 2008	Available for Grant 2007
1998 Long-Term Incentive Plan	263,000		66,000
2002 Stock Incentive Plan	974,000	322,000	301,000
2004 Employee Stock Incentive Plan	2,000,000	519,000	977,000
2008 Non-Employee Directors Stock Incentive Plan	300,000	255,000	
Total	3,537,000	1,096,000	1,344,000

Upon the exercise of stock options, the Company may issue the required shares out of authorized but unissued common stock or out of treasury stock, at management s discretion. As of May 2, 2007 the Board of Directors terminated the 2004 Non-Employee Directors Stock Option Plan; therefore, no further grants of shares will be made out of this plan. As of December 31, 2008 and 2007 there were 111,000 and 158,000, respectively, shares of common stock reserved for issuance under the ESPP and there were 789,000 and 742,000, respectively, shares issued under the plan.

Stock Grants

In 2008 the Compensation Committee of the Company s Board of Directors authorized grants of stock from approved stock incentive plans to non-employee Directors and certain Company executives and managers totaling 183,000 shares of common stock, which had an aggregate value of $1.8 million. The grants of stock during 2008 included 81,000 shares of common stock valued at $786,000 issued as part of the 2007 performance-based bonus plans for certain Company executives and managers. The Company recorded the expense related to the 2007 performance-based bonus plans during the year ended December 31, 2007. The remaining value of the stock granted will be recorded as an expense on the Company s Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

In 2007 the Compensation Committee of the Company s Board of Directors authorized grants of stock from approved stock incentive plans to non-employee Directors and certain Company executives totaling 172,000 shares of common stock, which had an aggregate value of $1.6 million. The grants of stock in 2007 included 68,000 shares of common stock valued at $587,000 issued as part of the 2006 performance-based bonus plan for certain Company executives. The Company recorded the expense related to the 2006 performance-based bonus plan during the year ended December 31, 2006. The remaining value of the stock granted will be recorded as an expense on the Company s Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

In 2006 the Compensation Committee of the Company s Board of Directors authorized grants of stock from approved stock incentive plans to certain Company executives and non-employee Directors totaling 54,000 shares of common stock, which had an aggregate value of $254,000. The value of the stock granted will be recorded as an expense on the Company s Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

A summary of stock grant activity for the years ended December 31, 2008, 2007, and 2006 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2005		
Granted	54,000	$ 4.70
Vested	(41,000)	4.45
Unvested at December 31, 2006	13,000	5.47
Granted	172,000	9.61
Vested	(82,000)	8.06
Canceled	(15,000)	9.26
Unvested at December 31, 2007	88,000	10.48
Granted	183,000	9.92
Vested	(119,000)	10.87
Unvested at December 31, 2008	152,000	$ 9.50

Stock Options

The Compensation Committee of the Company s Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company executives and employees totaling 403,000, 383,000, and 948,000 shares in 2008, 2007, and 2006, respectively, with exercise prices equal to the stock prices on the respective grant dates. The value of the stock options granted will be recorded as an expense on the Company s Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

A summary of the Company s stock option activity for the year ended December 31, 2008, 2007, and 2006 follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2005	1,754,000	$ 11.55	2.42	$ 505,000
Granted	948,000	4.98		
Exercised	(101,000)	2.25		
Forfeited	(103,000)	5.09		
Expired	(310,000)	26.67		
Outstanding at December 31, 2006	2,188,000	7.29	3.03	5,328,000
Granted	383,000	8.64		
Exercised	(410,000)	3.49		
Forfeited	(124,000)	8.27		
Expired	(178,000)	28.49		
Outstanding at December 31, 2007	1,859,000	6.31	3.19	3,992,000
Granted	403,000	10.15		
Exercised	(393,000)	5.12		
Forfeited	(16,000)	6.28		
Expired	(80,000)	11.06		
Outstanding at December 31, 2008	1,773,000	$ 7.23	3.63	$ 7,174,000
Vested and Expected to Vest	1,642,000	$ 7.27	3.61	$ 4,709,000
Exercisable at December 31, 2008	651,000	$ 6.83	2.40	$ 3,091,000

The following table summarizes information concerning outstanding and exercisable options at December 31, 2008:

Options Outstanding				Options Exercisable	
Range of Exercise Price	Average Number Outstanding	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 4.25 5.03	525,000	2.69	$ 4.70	227,000	$ 4.77
5.05 5.80	429,000	2.14	5.47	210,000	5.43
6.16 8.70	387,000	4.10	8.06	169,000	7.92
9.06 13.37	410,000	6.02	10.37	23,000	10.71
27.90 30.86	22,000	2.24	29.20	22,000	29.20
$ 4.25 30.86	1,773,000	3.63	$ 7.23	651,000	$ 6.83

