

CRYOLIFE INC  
Form 10-K  
February 21, 2008

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

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2007

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)

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**Florida**  
(State or other jurisdiction of  
incorporation or organization)

**59-2417093**  
(I.R.S. Employer  
Identification No.)

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

(Address of principal executive offices) (zip code)

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

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

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

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

None

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

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

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

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

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

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

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

As of June 30, 2007, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was \$330,152,012, computed using the closing price of \$13.01 per share of Common Stock on June 29, 2007, 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.

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As of February 15, 2008 the number of outstanding shares of Common Stock of the registrant was 27,625,643.

**Documents Incorporated By Reference**

<b>Document</b>	<b>Parts Into Which Incorporated</b>
Proxy Statement for the Annual Meeting of Shareholders to be filed within 120 days after December 31, 2007.	Part III

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**PART I****Item 1. Business.**  
**Overview**

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated January 19, 1984 in Florida, develops and commercializes biomaterials and implantable medical devices and preserves and distributes human tissues for cardiac and vascular transplant applications. The Company's biomaterials and implantable medical devices include BioGlue® Surgical Adhesive (BioGlue), CryoLife-O Brien Stentless Porcine Aortic Bioprosthesis, and ProPatch Soft Tissue Repair Matrix (ProPatch). Additionally, the Company distributes CardioWrap for MAST BioSurgery, Inc (MAST). The Company's products are often sold in international markets several years before they can be marketed in the U.S. In 2007 international revenues were 14% of total revenues.

*Products and Preservation Services*

*Tissue Preservation Services.* CryoLife distributes preserved human cardiac, vascular, and orthopaedic tissue to implanting institutions throughout the U.S., Canada, and Europe, although distribution of orthopaedic tissue is being phased out. 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 long-term need for 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 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 the majority of its pulmonary valve processing and anticipates that the first CryoValve SG may be available for shipment late in the first quarter of 2008.

*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 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 U.S. Food and Drug Administration (FDA) approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue under Conformité Européenne (CE) Mark product certification in the European Economic Area (EEA) for soft tissue repair procedures (which include cardiac, vascular, pulmonary, and additional soft tissue repair procedures). CryoLife has also received approval and distributes BioGlue for 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.

*CardioWrap.* In 2007 CryoLife began exclusive distribution of CardioWrap, a product of MAST, in the U.S. and the United Kingdom. CardioWrap is a bioresorbable sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries where the patient may face re-operation within six months.

*CryoLife-O Brien Stentless Porcine Aortic Bioprosthesis.* CryoLife distributes a porcine heart valve, the CryoLife-O Brien Stentless Porcine Aortic Bioprosthesis, in Europe. This valve contains minimal amounts of synthetic material compared to other glutaraldehyde-fixed porcine valves, which management believes decreases the risk of endocarditis, a debilitating and potentially fatal infection.

*ProPatch.* In December 2006 CryoLife received 510(k) clearance from the FDA for its ProPatch. ProPatch, developed from bovine pericardial tissue, is used to reinforce weakened soft tissues and provides a resorbable scaffold that is replaced by the patient's own soft tissue. 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 by the Company.

*Research and Development*

Through its continuing research and development activities, CryoLife endeavors to use its expertise in protein chemistry, biochemistry, and cell biology, and its understanding of the cardiac and vascular surgery medical specialties, to acquire and develop useful implantable products and technologies. CryoLife seeks to identify market areas that can benefit from preserved living tissues, implantable 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 substance 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's PHT is the base for several potential products in development. CryoLife is researching the use of derivatives of PHT for use in trauma surgery and is undertaking clinical evaluations to determine its utility as a nucleus pulposus replacement in spinal disc repair. Potential product line extensions include modifications to the BioGlue delivery system.

#### *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 product liability, securities, 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, and possible future lack of adequate capital. See Part I, Item 1A, "Risk Factors" below.

#### **2007 and 2008 Events**

##### *SynerGraft Processed Human Pulmonary Heart Valve 510(k) Clearance*

On February 7, 2008 CryoLife received 510(k) clearance from the Food and Drug Administration (FDA) for its CryoValve<sup>®</sup>SG pulmonary human heart valve processed with the Company's proprietary SynerGraft technology. CryoLife's proprietary SynerGraft technology is designed to remove donor cells and cellular remnants from the valve without compromising the integrity of the underlying collagen matrix. The CryoValve SG pulmonary human heart valve 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 his own pulmonary valve. The CryoValve SG is then surgically implanted in place of the removed native pulmonary valve.

At the FDA's request, CryoLife is planning a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process. Data to be collected is expected to include long-term safety and hemodynamic function, immune response, and explant analysis. CryoLife believes that this information may help it ascertain whether the SynerGraft process reduces the immune response of the transplanted heart valve and allows for the collagen matrix to recellularize with the recipient's own cells.

CryoLife has begun using the SynerGraft technology for the majority of its pulmonary valve processing and anticipates that the first CryoValve SG may be available for shipment late in the first quarter of 2008.

##### *Trophic Solutions License Agreement*

On January 8, 2008 CryoLife announced that it had signed an exclusive license agreement with Trophic Solutions, LLC (Trophic) to develop and market products related to the cold storage and preservation of internal organs prior to transport. Under terms of the agreement, the Company will license from Trophic the right to develop, manufacture, and market products and processes derived from a patent owned by Trophic, which relates to solutions containing purified antimicrobial polypeptides and/or cell surface receptor binding proteins for use in the storage and preservation of internal organs prior to transplant. In early animal and human studies, the Trophic technology has shown that kidneys may be stored for up to six days prior to transplant without compromising graft function rather than three days using present technology. These studies also indicate that the solution may reduce or eliminate the need for pumping kidneys, which may reduce the cost of maintaining and transporting kidneys for transplant. The agreement gives CryoLife the exclusive right to determine if a commercial product can be developed using the process covered by the patent for a period of one year, which may be extended for an additional ninety days.

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*Proxy Biomedical Distribution Agreement*

On September 17, 2007 CryoLife announced that it had signed a distribution agreement allowing Proxy Biomedical Limited ( Proxy ) to include BioGlue in a hernia repair kit. In addition to BioGlue, the kit includes a surgical mesh from Proxy's line of proprietary synthetic polymer surgical meshes. Initially, Proxy will distribute the kits in Ireland, the United Kingdom, and Germany. Currently, the most common methods of hernia mesh fixation include sutures and tacking systems. Between 10% and 20% of patients complain of pain resulting from hernia repair, most often associated with the fixation method. It is anticipated that the use of BioGlue, designed to replace sutures and tacking systems, will help minimize this incidence of postoperative pain.

*Automatic Conversion of Preferred Stock*

On June 4, 2007 CryoLife announced that it was exercising its right to automatically convert the remaining shares of its 6% convertible preferred stock (the Preferred Stock ) into common stock. On June 25, 2007 the Company automatically converted the remaining 278,000 shares of its Preferred Stock into 1,726,000 shares of common stock at the conversion rate of approximately 6.2189 shares of common stock per share of Preferred Stock. The Company also issued 69,000 shares of common stock to preferred shareholders to satisfy the amount of dividends that would have accrued through April 1, 2008 ( the Dividend Make-Whole Payment ) in accordance with the terms of 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.

*CardioWrap Distribution Agreement*

CryoLife entered into two three-year agreements with MAST in 2007. One agreement was signed in January 2007 for the exclusive rights to distribute CardioWrap in the U.S. and the other agreement was signed in May 2007 for the exclusive rights to distribute CardioWrap in the United Kingdom. CardioWrap is a bioresorbable sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries in which the patient may face re-operation within six months. CardioWrap is made from polylactic acid, a polymer composed of lactic acid, similar to that which occurs naturally in the human body. CardioWrap maintains its strength during the healing process while slowly breaking down into lactic acid molecules. These molecules are ultimately metabolized into carbon dioxide and water and released from the body through the lungs. Available in several sizes and thicknesses, sheets of CardioWrap can be cut or shaped with scissors to the desired size, allowing CardioWrap to conform to most anatomical needs.

**FDA Correspondence and Notices**

*September 2007 FDA Inspection*

An FDA Form 483 Notice of Observations was issued in August 2005 in connection with the FDA inspections of the Company's facilities in July 2005. Since August 2005 the Company and FDA have corresponded regarding the observations noted and the adequacy of the Company's responses. In September 2007 the FDA re-inspected the Company and no FDA Form 483 Notice of Observations was issued.

**Strategy**

In 2006 the Company's management and Board of Directors completed a process with the assistance of a financial advisor to identify and evaluate potential strategies to enhance shareholder value. As a result of this process, the Company announced that it would continue to focus on growing its business and leveraging its strengths and expertise in its core marketplaces to generate revenue and earnings growth. 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 Distribution of BioGlue and Develop Derivative Products.* The Company intends to increase the market penetration of its BioGlue by (i) expanding awareness of the clinical advantages of BioGlue through continuing educational and marketing efforts directed to physicians, (ii) pursuing additional indications or product line extensions for the BioGlue technology in either the U.S. or internationally, (iii) pursuing indications for derivatives of the BioGlue technology in either the U.S. or internationally, and (iv) continuing to seek additional marketing approvals in other countries.

*Expand Distribution of Preserved Tissue.* The Company intends to increase the market penetration of its CryoLife preserved human heart valves, non-valved conduits, and vascular grafts by (i) expanding awareness of clinical



advantages of preserved human tissues through continuing educational efforts directed to physicians and tissue procurement agencies, (ii) improving and expanding its relationships with the approximately 75 tissue banks and organ procurement agencies across the U.S. which have recovered and sent tissue to the Company for preservation, (iii) increasing the number of tissue banks and organ procurement agencies that work with CryoLife, (iv) expanding its physician training activities, and (v) resuming the application of its SynerGraft technology to human pulmonary heart valves and investigating whether the SynerGraft technology can be applied to other tissues.

*Broaden Application of Preservation Services.* The Company will continue to collect, monitor, and evaluate implant data to (i) develop expanded uses for the human tissues currently preserved by the Company and (ii) identify new human tissues as candidates for preservation.

Additionally, the Company announced that it will pursue three additional key strategies designed to generate revenue and earnings growth. These three strategies include:

*Identify and evaluate acquisition opportunities of complementary product lines and companies.* The Company intends to leverage its 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. As a part of this strategy, in January 2007 the Company signed a three-year agreement to exclusively distribute CardioWrap, a bioresorbable sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries where the patient may face re-operation within six months. In January 2008 the Company entered into an exclusive agreement with Trophic to develop and market products related to the cold storage and preservation of internal organs prior to transport.

*License Company technology to third parties for non-competing uses.* The Company intends to increase the market penetration of its current technology platforms, including its PHT and its SynerGraft technologies, in medical specialties other than cardiac and vascular surgery by pursuing through strategic alliances additional indications or product line extensions for the PHT or SynerGraft technologies in either the U.S. or internationally. The Company will consider licensing opportunities for other existing products or for products in its research and development pipeline if the Company determines that licensing opportunities could enhance shareholder value. As part of this strategy, in October 2006 the Company signed a licensing and distribution agreement with BioForm Medical, Inc. ( BioForm ) for the development and commercialization of BioGlue for use in cosmetic and plastic surgery indications. 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. The clinical development of BioGlue for use in cosmetic and plastic surgery indications is ongoing. Additionally, in September 2007 the Company signed a distribution agreement allowing Proxy to include BioGlue in a hernia repair kit.

*Analyze and identify underperforming assets for potential sale or disposal.* The Company intends to 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 Products and Services .

## **Products and Services**

### *BioGlue and Related 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 fluids 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, 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 2 minutes. BioGlue is dispensed by a controlled delivery system that consists of either a reusable delivery device and disposable syringe or a disposable syringe and 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.

The Company estimates that aggregate U.S. sales for surgical adhesives and glues were approximately \$280 million in 2007. 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. CryoLife distributes BioGlue under CE Mark product certification in Europe, the Middle East, and Africa ( EMEA ) for soft tissue repair procedures (which include cardiac, vascular, pulmonary, and additional soft tissue repair procedures). 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%, 49%, and 55% of total revenues in 2007, 2006, and 2005, 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 glutaraldehyde, 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.

The Company is currently developing other products from its PHT platform. The Company has completed a pilot study in Europe and has filed for a CE Mark for BioDisc as a nucleus pulposus replacement in spinal disc repair. The Company is conducting preclinical research with BioFoam® for use in wound sealing in trauma surgery and parenchymal resection.

#### *Tissue Preservation Services*

The Company's proprietary preservation process involves the recovery of tissue from deceased human donors by tissue bank 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 (for example less than eight hours for transplants of the human heart). 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 presently preserved by the Company include human heart valves, non-valved conduits, and vascular tissue.

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 clinical research staff and technical 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 conduits preserved by the Company are used in reconstructive heart valve replacement surgery. CryoLife shipped approximately 65,500 preserved human heart valves and conduits from 1984 through 2007, including approximately 2,900 shipments in 2007. Revenues from human heart valve and conduit preservation services accounted for 23%, 20%, and 20% of total revenues in 2007, 2006, and 2005, 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 technical representatives, including its direct technical service representatives and customer service department. Management believes the Company offers advantages in the areas of clinical data and technical 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 conduit and patch tissue to surgeons who wish to perform certain specialized cardiac repair procedures. Each of these preserved human heart valves, non-valved conduits, and patches maintains a tissue structure which more closely resembles and performs like the patient's own tissue than non-human tissue alternatives.

As discussed above at 2007 and 2008 Events, on February 7, 2008 CryoLife received 510(k) clearance from the Food and Drug Administration for its CryoValve® SG pulmonary human heart valve processed with the Company's proprietary SynerGraft technology. CryoLife has begun using the SynerGraft technology for the majority of its pulmonary valve processing and anticipates that the first CryoValve SG may be available for shipment late in the first quarter of 2008.

The Company estimates that in 2007 the total annual heart valve and non-valved conduit replacement market in the U.S. was in excess of \$550 million. Management believes that approximately 102,000 heart valve replacement surgeries were conducted in the U.S. in 2007. Of this total number of heart valve and conduit surgeries, approximately 22,000 or 22%, involved mechanical heart valves, and approximately 80,000 or 78%, involved tissue heart valves, including porcine, bovine, and preserved human tissues.

Management believes preserved human heart valves and non-valved conduits 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 leading 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.

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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:

	Porcine			Bovine	
	Cryopreserved Human human tissue	Stented glutaraldehyde-fixed pig tissue and synthetic sewing ring	Stentless glutaraldehyde-fixed pig tissue	Mechanical pyrolytic carbon bi-leaflet and synthetic sewing ring	Pericardial glutaraldehyde-fixed cow tissue and synthetic sewing ring
Materials:					
Blood Flow Dynamics:	normal	moderate elevation	nearly normal	high elevation	moderate elevation
Mode of Failure:	gradual	gradual	expected to be gradual	catastrophic	gradual
Longevity:	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 and aortoiliac arteries for use as vascular grafts. The Company shipped approximately 48,900 human vascular tissues from 1986 through 2007, including approximately 3,300 shipments in 2007. Revenues from human vascular preservation services accounted for 24%, 21%, and 17% of total revenues in 2007, 2006, and 2005, respectively.

A surgeon's first choice for replacing diseased or damaged vascular tissue is generally the patient's own tissue. However, in cases of advanced vascular disease, the patient's tissue is often unusable and the surgeon may consider using synthetic grafts or preserved human vascular tissue. Small diameter synthetic vascular grafts are generally not suitable for below-the-knee surgeries because they have a tendency to occlude 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 make treatment with antibiotics difficult. 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 arteriosclerosis, a preserved saphenous vein can be implanted as a bypass graft for the diseased artery in order to improve blood flow and maintain a functional lower limb. The only alternative for many of these patients is amputation. Preserved vascular tissue can be used in a subset of coronary artery bypass procedures when the patient's own tissue is not available. Preserved aortoiliac arteries can be used in cases of abdominal aortic infection when the use of synthetic graft alternatives is often not an option for placement directly into an infected field.

*Human Orthopaedic Tissue.* The Company historically preserved human orthopaedic tissue for surgical replacements for 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. No cash was exchanged in the transaction. CryoLife will continue to distribute its existing orthopaedic tissue inventory through June 30, 2008. After that date CryoLife will become entitled to distribute RTI's remaining cardiac and vascular tissue inventory, and RTI will become entitled to distribute CryoLife's remaining orthopaedic tissue inventory. CryoLife will pay RTI a commission with respect to any of CryoLife's orthopaedic tissue distributed by RTI and will receive a commission from RTI with respect to any RTI cardiac tissue distributed by CryoLife. 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.

CryoLife shipped approximately 32,000 human connective tissues for the knee through the end of 2007, including approximately 900 shipments in 2007. Revenues from human orthopaedic preservation services accounted for 4%, 9%, and 7% of total revenues in 2007, 2006, and 2005, respectively.

#### *Medical Devices*

*CryoLife-O Brien Stentless Porcine Aortic Bioprosthesis.* The Company developed and commercialized its bioprosthetic cardiac and vascular devices based on its experience with preserved human tissue implants. The CryoLife-O Brien aortic bioprosthesis is a stentless porcine valve with design features that include a matched composite leaflet design that approximates human heart valve blood flow characteristics and that requires only a single suture line for surgical implantation. Stented porcine, bovine, and mechanical heart valves are typically fitted with synthetic sewing rings that are rigid and can impede normal blood flow. Unlike most other available porcine and bovine heart valves, the Company's stentless porcine heart valve has minimal synthetic materials, which decreases the risk of endocarditis, a debilitating and potentially deadly infection. Management believes these features provide advantages over certain other stentless porcine and bovine heart valves. Glutaraldehyde-fixed porcine and bovine heart valves are often preferred by surgeons for procedures involving elderly patients because they eliminate the risk of patient non-compliance with anti-coagulation drug therapy associated with mechanical valves, they are less expensive than allograft valves, and their shorter longevity is more appropriately matched with these patients' life expectancies. Glutaraldehyde-fixed porcine and bovine heart valves address an annual worldwide target heart valve market, which the Company estimates to have been \$1 billion in 2007.

CryoLife began exclusive worldwide distribution of this valve in 1992 and acquired all rights to the underlying technology in 1995. The Company's CryoLife-O Brien aortic bioprosthesis is marketed in Europe. Revenues from the CryoLife-O Brien aortic bioprosthesis represented less than 1% of total revenues in 2007 and 1% of total revenues in both 2006 and 2005.

*CardioWrap.* In early 2007 the Company entered into a three-year agreement with MAST to exclusively distribute CardioWrap, a bioresorbable sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries in which the patient may face re-operation within six months. CardioWrap is made from polylactic acid, a polymer composed of lactic acid, similar to that which occurs naturally in the human body. CardioWrap maintains its strength during the healing process while slowly breaking down into lactic acid molecules. These molecules are ultimately metabolized into carbon dioxide and water and released from the body through the lungs. Available in several sizes and thicknesses, sheets of CardioWrap can be cut or shaped with scissors to the desired size, allowing CardioWrap to conform to most anatomical needs. Revenues for CardioWrap represented less than 1% of total revenues in 2007.

