

CRYOLIFE INC  
Form 10-K  
February 22, 2007

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

Washington, D.C. 20549

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**FORM 10-K**

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(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, 2006

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

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**CRYOLIFE, INC.**

(Exact name of registrant as specified in its charter)

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**Florida**  
(State or other jurisdiction of

incorporation or organization)

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

**59-2417093**  
(I.R.S. Employer

Identification No.)

(Address of principal executive offices) (zip code)

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

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

Title of each class	Name of each exchange on which registered
Common Stock, \$.01 par value	New York Stock Exchange
Preferred Share Purchase Rights	New York Stock Exchange
6% Convertible Preferred Stock, \$.01 par value	New York Stock Exchange

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

None

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

Indicated 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, or a nonaccelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer

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, 2006, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was \$120,532,000, computed using the closing price of \$5.40 per share of Common Stock on June 30, 2006, the last trading day of the registrant's most recently completed second fiscal quarter, as reported by the New York Stock Exchange, based on management's belief that Registrant has no affiliates other than its directors and executive officers.

As of February 16, 2007 the number of outstanding shares of Common Stock of the registrant was 24,988,465.

Documents Incorporated By Reference

Document	Parts Into Which Incorporated
Proxy Statement for the Annual Meeting of Shareholders to be filed within 120 days after December 31, 2006.	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, implantable medical devices, and preserves and distributes human tissues for cardiovascular and vascular transplant applications. The Company's biomaterials and implantable devices include BioGlue® Surgical Adhesive (BioGlue), porcine heart valves, and vascular grafts of bovine tissue processed using the Company's proprietary SynerGraft® technology. The Company's products are often marketed internationally several years before they can be marketed in the U.S. In 2006 international revenues were 15% of total revenues.

*BioGlue*

CryoLife's proprietary product BioGlue, designed for cardiovascular, 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 60 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 include cardiovascular, pulmonary, and additional soft tissue repair procedures). CryoLife has also received approval and distributes BioGlue for soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in Australia, and several other countries in Central and South America, and Asia.

*Human Tissue Preservation and Distribution*

CryoLife distributes preserved human cardiovascular, vascular, and orthopaedic tissue to implanting institutions throughout the U.S., Canada, and Europe, although distribution of orthopaedic tissue is being phased out. See Recent Events Exchange and Service Agreement with RTI. CryoLife preserves 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 cryopreserved 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.

*Other Products*

CryoLife distributes a porcine heart valve, the CryoLife O'Brien® aortic heart valve in Europe, the Middle East, and Africa (EMEA). This valve contains minimal amounts of synthetic material compared to other glutaraldehyde-fixed porcine valves. This decreases the risk of endocarditis, a debilitating and potentially fatal infection. CryoLife also markets its SynerGraft bovine vascular graft, the SynerGraft Model 100, in the EMEA. This bovine vascular graft utilizes CryoLife's SynerGraft process, a proprietary process that involves the depopulation of cells leaving a matrix of protein fibers that has the potential to be repopulated with the recipient's cells. CryoLife believes that this process increases graft longevity, and improves the biocompatibility and functionality of the tissue.

In 2007 CryoLife will begin exclusive distribution of CardioWrap® a product of MAST BioSurgery, Inc. CardioWrap is a bioresorbable thin film sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries where the patient may face re-operation within six months.

*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 cardiovascular 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 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. In addition the Company continues to explore technologies that may further enhance the safety of its tissue processing.

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 the PHT technology as a potential nucleus pulposus replacement in spinal disc repair and for use in trauma surgery. 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, inability to obtain sufficient insurance coverage, possible inability to protect the intellectual property rights in the Company's technology, the possible inability to obtain necessary regulatory approvals, and possible future lack of capital. See Part I, Item 1A, "Risk Factors" below.

#### **Recent Events**

##### *Additional Regulatory Approvals*

On December 11, 2006 the Company announced that it has received 510(k) clearance from the FDA for its ProPatch Soft Tissue Repair Matrix ( 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.

On December 13, 2006 the Company announced that it has received CE Mark and Health Canada approval for a new rigid applicator tip for its BioGlue Surgical Adhesive. The new tip, designed to reach beyond 27 cm, enables precise delivery of BioGlue over an extended length.