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

	2008	2007	2006
Weighted average fair value of options granted	$ 4.52	$ 3.98	$ 2.64
Intrinsic value of options exercised	$ 2,429,000	$ 3,106,000	$ 362,000

Employees purchased common stock totaling 48,000, 46,000, and 76,000 shares in 2008, 2007, and 2006, respectively, through the Company s ESPP. The value of the option portion of the stock purchased was recorded as an expense on the Company s Consolidated Statements of Operations in each quarterly period in accordance with SFAS 123R as discussed below.

Stock Compensation Expense

The Company uses the Black-Scholes model to value its stock option grants under SFAS 123R and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company s ESPP options is also determined using the Black-Scholes model and is expensed quarterly at the end of the purchase period, as the option is fully vested at that time. The fair value of stock options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk free interest rate. The term assumption is primarily based on the contractual term of the option and historic data related to exercise and post-vesting cancellation history experienced by the

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

The following weighted-average assumptions were used to determine the fair value of options under SFAS 123R:

	Year Ended					
	December 31, 2008		December 31, 2007		December 31, 2006	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected stock price volatility	.600	.759	.600	.527	.650	.417
Risk-free interest rate	2.34%	1.83%	4.62%	4.64%	4.80%	4.39%
Expected life of options	3.5 Years	.25 Years	3.4 Years	.25 Years	4.1 Years	.25 Years

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

	Year Ended December 31,		
	2008	2007	2006
Stock grant expense	$ 788	$ 1,262	$ 768
Stock option expense	1,311	865	852
Total stock compensation expense	$ 2,099	$ 2,127	$ 1,620

Included in this total stock compensation expense were expenses related to common stock grants, unvested options issued prior to and all options issued subsequent to the adoption of SFAS 123R, and compensation related to the Company s ESPP. These amounts were recorded as compensation expense and were subject to the Company s normal allocation of expenses to deferred preservation costs and inventory. The Company capitalized $145,000, $87,000, and $75,000 in the years ended December 31, 2008, 2007, and 2006, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

As of December 31, 2008 the Company had a total of $840,000 in total unrecognized compensation costs related to unvested stock grants, before considering the effect of expected forfeitures. This expense is expected to be recognized over each stock grant s vesting period. As of December 31, 2008 the Company had outstanding stock grants that complete vesting in 2009, 2010, and 2011.

As of December 31, 2008 there was approximately $3.2 million in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of December 31, 2008 this expense is expected to be recognized over a weighted average period of 3.1 years.

10. Shareholder Rights Plan

The Company has a shareholder rights agreement entered into in 1995 and amended in 2005. Under the rights agreement each share of the Company s common stock outstanding on December 11, 1995 is entitled to one Right, as defined in, and subject to, the terms of the rights agreement. A Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock (Series A Stock) of the Company at $33.33 per one one-hundredth of a Preferred Share, subject to adjustment. Additionally, each common share that has or shall become outstanding after December 11, 1995 is also entitled to a Right, subject to the terms and conditions of the rights agreement. The Rights, which expire on November 23, 2015, may be exercised only if certain conditions are met, such as the acquisition of 15% or more of the Company s common stock by a person or affiliated group (together with its affiliates, associates, and transferees, an Acquiring Person). Rights beneficially owned by an Acquiring Person become void from and after the time such persons become

Acquiring Persons, and Acquiring Persons have no rights whatsoever under the rights agreement.

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

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

11. Comprehensive Income

Components of comprehensive income consist of the following, net of applicable taxes (in thousands):

	2008	2007	2006
Net income	$ 32,908	$ 7,201	$ 365
Change in unrealized (loss) gain on investments	(3)	2	3
Change in translation adjustment	(77)	(162)	34
Comprehensive income	$ 32,828	$ 7,041	$ 402

At December 31, 2008 and 2007, components of accumulated other comprehensive loss consist of the following (in thousands):

	2008	2007
Unrealized gain on investments	$	$ 3
Translation adjustment	(80)	(3)
Total accumulated other comprehensive loss	$ (80)	$

12. Employee Benefit Plans

The Company has a 401(k) savings plan (the Plan) providing retirement benefits to all employees who have completed at least three months of service. The Company made matching contributions of 50% of each participant s contribution for up to 4% of each participant s salary in 2008, 2007, and 2006. Total Company contributions approximated $414,000, $357,000, and $340,000 for 2008, 2007, and 2006, respectively. Additionally, the Company may make discretionary contributions to the Plan that are allocated to each participant s account. In 2006 discretionary contributions of $56,000 were made by the plan administrator on behalf of the Company. No discretionary contributions were made in 2008 or 2007.