*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. Specific to orthopaedic surgical repairs, the device is intended for the reinforcement of soft tissues repaired by sutures or by suture anchors during tendon repair surgery, including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. 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.

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

See Note 17 to the Company's consolidated financial statements regarding segment and geographic information at Part II, Item 8, of this Form 10-K.

### **Procurement, Distribution, and Marketing**

#### *BioGlue*

In the U.S. the Company markets BioGlue to physicians and distributes it through its technical representative employees. The Company markets and distributes BioGlue in international markets through direct technical representatives employed by the Company's wholly owned European subsidiary, CryoLife Europa, Ltd. (Europa), and other independent distributors. Through its technical 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. 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. Century Medical has submitted the application to the Japanese Ministry of Health and Welfare and the review process is ongoing.

#### *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 agencies 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 organ procurement agencies and tissue banks. 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 the costs associated with these procurement services. The procurement fee and related shipping costs, together with the charges for the preservation 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 94,000 donors. The Company has developed relationships with approximately 75 tissue banks and organ procurement agencies 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 over 30 individuals in donor services and donor quality assurance to work with organ procurement agencies and tissue banks. This includes five account managers who are stationed throughout the country to work directly with the organ procurement agencies. 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. These procedures are conducted under aseptic conditions in clean rooms. At the same time, 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 appropriately discarded.

The Company's cardiac, vascular, and orthopaedic tissues have been 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.

*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 technical 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, the procurement fee, and transportation costs.

The Company provides Company-owned liquid nitrogen freezers to certain client hospitals. The Company has currently installed approximately 300 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 1,086 cardiac and vascular surgeons who have implanted tissues preserved by the Company during the past twelve months. 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. Trained field support personnel provide support to implanting institutions and surgeons. The Company currently employs approximately 35 persons as technical service representatives and five region managers who deal primarily with cardiac and vascular surgeons and provide field support.

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 videotapes for physicians and coordinates peer to peer training at various medical institutions. In addition the Company coordinates laboratory sessions that utilize animal tissue 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.

To assist procurement agencies and tissue banks, the Company provides educational materials and training on procurement, dissection, packaging, and shipping techniques. The Company also produces educational videotapes 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.

#### *Medical Devices*

The Company markets and distributes CardioWrap in the U.S. and the United Kingdom. The Company markets and distributes the CryoLife-O'Brien Stentless Porcine Aortic Bioprosthesis in Europe. Marketing efforts for the CryoLife-O'Brien aortic bioprosthesis and CardioWrap are primarily directed toward cardiac surgeons.

#### *European Operations*

The Company markets its products in the EMEA region through its European subsidiary, CryoLife Europa Ltd, based in Guildford, United Kingdom. Europa, with its team of approximately fourteen 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.

#### *Backlog*

The limited supply of tissue that is donated and available for processing typically results in a backlog of orders in the Company's human tissue business. 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, CryoLife-O Brien aortic bioprosthesis, or CardioWrap.

## Competition

### *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 Healthcare's Tisseel, FloSeal, and CoSeal; Ethicon's Evicel, Surgiflo and Surgifoam; and Covidien's U.S. Surgical Division's Duraseal products. Additionally, Johnson & Johnson is under FDA review for a surgical adhesive for approval in vascular sealing. 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, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, and personnel resources than the Company.

These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals, and manufacturing and marketing such products. Certain of these competitors may obtain patent protection, approval, or clearance by the FDA or foreign countries, or product commercialization earlier than the Company, any of which could materially adversely affect the Company. The Company could also have to compete with respect to manufacturing efficiency and marketing capabilities.

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.

### *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 its recent approval of its SynerGraft processed human pulmonary heart valve as discussed in 2007 and 2008 Events will enable 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.

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 and Stentless Porcine 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, and has a marketing and distribution arrangement with a non-profit tissue bank for supplies of preserved human 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. In addition management believes that at least two domestic tissue banks offer preservation services for human heart valves in competition with the Company. The Company



presently distributes its stentless porcine heart valve only outside the U.S. This stentless porcine heart valve competes with mechanical valves, stented and stentless porcine valves, human heart valves, and processed bovine pericardial heart valves. The Company is aware of at least six other companies that offer porcine and bovine pericardial heart valves.

*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. Currently, management believes that there is at least one other non-profit tissue bank that preserves and distributes human vascular tissue in competition with the Company. Companies offering either synthetic or allograft products may enter this market in the future.

## Research and Development

The Company endeavors to use its expertise in protein chemistry, biochemistry, and cell biology, and its understanding of the needs of the cardiac and vascular surgery medical specialties to expand its surgical adhesive and preservation businesses and to develop or acquire implantable products and technologies for these specialties. The Company seeks to identify market areas that can benefit from preserved living tissues, implantable 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. The Company employs approximately 28 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, and bioengineering.

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, BioDisc, BioFoam, and other BioGlue derivatives, additional applications of its SynerGraft technology, and organ transplant solutions.

BioFoam, a product in the PHT platform, is in preclinical development. BioFoam contains a foaming agent, which has the potential to rapidly fill and seal internal body cavities, such as aneurysm sacs, and may provide hemostasis in penetrating wounds and trauma. The 2005, 2006, 2007, and 2008 U.S. Congress Defense Appropriations Conference Reports included \$930,000, \$2.3 million, \$1.0 million, and \$2.2 million, respectively, for the continued development of protein hydrogel technology for use on the battlefield. The Company applied for and was awarded the full \$930,000 under the 2005 bill and \$1.9 million under the 2006 bill. The Company applied for funding for BioFoam development under the 2007 bill but has not yet been notified of an award decision. The Company anticipates applying for funding under the 2008 bill during 2008. CryoLife is currently involved in initial animal trials related to this grant.

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 2-year follow-up have been completed. An interim analysis of the data was used for CE Mark submission in February 2007. The Company is waiting to hear the results of the submission from its Notified Body.

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. 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. CryoLife will remain the exclusive supplier of BioGlue for all applications. Under the terms of the agreement, CryoLife 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 is currently conducting a feasibility study under an investigational device exemption, or IDE, from the FDA. BioForm's strategy is to determine compelling aesthetic applications for BioGlue, demonstrate safety and effectiveness of this material in aesthetic applications, and launch BioGlue as an alternative fixation methodology to improve browplasty and certain other surgical and minimally invasive aesthetic procedures.

In January 2008 the Company signed an exclusive license agreement with Tropic to develop and market products related to the cold storage and preservation of internal organs prior to transport. Under terms of the agreement, the Company will license from Tropic the right to develop, manufacture, and market products and processes derived from a patent owned

by Trophic, which relates to solutions containing purified antimicrobial polypeptides and/or cell surface receptor binding proteins for use in the storage and preservation of internal organs prior to transplant. In early animal and human studies, the Trophic technology has shown that kidneys may be stored for up to six days prior to transplant without compromising kidney function rather than three days using present technology. These studies also indicate that the solution may reduce or eliminate the need for pumping kidneys, which may reduce the cost of maintaining and transporting kidneys for transplant. The agreement gives CryoLife the exclusive right to determine if a commercial product can be developed using the process covered by the patent for a period of one year, which may be extended for an additional ninety days.

At the FDA's request, CryoLife is planning a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process. Data to be collected is expected to include long-term safety and hemodynamic function, immune response, and explant analysis. CryoLife believes that this information may help it ascertain whether the SynerGraft process reduces the immune response of the transplanted heart valve and allows for the collagen matrix to recellularize with the recipient's own cells. In addition CryoLife intends to investigate whether the SynerGraft technology can be applied to other human or animal tissues.

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 implantable medical devices, based on the size of the potential market for any specific product candidate and the estimated development time and cost required to bring the product to market. 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 2007, 2006, and 2005 the Company spent approximately \$4.5 million, \$3.5 million, and \$3.7 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 5%, 4%, and 5% of the Company's revenues for the years 2007, 2006, and 2005, respectively.

## **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.

### *Human Tissue Processing*

The human 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 nine clean rooms dedicated to processing. Currently, there are approximately 70 technicians employed in this area, and the laboratory is staffed for 24 hours per day, 365 days per year operations. In 2007 the laboratory packaged approximately 15,400 human tissues. 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 donated tissue. To produce at full capacity levels, CryoLife would have to increase the amount of donated tissues, which the Company could attempt to do by increasing the number of relationships with organ procurement agencies and tissue banks, or working to increase donor awareness to increase tissue donation. If additional donated tissues were obtained, the Company would need to increase the number of employees, expand its second and third shift, 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 17 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 5% of total capacity. To produce at full capacity levels, the Company would need to increase the number of employees, add work shifts, and install automated filling and pouching equipment.

### *Bioprosthetic Cardiac and Vascular Devices*

The bioprosthesis laboratory at the Company's headquarters facility is responsible for the manufacturing of the CryoLife-O'Brien stentless aortic bioprosthesis, and ProPatch surgical mesh. This laboratory is approximately 20,000 square feet with a suite of six clean rooms for tissue processing. Currently, this laboratory employs seven technicians.

### *Europa*

The Company maintains a leased facility located in Guildford, United Kingdom for its European subsidiary, Europa, which contains approximately 3,400 square feet of office and warehousing space.

### **Quality Assurance**

The Company's operations encompass the manufacturing of bioadhesives and bioprosthetics and human tissue preservation services. In all of its facilities the Company is subject to regulatory standards for good manufacturing practices, including current Quality System Regulations, which are the FDA regulatory requirements for medical device manufacturers and current Good Tissue Practices (cGTPs), which are the FDA regulatory requirements for processing of human tissue. The FDA periodically inspects Company facilities to review Company compliance with these and other regulations. The Company also operates according to International Organization for Standardization (ISO) 13485 Quality System Requirements, an internationally recognized voluntary system of quality management for companies that design, develop, manufacture, distribute, and service medical devices. The Company maintains a Certification of Approval to the ISO 13485. Lloyd's Register Quality Assurance Limited (LRQA) issues this approval. LRQA is a notified body officially recognized by the EEA to perform assessments of compliance with ISO 13485 and its derivative standards. 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.

### *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 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.

Each manufacturing facility is subject to periodic inspection by the FDA and LRQA to independently review the Company's compliance with its systems and regulatory requirements.

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*Tissue Preservation Services*

The Company employs a comprehensive quality assurance program in all of its tissue processing activities. The Company is subject to 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 best recovery practices.

Upon receipt by the Company, each 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 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 Georgia, New York, Florida, Maryland, and California annually license the Company's tissue processing facilities as facilities that process, store, and distribute human tissue for implantation. The regulatory bodies of these states perform inspections of the facilities as required to ensure compliance with state law and regulations.

**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 39 U.S. patents and 90 foreign patents, including patents relating to its technology for human cardiac and vascular tissue preservation, tissue revitalization prior to freezing, tissue transport, BioGlue, PHT, and tissue packaging. The Company has approximately 12 pending U.S. patent applications and 28 pending foreign applications that relate to areas including 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.

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. To the extent that any of the Company's products or services 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 its products or technologies do not infringe patents that may be granted in the future pursuant to pending patent applications or that its products do not infringe any patents or proprietary rights of third parties. The Company may incur substantial legal fees in defending against a patent infringement claim or in asserting claims against third parties. 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 these 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 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.

## **Government Regulation**

### *U.S. Federal Regulation of Medical Devices*

Because BioGlue and certain human heart valves are, and other Company products may in the future be, regulated as medical devices, the Company and these products are subject to the provisions of the Federal Food, Drug, and Cosmetic Act ( FDCA ) and implementing regulations of the FDA. Pursuant to the FDCA, the FDA regulates the manufacture, distribution, labeling, and promotion of medical devices in the U.S. Also, various foreign countries in which the Company's products are, or may be, distributed impose additional regulatory requirements.

The 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 experiences 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. An approval by the FDA exempts such devices 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 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 allograft heart valves being classified as Class II Medical Devices and has 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.

On February 7, 2008 CryoLife received 510(k) clearance from the Food and Drug Administration (FDA) for its CryoValve® SG pulmonary human heart valve processed with the Company's proprietary SynerGraft technology as discussed in 2007 and 2008 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 FDA approval 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.

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

The Company's non-valved conduits, vascular grafts, and orthopaedic tissues are not currently subject to regulation under the FDCA as medical devices.

However, the FDA does regulate these products 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 (21 C.F.R. Parts 1270 and 1271). Historically, heart valves were one of a small number of processed human tissues over which the FDA asserted medical device jurisdiction. 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, 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 may have a material adverse effect on the Company.

#### *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, biological products, or 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 tissue. The activities engaged in by the Company require it to be licensed as a clinical laboratory and tissue bank under Georgia, New York, California, Maryland, and Florida 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 adversely affect the Company's operations. Certain employees of the Company have obtained other required state licenses.

#### *Foreign Approval Requirements*

Sales of medical devices and biological products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. Approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to commercial distribution of the product in those countries. The time required to obtain foreign 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 aortic bioprosthesis. BioGlue may be exported to more than 70 countries outside the U.S. and the CryoLife-O'Brien aortic bioprosthesis may be exported to more than 40 countries outside the U.S.

### **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 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, 2007 the Company had approximately 405 employees. These employees included six persons with Ph.D. degrees, two with an M.D. degree, 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](http://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**

**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 Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001 (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 and decreased market demand for our services. 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 and the foregoing factors continue to challenge us. Any future recalls or other regulatory action by the FDA would likely have a material adverse impact on our revenues, cash flow and profitability.

The FDA continues to periodically reinspect 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 believed that we were not responsive to their requests for any suggested improvement or that our products were 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 such an order were received, our revenues, profits, and cash flow could be materially and adversely affected.

**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.

**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 us to consider selling or otherwise disposing of. Although management has begun to implement these strategies, we cannot be certain that they will ultimately enhance shareholder value.

**Our Credit Facility Expired On February 8, 2008 And Our Ability To Pursue Significant Acquisitions May Be Dependent On Obtaining A New Credit Facility.**

On February 8, 2005 we entered into a \$15 million credit agreement with Wells Fargo Foothill, Inc. to address some of our liquidity needs. The credit facility expired on February 8, 2008, at which time the outstanding principal balance of \$4.5 million was paid from cash reserves. If we do not obtain a new credit facility, we may be limited in our ability to pursue any significant acquisitions of products or companies, to the extent that we are unable to access the equity markets.



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

We estimate that at December 31, 2007, we had approximately \$37.0 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.

**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 be a material adverse effect on our business, financial condition, results of operations, 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 new 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.

**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. If the supply of donated human tissue is materially reduced, this would restrict our growth and adversely affect our business, results of operations, financial condition, and cash flows. We rely primarily upon the efforts of third party procurement agencies, tissue banks (most of which are not-for-profit), and others to educate the public and foster a willingness to donate tissue.

**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 to 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 processed human tissues. If these conditions persist, our results of operations and cash flows will continue to be adversely affected. If additional 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 and profits would 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 allograft 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. 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 business, financial position, results of operations 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. 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, 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 reduce our revenues and materially and adversely affect our business, results of operations, financial position and cash flows.

In addition to the recall resulting from the FDA Order, we have in the past suspended and in the future may have to suspend the distribution of 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 medical products could materially and adversely affect our revenues and profits.

**We May Receive A Form 483 Notice Of Observations From The FDA And We May Be Unable To Address The Concerns Raised By The FDA In Such Form 483.**

The FDA has issued Form 483 Notices of Observations in the past that have noted deficiencies in our operations, including process validation, complaint handling and reporting, and root cause 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, which could materially and adversely affect our business, results of operations, financial position, or cash flows. The FDA could institute additional recalls of products, require us to perform additional tests, begin to require prescriptions for products where they are not currently required, halt the shipping or processing of products, or require additional approvals for marketing our products or services.

**SynerGraft Processed Pulmonary Heart Valves May Not Be Accepted By The Marketplace.**

CryoValve SG 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 the majority of its pulmonary valves with its SynerGraft technology. In that event, the Company would need to return to processing some or all of its pulmonary heart valves without the SynerGraft technology, which could significantly reduce the expected benefits of the SynerGraft technology.

**SynerGraft Processed Pulmonary Heart Valves Must Be Shipped And Implanted Within One Year Or We Will Be Required To Discard Them.**

We are currently using the SynerGraft technology for the majority of our pulmonary heart valve processing pursuant to the 510(k) approval we have received for the SynerGraft treated valves. Our SynerGraft pulmonary heart valves must be discarded if they are not implanted within one year of being preserved, whereas our non-SynerGraft processed pulmonary heart valves do not have to be discarded if not implanted within one year of cryopreservation. Accordingly, if we do not implant our SynerGraft pulmonary heart valves within one year of cryopreservation, we may lose more tissues than before we started processing pulmonary heart valves with the SynerGraft technology, which could have a material adverse effect on our revenues, profitability, and cash flow.

**Our SynerGraft Post-clearance Study May Not Provide Expected Results.**

At the FDA's request, we are planning a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process. 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 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 benefits that we anticipated for the use of this process.

**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 on 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. Revenue from international human tissue preservation services was \$896,000, \$572,000 and \$193,000 for

the years ended December 31, 2007, 2006 and 2005, respectively. We also offer BioGlue and other products for use in other countries.

**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. Our facilities are subject to periodic inspection by the FDA, 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 sell 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. We also were subject to the FDA Order, which decreased our revenues, increased our processing costs, and materially and adversely affected our business, results of operations, financial condition, 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 materially and adversely affect our business.

**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, product liability lawsuits 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 February 15, 2008, we know of two pending lawsuits against us arising out of our allograft heart valve and orthopaedic tissue services. We believe that our product liability insurance covers these two lawsuits, and both lawsuits are in the pre-discovery or discovery stages. In addition other parties have made complaints against us that may result in lawsuits in future periods.

Our December 31, 2007 Consolidated Balance Sheet reflects a liability of approximately \$330,000 for the estimated cost of resolving these claims. The amounts recorded were estimates and do not reflect actual settlement arrangements or final judgments, the latter of which could include punitive damages, nor do they represent cash set aside for the purpose of making payments. This balance sheet also reflects a \$6.3 million liability which is included as a component of accrued expenses and other current liabilities of \$3.2 million and other long-term liabilities of \$3.1 million for the estimated cost of resolving unreported product liability claims. Our product liability insurance policies do not include coverage for any punitive damages. See Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies Product Liability Claims for a description of our accounting treatment for product liability claims.

Several putative class action lawsuits were filed in July through September 2002 against us and certain of our officers, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, based on a series of purportedly materially false and misleading statements to the market. On July 21, 2005 we reached an agreement in principle to settle the securities class action lawsuit and the settlement became final later in the year. In August 2002 and January 2003 purported shareholder derivative actions were filed. A settlement was also reached in those cases and became final in 2005. Our insurance proceeds were insufficient to fund the costs of defending and settling the securities class action and derivative lawsuits.