##### *Agreement with BioForm Medical, Inc.*

In October 2006 the Company announced that it has 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 United States, Canada, and various countries in Europe. In addition, BioForm will oversee all aspects of the marketing, sales and distribution of BioGlue in the United States, 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.

##### *Exchange and Service Agreement with RTI*

On December 19, 2006 the Company announced that it had entered into an exchange and service agreement with Regeneration Technologies, Inc., and certain of its affiliates (collectively, RTI ), respecting procurement, processing, and distribution activities for cardiovascular and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife (the RTI Agreement ). According to the RTI Agreement, CryoLife ceased accepting for processing donated human orthopaedic tissue commencing January 1, 2007 and will work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise, on January 1, 2007 RTI ceased accepting donated human cardiovascular and vascular tissues for processing and will work to transition its arrangements for recovery of these tissues to CryoLife. Certain physical assets relating to the tissues that are the subject of the agreement may also be transferred between the parties. 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 cardiovascular and vascular tissue inventory, through June 30, 2008. After that date CryoLife will become entitled to distribute RTI's remaining cardiovascular and vascular tissue inventory, and RTI will become entitled to distribute CryoLife's remaining orthopaedic tissue inventory, for a fee. 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. See discussions on the financial impact of this transaction in Part II, Item 8, Note 3 of the Notes to Consolidated Financial Statements.

#### *Agreement with the Cleveland Clinic to Develop Aortic Mitral Allograft*

On January 10, 2007 the Company announced that it has entered into an agreement with the Cleveland Clinic to develop an innovative allograft, or human tissue, heart valve for patients suffering from serious heart infections. Under the terms of the agreement, the Company will work with the Cleveland Clinic to develop a combination aortic-mitral allograft heart valve to be used in patients with infective endocarditis, a condition in which the structures of the heart, particularly the heart valves, are infected.

#### *CardioWrap Distribution Agreement*

On January 17, 2007 the Company announced that it has signed a multi-year agreement with MAST Biosurgery, Inc. to distribute CardioWrap, a bioresorbable thin film sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries in which the patient may face re-operation within six months. The agreement gives CryoLife the exclusive rights to distribute CardioWrap in the U.S. for three years. 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 Order on Human Tissue Preservation and Other FDA Correspondence and Notices**

##### *FDA Order on Human Tissue Preservation*

On August 13, 2002 the Company 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, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order (i.e. 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 the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues.

The FDA allowed non-valved cardiac and vascular tissues covered by the recall to be distributed beginning in late September 2002, subject to specified conditions. The Company changed its processing procedures and took other actions intended to address the FDA's concerns, and now processes non-valved cardiac and vascular tissues. The Company processed orthopaedic tissues through December 31, 2006 when it ceased processing orthopaedic tissues pursuant to the RTI Agreement discussed above in Recent Events.

See Part I, Item 3, Legal Proceedings for a discussion of certain material legal proceedings relating to the FDA Order and other matters.

##### *Other FDA Correspondence and Notices*

##### July 2005 483

An FDA Form 483 Notice of Observations (483) was issued in August 2005 in connection with the FDA inspections of the Company's facilities in July 2005 (July 2005 483). The Company responded to the July 2005 483 in August 2005, in September 2005, and in October 2005. In April 2006 the FDA responded on the adequacy of the Company's responses. The Company responded to the FDA in June 2006. In response to the July 2005 483 the Company has implemented new systems and procedures and revised existing systems and procedures. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information related to the inspections, and has the authority to take other actions, which may be more burdensome. The Company has cooperated and will continue to cooperate with the FDA to review process improvements and address any outstanding observations.

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### SynerGraft

On February 20, 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company's SynerGraft processed human cardiac tissues (CryoValve® SG) and that premarket approval marketing authorization should be obtained for the Company's SynerGraft processed human vascular tissues (CryoValve® SG) when marketed or labeled as an arteriovenous (A-V) access graft. The agency's position is that use of the SynerGraft technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On February 4, 2004 the Company received a letter from the FDA requesting additional information. On August 24, 2004 the Company submitted an amendment to its original 510(k) submission providing clarification and additional information. The FDA requested further additional information in November 2004. On June 8, 2005 CryoLife responded to some of these additional requests. CryoLife also has initiated an appeal of other requests through administrative procedures. The FDA requested further additional information in January 2006. Since March 2006 the Company has had discussions with the FDA to address the outstanding requests for additional information and seek clearance for the CryoValve SG pulmonary valve. On July 21, 2006 the Company submitted an amendment to its 510(k) application addressing information requested by the FDA. The Company has undertaken further clinical and preclinical evaluations in response to requests by the FDA. These evaluations were submitted to the FDA in an additional 510(k) amendment on February 20, 2007. The FDA may still require that additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed CryoValve SG.