13. Income (Loss) Per Common Share

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

	2008	2007	2006
Numerator for basic income (loss) per common share:			
Net income	$ 32,908	$ 7,201	$ 365
Effect of preferred stock [a]		(243)	(973)
Net income (loss) applicable to common shares	$ 32,908	$ 6,958	$ (608)
Denominator for basic income (loss) per common share:			
Basic weighted-average common shares	27,800	26,331	24,829
Basic income (loss) per common share	$ 1.18	$ 0.26	$ (0.02)
Numerator for diluted income (loss) per common share:			
Net income	$ 32,908	$ 7,201	$ 365
Effect of preferred stock [a, b]		(243)	(973)
Net income (loss) applicable to common shares	$ 32,908	$ 6,958	$ (608)
Denominator for diluted income (loss) per common share:			
Basic weighted-average common shares	27,800	26,331	24,829
Effect of dilutive convertible preferred stock [b]			
Effect of dilutive stock options [c]	498	582	
Effect of contingently returnable shares	53	10	
Effect of contingent stock awards		51	
Adjusted weighted-average common shares	28,351	26,974	24,829
Diluted income (loss) per common share	$ 1.16	$ 0.26	$ (0.02)

[a] The amount of the accumulated dividend on the Preferred Stock reduced the Company s net income applicable to common shares by $243,000 for the year ended December 31, 2007 and offset the Company s net income and resulted in a net loss applicable to common shares with a total unfavorable effect of $973,000 for the year ended December 31, 2006.

[b] The amount of the accumulated dividend on the Preferred Stock reduced the Company s net income applicable to common shares by $243,000 for the year ended December 31, 2007. The adjustment for the Dividend Make-Whole Payment for conversions during the period and the adjustment for the quarterly revaluation of the derivative liability would have instead increased net income applicable to common shareholders by $821,000 for the year ended December 31, 2007. The common shares that would have been issued to shareholders at the beginning of the year for the conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 976,000 for the year ended December 31, 2007. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

The amount of the accumulated dividend on Preferred Stock offset the Company s net income and resulted in a net loss applicable to common shares with a total unfavorable effect of $973,000 for the year ended December 31, 2006. The adjustment for the quarterly revaluation of the derivative liability would have instead increased the net income applicable to common shareholders by $121,000 for the year ended December 31, 2006, and the common shares that would be issued to shareholders upon conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average common shares by 2.2 million for the year ended December 31, 2006. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

[c] Outstanding options to purchase the Company s common stock that would have resulted in additional dilutive common shares of 229,000 for the year ended December 31, 2006 were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128 due to the Company s net loss applicable to common shareholders during 2006.

In future periods basic and diluted earnings per common share are expected to be affected by the fluctuations in the fair value of the Company s common stock and the exercise and issuance of additional stock options and contingently returnable shares.

14. Income Taxes

Income Tax Expense

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

	2008	2007	2006
Domestic	$ 13,330	$ 7,570	$ 358
Foreign	206	(1)	292
Income before income taxes	$ 13,536	$ 7,569	$ 650

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

	2008	2007	2006
Current:			
Federal	$ 391	$ 253	$ 85
State	273	36	(58)
Foreign	69	79	(17)
	733	368	10
Deferred:			
Federal	$ (16,959)	$	$
State	(3,153)		
Foreign	7		275
	(20,105)		275
Income tax (benefit) expense	$ (19,372)	$ 368	$ 285

The Company s income tax benefit of $19.4 million in 2008 was primarily due to $20.1 million in reversals of the Company s valuation allowance on its deferred tax assets, partially offset by current tax expense including alternative minimum tax on the Company s taxable income that could not be offset by the Company s net operating loss carryforwards, state tax obligations, and foreign taxes on income of the Company s wholly owned European subsidiary. Income tax expense in 2007 and 2006 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.