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, results of operations, and cash flows. Further, if the costs of pending or unreported but incurred product liability claims exceed our current estimates, our business, financial condition and results of operations 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 profitability. Unlike the prior year's policy, the 2003/2004 products liability policy did not cover any claims which arose prior to the insurance policy year. Our current products liability insurance policy is a five-year claims-made policy covering claims since the commencement of the 2003/2004 policy year and expires in March 2008. We are currently evaluating with prospective insurers the available coverage and cost for products liability insurance. It is possible that there could be increases in both cost and retention, although we expect the coverage to be a six-year claims-made policy. We are also currently evaluating with prospective insurers available coverage and cost for director's and officer's insurance policies which expire in April 2008. We cannot be certain that we will be successful in obtaining satisfactory coverage once our current coverage expires, which could adversely impact our liquidity if we suffer material uninsured claims liability.

**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 and surgical sealants.

Management believes that at least two domestic tissue banks offer preservation services for allograft 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 Healthcare's Tisseel, FloSeal, and CoSeal, Ethicon's Evicel, Surgiflo, and Surgifoam, and Covidien's U.S. Surgical Division's Duraseal products. We are also aware that a few companies have surgical adhesive products under development. For example, Johnson & Johnson is under FDA review for a surgical adhesive for approval in vascular sealing that could compete with BioGlue in certain applications. 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.

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. If we fail to compete effectively, this could materially and adversely affect our business, financial condition, results of operations, and cash flows. Our competitors may gain competitive advantages that may be difficult to overcome.

**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, including new applications of our BioGlue and related technology. We are uncertain whether we can develop new products and services to a commercially acceptable form. 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 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 materially and adversely affect our business, financial condition, results of operations, 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, which could include new products based on our Protein Hydrogel Technology such as BioFoam, and BioDisc, and other products such as ProPatch, 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.

**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 Not Be Able To Pursue One Of Our Strategies For Increasing 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;

Adverse economic or political changes;

More limited protection for intellectual property in some countries;

Changes in our international distribution network and direct sales force;

Changes in currency exchange rates;



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

Potentially adverse tax consequences of overlapping tax structures.

### **We Are Dependent On Our Key Personnel.**

Our business and future operating results depend in significant part upon the continued contributions of our key technical personnel and senior management, many of whom would be difficult to replace, including our CEO, Steven G. Anderson. Our business and future operating results also depend in significant part upon our ability to attract and retain qualified management, processing, technical, marketing, sales, and support personnel for our operations. Competition for such personnel is intense and we cannot promise that we will be successful in attracting and retaining such personnel. We do not

have key life insurance 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 materially and adversely affect our ability to efficiently operate our business.

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

Government regulation in the U.S., the EMEA, and other jurisdictions can determine the success of our and our competitors' efforts to market and develop services and products. The FDA, pursuant to rules it promulgated under the PHS Act, currently regulates allograft tissues as human tissue. These rules 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 finalized and implemented good tissue practice regulations akin to good manufacturing practices, which must be followed by tissue banks and processors of human tissue. These good tissue practice regulations will increase regulatory oversight of CryoLife and other processors of human tissue. Although we and our competitors are endeavoring to satisfy the new regulations when they go into effect, there can be no assurance of success.

BioGlue is regulated as a Class III medical device. Fixed porcine heart valve products are classified as Class III medical devices. We may not obtain the FDA approval required to distribute our porcine heart valve products in the U.S. Whether we are able to distribute these products within the EEA will depend on whether we can maintain the CE Mark for these products and their ISO 13485 certifications, of which we cannot be certain.

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) approval process may also require clinical trials and take many years; for example the 510(k) approval for the CryoValve SG took a number of 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 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 products or services. Products or services marketed pursuant to FDA or foreign oversight or approvals are subject to continuing regulation. In the U.S., devices and biologics must be manufactured in registered establishments, and, in the case of biologics, licensed establishments and must be produced in accordance with Quality System Regulations. Manufacturing facilities and processes are subject to periodic FDA inspection. 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 materially and adversely affect our business, financial condition, results of operations, and cash flows.

In addition, 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. We cannot be certain that restrictive interpretations of NOTA will not be adopted in the future which will 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.

U.S. and foreign governments and regulatory agencies may adopt more restrictive laws or regulations in the future that could materially and adversely affect our business, financial condition, results of operations, 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. 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. Furthermore, we cannot be certain that competitors will not independently develop similar technologies or duplicate our technologies or design around the patented aspects of such technologies. We cannot be sure that our proposed technologies will not infringe patents or other rights owned by others.

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 materially and adversely affect our business, financial condition, results of operations, 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, vascular, and orthopaedic tissues may be particularly susceptible to third-party cost containment measures. For example, the initial cost of a preserved allograft 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 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 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 CryoValve SG.

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 negatively impact revenue growth and materially and adversely affect our business, financial condition, results of operations, and cash flows.

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**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 materially and adversely affect our business, financial condition, results of operations, and cash flows.

**Risks Related To Our Capital Stock**

**Trading Prices For Our Securities 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, 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, changes in earnings estimates by securities analysts, or other events or factors, many of which are beyond our control. 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. Changes in the trading price of our common stock may bear no relation to our actual operational or financial results. If our share prices do not meet the requirements of the New York Stock Exchange, our shares may be delisted. Our closing common stock price in the period January 1, 2005 to February 15, 2008 has ranged from a high of \$14.81 to a low of \$2.99.

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-related 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 harm our financial condition and results of operations.

**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 Restrictions And Lack Of Liquidity.**

We have not paid, and do not presently intend to pay, cash dividends on our common stock. In addition, under Florida law and under the restrictions set forth in our credit agreement, 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," and similar expressions generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-K. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Part I, Item 1A. "Risk Factors" and elsewhere in this Form 10-K.

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

The Company's ability to increase, and methods for increasing, BioGlue and preserved tissue market penetration;

The Company's continued use of human tissue implant data;

The expected benefits of surgical adhesives and sealants;

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

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

Expected increases in grant revenues;

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

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,

Expected decreases in revenues from the distribution of orthopaedic tissue;

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

Expectations regarding capital expenditures;

Expected usage of SynerGraft technology;

Expected timing regarding availability of CryoValve SG;

Commercialization plans regarding ProPatch;

Potential BioGlue product line extensions;

The potential benefits of products licensed from Trophic Solutions;

Information regarding the expected SynerGraft post-clearance study;

The ability of BioGlue to minimize post-operative pain following hernia operations;

The expected outcome of lawsuits filed against the Company;

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

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

The receipt of governmental grants for BioFoam development;

Future increases in research and development expenses;

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

Expected impact of adoption of new accounting pronouncements;

Expected seasonality trends;

Anticipated impact of changes in interest rates;

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

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Those issues most likely to impact the Company's future financial performance and cash flows;

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

The adequacy of the Company's financial resources; 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, 2007 (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, United Kingdom. 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 offsite 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 nine 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 5% of total capacity. To produce at full capacity levels, the Company would need to increase the number of employees, add work shifts, and install automated filling and pouching equipment. The bioprosthesis manufacturing laboratory contains approximately 20,000 square feet with a suite of six clean rooms. The research and development laboratory is approximately 10,500 square feet with a suite of five clean rooms. The microbiology laboratory is approximately 8,000 square feet with a suite of five clean rooms. The pathology laboratory is approximately 1,100 square feet. The Europa facility located in Guildford, United Kingdom contains approximately 3,400 square feet of leased office and warehousing space.

**Item 3. Legal Proceedings.**

***Product Liability Claims***

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 preserved by the Company. The plaintiff alleges that such tissue was contaminated and resulted in an infection in his knee requiring further surgery. The plaintiff seeks \$10 million in compensatory damages and \$100 million in punitive damages against the Company. The Company intends to defend against this lawsuit and believes that it has adequate insurance coverage for this particular case.

**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	69	President, Chief Executive Officer, and Chairman
Scott B. Capps	Since 2007	41	Vice President, Clinical Research
David M. Fronk	Since 1998	44	Vice President, Regulatory Affairs and Quality Assurance
Albert E. Heacox, Ph.D.	Since 1989	57	Senior Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	43	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Gerald B. Seery	Since 2005	51	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 Guidant 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.

**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 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.

<b>2007</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 9.51	\$ 7.00
Second quarter	15.20	8.25
Third quarter	14.34	7.60
Fourth quarter	9.88	6.20
<b>2006</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 5.65	\$ 2.95
Second quarter	5.50	4.25
Third quarter	6.90	5.07
Fourth quarter	7.80	5.70

As of February 15, 2008 the Company had 460 shareholders of record.

The Company has never declared or paid any cash dividends on its common stock. 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. In addition any credit facility the Company enters into in the future could restrict or prohibit the payment of cash dividends on the Company's common stock.

**Issuer Purchases of Equity Securities**

The Company did not purchase any of its equity securities during the quarter ended December 31, 2007. The Company currently has no stock repurchase program, publicly announced or otherwise. The Company does periodically purchase shares tendered in payment of the exercise price of outstanding options.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table provides information as of December 31, 2007 with respect to shares of CryoLife common stock that may be issued under existing equity compensation plans. CryoLife's Board of Directors in the past has awarded grants of options to directors, executive officers, and employees on a case-by-case basis when sufficient shares were not available under equity compensation plans approved by shareholders. CryoLife does not intend to continue this practice except to the extent that shares are otherwise unavailable under shareholder-approved plans and the grants are permitted by applicable NYSE rules.

	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights</b>	<b>Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</b>
	(a)	(b)	(c)
Plans approved by shareholders	1,830,836	\$ 6.29	1,343,536
Plans not approved by shareholders	28,925	7.60	
<b>Total</b>	<b>1,859,761</b>	<b>\$ 6.31</b>	<b>1,343,536</b>



**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,				
	2007	2006	2005	2004	2003
<b>Operations</b>					
Revenues	\$ 94,763	\$ 81,311	\$ 69,282	\$ 62,384	\$ 59,532
Net income (loss)	7,201	365	(19,535)	(18,749)	(32,294)
Net income (loss) applicable to common shareholders	6,958	(608)	(20,312)	(18,749)	(32,294)
Research and development expense as a percentage of revenues	4.7%	4.4%	5.4%	6.3%	6.1%
<b>Income (loss) Per Common Share</b>					
Basic	\$ 0.26	\$ (0.02)	\$ (0.85)	\$ (0.81)	\$ (1.64)
Diluted	\$ 0.26	\$ (0.02)	\$ (0.85)	\$ (0.81)	\$ (1.64)
<b>Year-End Financial Position</b>					
Total assets	\$ 92,684	\$ 79,865	\$ 76,809	\$ 73,261	\$ 75,027
Working capital	40,750	26,472	23,922	19,689	14,790
Long term liabilities	5,355	4,864	4,909	5,629	5,716
Convertible preferred stock		3	3		
Shareholders' equity	62,627	52,088	50,621	49,660	48,338
Current ratio <sup>1</sup>	3:1	2:1	2:1	2:1	2:1
Shareholders' equity per diluted common share	\$ 2.32	\$ 2.10	\$ 2.11	\$ 2.16	\$ 2.46

<sup>1</sup> Current assets divided by current liabilities.

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

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated January 19, 1984 in Florida, develops and commercializes biomaterials and implantable medical devices, and preserves and distributes human tissues for cardiac and vascular transplant applications. The Company's biomaterials and implantable medical devices include BioGlue® Surgical Adhesive (BioGlue), CryoLife-O<sup>2</sup> Bristentless Porcine Aortic Bioprosthesis, and ProPatch Soft Tissue Repair Matrix (ProPatch). Additionally, the Company distributes CardioWrap for MAST BioSurgery, Inc (MAST).

For CryoLife the year ended December 31, 2007 featured a return to profitability as the Company reported net income and positive cash flows from operations for four straight quarters. This profitability was driven by strong revenue growth as total revenues increased 17% in 2007 as compared to 2006. See the Results of Operations section below for additional analysis of the fourth quarter results. See Part I, Item 1, Business, for further discussion of the Company's business and activities during 2007.

**Recent Events***SynerGraft Processed Human Pulmonary Heart Valve 510(k) Clearance*

On February 7, 2008 CryoLife received 510(k) clearance from the Food and Drug Administration (FDA) for its CryoValve<sup>®</sup> SG pulmonary human heart valve processed with the Company's proprietary SynerGraft technology. CryoLife's proprietary SynerGraft technology is designed to remove donor cells and cellular remnants from the valve without compromising the integrity of the underlying collagen matrix. The CryoValve SG pulmonary human heart valve 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 his own pulmonary valve. The CryoValve SG is then surgically implanted in place of the removed native pulmonary valve.

At the FDA's request, CryoLife is planning a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process. Data to be collected is expected to include long-term safety and hemodynamic function, immune response, and explant analysis. CryoLife believes that this information may help it ascertain whether the SynerGraft process reduces the immune response of the transplanted heart valve and allows for the collagen matrix to recellularize with the recipient's own cells.

CryoLife has begun using the SynerGraft technology for the majority of its pulmonary valve processing and anticipates that the first CryoValve SG may be available for shipment late in the first quarter of 2008.

#### ***Trophic Solutions License Agreement***

On January 8, 2008 CryoLife announced that it had signed an exclusive license agreement with Trophic Solutions, LLC ( Trophic ) to develop and market products related to the cold storage and preservation of internal organs prior to transport. Under terms of the agreement, the Company will license from Trophic the right to develop, manufacture, and market products and processes derived from a patent owned by Trophic, which relates to solutions containing purified antimicrobial polypeptides and/or cell surface receptor binding proteins for use in the storage and preservation of internal organs prior to transplant. In early animal and human studies, the Trophic technology has shown that kidneys may be stored for up to six days prior to transplant without compromising graft function rather than three days using present technology. These studies also indicate that the solution may reduce or eliminate the need for pumping kidneys, which may reduce the cost of maintaining and transporting kidneys for transplant. The agreement gives CryoLife the exclusive right to determine if a commercial product can be developed using the process covered by the patent for a period of one year, which may be extended for an additional ninety days.

#### **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.

**Product Liability Claims:** In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. As of February 15, 2008 two product liability lawsuits were pending against the Company arising out of the Company's allograft heart valve and orthopaedic tissue services. These lawsuits are covered by product liability insurance and are in the pre-discovery or discovery stages. Other parties have made complaints that may result in lawsuits in future periods.

The Company performed an analysis as of December 31, 2007 of the pending product liability lawsuit and other claims based on settlement negotiations to date and advice from counsel. As of December 31, 2007 the Company had accrued approximately \$330,000 for the pending product liability lawsuits. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the December 31, 2007 Consolidated Balance Sheet. As of December 31, 2006 the Company had accrued a total of approximately \$330,000 for a pending product liability lawsuit. The lawsuit to which this accrual related was settled in the first quarter of 2007. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the December 31, 2006 Consolidated Balance Sheet.

On April 1, 2007 the Company bound coverage for the 2007/2008 insurance policy year. This policy is a five-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2008 and reported during the period April 1, 2007 through March 31, 2008 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its 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. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In January 2008 the Company retained an independent actuarial firm to perform estimates of the unreported claims as of December 31, 2007. The independent firm estimated the unreported product loss liability 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 independent actuarial firm used a number of assumptions in order to estimate the unreported product 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 for accident years 2001 through 2007 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 50% lower than non-BioGlue claims per million dollars of revenue. The 50% 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 product liability loss, but accuracy of the actuarial firm's 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.

Based on the actuarial valuation performed in January 2008 as of December 31, 2007, the Company estimated that its liability for unreported product liability claims was \$6.3 million as of December 31, 2007. The \$6.3 million balance is included as a component of accrued expenses and other current liabilities of \$3.2 million and other long-term liabilities of \$3.1 million on the December 31, 2007 Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$11.9 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of December 31, 2007, \$2.4 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.4 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.3 million on the December 31, 2007 Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to December 31, 2007. Actual results may differ from this estimate.

As of December 31, 2006 the Company accrued \$6.6 million for unreported product liability claims and recorded a receivable of \$2.3 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$6.6 million accrual was included as a component of accrued expenses and other current liabilities of \$3.3 million and other long-term liabilities of \$3.3 million on the December 31, 2006 Consolidated Balance Sheet. The \$2.3 million insurance recoverable was included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.2 million on the December 31, 2006 Consolidated Balance Sheet.

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***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. Tissue is procured from deceased human donors by organ and tissue procurement agencies, 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 ( ARB 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, double 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 includes 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 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 \$453,000, \$1.2 million, and \$1.8 million for the years ended December 31, 2007 2006, and 2005, respectively, for the value of certain deferred preservation costs that exceeded market value. The amount of these write-downs are primarily due to excess current period tissue processing costs that exceeded market value based on recent average service fees. Actual results may differ from these estimates.

The Company also recorded write-downs of \$366,000 for the year ended December 31, 2007 due to the impairment of certain vascular and orthopaedic tissues. The Company also recorded write-downs of \$588,000 for the year ended December 31, 2006 due to the impairment of certain orthopaedic tissues. The tissues were impaired in the period the Company determined that the tissues were not expected to ship prior to the expiration date of the tissues' packaging. The Company also recorded a write-down of \$2.8 million in the year ended December 31, 2006 due to the impairment of certain orthopaedic tissues and processing materials as a result of the exchange and service agreement with Regeneration Technologies, Inc., and certain of its affiliates (the RTI Agreement ) discussed in Part II, Item 8, Note 2 of the Notes to Summary Consolidated Financial Statements. This write-down was based on the Company's estimate of the tissues that would be shipped during the 18-month period subsequent to December 31, 2006 in which the Company can continue to distribute its orthopaedic tissues. The amount of tissues shipped during that period could differ significantly from this initial estimate resulting in higher margins on shipments of orthopaedic tissues during the 18-month period or additional write-downs in future periods. Cost of preservation services was favorably affected during the year ended December 31, 2007 by shipments of orthopaedic tissue with a zero cost basis for which revenues were recognized but costs, estimated to be \$347,000, had already been written-down in previous periods.

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. As of December 31, 2006 deferred preservation costs consisted of \$4.7 million for allograft heart valve tissues, \$1.0 million for non-valved cardiac tissues, \$11.3 million for vascular tissues, and \$2.3 million 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 product liability claims, and operating losses. The Company periodically assesses the recoverability of its deferred tax assets, in accordance with Statement of Financial Accounting Standards ( 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 when, as a result of this analysis, management believes it is more likely than not that its deferred tax assets will not be realized. In assessing the recoverability of its deferred tax assets at December 31, 2007, the Company reviewed its historical operating results, including the reasons for its operating losses in prior years and uncertainties regarding projected future operating results. Based on the results of this analysis, discussed further below, at December 31, 2007 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized.

Based on the Company's results for the year ended December 31, 2007, and its projections for 2008, the Company anticipates that it will utilize a portion of its net operating loss carryforwards in the 2008 income tax year to offset its U.S. taxable income, as it did in the 2007 and 2006 tax years. Although CryoLife is beginning to utilize its net operating loss carryforwards, the Company currently believes that a change in its determination of the recoverability of its deferred tax assets is not yet warranted. CryoLife will continue to evaluate its determination in accordance with the guidance in SFAS 109, which indicates the Company's net losses in recent years constitute significant evidence against the recoverability of its deferred tax assets that is difficult to overcome. CryoLife will reverse the remaining valuation allowance, or a portion thereof, when and if its deferred tax assets meet the SFAS 109 more likely than not standard for recognition. Also, 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.