On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that certain additional cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On September 14, 2004 the Company met with the FDA to discuss the data to be used to support a formal Request for Designation (RFD) filing for SynerGraft processed non-valved cardiac and vascular tissue, including the CryoVein SG. An RFD submission establishes the regulatory status of the tissue. The Company submitted the RFD on October 5, 2004. The FDA affirmed its original decision in letters received in December 2004. That decision was subject to an administrative appeal. On October 20, 2005 CryoLife was informed that the FDA had denied the appeal and that CryoLife will be unable to distribute CryoVein tissues with the SynerGraft technology until further submissions and FDA approvals are granted. The Company is evaluating whether it will file and seek FDA approvals for CryoVein SG or discontinue the CryoVein SG.

As a result of these FDA communications, in 2003 the Company suspended the use of the SynerGraft technology in the processing of allograft tissue and the distribution of tissues on hand previously processed with the SynerGraft technology until the regulatory issues associated with these tissues are resolved. Additionally, the Company discontinued labeling its vascular grafts for use as A-V access grafts. Until such time as the issues surrounding SynerGraft are resolved, the Company is employing its traditional processing methods on these tissues. As of December 31, 2006 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Consolidated Balance Sheets.

### **Strategy**

On January 18, 2006 the Company announced it had engaged Piper Jaffray & Co. to assist the Company's management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. On November 2, 2006, the Company announced that in connection with its strategic analysis, the Board determined that shareholder value was not likely to be maximized through a sale of the Company, or of a major product line, at that time. Further, the Board concluded that the significant improvements in the Company's operating results in the second and third quarters of 2006, coupled with improvements in the Company's liquidity, made it unnecessary for the Company to pursue a capital-raising transaction at that time. 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 its 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 Human Tissue.* The Company intends to increase the market penetration of its CryoLife preserved human heart valves, non-valved conduits, and vascular grafts by (i) increasing yields of implantable tissue per donor, (ii) expanding awareness of clinical advantages of preserved human tissues through continuing educational efforts directed to physicians and tissue procurement agencies, (iii) improving and expanding its relationships with the approximately 80 tissue banks and organ procurement agencies across the U.S. which have recovered and sent tissue to the Company for preservation, (iv) increasing the number of tissue banks and organ procurement agencies that work with CryoLife, (v) expanding its physician training activities, and (vi) resuming the application of its SynerGraft technology to human heart valves, non-valved conduits, and vascular grafts, if required FDA approvals are obtained. In an effort to increase its market penetration of CryoLife preserved human heart valves, non-valved conduits, and vascular grafts the Company entered into the RTI Agreement in December 2006 in order to increase cardiovascular and vascular procurement and market share for these 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 cryopreserved by the Company and (ii) identify new human tissues as candidates for cryopreservation.

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 (i) to leverage its current distribution channel and its expertise in the cardiovascular and vascular medical specialties by selectively pursuing the potential acquisition, distribution or licensing of additional technologies that complement existing services and products, and (ii) to attempt to leverage its current technology platform, including its protein hydrogel technology and its SynerGraft technology, into medical specialties other than cardiovascular and vascular surgery by selectively pursuing the potential acquisition, distribution or licensing of additional technologies. As a part of this strategy, in January 2007 the Company signed a three-year agreement to exclusively distribute CardioWrap, a bioresorbable thin film sheet used to replace the pericardium in cardiac reconstruction and other cardiac surgeries where the patient may face re-operation within six months.

*License Company technology to third parties for non-competing uses.* The Company intends to increase the market penetration of its BioGlue by (i) pursuing through strategic alliances additional indications or product line extensions for the BioGlue technology in either the U.S. or internationally, and (ii) pursuing through strategic alliances indications for derivatives of the BioGlue technology 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 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 United States, Canada, and various countries in Europe.