Such amounts differ from the amounts computed by applying the U.S. federal income tax rate of 35% in 2008 and 34% in 2007 and 2006 to pretax income as a result of the following (in thousands):

	2008	2007	2006
Tax expense at statutory rate	$ 4,738	$ 2,573	$ 221
Increase (reduction) in income taxes resulting from:			
Reversal of deferred tax valuation allowance	(20,105)		
Other changes in deferred tax valuation allowance	(4,932)	(3,257)	(330)
Equity compensation	232	275	175

Research and development credit	(77)	(70)	(126)
Extraterritorial income exclusion			(49)
State income taxes, net of federal benefit	592	359	3
Non-deductible entertainment expenses	134	99	81
Foreign income taxes	52	8	258
Loss on preferred stock dividend make-whole payments		279	41
Disallowed executive compensation deduction		82	
Other	(6)	20	11
	$ (19,372)	$ 368	$ 285

Deferred Taxes

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

	2008	2007
Deferred tax assets:		
Allowance for bad debts	$ 74	$ 67
Property	1,561	851
Accrued expenses	2,793	3,579
Loss carryforwards	12,273	19,300
Credit carryforwards	4,913	4,223
Deferred preservation costs and inventory reserves	1,386	1,106
Other	1,171	384
Less valuation allowance	(2,776)	(28,228)
Net deferred tax assets	21,395	1,282
Deferred tax liabilities:		
Intangible assets	(919)	(872)
Prepaid items	(364)	(410)
Other	(27)	(27)
Total gross deferred tax liabilities	(1,310)	(1,309)
Total net deferred tax assets (liabilities)	$ 20,085	$ (27)

The Company periodically assesses the recoverability of its deferred tax assets in accordance with SFAS No. 109 Accounting for Income Taxes (SFAS 109), 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.

As of December 31, 2007, the Company performed an analysis in accordance with SFAS 109 of the recoverability of its deferred tax assets. This analysis included consideration of a variety of factors, which included the Company s historical operating results and uncertainties regarding projected future operating results. The Company concluded that a valuation allowance was needed on its deferred tax assets as of December 31, 2007. The Company performed additional assessments as of March 31, 2008, June 30, 2008, and September 30, 2008 and determined at each of these dates that 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 in accordance with SFAS No. 109, 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 $20.1 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, state apportionment, 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, 2008 the Company had a total of $2.8 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax asset of $20.1 million. As of December 31, 2007 the Company had a total of $28.2 million in valuation allowances against deferred tax assets and a net deferred tax liability of $27,000 related to taxes in a foreign jurisdiction.

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 2005 to 2008 remain open to examination by the major taxing jurisdictions to which the Company is subject.

As of December 31, 2008, the Company had approximately $19.9 million of gross U.S. federal net operating loss carryforwards that will begin to expire in the 2023 tax year, approximately $5.2 million of tax effected state net operating loss carryforwards that will begin to expire in 2009, $1.9 million in research and development tax credit carryforwards that will begin to expire in 2009, and $290,000 in credits from the state of Texas that will fully expire by 2027. The Company has gross excess tax benefits on share based compensation totaling $2.4 million at December 31, 2008 that will be recorded as additional paid in capital when the Company is able to realize a tax deduction and reduce taxes payable for these amounts. Additionally, at December 31, 2008 the Company had $2.7 million in alternative minimum tax credit carryforwards that do not expire.

Uncertain Tax Positions

The Company accounts for its uncertain tax positions in accordance with FIN 48. The Company adopted the provisions of FIN 48 on January 1, 2007. As a result, the Company recorded $1.7 million in unrecognized tax liabilities plus estimated interest and penalties of $283,000. The aggregate $2.0 million liability was accounted for as a decrease to the January 1, 2007 balance of retained earnings of $762,000 and a reclassification of a portion of the valuation allowances against the Company s deferred tax assets of $1.2 million to an uncertain tax liability, which was recorded as a reduction to certain deferred tax assets on the Company s Consolidated Balance Sheet.

A reconciliation of the beginning and ending balances of the unrecognized tax liability is as follows (in thousands):

	2008	2007
Beginning balance	$ 1,736	$ 1,694
Increases related to prior year tax positions		18
Increases related to current year tax positions	63	42
Settlements		(18)
Ending balance	$ 1,799	$ 1,736

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

	2008	2007
Beginning balance	$ 347	$ 283
Accrual of interest and penalties	84	64
Ending balance	$ 431	$ 347

15. Transactions with Related Parties

The Company expensed $142,000, $158,000, and $135,000 in 2008, 2007, and 2006, respectively, relating to supplies for clinical trials purchased from a company whose Chief Financial Officer is a member of the Company s Board of Directors and a shareholder of the Company.