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. As of December 31, 2006 the Company had a total of \$33.0 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$226,000 related to taxes in a foreign jurisdiction.

The tax years 2004-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject.

**Valuation of Long-lived and Intangible Assets and Goodwill:** 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 year ended December 31, 2007 the Company did not experience any factors that indicated an SFAS 144 impairment review was warranted. For the years ended December 31, 2006 and 2005, the Company performed an SFAS 144 impairment analysis, due to a variety of triggering factors including its operating performance. In these periods the undiscounted future cash flows of the Company's asset groups exceeded their carrying values. 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 goodwill resulting from business acquisitions and other non-amortizing intangible assets be subject to annual impairment testing. The Company's non-amortizing intangible assets as of December 31, 2007 consist of trademarks and, as a result of the RTI Agreement, procurement contracts and access to the procurement of cardiac and vascular human tissues previously received by RTI. In accordance with SFAS 142, the Company performed an analysis on its non-amortizing intangible assets as of December 31, 2007. 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, 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**

In December 2007 the Financial Accounting Standards Board ( FASB ) issued SFAS No. 141 Revised Business Combinations ( SFAS 141R ). SFAS 141R revises the accounting and disclosure requirements for business combinations and is effective for fiscal years beginning after December 15, 2008. The Company is in the process of evaluating the impact of SFAS 141R on its results of operations and financial position.

The Company will be required to adopt SFAS No. 157 Fair Value Measurements ( SFAS 157 ) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The Company does not anticipate that the adoption of SFAS 157 will have a material affect on its results of operations or financial position.

The Company will be required to adopt SFAS No. 159 The Fair Value Option for Financial Assets and Liabilities ( SFAS 159 ) for the fiscal year beginning January 1, 2008. SFAS 159 provides the option to report certain financial assets and liabilities at fair value, with the intent to mitigate volatility in financial reporting that can occur when related assets and liabilities are measured differently. The Company does not expect to voluntarily implement the optional fair value measurements portions of SFAS 159 for eligible items. Therefore, the Company does not anticipate that the adoption of SFAS 159 will have a material affect on its results of operations or financial position.

**Results of Operations**

(In thousands)

*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 and the change in BioGlue revenues 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.

As discussed in Part II, Item 8, Note 18 of the Notes to Summary Consolidated Financial Statements, on February 7, 2008 the Company obtained FDA clearance of its 510(k) premarket notification for the CryoValve SG. Therefore, the





Company could experience an increase in its 2008 cardiac preservation services revenues as a result of shipments of the CryoValve SG, which are expected to have a premium fee over the standard processed CryoValve. However, there are no guarantees that the CryoValve SG will demand premium fees or that shipments of the CryoValve SG will occur at material levels.

### *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 is no longer actively marketing its orthopaedic preservation services.

Although CryoLife will continue to ship its existing orthopaedic tissues, pursuant to the RTI Agreement, through June 30, 2008, the Company anticipates that orthopaedic service revenues for the first half of 2008 will decrease significantly compared to the same period in 2007 due to the limited tissues available for shipment as the higher demand orthopaedic

tissues and sizes are exhausted from the Company's tissue inventories, and due to the transition of the Company's orthopaedic tissue customers to alternative suppliers.

In accordance with the RTI agreement, RTI is entitled to market and solicit orders for CryoLife's remaining orthopaedic tissue inventory subsequent to June 30, 2008. If CryoLife ships any orthopaedic tissues at RTI's direction, CryoLife will recognize orthopaedic preservation services revenue and pay a corresponding commission to RTI. CryoLife does not currently anticipate that it will recognize material revenues from the shipment of orthopaedic tissues subsequent to June 30, 2008.

**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%	1%

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 U.S. Congress 2005 Defense Appropriations Conference Report (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 from the 2006 Defense Appropriations Conference Report, (the 2006 DOD Grant) in connection with further development of BioFoam. The 2007 Defense Appropriations Conference Report (the 2007 DOD Grant) included approximately \$1.0 million for the continued development of protein hydrogel technology for use on the battlefield. CryoLife applied for funding under this bill during 2007. The Company does not currently know if and when it will be approved to receive funding under the 2007 DOD Grant or receive the final funding awarded under the 2006 DOD Grant.

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.

The Company anticipates that grant revenues could increase in 2008 over 2007 related to spending on BioFoam research.

## 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 the current year periods as compared to the prior year periods is 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.

The Company anticipates that cost of preservation services as a percentage of preservation services revenues in 2008 may be favorably impacted by shipments of the CryoValve SG, as CryoValve SG are expected to have a premium fee over the standard processed CryoValve.

**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 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 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 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 Protein Hydrogel Technologies ( PHT ). SynerGraft products and tissues include the Company's allograft and xenograft heart valves and vascular grafts and ProPatch Soft Tissue Repair Matrix. PHT includes BioGlue, BioFoam, BioDisc, and related products.

The Company anticipates that research and development expenses for 2008 will exceed 2007, primarily due to increased spending on research related to PHT, particularly BioFoam and BioDisc, and tissue preservation as well as spending on research related to SynerGraft products and tissues, ProPatch, and for the cold storage and preservation of internal organs related to the Company's agreement with Trophic Solutions, LLC discussed in Recent Events above. The BioFoam spending increase is expected to be due primarily to funds the Company has obtained pursuant to the 2005 and 2006 Defense Appropriation Conference Report discussed in Revenues Other Revenues above.

### *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, discussed in Part II, Item 8, Note 14 of the Notes to Consolidated Financial Statements. 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 Preferred Stock to common stock in excess of the Derivative liability accrued in prior periods, as discussed in Part II, Item 8, Note 7 of the Notes to Consolidated Financial Statements.

As the Preferred Stock was fully converted to common stock in the second quarter, 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 cannot be offset by the Company's net operating loss carryforwards and estimated 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 a further discussion of the Company's income tax expense and related items.

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 cannot 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 cannot 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.

*Year Ended December 31, 2006 Compared to Year Ended December 31, 2005*

**Revenues**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2006	2005	2006	2005
Revenues	\$ 21,090	\$ 17,961	\$ 81,311	\$ 69,282

Revenues increased 17% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005. The increase was primarily due to an increase in tissue preservation service revenues, as well as an increase in BioGlue revenues as compared to the prior year period.

Revenues increased 17% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005. The increase was primarily due to an increase in tissue preservation service revenues, as well as an increase in BioGlue revenues as compared to the prior year period.

A detailed discussion of the change in preservation services revenues for each of the three major tissue types distributed by the Company and the change in BioGlue revenues is presented below.

*Cardiac Preservation Services*

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2006	2005	2006	2005
Revenues	\$ 4,438	\$ 3,355	\$ 15,988	\$ 13,762
Cardiac revenues as a percentage of total revenue	21%	19%	20%	20%

Revenues from cardiac preservation services increased 32% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005. This increase was primarily due to an increase in average service fees, which increased revenues by 18%, and a 20% increase in unit shipments of cardiac tissues, which increased revenues by 14%.

Revenues from cardiac preservation services increased 16% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005. This increase was primarily due to an increase in average service fees, which increased revenues by 10%, and a 15% increase in unit shipments of cardiac tissues, which increased revenues by 6%.



The increase in average service fees for the three and twelve months ended December 31, 2006 was primarily due to the fee increases that went into effect in January 2006 on all cardiac tissues and in July 2006 on certain non-valved cardiac tissues. The increase in cardiac volume for the three and twelve months ended December 31, 2006 was primarily due to increased shipments of pulmonary valves and non-valved cardiac tissues. To a lesser extent, the three months ended December 31, 2006 also exhibited an increase in aortic valve shipments. The increases in cardiac shipments were a result of increased availability of tissues due to improvements in procurement and tissue processing yields and due to strengthening demand for the Company's tissues, particularly in the pediatric cardiac market. The increases in the number of tissue shipments did not result in proportional increases in cardiac revenues due to a shift in product mix, as the increases were primarily experienced in products with smaller per unit revenues than the average cardiac tissue.

The Company's procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, increased 13% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005, and 12% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005.

#### *Vascular Preservation Services*

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2006	2005	2006	2005
Revenues	\$ 3,890	\$ 3,172	\$ 16,956	\$ 11,453
Vascular revenues as a percentage of total revenue	18%	18%	21%	17%

Revenues from vascular preservation services increased 23% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005. This increase was primarily due to an increase in average service fees, which increased revenues by 14%, and an 8% increase in unit shipments of vascular tissues, which increased revenues by 9%.

Revenues from vascular preservation services increased 48% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005. This increase was primarily due to a 30% increase in unit shipments of vascular tissues, which increased revenues by 36%, 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, 2006 is primarily due to increases in shipments of saphenous veins, due in part to increased availability of tissues as a result of improvements in procurement levels and tissue processing yields, coupled with a strong demand for these tissues, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations. The increase in shipments of saphenous veins is a continuation of the favorable trend that began in the fourth quarter of 2005. The increase in average service fees for the three and twelve months ended December 31, 2006 was primarily due to the fee increases that went into effect in January 2006 on all vascular tissues.

The Company's procurement of vascular tissues increased 14% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005, and 31% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005.

#### *Orthopaedic Preservation Services*

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2006	2005	2006	2005
Revenues	\$ 1,911	\$ 1,561	\$ 7,134	\$ 5,092
Orthopaedic revenues as a percentage of total revenue	9%	9%	9%	7%

Revenues from orthopaedic preservation services increased 22% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005. This increase was primarily due to an increase in average service



fees, which increased revenues by 16%, and a 16% increase in unit shipments of orthopaedic tissues, which increased revenues by 6%.

Revenues from orthopaedic preservation services increased 40% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005. This increase was primarily due to a 24% increase in unit shipments of orthopaedic tissues, which increased revenues by 26% and an increase in average service fees, which increased revenues by 14%.

The increase in average service fees for the three and twelve months ended December 31, 2006 was primarily due to the fee increases that went into effect in January 2006 on all orthopaedic tissues and in July 2006 for certain orthopaedic tissues. The increase in orthopaedic volume for the three and twelve months ended December 31, 2006 was primarily due to an increase in shipments of boned tendons, and to a lesser extent shipments of non-boned tendons and menisci, primarily due to reestablishment of the Company's presence in the orthopaedic tissue business and the rebuilding of the Company's supply of tissues available for shipment. The increase in orthopaedic volume for the twelve months ended December 31, 2006 was also due to an increase in shipments of osteochondral grafts, which were reintroduced in a cryopreserved condition in the first quarter of 2005.

Until January 1, 2007 the Company procured orthopaedic tissues, which include knees, from which osteochondral grafts, menisci, and boned tendons are processed, and individual tendons, which are primarily non-boned. The Company's procurement of all orthopaedic tissues decreased 13% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005, and increased 9% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005. The Company's procurement of knees decreased 26% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005, and increased 9% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005.

### *BioGlue*

	<b>Three Months Ended December 31,</b>		<b>Twelve Months Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>Revenues</b>	<b>\$ 10,491</b>	<b>\$ 9,645</b>	<b>\$ 40,025</b>	<b>\$ 37,985</b>
BioGlue revenues as a percentage of total revenue	50%	54%	49%	55%

Revenues from the sale of BioGlue increased 9% for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005. This increase was primarily due to an increase in average selling prices, which increased revenues by 5%, a 2% increase in the amount of BioGlue milliliters shipped, which increased revenues by 3%, and the effect of foreign currency exchange, which increased revenues by 1%.

Revenues from the sale of BioGlue increased 5% for the twelve months ended December 31, 2006 as compared to the twelve months ended December 31, 2005. This increase was primarily due to an increase in average selling prices, which increased revenues by 5%.

The increase in average selling prices for the three and twelve months ended December 31, 2006 was primarily due to list price increases that went into effect in January and July 2006 domestically and in certain international markets. The increase in BioGlue volume for the three months ended December 31, 2006 was primarily due to an increase in unit shipments of BioGlue syringes partially offset by a decrease in BioGlue cartridge products, as more customers transition to the newer BioGlue syringe products, and a decrease in accessory sales. Accessory sales were negatively impacted by the success of the BioGlue syringe product, which does not utilize a separate delivery device or require the purchase of separate applicator tips, although a variety of optional applicator tips are available for the BioGlue syringe.

Domestic revenues accounted for 74% of total BioGlue revenues for both the three and twelve months ended December 31, 2006, and 75% and 76% of total BioGlue revenues for the three and twelve months ended December 30, 2005, respectively.

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### ***Other Revenues***

Other revenues were \$122,000 and \$196,000 respectively, for the three and twelve months ended December 31, 2006 and \$43,000 for both the three and twelve months ended December 31, 2005. Other revenues for the three and twelve months ended December 31, 2006 included revenues for research grants and revenues related to the licensing of the Company's technology to a third party. Other revenues for the three and twelve months ended December 31, 2005 included revenues for research grants.

Grant revenues in 2005 and 2006 are related to funding received under the U.S. Congress 2005 Defense Appropriations Conference Report, (the 2005 DOD Grant), which included \$930,000 for the development of protein hydrogel technology for use on the battlefield. The Company applied for and was awarded the full \$930,000 allocated under the 2005 DOD Grant in connection with its development of BioFoam®. The Company has received advances totaling \$930,000 under this grant during 2005 and 2006, and began recognizing revenues for expenses incurred related to this grant during the fourth quarter of 2005. The Company is currently involved in the initial BioFoam animal trial funded by this grant revenue.

The U.S. Congress 2006 Defense Appropriations Conference Report included approximately \$2.3 million for the continued development of protein hydrogel technology for use on the battlefield. CryoLife applied for funding for BioFoam development under this bill in July 2006, but has not yet received notice of any award decision. The 2007 Defense Appropriations Conference Report included approximately \$1.0 million for the continued development of protein hydrogel technology for use on the battlefield. CryoLife anticipates applying for funding under this bill during 2007.

### **Costs and Expenses**

#### ***Cost of Preservation Services***

Cost of preservation services was \$9.2 million and \$6.4 million for the three months ended December 31, 2006 and 2005, respectively, representing 90% and 79%, respectively, of total preservation service revenues during such periods. Cost of preservation services for the three 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 discussed above and the write-down of \$140,000 of certain deferred preservation costs that exceeded market value. Cost of preservation services for the three months ended December 31, 2005 includes the write-down of \$499,000 of certain deferred preservation costs that exceeded market value.

Cost of preservation services was \$30.0 million and \$24.4 million for the twelve months ended December 31, 2006 and 2005, respectively, representing 75% and 80%, respectively, of total preservation service revenues during such periods. Cost of preservation services for the 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, the write-down of \$1.2 million of certain deferred preservation costs that exceeded market value, and the write-down of \$588,000 due to the impairment of certain orthopaedic tissues. Cost of preservation services for the twelve months ended December 31, 2005 includes the write-down of \$1.8 million of certain deferred preservation costs that exceeded market value.

The write-down of deferred preservation costs as a result of the RTI Agreement during 2006 was based on an estimate of the tissues that will be shipped during the 18-month period subsequent to December 31, 2006 in which the Company can continue to distribute its existing orthopaedic tissues. The amount of tissues shipped during that period could differ significantly from this initial estimate resulting in higher margins on shipments of orthopaedic tissues during the 18-month period or additional write-downs in future periods. 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.

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 a fee increase effective July 1, 2006, in part to address these tissues, which have had costs in excess of the average service fees. The decrease of the write-down in the 2006 periods as compared to 2005 periods was primarily due to the effect of this fee increase on the Company's average service fees for the affected tissue types.

The write-down due to the impairment of certain orthopaedic tissues during the twelve months ended December 31, 2006 was the result of excess tissue inventory levels above those expected to ship before the expiration date of the tissue's packaging.

After considering the effects of the write-downs discussed above, the remaining increase in cost of preservation services for the three and twelve months ended December 30, 2006 is primarily due to increased preservation service volume as compared to the same period in 2005. After considering the effects of the write-downs discussed above, cost of preservation services as a percentage of total preservation service revenues decreased. The decrease is primarily due to improvements in preservation margins as a result of improvements in the Company's tissue processing yields, an increase in average service fees due to fee increases implemented in 2006, and to a lesser extent an increase in the amount of tissues processed.

### ***Cost of Products***

Cost of products was \$1.9 million for both the three months ended December 31, 2006 and 2005, representing 18% and 20%, respectively, of total product revenues during such periods. Cost of products was \$7.5 million and \$8.1 million for the twelve months ended December 31, 2006 and 2005, respectively, representing 18% and 21%, respectively, of total product revenues during such periods.

The cost of products decreased for the twelve months ended December 31, 2006 and the cost of products as a percentage of total product revenues decreased for the three and twelve months ended December 31, 2006, primarily due to improvements in BioGlue margins from period to period. These margin improvements were a result of improvements in BioGlue average selling prices due to the price increases which went into effect in January and July 2006 and greater manufacturing throughput, which reduced the per unit cost to produce BioGlue. Cost of products for the three months ended December 31, 2006 was flat compared to the three months ended December 31, 2005 as the lower per unit cost to produce BioGlue was offset by increases in BioGlue sales volume.

### ***General, Administrative, and Marketing Expenses***

General, administrative, and marketing expenses increased 9% to \$11.4 million for the three months ended December 31, 2006, compared to \$10.5 million for the three months ended December 31, 2005, representing 54% and 58%, respectively, of total revenues during such periods. General, administrative, and marketing expenses for the three months ended December 31, 2006 includes an unfavorable charge of \$751,000 for stock-based compensation expenses and a favorable adjustment of \$333,000 for the adjustment of reserves for product liability losses. General, administrative, and marketing expenses for the three months ended December 31, 2005 includes a favorable adjustment to legal and settlement accruals of \$683,000, an accrual of \$150,000 for post employment benefits related to the signing of a compensation agreement by one of the Company's senior executives, and an \$118,000 charge for stock-based compensation. After considering the effect of these items, general, administrative, and marketing expenses for the three months ended December 31, 2006 increased slightly, primarily due to an increase in executive bonus accruals, partially offset by a decrease in legal and professional fees.

General, administrative, and marketing expenses decreased 22% to \$41.5 million for the twelve months ended December 31, 2006, compared to \$53.2 million for the twelve months ended December 31, 2005, representing 51% and 77%, respectively, of total revenues during such periods. General, administrative, and marketing expenses for the twelve months ended December 31, 2006 includes a favorable adjustment of \$2.0 million related to the settlement of insurance coverage disputes with former insurance carriers, net of associated legal fees, an unfavorable charge of \$1.5 million for stock-based compensation expenses, a favorable adjustment of \$784,000 for the adjustment of reserves for product liability losses, and an accrual of \$448,000 for post employment benefits. General, administrative, and marketing expenses for the twelve months ended December 31, 2005 includes an accrual of \$11.6 million in expense related to the settlement of the shareholder class action lawsuit and related legal fees, a favorable adjustment of \$961,000 for the adjustment of reserves for product liability losses, an accrual of \$851,000 for post employment benefits, and \$285,000 charge for stock-based compensation. After considering the effect of these items, general, administrative, and marketing expenses for the twelve months ended December 31, 2006 increased, primarily due to an increase in marketing commissions to support revenue growth and an increase in executive bonus accruals, partially offset by a decrease in legal and professional fees.