*Analyze and identify underperforming assets for potential sale or disposal.* The Company intends 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 the RTI Agreement in which the Company ceased processing orthopaedic tissues on January 1, 2007 in exchange for a non-compete agreement from RTI for cardiovascular and vascular tissues and the potential to receive additional cardiovascular and vascular procurement, which was previously being received by RTI.

## **Products and Services**

### *Implantable Biomaterials for Use as Surgical Adhesives and Sealants*

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 cardiovascular 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 a cross-linking agent. BioGlue has a tensile strength that is four to five times that of fibrin sealants. Worldwide clinical applications for BioGlue include cardiovascular, vascular, pulmonary, and soft tissue repair.

BioGlue is the first product to be developed from the Company's Protein Hydrogel Technology. 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 conducting a clinical trial for BioDisc to determine its clinical utility 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.

The Company estimates that aggregate U.S. sales for surgical adhesives and glues was approximately \$250 million in 2006. CryoLife is authorized to distribute BioGlue throughout the U.S. and more than 60 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 the EEA for soft tissue repair procedures (which include cardiovascular, pulmonary, and additional soft tissue repair procedures). CryoLife has also received approval and distributes BioGlue for soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in Australia, and several other countries in Central and South America and Asia. In mid-2004 the Company introduced the 2 ml and the 5 ml syringe delivery system, which provides BioGlue without a separate delivery system. The 10 ml version of the syringe delivery system was approved by the FDA and CE Marked for distribution in late 2005 and approved by Canada in February 2006. Prior to the release of the syringe delivery system, BioGlue was only available for use with a two-part applicator system. The syringe spreader tip, which allows for a wider application of BioGlue, was added to the BioGlue CE Mark approval in May 2005, received Canadian approval in April 2005, and received FDA approval in January 2006. The rigid applicator tip, designed to reach beyond 27 cm, received Canadian and CE Mark approvals in November and December 2006, respectively. Revenues from BioGlue represented 49%, 55%, and 57% of total revenues, respectively, in 2006, 2005, and 2004.

#### *Preservation of Human Tissue for Transplant*

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 cryopreserved 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 cryopreserved 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 cryopreserved 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 cryopreserved 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 to improve their tissue recovery techniques and, thereby, increase the yield of usable tissue.

*Human Cardiovascular Tissue.* The human heart valves and conduits cryopreserved by the Company are used in reconstructive heart valve replacement surgery. CryoLife shipped approximately 62,600 cryopreserved human heart valves and conduits from 1984 through 2006, including approximately 2,200 shipments in 2006. Revenues from human heart valve and conduit preservation services accounted for 20% of total revenues in 2006, 2005, and 2004. Based on CryoLife's records of documented implants, management believes that the acceptance of the Company's cryopreserved allograft heart valve is due in part to physicians' recognition of the longevity and natural functionality of the Company's cryopreserved human tissues, the Company's documented clinical data, and the Company's technical representation, which includes its direct technical service representatives and customer service department. Management believes the Company offers advantages in the area of clinical data and technical service representatives as compared to other allograft processors and that the Company's allograft tissues offer advantages in certain areas over mechanical, porcine, and bovine heart valve alternatives. The Company currently applies its preservation services to human aortic and pulmonary heart valves for implantation by cardiac surgeons. In addition the Company provides cryopreserved human non-valved conduit and patch tissue to surgeons who wish to perform certain specialized cardiac repair procedures. Each of these cryopreserved 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.

In February 2000 the Company began distributing in the U.S. cryopreserved human heart valves and conduits utilizing its SynerGraft decellularization technology which may reduce antigens. As discussed in FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices, in early 2003 the Company suspended the use of SynerGraft technology in the processing of allograft heart valves and vascular tissue until the regulatory status of the CryoValve SG and CryoVein SG is resolved.

The Company estimates that the total annual heart valve and non-valved conduit replacement market in the U.S. in 2006 was in excess of \$500 million. Management believes that approximately 98,000 heart valve replacement surgeries were conducted in the U.S. in 2006. Of this total number of heart valve and conduit surgeries, approximately 24,000 or 24%, involved mechanical heart valves, and approximately 74,000 or 76%, involved tissue heart valves, including porcine, bovine, and cryopreserved human tissues.