A member of the Company s Board of Directors and a shareholder of the Company is a current employee of and the former Chief of Thoracic Surgery of a university hospital that generated preservation services and product revenues of $452,000, $376,000, and $151,000 with the Company in 2008, 2007, and 2006, respectively. Additionally, the son of the member of the Company s Board of Directors mentioned above is employed by a medical center that generated preservation services and product revenues of $258,000, $230,000, and $120,000 with the Company in 2008, 2007, and 2006, respectively.

16. Segment and Geographic Information

The Company has two reportable segments organized according to its services and products: Preservation Services and Medical Devices.

The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues and from shipments of previously preserved orthopaedic tissues. The Medical Devices segment includes external revenues from product sales of BioGlue and Hemostase as well as sales of other medical devices. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company s management, is segment gross margin, or net external revenues less cost of preservation services and products. The Company does not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below.

The following table summarizes revenues, cost of preservation services and products, and gross margins for the Company s operating segments (in thousands):

	2008	2007	2006
Revenue:			
Preservation services	$ 53,656	$ 49,002	$ 40,078
Medical devices	50,493	44,712	41,037
All other[a]	910	1,049	196
	$ 105,059	$ 94,763	$ 81,311
Cost of preservation services and products:			
Preservation services	$ 29,112	$ 28,433	$ 29,958
Medical devices	8,153	7,108	7,463
	$ 37,265	$ 35,541	$ 37,421
Gross margin:			
Preservation services	$ 24,544	$ 20,569	$ 10,120
Medical devices	42,340	37,604	33,574
All other[a]	910	1,049	196
	$ 67,794	$ 59,222	$ 43,890

[a] All other designation includes 1) grant revenue and 2) revenues related to the licensing of the Company s technology to a third party.

Net revenues by product for the years ended December 31, 2008, 2007, and 2006 were as follows (in thousands):

	2008	2007	2006
Preservation services:			
Cardiac tissue	$ 25,514	$ 22,098	$ 15,988
Vascular tissue	27,417	22,702	16,956
Orthopaedic tissue	725	4,202	7,134
Total preservation services	53,656	49,002	40,078
Products:			
BioGlue	48,570	43,884	40,025
Other medical devices	1,923	828	1,012
Total products	50,493	44,712	41,037
All other[a]	910	1,049	196
	$ 105,059	$ 94,763	$ 81,311

[a] All other designation includes 1) grant revenue and 2) revenues related to the licensing of the Company s technology to a third party.

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2008, 2007, and 2006 were as follows (in thousands):

	2008	2007	2006
U.S.	$ 89,297	$ 81,023	$ 69,467
International	15,762	13,740	11,844
Total	$ 105,059	$ 94,763	$ 81,311

At December 31, 2008, 2007, and 2006, over 95% of the long-lived assets of the Company were held in the U.S., where all Company manufacturing facilities and the corporate headquarters are located.

SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE:				
2008	$ 25,568	$ 27,155	$ 26,804	$ 25,532
2007	24,524	23,011	22,160	25,068
2006	19,449	20,754	20,018	21,090
GROSS MARGIN:				
2008	$ 16,258	$ 17,866	$ 17,161	$ 16,509
2007	14,944	14,154	13,970	16,154
2006	10,763	11,638	11,488	10,001
NET INCOME (LOSS):				
2008	$ 2,765	$ 3,888	$ 3,556	$ 22,699*
2007	1,354	1,291	1,907	2,649
2006	(1,780)	217	1,978	(50)
INCOME (LOSS) PER COMMON SHARE DILUTED:				
2008	$ 0.10	$ 0.14	$ 0.12	$ 0.80*
2007	0.04	0.05	0.07	0.10
2006	(0.08)	(0.00)	0.07	(0.01)

* The fourth quarter 2008 net income and income per common share diluted includes the effect of $20.1 million for the reversal of the Company s valuation allowance on its deferred tax assets.

SCHEDULE II

CRYOLIFE, INC. AND SUBSIDIARIES

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2008, 2007, and 2006

Description	Balance Beginning of Period	Additions	Deductions	Balance End of Period
Year ended December 31, 2008:				
Allowance for doubtful accounts	$ 180,000	$ 146,000	$ 126,000	$ 200,000
Year ended December 31, 2007:				
Allowance for doubtful accounts	$ 130,000	$ 167,000	$ 117,000	$ 180,000
Year ended December 31, 2006:				
Allowance for doubtful accounts	$ 105,000	$ 65,000	$ 40,000	$ 130,000