### ***Gain on Exit Activities***

Gain on exit activities was \$2.6 million for the three and twelve months ended December 31, 2006, compared to zero for the three and twelve months ended December 31, 2005. This represents the gain associated with the RTI Agreement entered into in December 2006. The gain is 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 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 is 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 in that section 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. 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***

Research and development expenses were \$975,000 for the three months ended December 31, 2006, compared to \$980,000 for the three months ended December 31, 2005, representing 5% and 6%, respectively, of total revenues during each such period. Research and development expenses were \$3.5 million for the twelve months ended December 31, 2006, compared to \$3.7 million for the twelve months ended December 31, 2005, representing 4% and 5%, respectively, of total revenues during each such period. The decrease in research and development expenses in both the three and twelve month periods ended December 31, 2006 was due to timing delays for planned external research studies. Research and development spending in 2006 and 2005 was primarily focused on the Company's tissue preservation, SynerGraft (which includes allograft and xenograft heart valves, vascular grafts, and ProPatch), and PHT (which includes BioGlue, BioFoam, BioDisc, and related products).

#### ***Other Costs and Expenses***

Interest expense increased to \$153,000 for the three months ended December 31, 2006, compared to \$126,000 for the three months ended December 31, 2005. Interest expense increased to \$657,000 for the twelve months ended December 31, 2006, compared to \$346,000 for the twelve months ended December 31, 2005. The increase in interest expense for the three and twelve months ended December 31, 2006 was primarily due to higher borrowings under the Company's prior Credit Agreement as compared to the same period in 2005 and higher interest rates on these borrowings, as the bank's prime lending rate had increased since the 2005 period. Interest expense for the three and twelve months ended December 31, 2006 and 2005 included interest incurred related to the Credit Agreement, notes payable, and capital leases.

Interest income decreased to \$105,000 for the three months ended December 31, 2006, compared to \$123,000 for the three months ended December 31, 2005. Interest income decreased to \$409,000 for the twelve months ended December 31, 2006, compared to \$531,000 for the twelve months ended December 31, 2005. Interest income for the three and twelve months ended December 31, 2006 and 2005 was primarily due to interest earned on the Company's cash, cash equivalents, and marketable securities.

The change in valuation of the Derivative was an expense of \$10,000 for the three months ended December 31, 2006 as compared to income of \$512,000 for the three months ended December 31, 2005. The change in valuation of the Derivative was an expense of \$121,000 for the twelve months ended December 31, 2006 as compared to income of \$140,000 for the twelve months ended December 31, 2005. The valuation of the Derivative in these periods was a function of several variables including the price and expected volatility of the Company's common stock, the number of shares of Preferred Stock outstanding, and the general level of U.S. interest rates. The change in valuation of the Derivative in the three and twelve months ended December 31, 2005 also includes the amount of the Dividend Make-Whole Payment on preferred shares converted during the period.

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 cannot 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 cannot 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.

The Company's income tax benefit of \$618,000 and \$428,000 for the three and twelve months ended December 31, 2005, respectively, was primarily related to foreign taxes on income of the Company's wholly owned European subsidiary.

#### ***Seasonality***

The demand for BioGlue appears to be seasonal, with a flattening or 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 fewer surgeries being performed on adult patients in the summer months. The Company will continue to evaluate the seasonal nature of BioGlue sales.

The demand for the Company's cardiac tissue preservation services has historically been seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiac tissue 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 CryoLife's cardiac tissues. This seasonal trend has been obscured in recent years, but the Company expects that this seasonal trend will be more apparent in future years.

The demand for the Company's human vascular tissue preservation services and bioprosthetic cardiac and vascular devices does not appear to be seasonal. Due to the RTI Agreement and the expected decline in shipments of orthopaedic tissue, the Company does not expect seasonality trends to impact its revenues related to orthopaedic tissues.

## **Liquidity and Capital Resources**

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

At December 31, 2007 net working capital (current assets of \$65.5 million less current liabilities of \$24.7 million) was \$40.8 million, with a current ratio (current assets divided by current liabilities) of 3 to 1, compared to net working capital of \$26.5 million, with a current ratio of 2 to 1 at December 31, 2006.

The Company's primary capital requirements for the twelve months ended December 31, 2007 arose out of general working capital needs, 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 2007.

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

In January 2006 the Company engaged a financial advisor to assist the Company's management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. In November 2006 the Company announced that as a result of this review, the Board of Directors has directed management to actively pursue three key strategies in addition to continuing to focus on growing its business and leveraging its strengths and expertise in its core marketplaces. These three strategies are designed to generate revenue and earnings growth: identify and evaluate acquisition opportunities of complementary product lines and companies; license Company technology to third parties for non-competing uses; and 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.

On February 8, 2005 CryoLife and its subsidiaries entered into the Credit Agreement with Wells Fargo Foothill, Inc. as lender to address some of its liquidity needs. As of December 31, 2007 the outstanding balance under the Credit Agreement was \$4.5 million and the remaining borrowing availability was \$10.0 million. The Company also had outstanding a \$500,000 letter of credit sub facility under the Credit Agreement, relating to one of the Company's product liability insurance policies. The Credit Agreement expired on February 8, 2008, at which time the Company paid the outstanding principal balance of \$4.5 million from cash on hand. The Company also remitted approximately \$500,000 as collateral to cover the remaining term of the letter of credit agreement, which expires in April 2008. It is the Company's current intent to obtain new debt financing during 2008 to provide additional liquidity to fund the Company's strategic directives as discussed above, although there is no guarantee that such financing can be obtained on terms acceptable to the Company, or at all. Management does not believe that debt financing is needed to fund the Company's continuing operations for the next twelve months.

The Company's cash equivalents include advance funding received under the 2005 DOD Grant and the 2006 DOD Grant for the continued development of protein hydrogel technology for use on the battlefield. As of December 31, 2007 \$1.2 million of cash equivalents were recorded on the Company's Consolidated Balance Sheet related to the 2005 and 2006 DOD grants. These funds must be used for the specified purposes.

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

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***Product Liability Claims***

As discussed in Part II, Item 8, Note 8 of the Notes to Summary Consolidated Financial Statements, as of December 31, 2007 the Company had a \$330,000 accrual for pending product liability lawsuits and claims. The timing and amount of actual future payments with respect to 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 Part II, Item 8, Note 8 of the Notes to Summary Consolidated Financial Statements, at December 31, 2007 the Company had accrued a total \$6.3 million for the estimated costs of unreported product liability claims related to services performed and products sold prior to December 31, 2007 and had recorded a receivable of \$2.4 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 \$11.9 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The \$6.3 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 \$9.3 million for the twelve months ended December 31, 2007 as compared to net cash used of \$1.1 million for the twelve months ended December 31, 2006. The current year cash provided was primarily due to net income generated by the Company during the period and non-cash expenses, partially offset by an increase in deferred preservation costs.

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. For the twelve months ended December 31, 2007 the Company's \$7.2 million net income included non-cash items that generated favorable and unfavorable adjustments to net income. For the twelve months ended December 31, 2007 these adjustments included a favorable \$3.9 million in depreciation expense, a favorable \$2.1 million in non-cash compensation, primarily related to SFAS 123R expense for new and existing stock options and the granting of stock awards, a favorable \$821,000 for the change in valuation of derivative, primarily related to the Dividend Make-Whole Payment on Preferred Stock converted during the period, a favorable \$819,000 in write-downs for impairment of deferred preservation costs, and a favorable \$527,000 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, 2007 these changes included an unfavorable \$8.4 million and \$454,000 due to the buildup of deferred preservation costs and inventories, respectively, for which vendors and employees have already been paid, and a favorable \$2.1 million and \$842,000 due to the timing differences between the recording of accrued expenses and other current liabilities and accounts payable, respectively, and the actual payment of cash, and a favorable \$685,000 due to the expensing of prepaid assets for which cash had already been paid out.

***Net Cash from Investing Activities***

Net cash provided by investing activities was \$446,000 for the twelve months ended December 31, 2007, as compared to net cash used in investing activities of \$557,000 for the twelve months ended December 31, 2006. The current year cash provided was primarily due to \$14.2 million in sales and maturities of marketable securities, partially offset by \$12.3 million in purchases of marketable securities and \$1.2 million in capital expenditures.

***Net Cash from Financing Activities***

Net cash provided by financing activities was \$743,000 for the twelve months ended December 31, 2007, as compared to net cash used in financing activities of \$968,000 for the twelve months ended December 31, 2006. The current year cash provided was primarily due to \$1.7 million in proceeds from the exercise of options and the issuance of stock, partially offset by \$486,000 in payments of preferred stock dividends and \$478,000 in purchases of treasury stock, related to the payment of the exercise price of stock options by tendering shares of common stock. During the twelve months ended December 31, 2007 the favorable effect of \$1.9 million in financing of insurance policies was fully offset by the related principle payments and \$533,000 in proceeds from debt issuance were largely offset by \$532,000 in related principle payments.

**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 are as follows (in thousands):

	Total	2008	2009	2010	2011	2012	Thereafter
Operating leases	\$ 17,512	\$ 2,415	\$ 2,275	\$ 2,153	\$ 2,145	\$ 2,187	\$ 6,337
Line of credit	4,506	4,506					
Compensation payments	3,127	1,142			992	993	
Purchase commitments	951	844	107				
Royalty payments	726	726					
Licensing agreement obligations	150	150					
Capital lease obligations	140	53	52	35			
Insurance premium obligations	123	123					
Other obligations	659	604	55				
Total contractual obligations	\$ 27,894	\$ 10,563	\$ 2,489	\$ 2,188	\$ 3,137	\$ 3,180	\$ 6,337

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, leases on housing for expatriates, and leases on a variety of office equipment.

The line of credit obligation results from the Company's borrowing of funds under its prior Credit Agreement. These amounts were paid on February 8, 2008, the Credit Agreement expiration date.

The Company's compensation payment obligations represent cash payments made for its 2007 corporate bonus plans and estimated payments for post employment benefits for the Company's Chief Executive Officer (CEO). The timing of the post employment benefits is based on the December 2010 expiration date of the CEO's 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 primarily related to the Company's BioGlue revenues.

The Company's licensing agreement obligations are due to the licensing of technology from a third party. The schedule does not include additional payments of up to \$1.2 million which are contingent upon the outcome of the Company's research activities.

The Company's capital lease obligations result from the financing of certain of the Company's equipment. The Company's insurance premium obligations represent installment payments related to payment plans related to certain of the Company's insurance policies.

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 any estimated liability for product liabilities, as no amounts were due under contractual obligations. The schedule of contractual obligations does not include \$1.0 million in advance funding received under the 2005 DOD Grant and the 2006 DOD Grant for which a specific timetable of spending has not been established and for which there are no current agreements or contracts in place. The schedule of contractual obligations above excludes any estimated liability for uncertain tax positions, currently estimated to be \$2.1 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made by any taxing authorities.





### ***Capital Expenditures***

The Company expects that its capital expenditures in 2008 will be similar to its expenditures in 2007, which were approximately \$1.2 million. Planned capital expenditures for 2008 are primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment needed to support the Company's business. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to generate cash flows.

### **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 \$14.5 million and the interest incurred on the line of credit balance of \$4.5 million as of December 31, 2007. The Company's short-term investments in marketable securities of \$3.0 million as of December 31, 2007 can also be affected by changing interest rates to the extent that these items contain variable interest rates or are subject to maturity or sale during a period of changing interest rates. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the twelve months ended December 31, 2007, affecting the Company's cash equivalents and short-term investments or borrowings under the Company's prior Credit Agreement would not have a material impact on the Company's financial position, results of operations, or cash flows.

The Company may obtain new debt financing during 2008 to provide additional liquidity to fund the Company's strategic directives as discussed in Part II, Item 7. Liquidity above. There is no guarantee that the Company will be able to obtain financing at rates acceptable to the Company, at rates comparable to the Company's historic experiences, or at all.

#### ***Foreign Currency Exchange Rate Risk***

The Company has balances, such as 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 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. A 10% adverse change in foreign currency rates as compared to the rates on December 31, 2007 affecting the Company's balances denominated in foreign currencies would not have a material impact on the Company's financial position, results of operations, 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 Company's most recent Disclosure Controls evaluation as of December 31, 2007, 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, 2007, 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 Controls over Financial Reporting under Sarbanes-Oxley Section 404, included in Part II, Item 8, Financial Statements and Supplementary Data 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, included in Part II, Item 8, Financial Statements and Supplementary Data 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 set forth in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 29, 2008, 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 set forth in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 29, 2008.

**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 set forth in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 29, 2008.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The response to Item 13 is incorporated herein by reference to the information set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission not later than April 29, 2008.

**Item 14. Principal Accounting Fees and Services.**

The response to Item 14 is incorporated herein by reference to the information set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission not later than April 29, 2008.

**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:

<b>Exhibit Number</b>	<b>Description</b>
2.1	Reserved.
3.1*	Amended and Restated Articles of Incorporation of the Company. (Restated solely for the purpose of filing with the Commission).
3.2	Reserved.
3.3	Reserved.
3.4	Reserved.
3.5	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.4 to the Registrant's Current Report on Form 8-K filed August 1, 2007.)
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 between CryoLife, Inc., Certain Subsidiaries of CryoLife, Inc., and Wells Fargo Foothill, Inc., dated February 8, 2005.
10.2(a)	First Amendment to the Credit Agreement signed on September 27, 2005, amends the February 8, 2005 Credit Agreement between Wells Fargo Foothill, Inc., CryoLife, Inc., and its subsidiaries. (Incorporated herein by reference to Exhibit 10.2.1 to Form 8-K filed on September 28, 2005.)

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- 10.2(b) Second Amendment to the Credit Agreement, dated October 17, 2006, amends the February 8, 2005 Credit Agreement between Wells Fargo Foothill, Inc., CryoLife, Inc., and its subsidiaries, as amended on September 27, 2005. (Incorporated herein by reference to Exhibit 10.2(b) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
- 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.)

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Exhibit Number	Description
10.4	CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Appendix 1 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.5+	Exchange and Service Agreement, dated December 15, 2006, by and between CryoLife, Inc. and Regeneration Technologies, Inc. and its affiliates RTI Donor Services, Inc. and Regeneration Technologies, Inc. Cardiovascular. (Incorporated herein by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.6	Form of 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, 2007.)
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)	Amended and restated employee agreement with Steven G. Anderson dated as of July 30, 2007. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed August 1, 2007.)
10.9(b)	Employment Agreement, by and between the Company and D. Ashley Lee, dated September 5, 2005. (Incorporated herein by reference to Exhibit 10.2 to Form 8-K dated September 5, 2005 and filed September 9, 2005.)
10.9(c)	First Amendment to Employment Agreement, dated May 4, 2006, by and between the Company and D. Ashley Lee. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006.)
10.9(d)	Employment Agreement, by and between the Company and Gerald B. Seery, dated November 1, 2005. (Incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005.)
10.9(e)	Form of Amendment, dated May 2, 2007, to Fiscal Year 2007 Executive Incentive Plan Bonus Agreements entered into with each of Steven G. Anderson, D. Ashley Lee, Gerald B. Seery, Albert E. Heacox, and David M. Fronk. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.)
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	Form of Employment Agreement, by and between the Company and each of Albert E. Heacox, Ph.D. and David M. Fronk, 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 September 30, 2006.)
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 Amlis Land Development I Limited Partnership, dated April 18, 1995.

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Exhibit Number	Description
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.)
10.18	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	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.)
10.21	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.)
10.22*	Technology License Agreement between the Company and Colorado State University Research Foundation dated March 28, 1996.
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.)
10.28	Reserved.
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.)

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Exhibit Number	Description
10.33	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.34	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.35	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.36	Form of Grant of Non-Qualified Stock Option to Directors. (Incorporated herein by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.37	Grant of Incentive Stock Option to Steven G. Anderson, dated May 4, 2006. (Incorporated herein by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.38	International Distribution Agreement, dated September 17, 1998, between the Company and Century Medical, Inc. (Incorporated by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.39-10.40	Reserved.
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.
14	Code of Business Conduct and Ethics. (Incorporated herein by reference to Exhibit 14 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.)
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. Amended and restated employee agreement with Steven G. Anderson dated as of July 30, 2007. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed August 1, 2007.)
3. Employment Agreement, by and between the Company and D. Ashley Lee, dated September 5, 2005. (Incorporated by reference to Exhibit 10.2 to Form 8-K dated September 5, 2005 and filed September 9, 2005.)
4. First Amendment to Employment Agreement, dated May 4, 2006, by and between the Company and D. Ashley Lee. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006.)
5. Employment Agreement, by and between the Company and Gerald B. Seery, dated November 1, 2005. (Incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005.)
6. Form of Amendment, dated May 2, 2007, to Fiscal Year 2007 Executive Incentive Plan Bonus Agreements entered into with each of Steven G. Anderson, D. Ashley Lee, Gerald B. Seery, Albert E. Heacox, and David M. Fronk. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007.)
7. Form of Employment Agreement, by and between the Company and each of Albert E. Heacox, Ph.D. and David M. Fronk, 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 September 30, 2006.)
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.)

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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. Form of Purchase Agreement between CryoLife, Inc. and Piper Jaffray & Co. dated March 15, 2005. (Incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the Commission on March 15, 2005.)
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.)

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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 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, 2007.)
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.)

\* 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 21, 2008

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 <b>Steven G. Anderson</b>	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	February 21, 2008
/s/ D. ASHLEY LEE <b>D. Ashley Lee</b>	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 21, 2008
/s/ AMY D. HORTON <b>Amy D. Horton</b>	Chief Accounting Officer (Principal Accounting Officer)	February 21, 2008
/s/ THOMAS F. ACKERMAN <b>Thomas F. Ackerman</b>	Director	February 21, 2008
/s/ JAMES S. BENSON <b>James S. Benson</b>	Director	February 21, 2008
/s/ DANIEL J. BEVEVINO <b>Daniel J. Bevevino</b>	Director	February 21, 2008
/s/ JOHN M. COOK <b>John M. Cook</b>	Director	February 21, 2008
/s/ RONALD C. ELKINS, M.D. <b>Ronald C. Elkins, M.D.</b>	Director	February 21, 2008
/s/ RONALD D. MCCALL <b>Ronald D. McCall</b>	Director	February 21, 2008

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

The management of CryoLife, Inc. and subsidiaries (CryoLife, 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. CryoLife's internal control over financial reporting includes policies and procedures that:

- (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of CryoLife;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and directors of CryoLife; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of CryoLife's assets that could have a material effect on the 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, 2007. 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, 2007, the company's internal control over financial reporting is effective based on those criteria.