Management believes cryopreserved 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 cryopreserved by the Company, allow for more normal blood flow and provide higher cardiac output than 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 stented porcine valves for patients who have or are at risk to contract endocarditis.

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

	<b>Cryopreserved Human</b>	<b>Porcine</b>		<b>Bovine</b>	
	<b>human tissue</b>	<b>Stented</b>	<b>Stentless</b>	<b>Mechanical</b>	<b>Pericardial</b>
Materials:	human tissue	glutaraldehyde-fixed pig tissue and synthetic sewing ring	glutaraldehyde-fixed pig tissue	pyrolitic carbon bi-leaflet and synthetic sewing ring	glutaraldehyde-fixed cow tissue and synthetic sewing ring
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
Responsiveness to Antibiotic Treatment of Endocarditis:	high	low	moderate	low	low

While the clinical benefits of cryopreserved 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 Tissues.* The Company cryopreserves human saphenous veins for use in vascular surgeries that require small diameter conduits (3 mm to 6 mm), such as coronary bypass surgery and peripheral vascular reconstructions. Failure to bypass or revascularize an obstruction in such cases may result in death or the loss of a limb. The Company also cryopreserves femoral veins and arteries for use as vascular grafts. The Company shipped approximately 45,600 human vascular tissues from 1986 through 2006, including approximately 2,800 shipments in 2006. Revenues from human vascular preservation services accounted for 21%, 17%, and 16% of total revenues, respectively, in 2006, 2005, and 2004.

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 transplanted 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. Cryopreserved human vascular tissues tend to remain open longer and as such are used in indications where synthetics 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, cryopreserved human vascular tissues are also a preferred graft alternative for patients with previously infected graft sites. The Company's cryopreserved human vascular tissues are used for peripheral vascular reconstruction, coronary artery bypass surgeries, and venous valve transplantation. In cases of peripheral arteriosclerosis, a cryopreserved 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. A subset of coronary artery bypass procedures are re-operations and are candidates for preserved vascular tissue when the patient's own tissue is not available.

*Human Orthopaedic Tissue.* The Company historically provided preservation services for surgical replacements for the meniscus and the anterior and posterior cruciate ligaments, 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 cardiovascular and vascular tissue processed and distributed by RTI and orthopaedic tissue for the

knee processed and distributed by CryoLife. According to the RTI Agreement, CryoLife ceased accepting for processing donated human orthopaedic tissue on January 1, 2007 and will work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. CryoLife will continue to distribute its existing orthopaedic tissue inventory through June 30, 2008. After that date RTI will become entitled to distribute CryoLife's remaining orthopaedic tissue inventory, for a fee. 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.

CryoLife shipped approximately 31,100 human connective tissues for the knee through the end of 2006, including approximately 1,800 shipments in 2006. Revenues from human orthopaedic preservation services accounted for 9%, 7%, and 5% of total revenues, respectively, in 2006, 2005, and 2004.

Human menisci provide orthopaedic surgeons with an alternative treatment in cases where a patient's meniscus has been completely removed (meniscectomy). When a patient has a damaged meniscus, the current surgical alternatives are to repair, partially remove, or completely remove the patient's meniscus, with partial removal being the most common procedure. Meniscal removal increases the risk of premature knee degeneration and arthritis, and typically results in the need for knee replacement surgery at some point during the patient's life. Management believes that there are no synthetic total menisci on the market.

Tendons are primarily used for the reconstruction of the anterior and posterior cruciate ligaments in cases where the patient's ligaments are irreparably damaged. Surgeons have traditionally removed a portion of the patient's patellar tendon from the patient's undamaged knee for use in repairing a damaged anterior cruciate ligament. Cryopreserved tendons provide an alternative to this procedure. Because surgeries using preserved human tissue do not involve the removal of any of the patient's own patellar tendon, the patient recovery period is typically shorter. Additionally, in May 2005 the Company began shipping tendons terminally sterilized with gamma irradiation. The Company obtained a non-exclusive license for this technology from Clearant, Inc. for a period of time equal to the life of the last licensed patent related to this technology. This technology is designed to inactivate pathogens including bacteria and fungi. In January 2007 CryoLife terminated this license agreement as a result of the RTI Agreement discussed above.