CryoLife's independent registered public accounting firm has issued an audit report on our assessment of CryoLife's internal control over financial reporting.

CryoLife, Inc.

February 21, 2008

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**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, 2007, 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 appearing under Item 8. 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, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. 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 generally accepted accounting principles, 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 its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 of the Company and our report dated February 21, 2008 expressed an unqualified opinion on those financial statements and financial statement schedule and included an explanatory paragraph relating to the Company's adoption on October 1, 2005 of Statement of Financial Accounting Standards No. 123R - Share Based Payment and the Company's adoption on January 1, 2007 of Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes .

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 21, 2008



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**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, 2007 and 2006, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. 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 CryoLife, Inc. and subsidiaries at December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, 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 1 to the consolidated financial statements, the Company changed its method of accounting for share based payments effective October 1, 2005 in accordance with the adoption of Statement of Financial Accounting Standards No. 123R Share Based Payment. Also, as discussed in Note 14 to the consolidated financial statements, the Company changed the manner in which it accounts 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2007, 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 21, 2008 expressed an unqualified opinion on the Company's internal control over financial reporting.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 21, 2008

## CRYOLIFE, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31,	
	2007	2006
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 14,460	\$ 4,133
Marketable securities, at market	2,987	3,965
Restricted securities		571
<b>Receivables:</b>		
Trade accounts, less allowance for doubtful accounts of \$180 in 2007 and \$130 in 2006	12,311	12,553
Income taxes		148
Other	1,373	1,255
<b>Total receivables</b>	<b>13,684</b>	<b>13,956</b>
Deferred preservation costs, net	26,903	19,278
Inventories	5,607	5,153
Prepaid expenses and other assets	1,811	2,329
<b>Total current assets</b>	<b>65,452</b>	<b>49,385</b>
<b>Property and equipment:</b>		
Equipment	19,472	19,911
Furniture and fixtures	5,295	5,196
Leasehold improvements	28,946	28,937
Construction in progress	38	30
Total property and equipment	53,751	54,074
Less accumulated depreciation and amortization	35,111	32,684
<b>Net property and equipment</b>	<b>18,640</b>	<b>21,390</b>
<b>Other assets:</b>		
Patents, less accumulated amortization of \$1,648 in 2007 and \$1,372 in 2006	3,906	4,226
Trademarks and other intangibles, less accumulated amortization of \$417 in 2007 and \$192 in 2006	3,213	3,362
Deferred income taxes	148	
Other	1,325	1,502
<b>Total assets</b>	<b>\$ 92,684</b>	<b>\$ 79,865</b>

See accompanying notes to consolidated financial statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31,	
	2007	2006
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,956	\$ 2,475
Accrued compensation	2,963	2,599
Accrued expenses	5,611	5,637
Accrued procurement fees	5,161	4,734
Deferred income	1,111	1,223
Deferred income taxes	175	26
Derivative liability		235
Line of credit	4,506	4,507
Current maturities of capital lease obligations	43	40
Other current liabilities	2,176	1,437
<b>Total current liabilities</b>	<b>24,702</b>	<b>22,913</b>
Capital lease obligations, less current maturities	81	124
Deferred income taxes		200
Other	5,274	4,540
<b>Total liabilities</b>	<b>30,057</b>	<b>27,777</b>
<b>Shareholders equity:</b>		
Preferred stock \$.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, 325 shares issued and outstanding in 2006		3
Common stock \$.01 par value per share, 75,000 shares authorized, 28,526 shares issued in 2007 and 25,813 shares issued in 2006	285	258
Additional paid-in capital	120,562	115,605
Retained deficit	(52,981)	(59,177)
Accumulated other comprehensive income		160
Treasury stock at cost, 949 shares in 2007 and 906 shares in 2006	(5,239)	(4,761)
<b>Total shareholders equity</b>	<b>62,627</b>	<b>52,088</b>
<b>Total liabilities and shareholders equity</b>	<b>\$ 92,684</b>	<b>\$ 79,865</b>

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,		
	2007	2006	2005
<b>Revenues:</b>			
Preservation services	\$ 49,002	\$ 40,078	\$ 30,307
Products	44,712	41,037	38,932
Other	1,049	196	43
<b>Total revenues</b>	<b>94,763</b>	<b>81,311</b>	<b>69,282</b>
<b>Costs and expenses:</b>			
Preservation services (including write-downs of \$819 in 2007, \$4,537 in 2006, and \$1,797 in 2005)	28,433	29,958	24,357
Products	7,108	7,463	8,065
General, administrative, and marketing	46,470	41,545	53,225
Gain on exit activities		(2,620)	
Research and development	4,453	3,547	3,724
Interest expense	677	657	346
Interest income	(527)	(409)	(531)
Change in valuation of derivative	821	121	(140)
Other (income) expense, net	(241)	399	199
<b>Total costs and expenses</b>	<b>87,194</b>	<b>80,661</b>	<b>89,245</b>
<b>Income (loss) before income taxes</b>	<b>7,569</b>	<b>650</b>	<b>(19,963)</b>
Income tax expense (benefit)	368	285	(428)
<b>Net income (loss)</b>	<b>\$ 7,201</b>	<b>\$ 365</b>	<b>\$ (19,535)</b>
Effect of preferred stock dividends	(243)	(973)	(777)
<b>Net income (loss) applicable to common shares</b>	<b>\$ 6,958</b>	<b>\$ (608)</b>	<b>\$ (20,312)</b>
<b>Income (loss) per common share:</b>			
Basic	\$ 0.26	\$ (0.02)	\$ (0.85)
Diluted	\$ 0.26	\$ (0.02)	\$ (0.85)
<b>Weighted average common shares outstanding:</b>			
Basic	26,331	24,829	23,959
Diluted	26,974	24,829	23,959

See accompanying notes to consolidated financial statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2007	2006	2005
<b>Net cash flows from operating activities:</b>			
Net income (loss)	\$ 7,201	\$ 365	\$ (19,535)
Adjustments to reconcile net income (loss) to net cash from operating activities:			
Gain on sale of marketable equity securities			(3)
Loss on disposal of assets	130	426	108
Depreciation of property and equipment	3,929	4,560	4,759
Amortization	527	284	277
Provision for doubtful accounts	167	65	57
Write-down of deferred preservation costs and inventories	819	1,758	1,797
Net non-cash gain on exit activities		(31)	
Deferred income taxes	(961)	226	
Non-cash compensation	2,127	1,620	322
Change in valuation of derivative	821	121	(140)
Other non-cash adjustments to income	(220)	(182)	1,771
Changes in operating assets and liabilities:			
Trade and other receivables	(23)	(2,431)	(1,854)
Income taxes	30	213	1,024
Deferred preservation costs	(8,444)	(9,800)	(6,934)
Inventories	(454)	(600)	158
Prepaid expenses and other assets	685	397	27
Accounts payable	842	155	(712)
Accrued expenses and other liabilities	2,116	1,783	361
<b>Net cash flows provided by (used in) operating activities</b>	<b>9,292</b>	<b>(1,071)</b>	<b>(18,517)</b>
<b>Net cash flows from investing activities:</b>			
Capital expenditures	(1,207)	(1,642)	(989)
Net proceeds from sale of assets	19	13	12
Purchases of marketable securities	(12,331)	(17,385)	(21,690)
Sales and maturities of marketable securities	14,155	18,562	20,841
Other	(190)	(105)	(208)
<b>Net cash flows provided by (used in) investing activities</b>	<b>446</b>	<b>(557)</b>	<b>(2,034)</b>
<b>Net cash flows from financing activities:</b>			
Proceeds from debt issuance	532	710	4,847
Principal payments of debt	(533)	(553)	(317)
Principal payments on capital leases	(40)	(570)	(741)
Proceeds from financing of insurance policies	1,912	2,349	2,482
Principal payments on short-term note payable	(1,912)	(2,349)	(2,482)
Proceeds from exercise of options and issuance of stock	1,748	468	372
Proceeds from equity offering			19,098
Payment of preferred stock dividend and make whole payments	(486)	(973)	(533)
Purchase of treasury stock	(478)	(50)	
<b>Net cash flows provided by (used in) financing activities</b>	<b>743</b>	<b>(968)</b>	<b>22,726</b>
<b>Increase (decrease) in cash</b>	<b>10,481</b>	<b>(2,596)</b>	<b>2,175</b>

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Effect of exchange rate changes on cash	(154)	98	(257)
Cash and cash equivalents, beginning of year	4,133	6,631	4,713
<b>Cash and cash equivalents, end of year</b>	<b>\$ 14,460</b>	<b>\$ 4,133</b>	<b>\$ 6,631</b>

See accompanying notes to consolidated financial statements.

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## 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	Treasury Stock		Total Shareholders Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
<b>Balance at December 31, 2004</b>			24,805	\$ 248	\$ 94,624	\$ (38,257)	\$ 361	(1,390)	\$ (7,316)	\$ 49,660
Net loss						(19,535)				(19,535)
Other comprehensive loss							(238)			(238)
Comprehensive loss										(19,773)
Equity offering	417	4			18,054					18,058
Conversion of preferred stock and dividend make-whole payments	(92)	(1)	694	7	779					785
Dividend payments on preferred stock						(777)				(777)
Exercise of options			36		111			(2)	(17)	94
Equity compensation			(3)		322					322
Employee stock purchase plan			50	1	278					279
Payment of treasury shares					(661)			500	2,634	1,973
<b>Balance at December 31, 2005</b>	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
<b>Balance at December 31, 2006</b>	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	(325)	(3)	2,100	21	1,038					1,056

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payments									
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
<b>Balance at December 31, 2007</b>	<b>28,526</b>	<b>\$ 285</b>	<b>\$ 120,562</b>	<b>\$ (52,981)</b>	<b>\$</b>	<b>(949)</b>	<b>\$ (5,239)</b>	<b>\$</b>	<b>62,627</b>

See accompanying notes to consolidated financial statements.



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**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), incorporated January 19, 1984 in Florida, develops and commercializes biomaterials and implantable medical devices and preserves and distributes human tissues for cardiac and vascular transplant applications. The Company's biomaterials and implantable medical devices include BioGlue® Surgical Adhesive (BioGlue), CryoLife-O Brien Stentless Porcine Aortic Bioprosthesis, and ProPatch Soft Tissue Repair Matrix (ProPatch). Additionally, the Company distributes CardioWrap for MAST BioSurgery, Inc (MAST). Historically, the Company preserved and distributed human orthopaedic tissue for transplant applications. CryoLife ceased processing human orthopaedic tissue effective January 1, 2007 but will continue to market and distribute its existing orthopaedic tissues through June 30, 2008.

CryoLife distributes preserved human cardiac, vascular, and orthopaedic tissue to implanting institutions throughout the U.S., Canada, and Europe, although distribution of orthopaedic tissue is being phased out. 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. CryoLife is authorized to distribute BioGlue throughout the United States and in more than 70 other countries for designated applications. In the U.S. BioGlue is U.S. Food and Drug Administration (FDA) approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue under Conformité Européene (CE) Mark product certification in the European Economic Area (EEA) for soft tissue repair procedures (which includes cardiac, vascular, pulmonary, and additional soft tissue repair procedures). 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. CryoLife also distributes the CryoLife-O Brien Stentless Porcine Aortic Bioprosthesis in Europe. In December 2006 CryoLife received 510(k) clearance from the FDA for its ProPatch Soft Tissue Repair Matrix (ProPatch). In 2007 CryoLife began exclusive distribution of CardioWrap, a product of MAST, in the U.S. and the United Kingdom. CardioWrap is a bioresorbable sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries where the patient may face re-operation within six months.

***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 product liability claims, claims incurred but not reported, and amounts recoverable from insurance companies, cost of share based payments and the related income statement expense or pro-forma expense, 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 in accordance with the American Institute of Certified Public Accountants (AICPA) Statement of Position 93-7 Reporting on Advertising Costs (SOP 93-7). 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 \$1.0 million, \$796,000, and \$700,000 for the years ended December 31, 2007, 2006, and 2005, 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 Defense Appropriations Conference Report (the 2005 DOD Grant) and the U.S. Congress 2006 Defense Appropriations Conference Report (the 2006 DOD Grant) for the continued development of protein hydrogel technology for use on the battlefield. 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, 2007 and 2006 \$1.0 million and \$770,000, respectively, of cash equivalents and deferred income were recorded on the Company's Consolidated Balance Sheets related to the 2005 and 2006 DOD grants.

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

	2007	2006	2005
<b>Cash paid during the year for:</b>			
Interest	\$ 691	\$ 635	\$ 276
Income taxes	416	34	216
<b>Non-cash investing and financing activities:</b>			
Payment of make whole payments in common stock	\$ 1,056	\$	\$ 786
Non-cash acquisition of intangibles		2,909	
Assets acquired under capital leases		180	
Payment of legal settlement in stock			1,973
Accounts payable and accrued expenses for the purchase of property and equipment			21

**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) 115 (as amended) Accounting For Certain Investments in Debt and Equity Securities (SFAS 115). Each month 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, 2007 \$3.0 million of marketable securities were designated as available-for-sale. As of December 31, 2006 \$4.0 million of marketable securities were designated as available-for-sale, and \$571,000 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 product liability insurance policies and, therefore, they were reported as restricted securities on the December 31, 2006 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. Tissue is procured from deceased human donors by organ and tissue procurement agencies, 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 ARB No. 43 Chapter 4, Inventory Pricing (ARB 43). 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, double 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 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 \$453,000, \$1.2 million, and \$1.8 million in the years ended December 31, 2007, 2006, and 2005, respectively, for the value of certain deferred preservation costs that exceeded market value. The amount of these write-downs are primarily due to excess current period tissue processing costs that exceeded market value based on recent average service fees. Actual results may differ from these estimates.

The Company also recorded write-downs of \$366,000 for the year ended December 31, 2007 due to the impairment of certain vascular and orthopaedic tissues. The Company also recorded write-downs of \$588,000 for the year ended December 31, 2006 due to the impairment of certain 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 also recorded a write-down of \$2.8 million in the year ended December 31, 2006 due to the impairment of certain orthopaedic tissues and processing materials as a result of the exchange and service agreement with Regeneration Technologies, Inc., (the RTI Agreement) discussed in Note 2 below. This write-down was based on the Company's estimate of the tissues that would be shipped during the 18-month period subsequent to December 31, 2006 in which the Company can continue to distribute its existing 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. As of December 31, 2006 deferred preservation costs consisted of \$4.7 million for allograft heart valve tissues, \$1.0 million for non-valved cardiac tissues, \$11.3 million for vascular tissues, and \$2.3 million for orthopaedic tissues.

### ***Inventories***

Inventories are comprised of implantable surgical adhesives and other implantable 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, double freight, and rehandling costs and requires allocation of fixed production overheads to be based on the normal capacity of the production facilities as necessary 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, procurement contracts, and access to the procurement of cardiac and vascular human tissues previously received by RTI as a result of the RTI Agreement discussed in Note 2 below. The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. 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).

As of December 31, 2007 and 2006 gross 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
<b><u>December 31, 2007</u></b>			
Patents	\$ 5,554	\$ 1,648	17 Years
Customer lists	611	187	3 Years
Non-compete agreement	381	38	10 Years
<b><u>December 31, 2006</u></b>			
Patents	\$ 5,598	\$ 1,372	17 Years
Customer lists	515		3 Years
Non-compete agreement	381		10 Years

As of December 31, 2007 and 2006 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	2007	2006
Trademarks	\$ 433	\$ 453

Procurement contracts

2,013

2,013

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As of December 31, 2007 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2008	2009	2010	2011	2012	Total
Amortization expense	\$ 549	\$ 547	\$ 357	\$ 334	\$ 318	\$ 2,105

***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 year ended December 31, 2007 the Company did not experience any factors that indicated an SFAS 144 impairment review was warranted. For the years ended December 31, 2006 and 2005, the Company performed an SFAS 144 impairment analysis, due to a variety of triggering factors including its operating performance. In these periods the undiscounted future cash flows of the Company's asset groups exceeded their carrying values. Therefore, management concluded that there was not an impairment of the Company's long-lived tangible and amortizing intangible assets.

SFAS No. 142 requires that goodwill resulting from business acquisitions and other non-amortizing intangible assets be subject to annual impairment testing. The Company's non-amortizing intangible assets as of December 31, 2007 consist of trademarks and, as a result of the RTI Agreement discussed in Note 2 below, procurement contracts and access to the procurement of cardiac and vascular human tissues previously received by RTI. In accordance with SFAS 142, the Company performed an analysis on its non-amortizing intangible assets as of December 31, 2007. 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, 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.

#### ***Product Liability Claims***

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. The Company maintains claims-made insurance policies to mitigate its 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. The Company periodically evaluates its exposure to unreported product liability claims, and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In January 2008 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed as of December 31, 2007. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby,

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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

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claims model blending the Company's historical average cost per claim with industry claims data. The Company records accruals for estimated costs for unreported 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 product liability claims, the Company periodically evaluates its exposure related to settled but unpaid claims and pending product liability 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 product liability claims based on its analysis.

#### ***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 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 when, as a result of this analysis, management believes it is more likely than not that its deferred tax assets will not be realized. In assessing the recoverability of its deferred tax assets at December 31, 2007 the Company reviewed its historical operating results, including the reasons for its operating losses in prior years and uncertainties regarding projected future operating results. Based on the results of this analysis, discussed further below, at December 31, 2007 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized.

Based on the Company's results for the year ended December 31, 2007 and its projections for 2008, the Company anticipates that it will utilize a portion of its net operating loss carryforwards in the 2008 income tax year to offset its U.S. taxable income, as it did in the 2007 and 2006 tax years. Although CryoLife is beginning to utilize its net operating loss carryforwards, the Company currently believes that a change in its determination of the recoverability of its deferred tax assets is not yet warranted. CryoLife will continue to evaluate its determination in accordance with the guidance in SFAS 109, which indicates the Company's net losses in recent years constitute significant evidence against the recoverability of its deferred tax assets that is difficult to overcome. CryoLife will reverse the remaining valuation allowance, or a portion thereof, when and if its deferred tax assets meet the SFAS 109 more likely than not standard for recognition. Also, the realizability of the Company's deferred tax assets could be limited in future periods following a change in control as mandated by 382 of the Internal Revenue Code of 1986, as amended.

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. As of December 31, 2006 the Company had a total of \$33.0 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$226,000 related to taxes in a foreign jurisdiction.

The tax years 2004-2007 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.



The Company adopted SFAS 123 Revised Share-Based Payment ( SFAS 123R ) on October 1, 2005. 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 adopted SFAS 123R using the modified version of prospective application, as defined in SFAS 123R.