Osteoarticular allografts represent a biological alternative for the replacement of injured or diseased portions of the articular surface of the knee. Osteoarticular allografts are used for patients in whom cartilage defects are extensive and there is not enough autograft tissue available for harvesting.

#### *Medical Devices*

*CryoLife O Brien Aortic Heart Valve.* The Company developed and commercialized its bioprosthetic cardiovascular and vascular devices based on its experience with cryopreserved human tissue implants. The CryoLife O Brien aortic heart valve 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 2006.

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 heart valve is marketed in the EMEA region. Revenues from the CryoLife O Brien aortic heart valve represented 1% of total revenues in 2006, 2005, and 2004.

*SynerGraft Model 100 Vascular Graft.* In July 2001 the Company received CE Mark approval for its SynerGraft Model 100 vascular graft for dialysis access. The SynerGraft Model 100 vascular graft is produced from a bovine ureter in lengths of 25, 30, 35, and 50 cm. The SynerGraft Model 100 vascular graft can be stored at room temperature. The Company's SynerGraft decellularization technology which may reduce antigens involves the removal of cells from the structure of animal tissue, leaving a collagen matrix that has the potential to repopulate in the recipient with the recipient's own cells. Animal

studies and explants from human recipients have documented that allograft heart valves processed with the SynerGraft process have repopulated themselves in the recipient with the recipient's own cells. This process is designed to increase allograft longevity, and more generally to improve the biocompatibility and functionality of such tissue.

*CardioWrap.* On January 17, 2007 the Company announced that it has signed a three-year agreement with MAST Biosurgery, Inc. to exclusively distribute CardioWrap, a bioresorbable thin film 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.

*ProPatch Soft Tissue Repair Matrix.* On December 11, 2006 the Company announced that it has received 510(k) clearance from the FDA for its ProPatch Soft Tissue Repair Matrix. 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.

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

## **Procurement, Sales, 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 representatives. Through its technical representatives, the Company conducts field training for doctors 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. The application has been submitted to the Japanese Ministry of Health and Welfare. The review process is ongoing.

### *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 cryopreserved 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 with which the implanting physician is associated. The Company has developed relationships with approximately 80 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 approximately 27 individuals in donor services to work with organ procurement agencies and tissue banks. This includes five account managers who are stationed throughout the country to work directly with our customers. 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.

Cardiovascular, vascular, and orthopaedic tissues are cryopreserved 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 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 987 cardiovascular and vascular surgeons and over 352 orthopaedic surgeons who have implanted tissues cryopreserved 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 cryopreserved human tissue and on proper implantation techniques. Trained field support personnel provide support to implanting institutions and surgeons. The Company currently employs approximately 34 persons as technical service representatives and four region managers who deal primarily with cardiovascular and vascular surgeons and provide field support. These representatives receive a base salary with a performance bonus. The Company currently has approximately 180 independent technical service representatives and sub-representatives who are employed by distributor groups who deal primarily with orthopaedic surgeons and who are paid on a commission basis.

The Company sponsors physician training seminars where physicians teach other physicians the proper technique for handling and implanting cryopreserved human tissue. The Company also produces educational videotapes for physicians and coordinates live surgery demonstrations 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 cryopreserved 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.

### *Bioprosthetic Cardiovascular Devices*

The Company markets and distributes the CryoLife O Brien stentless aortic heart valve and the SynerGraft Model 100 Vascular Graft in the EMEA region. Marketing efforts for the CryoLife O Brien aortic heart valve are primarily directed toward cardiac surgeons. Marketing efforts for the SynerGraft Model 100 are primarily directed toward vascular surgeons.

### *European Operations*

The Company markets its products in the EMEA regions through its European subsidiary, CryoLife Europa Ltd, based in Guildford, United Kingdom. Europa, with its team of approximately eleven employees, provides customer service, logistics, marketing, and clinical support to cardiovascular, vascular, thoracic, and general surgeons throughout the EMEA regions. Europa markets and distributes the Company's complete range of products through its direct sales representatives in England and Wales and a network of independent agents and distributors in the EMEA regions.

### *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 heart valves, or SynerGraft bovine vascular grafts.

### **Research and Development**

The Company uses its expertise in biochemistry and cell biology, and its understanding of the needs of the cardiovascular, and vascular, surgery medical specialties, to expand its surgical adhesive and preservation businesses in the U.S. 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 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 18 people in its research and development department, including seven PhDs with specialties in the fields of molecular biology, protein chemistry, vascular physiology, and biochemistry.