In periods prior to October 1, 2005 the Company elected to follow Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees and related interpretations ( APB 25 ) in accounting for its employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equaled the market price of the underlying stock on the date of the grant, no compensation expense was recognized. In accordance with APB 25 the compensation recorded for employee stock grants was equal to the value of the grant on the measurement date, the date of the grant, as determined by the closing price of the Company's common stock on that date. Some employee stock grants vest in future periods based on a requirement of continued service to the Company. For these stock grants the amount of the stock grant was recorded as additional paid-in capital in the equity section of the Company's Consolidated Balance Sheets, and was expensed over the vesting period.

Prior to the adoption of SFAS 123R, the Company followed the provisions of SFAS 123 which required that the Company provide pro forma information regarding net income (loss) and income (loss) per common share and that the pro forma information be determined as if the Company had accounted for its employee stock options granted under the fair value method of that statement. The fair values for the options accounted for under APB 25 were estimated at the dates of grant using a Black-Scholes option-pricing model. For purposes of pro forma disclosures, the estimated fair values of the options were amortized to expense over the options' vesting periods.

#### ***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***

In accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities ( SFAS 133 ), 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, 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 and derivative liabilities, approximated fair value at December 31, 2007 and 2006.

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

In December 2007 the FASB issued SFAS No. 141 Revised Business Combinations ( SFAS 141R ). SFAS 141R revises the accounting and disclosure requirements for business combinations and is effective for fiscal years beginning after December 15, 2008. The Company is in the process of evaluating the impact of SFAS 141R on its results of operations and financial position.

The Company will be required to adopt SFAS No. 157 Fair Value Measurements ( SFAS 157 ) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The Company does not anticipate that the adoption of SFAS 157 will have a material affect on its results of operations or financial position.

The Company will be required to adopt SFAS No. 159 The Fair Value Option for Financial Assets and Liabilities ( SFAS 159 ) for the fiscal year beginning January 1, 2008. SFAS 159 provides the option to report certain financial assets and liabilities at fair value, with the intent to mitigate volatility in financial reporting that can occur when related assets and liabilities are measured differently. The Company does not expect to voluntarily implement the optional fair value measurements portions of SFAS 159 for eligible items. Therefore, the Company does not anticipate that the adoption of SFAS 159 will have a material affect on its results of operations or financial position.

## 2. Exchange and Service Agreement

On December 19, 2006 CryoLife announced that it had entered into an exchange and service agreement (the RTI Agreement ) with Regeneration Technologies, Inc., and certain of its affiliates, (collectively, 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 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 will continue to distribute its existing orthopaedic tissue inventory, and RTI will continue to distribute its existing cardiac and vascular tissue inventory, through June 30, 2008. After that date CryoLife will become entitled to distribute RTI s remaining cardiac and vascular tissue inventory, and RTI will become entitled to distribute CryoLife s remaining orthopaedic tissue inventory. CryoLife will pay RTI a commission with respect to any of CryoLife s orthopaedic tissue distributed by RTI and will receive a commission from RTI with respect to any RTI cardiac tissue distributed by CryoLife. 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 can continue 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 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. 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 and based upon a valuation study prepared by an independent valuation consultant.

### 3. Cash Equivalents and Marketable Securities

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

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

December 31, 2006	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	\$ 2,484	\$	\$ 2,484
Marketable securities:			
Government entity sponsored debt securities	\$ 3,964	\$ 1	\$ 3,965
Restricted securities:			
Government entity sponsored debt securities	\$ 571	\$	\$ 571

There were no gross realized gains or losses on sales of available-for-sale securities for the years ended December 31, 2007 and 2006.

Differences between cost and market listed above, consisting of a net unrealized holding gain of \$3,000 and \$1,000 at December 31, 2007 and 2006, respectively, are included as a separate component of other comprehensive income in the shareholders' equity section of the Consolidated Balance Sheets.

At December 31, 2007 and 2006 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):

	2007	2006
Raw materials	\$ 2,956	\$ 3,048
Work-in-process	650	479
Finished goods	2,001	1,626
Total Inventories	\$ 5,607	\$ 5,153

### 5. Debt

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. as lender (the "Credit Agreement"). The Credit Agreement provided for a revolving credit facility in an aggregate amount equal to the lesser of \$15.0 million (including a letter of credit sub facility of up to an aggregate of \$2.0 million) or a borrowing base determined in accordance with the terms of the Credit Agreement. Generally, the borrowing base was 20% of the appraised value of the business of CryoLife, reduced by specified lender reserves. The Credit Agreement placed limitations on the amount that the Company could borrow, and included various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife either (i) maintain quarterly a minimum aggregate borrowing availability under the Credit Agreement, less certain payables incurred outside the Company's historical practices, plus unrestricted cash and cash equivalents, as defined ("Availability"), of at least \$12.5 million or (ii) achieve as of each quarter end a minimum level of earnings before extraordinary gains, interest, taxes, depreciation, and amortization ("EBITDA"), BioGlue gross margins of at least 70% for the preceding twelve months, as well as Availability of at least \$5.0 million. In the first quarter of 2007 the



Company obtained a \$500,000 letter of credit sub facility relating to one of the Company's product liability insurance policies. This reduced the Company's aggregate borrowing capacity under the Credit Agreement to \$14.5 million. The Credit Agreement also included customary conditions on incurring new indebtedness and prohibited payments of cash dividends on the Company's common stock. There was no restriction on the payment of stock dividends. Commitment fees were paid based on the unused portion of the facility.

Amounts borrowed under the Credit Agreement were secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bore interest at the bank's prime rate plus 1%, which aggregated 8.25% as of December 31, 2007 and 9.25% as of December 31, 2006. As of December 31, 2007 and 2006 the outstanding balance of the Credit Agreement was \$4.5 million.

The Credit Agreement expired on February 8, 2008, at which time the outstanding principal balance of \$4.5 million was paid from cash on hand. The Company also remitted approximately \$500,000 as collateral to cover the remaining term of the letter of credit agreement discussed above.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In the second quarter of 2007 the Company entered into two agreements to finance approximately \$1.4 million and \$478,000 in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. 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, 2007 the aggregate outstanding balance under these agreements was zero.

In the second quarter of 2006 the Company entered into two agreements to finance approximately \$1.6 million and \$715,000 in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. The amounts financed accrued interest at 6.71% and 6.7%, respectively, and were payable in equal monthly payments over a nine month and an eight month period, respectively. As of December 31, 2007 the aggregate outstanding balance under these agreements was zero.

Total interest expense was \$677,000, \$657,000, and \$346,000 in 2007, 2006, and 2005 respectively.

## 6. Convertible Preferred Stock

On March 18 and April 19, 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 on the first day of January, April, July, and October, commencing July 1, 2005. Any dividends were required to be declared by the Company's Board of Directors and to come from funds legally available for dividend payments. On March 13, 2007 the Company declared a dividend of \$0.75 per share on its Preferred Stock. The dividend of approximately \$243,000 was paid on April 2, 2007 to shareholders of record on March 22, 2007. No dividends were declared in the remainder of 2007. The Company made cash payments of \$486,000, \$973,000, and \$533,000 in the years ended December 31, 2007, 2006, and 2005, 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 4,600,000 shares of common stock for issuance upon conversion. Through June 4, 2007 holders had voluntarily converted a cumulative 139,000 shares of Preferred Stock into 867,000 shares of common stock, of which 47,000 shares of Preferred Stock were voluntarily converted into 292,000 shares of common stock in the second quarter of 2007.

The Preferred Stock contained provisions that allowed the Company to automatically 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 1,726,000 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 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, 2007 there were no outstanding shares of Preferred Stock as a result of the second quarter automatic conversion of the Preferred Stock to common stock.

## **7. Derivatives**

In accordance with SFAS 133, 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). 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 prior to the conversion of the Preferred Stock as discussed in Note 6 above. Changes in the fair value of the Derivative were recognized in the line item change in valuation of derivative as a non-operating income/expense on the Company's Consolidated Statements of Operations.

The Company determined the fair value of the Derivative to be \$1.0 million on March 18, 2005, the date of issuance. The Company determined the fair value of the Derivative related to the issuance of additional Preferred Stock upon exercise of the underwriter's over allotment option to be \$32,000 on April 19, 2005, the date of issuance. The proceeds from the Preferred Stock recorded on the Consolidated Balance Sheets were reduced by these amounts, which were allocated to the Derivative.

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. The Company recorded other income of \$140,000 for the year ended December 31, 2005 related to voluntary conversions of the Preferred Stock to common stock and the quarterly revaluations of the Derivative.

At December 31, 2007 there was no remaining derivative liability as a result of the second quarter 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 housing for expatriated employees, 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 the offsetting accrual of \$1.3 million for the years ended December 31, 2007 and 2006, respectively, recorded in other long-term liabilities.

Future minimum lease payments under non-cancelable leases as of December 31, 2007 are as follows (in thousands):

	Leases	
	Capital	Operating
2008	\$ 53	\$ 2,415
2009	52	2,275
2010	35	2,153
2011		2,145
2012		2,187
Thereafter		6,337
<b>Total minimum lease payments</b>	<b>\$ 140</b>	<b>\$ 17,512</b>
Less amount representing interest at a weighted average 9% interest rate		16
<b>Present value of net minimum lease payments</b>		<b>124</b>
Less current maturities		43
<b>Capital lease obligations, less current maturities</b>	<b>\$ 81</b>	

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

	2007	2006
Equipment	\$ 937	\$ 937
Furniture and fixtures	765	765
Leasehold improvements	1,244	1,244
<b>Total</b>	<b>\$ 2,946</b>	<b>\$ 2,946</b>

The amortization of the Company's assets acquired under capital leases is recorded as depreciation expense based on the life of the lease. Total rental expense for operating leases was \$2.3 million, \$2.3 million, and \$2.4 million for 2007, 2006, and 2005 respectively. In 2005 the Company recorded rental income of \$258,000 under a sublease that terminated during 2005.

### *Litigation, Claims, and Assessments*

#### *Product Liability Claims*

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. As of February 15, 2008 two product liability lawsuits were pending against the Company arising out of the Company's allograft heart valve and orthopaedic tissue preservation services. These lawsuits are covered by product liability insurance and are in the pre-discovery or discovery stages. Other parties have made complaints that may result in lawsuits in future periods.

The Company performed an analysis as of December 31, 2007 of the pending product liability lawsuits and other claims based on settlement negotiations to date and advice from counsel. As of December 31, 2007 the Company had accrued a total of approximately \$330,000 for the pending product liability lawsuits. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the December 31, 2007 Consolidated Balance Sheet. As of December 31, 2006 the Company had accrued a total of approximately \$330,000 for a pending product liability lawsuit. The lawsuit to which this accrual related was settled in the first quarter of 2007. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the December 31, 2006 Consolidated Balance Sheet.

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On April 1, 2007 the Company bound coverage for the 2007/2008 insurance policy year. This policy is a five-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2008 and reported during the period April 1, 2007 through March 31, 2008 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its 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

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incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In January 2008 the Company retained an independent actuarial firm to perform estimates of the unreported claims as of December 31, 2007. The independent firm estimated the unreported product loss liability 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 independent actuarial firm used a number of assumptions in order to estimate the unreported product 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 for accident years 2001 through 2007 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 50% lower than non-BioGlue claims per million dollars of revenue. The 50% 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 product liability loss, but the accuracy of the actuarial firm's 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.

Based on the actuarial valuation performed in January 2008 as of December 31, 2007, the Company estimated that its liability for unreported product liability claims was \$6.3 million as of December 31, 2007. The \$6.3 million balance is included as a component of accrued expenses and other current liabilities of \$3.2 million and other long-term liabilities of \$3.1 million on the December 31, 2007 Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$11.9 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of December 31, 2007, \$2.4 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.4 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.3 million on the December 31, 2007 Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to December 31, 2007. Actual results may differ from this estimate.

As of December 31, 2006 the Company accrued \$6.6 million for unreported product liability claims and recorded a receivable of \$2.3 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$6.6 million accrual was included as a component of accrued expenses and other current liabilities of \$3.3 million and other long-term liabilities of \$3.3 million on the December 31, 2006 Consolidated Balance Sheet. The \$2.3 million insurance recoverable was included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.2 million on the December 31, 2006 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.

**Class Action Lawsuit**

Several putative class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, that principally alleged that the Company made misrepresentations and omissions relating to product safety and the Company did not comply with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint sought certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation.

On July 21, 2005 the Company reached an agreement in principle to settle the securities class action lawsuit. The settlement resolved all claims asserted against the Company and the individual defendants in this case. The terms of the settlement included a total settlement of \$23.25 million in cash and stock. The cash payment, which included approximately \$12.0 million in insurance proceeds and approximately \$9.3 million in Company funds, was paid in the third and fourth quarters of 2005. The Company transferred 500,000 shares valued at \$2.0 million in the fourth quarter of 2005 in payment of the stock portion of the settlement. The Company and the individual defendants have denied any wrongdoing and liability whatsoever, and the settlement does not contain any admission of liability.

**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 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.

As of December 31, 2007 the Company is authorized to grant under the Company's plans up to the following number of shares:

<b>Plan</b>	<b>Shares</b>
1998 Long-Term Incentive Plan	900,000
2002 Stock Incentive Plan	974,000
2004 Employee Stock Incentive Plan	2,000,000

As of December 31, 2007 and 2006 there were 1.3 million and 1.9 million, respectively, shares of common stock reserved for future issuance under the Company's stock option and stock incentive plans after considering prior grants. 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.

**Stock Grants**

In February 2007 the Compensation Committee of the Company's Board of Directors approved the terms of the Company's 2007 performance-based bonus plans to recognize the performance of the Company's executives and managers. A portion of the awards to be issued under these plans will be paid in Company stock pursuant to the Company's existing stock incentive plans, if the required performance is achieved. The Company recorded a liability of \$788,000 related to this stock grant during the year ended December 31, 2007. The Company expects to pay out cash and stock related to these bonus plans in the first quarter of 2008.



In 2007 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 172,000 shares of common stock. The stock, which had an aggregate value of \$1.6 million, was valued based on the stock prices on the respective grant dates. The grants of stock in 2007 include 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 entire 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. The stock, which had an aggregate value of \$254,000, was valued based on the stock prices on the respective grant dates. 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.

In 2005 there were no stock grants issued by the Compensation Committee of the Company's Board of Directors.

As of December 31, 2007 and 2006 CryoLife had a total of \$606,000 and \$73,000, respectively, in additional paid-in capital related to stock grants in the shareholder's equity section of the Company's Consolidated Balance Sheets.

A summary of stock grant activity for the years ended December 31, 2007, 2006, and 2005 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2004	32,000	\$ 6.91
Vested	(29,000)	6.91
Canceled	(3,000)	6.91
Unvested at December 31, 2005		
Granted	54,000	4.70
Vested	(41,000)	4.45
Unvested at December 31, 2006		
Granted	172,000	9.61
Vested	(82,000)	8.06
Canceled	(15,000)	9.26
Unvested at December 31, 2007		
	88,000	\$ 10.48

### *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 383,000, 948,000, and 115,000 shares in 2007, 2006, and 2005, 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.

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A summary of Company's stock option transactions under the plans as of and for the year ended December 31, 2007, 2006, and 2005 follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2004	2,293,000	\$ 11.04	2.78	\$ 3,354,000
Granted	115,000	7.08		
Exercised	(36,000)	3.14		
Forfeited	(126,000)	5.62		
Expired	(492,000)	10.24		
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	(179,000)	28.38		
Outstanding at December 31, 2007	1,858,000	\$ 6.31	3.19	\$ 3,993,000
Vested and Expected to Vest	1,777,000	\$ 6.33	0.84	\$ 3,817,000
Exercisable at December 31, 2007	809,000	\$ 6.74	1.92	\$ 1,768,000

The following table summarizes information concerning outstanding and exercisable options at December 31, 2007:

Range of Exercise Price	Options Outstanding			Options Exercisable		
	Average Number Outstanding	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ 2.20-4.78	381,000	2.52	\$ 3.95	162,000	\$ 3.48	
4.88-5.05	455,000	3.54	5.02	152,000	5.00	
5.27-5.80	403,000	2.96	5.56	183,000	5.43	
6.16-8.70	482,000	3.87	7.87	200,000	7.28	
9.06-30.86	137,000	2.20	13.89	112,000	14.97	
\$ 2.20-30.86	1,858,000	3.19	\$ 6.31	809,000	\$ 6.74	

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

	2007	2006	2005
Weighted average fair value of options granted	\$ 3.98	\$ 2.64	\$ 3.51



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Intrinsic value of options exercised \$ 3,106,000 \$ 362,000 \$ 148,000  
Employees purchased common stock totaling 46,000, 76,000, and 50,000 shares in 2007, 2006, and 2005, 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 adopted SFAS 123R on October 1, 2005. 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 adopted SFAS 123R using the modified version of prospective application, as defined in SFAS 123R, and, as such, the adoption did not affect prior interim or year end periods.

In anticipation of the adoption of SFAS 123R on September 30, 2005, the Company's Board of Directors approved the accelerated vesting of unvested and out-of-the-money options with an exercise price equal to or greater than \$6.97, the closing price of the Company's common stock on September 29, 2005. Vesting was accelerated on a total of 167,000 options for 29 employees with a range of exercise prices from \$7.03 to \$31.99. As a result of this accelerated vesting, the Company recorded on a pro forma basis an additional expense of \$1.4 million for the three and nine months ended September 30, 2005. This expense is deducted from the net loss applicable to common shares as reported to calculate net loss applicable to common shareholders pro forma and the corresponding pro forma loss per share amounts in the tables below. The decision to initiate the accelerated vesting, which the Company believed to be in the best interest of the Company and its shareholders, was made primarily to reduce compensation expense related to unvested out-of-the-money options that might be recorded in future periods following the Company's adoption of SFAS 123R on October 1, 2005.

Beginning October 1, 2005 both the Company's 15% discount and the look back portion of ESPP stock purchases are considered a stock option, and as such, must be expensed as stock compensation on the Company's Consolidated Statements of Operations in accordance with SFAS 123R.

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, 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.

During the fourth quarter of 2007 the Company's valuation analyst performed its annual review of the underlying assumptions the Company uses in its Black-Scholes model for the valuation of options in accordance with SFAS 123R. During this review the Company evaluated the volatility, expected term, and forfeitures. The Company began using these revised assumptions for all options granted beginning in the fourth quarter of 2007.

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

	Twelve Months Ended December 31, 2007		Twelve Months Ended December 31, 2006	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	.600	.527	.650	.417
Risk-free interest rate	4.62%	4.64%	4.80%	4.39%
Expected life of options	3.4 Years	.24 Years	4.1 Years	.24 Years

	Three Months Ended December 31, 2005	
	Stock Options	ESPP Options
Expected dividend yield	0%	0%
Expected stock price volatility	.650	.525
Risk-free interest rate	4.32%	3.55%
Expected life of options	5 Years	.25 Years

The modified prospective approach requires that the Company expense over the remaining vesting period the value it previously calculated under the fair value method for stock options issued prior to the adoption of SFAS 123R. As of October 1, 2005, the date of adoption, there was approximately \$593,000 in total unrecognized compensation cost related to



unvested stock, before considering estimated forfeitures. That cost is expected to be recognized based on the vesting of the underlying option awards through the quarter ended June 30, 2010.

The following table summarizes stock compensation expenses:

	Year Ended December 31,		
	2007	2006	2005
Stock grant expense	\$ 1,262,000	\$ 768,000	\$ 202,000
Stock option expense	865,000	852,000	120,000
<b>Total stock compensation expense</b>	<b>\$ 2,127,000</b>	<b>\$ 1,620,000</b>	<b>\$ 322,000</b>

Included in this total stock compensation expense were expenses related to common stock grants, options issued prior and 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 inventory and deferred preservation costs. The Company capitalized \$87,000, \$75,000, and \$37,000 in the years ended December 31, 2007, 2006, and 2005, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs. The Company did not recognize a tax benefit, or a related operating cash outflow and financing cash inflow, related to the compensation expense recorded in the years ended December 31, 2007, 2006, and 2005 as the Company is maintaining a full valuation allowance on its deferred tax assets. See Note 14 for additional discussions of the Company's income tax valuation.

As of December 31, 2007, 2006, and 2005 there was approximately \$2.7 million, \$2.1 million, and \$495,000, respectively, in total unrecognized compensation costs related to nonvested share-based compensation arrangements, before considering the effect of expected forfeitures. As of December 31, 2007, 2006, and 2005 this expense is expected to be recognized over a weighted average period of 1.6 years, 2.0 years, and 1.5 years, respectively.

In periods prior to October 1, 2005 the Company elected to follow APB 25 in accounting for its employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equaled the market price of the underlying stock on the date of the grant, no compensation expense was recognized. In accordance with APB 25, the compensation recorded for employee stock grants was equal to the value of the grant on the measurement date, the date of the grant, as determined by the closing price of the Company's common stock on that date. Some employee stock grants vested in future periods based on a requirement of continued service to the Company. For these stock grants, the amount of the stock grant was recorded as additional paid-in capital in the equity section of the Company's Consolidated Balance Sheets, and was expensed on a straight-line basis over the vesting period.

Pro forma information regarding net loss and loss per share was required by SFAS 123 for options accounted for under APB 25. SFAS 123 required that option valuation information be disclosed as if the Company accounted for its employee stock options granted under the fair value method of that statement. The fair values for these options were estimated at the dates of grant using a Black-Scholes option-pricing model and the following weighted-average assumptions were used:

	Nine Months Ended
	September 30, 2005 (unaudited)
Expected dividend yield	0%
Expected stock price volatility	.519
Risk-free interest rate	3.36%
Expected life of options	3.2 Years

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For purposes of pro forma disclosures, the estimated fair values of the options are amortized to expense over the options' vesting periods on a ratable basis. The Company's pro forma information follows (in thousands, except per share data):

	Nine Months Ended September 30, 2005 (unaudited)
Basic net loss applicable to common shares as reported	\$ (19,387)
Stock-based employee compensation:	
Add expense included in the determination of net loss	166
Deduct expense determined under the fair value based method for all awards	3,253
Basic net loss applicable to common shares pro forma	\$ (22,474)
Basic weighted-average shares	23,839
Basic loss per common share:	
As reported	\$ (0.81)
Pro forma	\$ (0.94)
	Nine Months Ended September 30, 2005 (unaudited)
Diluted net loss applicable to common shares as reported	\$ (19,387)
Stock-based employee compensation:	
Add expense included in the determination of net loss	166
Deduct expense determined under the fair value based method for all awards	3,253
Diluted net loss applicable to common shares pro forma	\$ (22,474)
Diluted weighted-average shares	23,839
Diluted loss per common share:	
As reported	\$ (0.81)
Pro forma	\$ (0.94)

#### 10. Shareholder Rights Plan

On November 1, 2005 the CryoLife, Inc. Board of Directors approved the amendment and restatement of the shareholder rights agreement, which was previously adopted by the Board in 1995. The Board of Directors determined that the amendment and extension of the rights agreement protected the long-term share value for the Company's shareholders. 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

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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

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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 (Loss)

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

	2007	2006	2005
Net income (loss)	\$ 7,201	\$ 365	\$ (19,535)
Unrealized gain (loss) on investments	2	3	(34)
Translation adjustment	(162)	34	(204)
Comprehensive income (loss)	\$ 7,041	\$ 402	\$ (19,773)

The tax effect on the change in unrealized gain (loss) on investments is zero, zero, and \$11,000 for the years ended December 31, 2007, 2006, and 2005, respectively.

At December 31, 2007, components of accumulated other comprehensive income consists of the following, (in thousands):

	2007	2006
Unrealized gain on investments	\$ 3	\$ 1
Translation adjustment	(3)	159
Total accumulated other comprehensive income	\$	\$ 160

## 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 2007, 2006, and 2005. Total Company contributions approximated \$357,000, \$340,000, and \$296,000 for 2007, 2006, and 2005, respectively. Additionally, the Company may make discretionary contributions to the Plan that is 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 2007 or 2005.

On May 16, 1996 the Company's shareholders approved the CryoLife, Inc. ESPP. 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. As of December 31, 2007 and 2006 there were 158,000 and 205,000, respectively, shares of common stock reserved under the ESPP and there were 742,000 and 695,000, respectively, shares issued under the plan.





**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):

	2007	2006	2005
Numerator for basic income (loss) per common share:			
Net income (loss)	\$ 7,201	\$ 365	\$ (19,535)
Effect of preferred stock <sup>a</sup>	(243)	(973)	(777)
Net income (loss) applicable to common shares	\$ 6,958	\$ (608)	\$ (20,312)
Denominator for basic loss per common share:			
Basic weighted-average common shares	26,331	24,829	23,959
Basic income (loss) per common share	\$ 0.26	\$ (0.02)	\$ (0.85)
Numerator for diluted income (loss) per common share:			
Net income (loss)	\$ 7,201	\$ 365	\$ (19,535)
Effect of preferred stock <sup>a, b</sup>	(243)	(973)	(777)
Net income (loss) applicable to common shares	\$ 6,958	\$ (608)	\$ (20,312)
Denominator for diluted income (loss) per common share:			
Basic weighted-average common shares	26,331	24,829	23,959
Effect of dilutive convertible preferred stock <sup>b</sup>			
Effect of dilutive stock options <sup>c</sup>	582		
Effect of contingently returnable shares	10		
Effect of contingent stock awards	51		
Adjusted weighted-average common shares	26,974	24,829	23,959
Diluted income (loss) per common share	\$ 0.26	\$ (0.02)	\$ (0.85)

<sup>a</sup> 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, 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, and increased the net loss applicable to common shares by \$777,000 for the year ended December 31, 2005.

<sup>b</sup> 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

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provisions of SFAS 128.

The amount of the accumulated dividend on Preferred Stock increased the Company's net loss by \$777,000 for the year ended December 31, 2005. The adjustment for voluntary conversions of Preferred Stock which took place during the period March 18, 2005 through December 31, 2005, and the adjustment for the quarterly revaluation of the derivative liability, would have instead increased the net loss applicable to common shareholders by \$140,000 for the year ended December 31, 2005. The common shares that would be issued to shareholders upon conversion of the remaining

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Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average common shares by 2.0 million for the year ended December 31, 2005. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

<sup>c</sup> Outstanding options to purchase the Company's common stock that would have resulted in additional dilutive common shares of 229,000 and 331,000 for the years ended December 31, 2006 and 2005, respectively, were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

In future periods the basic and diluted earnings per common share are expected to be affected by stock option transactions including the exercise of stock options and the issuance of additional stock options, contingently returnable shares, and contingent stock awards, as well as fluctuations in the fair value of the Company's common stock.

#### 14. Income Taxes

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

	2007	2006	2005
Domestic	\$ 7,570	\$ 358	\$ (19,956)
Foreign	(1)	292	(7)
<b>Income (loss) before income taxes</b>	<b>\$ 7,569</b>	<b>\$ 650</b>	<b>\$ (19,963)</b>

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

	2007	2006	2005
<b>Current:</b>			
Federal	\$ 253	\$ 85	\$ (557)
State	36	(58)	70
Foreign	79	(17)	123
	368	10	(364)
<b>Deferred:</b>			
Federal	\$	\$	\$
State			
Foreign		275	(64)
		275	(64)
<b>Income tax expense (benefit)</b>	<b>\$ 368</b>	<b>\$ 285</b>	<b>\$ (428)</b>

The Company's income tax expense of \$368,000 for 2007 was primarily due to alternative minimum tax on the Company's U.S. taxable income for 2007 that cannot be offset by the Company's net operating loss carryforwards, as well as taxes on the Company's wholly owned European subsidiary and certain state tax obligations.

Such amounts differ from the amounts computed by applying the U.S. federal income tax rate of 34% in 2007, 2006, and 2005 to pretax income as a result of the following (in thousands):

	2007	2006	2005
Tax expense (benefit) at statutory rate	\$ 2,573	\$ 221	\$ (6,787)
Increase (reduction) in income taxes resulting from:			

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Deferred tax valuation allowance	(3,257)	(330)	6,493
Research and development credit	(70)	(126)	(100)
Extraterritorial income exclusion		(49)	(54)
State income taxes, net of federal benefit	359	3	(142)
Loss (gain) on preferred stock dividend make-whole payments	279	41	(48)
Equity compensation	275	175	30
Non-deductible entertainment expenses	99	81	74
Disallowed executive compensation deduction	82		
Foreign income taxes	8	258	59
Other	20	11	47
	\$ 368	\$ 285	\$ (428)

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

	2007	2006
<b>Deferred tax assets:</b>		
Allowance for bad debts	\$ 67	\$ 50
Property	851	62
Accrued expenses	3,579	2,926
Loss carryforwards	19,300	23,603
Credit carryforwards	4,223	5,372
Deferred preservation costs and inventory reserves	1,106	1,467
Other	384	237
Less valuation allowance	(28,228)	(32,978)
<b>Net deferred tax assets</b>	<b>1,282</b>	<b>739</b>
<b>Deferred tax liabilities:</b>		
Intangible assets	(872)	(239)
Prepaid items	(410)	(441)
Other	(27)	(285)
<b>Total gross deferred tax liabilities</b>	<b>(1,309)</b>	<b>(965)</b>
<b>Total net deferred tax liabilities</b>	<b>\$ (27)</b>	<b>\$ (226)</b>

The Company periodically assesses the recoverability of its deferred tax assets, in accordance with SFAS No. 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 when, as a result of this analysis, management believes it is more likely than not that its deferred tax assets will not be realized. In assessing the recoverability of its deferred tax assets at December 31, 2007 the Company reviewed its historical operating results, including the reasons for its operating losses in prior years and uncertainties regarding projected future operating results. Based on the results of this analysis, discussed further below, at December 31, 2007 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized.

Based on the Company's results for the year ended December 31, 2007 and its projections for 2008, the Company anticipates that it will utilize a portion of its net operating loss carryforwards in the 2008 income tax year to offset its U.S. taxable income, as it did in the 2007 and 2006 tax years. Although CryoLife is beginning to utilize its net operating loss carryforwards, the Company currently believes that a change in its determination of the recoverability of its deferred tax assets is not yet warranted. CryoLife will continue to evaluate its determination in accordance with the guidance in SFAS 109, which indicates the Company's net losses in recent years constitute significant evidence against the recoverability of its deferred tax assets that is difficult to overcome. CryoLife will reverse the remaining valuation allowance, or a portion thereof, when and if its deferred tax assets meet the SFAS 109 more likely than not standard for recognition. Also, the realizability of the Company's deferred tax assets could be limited in future periods as mandated by 382 of the Internal Revenue Code of 1986, as amended.

The Company adopted the provisions of FIN 48 on January 1, 2007. As a result of the adoption of FIN 48, the Company recorded \$1.7 million in liabilities for unrecognized tax benefits 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. To the extent these unrecognized tax benefits are ultimately recognized, it would not affect the annual effective income tax rate due to the existence of the valuation allowance. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2007
Balance at January 1, 2007	\$ 1,694
Increases related to prior year tax positions	18
Increases related to current year tax positions	42
Settlements	(18)

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Balance at December 31, 2007	\$ 1,736
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The Company recognized interest and penalties related to uncertain tax positions of \$64,000 for the year ended December 31, 2007 in other income and expense on the Company's Consolidated Statements of Operations. As of December 31, 2007 the Company has approximately \$347,000 of accrued interest and penalties related to uncertain tax positions. The total uncertain tax liability of \$2.1 million as of December 31, 2007 was recorded as a reduction to deferred tax assets of \$1.2 million and a non current liability of \$839,000 on the Company's Consolidated Balance Sheet.

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.

The tax years 2004-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject.

As of December 31, 2007, the Company had approximately \$37.0 million of U.S. federal net operating loss carryforwards that will begin to expire in the 2023 tax year, approximately \$6.5 million of state net operating loss carryforwards that will begin to expire in 2008, \$2.9 million in research and development tax credit carryforwards that will begin to expire in 2009, and \$2.0 million of capital loss carryforwards that will begin to expire in 2008. Additionally, at December 31, 2007 the Company had \$2.4 million in alternative minimum tax credit carryforwards that do not expire.

#### **15. Executive Insurance Plan**

Pursuant to a supplemental life insurance program for certain executive officers of the Company, the Company and the executives shared in the premium payments and ownership of insurance policies on their lives. At death, policy proceeds equal to the premium contribution were due to the Company with the remaining proceeds due to the designated beneficiaries of the insured party. In 2003 the Company suspended all contributions to the plan in order to evaluate the plan in relation to Section 402(a) of the Sarbanes-Oxley Act of 2002. The Company's Board of Directors terminated this plan during 2005, and awarded as a bonus the Company's remaining interest in the plan to three executive officers who had participated in the plan. As a result the Company recorded compensation expense of approximately \$253,000 related to this plan in 2005.

#### **16. Transactions with Related Parties**

The Company expensed \$12,000, \$135,000, and \$27,000 in 2007, 2006, and 2005, respectively, relating to supplies for clinical trials purchased from a company whose CFO and Senior VP is a member of the Company's Board of Directors and a shareholder of the Company. The Company recorded products and preservation services revenue of \$666,000, \$151,000, and \$18,000 in 2007, 2006, and 2005, respectively, and recorded research and development expenses of \$5,000 and \$26,000 in 2007 and 2006, respectively, relating to a company whose former Chief of Thoracic Surgery is a member of the Company's Board of Directors and a shareholder of the Company.

#### **17. Segment and Geographic Information**

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

The Preservation Services segment includes external services revenue from preservation of cardiac, vascular, and orthopaedic allograft tissues. The Implantable Medical Devices segment includes external revenue from product sales of BioGlue and bioprosthetic devices, including the CryoLife-O'Brien Stentless Aortic Bioprosthesis, SynerGraft processed bovine vascular grafts, and CardioWrap. 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.

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

	2007	2006	2005
<b>Revenue:</b>			
Preservation services	\$ 49,002	\$ 40,078	\$ 30,307
Implantable medical devices	44,712	41,037	38,932
All other <sup>a</sup>	1,049	196	43
	<b>\$ 94,763</b>	<b>\$ 81,311</b>	<b>\$ 69,282</b>
<b>Cost of preservation services and products:</b>			
Preservation services	\$ 28,433	\$ 29,958	\$ 24,357
Implantable medical devices	7,108	7,463	8,065
	<b>\$ 35,541</b>	<b>\$ 37,421</b>	<b>\$ 32,422</b>
<b>Gross margin:</b>			
Preservation services	\$ 20,569	\$ 10,120	\$ 5,950
Implantable medical devices	37,604	33,574	30,867
All other <sup>a</sup>	1,049	196	43
	<b>\$ 59,222</b>	<b>\$ 43,890</b>	<b>\$ 36,860</b>

<sup>a</sup> 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, 2007, 2006, and 2005 were as follows (in thousands):

	2007	2006	2005
<b>Preservation services:</b>			
Cardiac tissue	\$ 22,098	\$ 15,988	\$ 13,762
Vascular tissue	22,702	16,956	11,453
Orthopaedic tissue	4,202	7,134	5,092
<b>Total preservation services</b>	<b>49,002</b>	<b>40,078</b>	<b>30,307</b>
<b>Products:</b>			
BioGlue	43,884	40,025	37,985
Other implantable medical devices	828	1,012	947
<b>Total products</b>	<b>44,712</b>	<b>41,037</b>	<b>38,932</b>
All other <sup>a</sup>	1,049	196	43
	<b>\$ 94,763</b>	<b>\$ 81,311</b>	<b>\$ 69,282</b>

<sup>a</sup> 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, 2007, 2006, and 2005 were as follows (in thousands):



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	2007	2006	2005
U.S.	\$ 81,023	\$ 69,467	\$ 58,869
International	13,740	11,844	10,413
<b>Total</b>	<b>\$ 94,763</b>	<b>\$ 81,311</b>	<b>\$ 69,282</b>

At December 31, 2007, 2006, and 2005, 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.

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## 18. Subsequent 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's proprietary SynerGraft technology is designed to remove donor cells and cellular remnants from the valve without compromising the integrity of the underlying collagen matrix. The CryoValve SG pulmonary human heart valve 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 his own pulmonary valve. The CryoValve SG is then surgically implanted in place of the removed native pulmonary valve.

At the FDA's request, CryoLife is planning a post-clearance study to seek evidence for the potential and implied long-term benefits of the SynerGraft process. Data to be collected is expected to include long-term safety and hemodynamic function, immune response, and explant analysis. CryoLife believes that this information may help it ascertain whether the SynerGraft process reduces the immune response of the transplanted heart valve and allows for the collagen matrix to recellularize with the recipient's own cells.

**SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

(in thousands, except per share data)

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
<b>REVENUE:</b>				
2007	\$ 24,524	\$ 23,011	\$ 22,160	\$ 25,068
2006	19,449	20,754	20,018	21,090
2005	17,665	17,198	16,458	17,961
<b>GROSS MARGIN:</b>				
2007	\$ 14,944	\$ 14,154	\$ 13,970	\$ 16,154
2006	10,763	11,638	11,488	10,001
2005	9,650	9,049	8,503	9,658
<b>NET INCOME (LOSS):</b>				
2007	\$ 1,354	\$ 1,291	\$ 1,907	\$ 2,649
2006	(1,780)	217	1,978	(50)
2005	(1,357)	(14,379)	(3,118)	(681)
<b>INCOME (LOSS) PER COMMON SHARE DILUTED:</b>				
2007	\$ 0.04	\$ 0.05	\$ 0.07	\$ 0.10
2006	(0.08)	(0.00)	0.07	(0.01)
2005	(0.06)	(0.61)	(0.14)	(0.04)

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## CRYOLIFE, INC. AND SUBSIDIARIES

## VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2007, 2006, and 2005

Description	Balance Beginning of Period	Additions	Deductions	Balance End of Period
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
Year ended December 31, 2005: Allowance for doubtful accounts	\$ 85,000	\$ 57,000	\$ 37,000	\$ 105,000

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