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 to further enhance its safety, its Protein Hydrogel Technology used in BioGlue and other BioGlue derivatives, additional applications of its SynerGraft technology, and its Activation Control Technology (ACT).

BioFoam, a derivative of the PHT, is in preclinical development. BioFoam contains an expansion 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 severe trauma. The 2005, 2006, and 2007 U.S. Congress Defense Appropriations Conference Reports included \$926,000, \$2.3 million, and \$1.0 million, respectively, for the continued development of protein hydrogel technology for use on the battlefield. The Company applied for and was awarded the full \$926,000 under the 2005 bill. The Company applied for funding for BioFoam development under the 2006 bill in July 2006 but has not yet been notified of an award decision. The Company anticipates applying for funding under the 2007 bill during 2007. CryoLife is currently involved in initial animal trials related to this grant.

BioDisc, a derivative of the PHT, is undergoing clinical evaluation to determine its clinical utility as a nucleus pulposus replacement in spinal disc repair. The nucleus pulposus is surrounded by fibrous tissue (annulus fibrosus) 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 fibrosus 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. The ten patient study enrollment has been completed and patient follow-up will continue through 2007. An interim analysis of data will be used for CE Mark submission anticipated in 2007.

In October 2006 the Company announced that it has 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 United States, Canada, and various countries in Europe. In addition, BioForm will oversee all aspects of the marketing, sales and distribution of BioGlue in the United States, 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.

In February 2001 the Company formed AuraZyme Pharmaceuticals, Inc. ( AuraZyme ) to foster the commercial development of its ACT. The ACT is a reversible linker technology that might have possible uses in the areas of fibrinolysis (blood clot dissolving), and other drug delivery applications. Since 1998 management has been seeking to advance the development of drug delivery therapies utilizing the ACT through grants, research and development partnerships, joint ventures, and equity investments thereby allowing the Company to focus its resources on the commercial development of its BioGlue, SynerGraft technology, and other products under development.

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 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. In 2006, 2005, and 2004 the Company spent approximately \$3.5 million, \$3.7 million, and \$3.9 million respectively, on research and development activities on new and existing products. These amounts represented approximately 4%, 5%, and 6% of the Company's revenues for the years 2006, 2005, and 2004, respectively. The Company's medical and scientific advisory board consults on various research and development programs. The Company's pre-clinical 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.

## **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 offsite warehouse space. Approximately 20,000 square feet are dedicated to thirty-one 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 environment for tissue dissection and processing, manufacturing, and packaging. Approximately 55 liquid nitrogen storage units maintain cryopreserved 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 cardiovascular and vascular tissue for transplant. The laboratory processed human orthopaedic tissues for transplant until December 31, 2006. On January 1, 2007 the laboratory ceased processing human orthopaedic tissues pursuant to the RTI Agreement. This laboratory contains approximately 15,600 square feet with a suite of nine clean rooms. Currently there are approximately 70 technicians employed in this area, and the laboratory is staffed for 24 hours per day, 365 days per year. In 2006 the laboratory packaged approximately 14,400 human allografts. The current processing level is estimated to be at about 20% 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.



### *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 16 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 Cardiovascular and Vascular Devices*

The bioprosthesis laboratory at the Company's headquarters facility is responsible for the manufacturing of the CryoLife O'Brien stentless aortic heart valve, the SynerGraft Model 100 Vascular Graft. 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 that 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. The FDA periodically inspects Company facilities to review Company compliance with these and other regulations. The Company also operates according to 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.

### *Bioadhesive and Bioprosthetic Manufacturing*

The Company employs a comprehensive quality assurance program in all of its manufacturing activities. The Company is subject to Quality System Regulations, additional FDA 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. Each process is documented along with all inspection results, including final finished product inspection and acceptance. 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. 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.

### *Preservation Services*

The Company also 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 also 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 cryopreserved, 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 by two independent tests 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 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. Human tissue processed by the Company must also comply with FDA regulations for determining donor eligibility and for processing human cell and tissue products for implantation under current Good Tissue Practices (cGTPs). The FDA periodically audits the Company's processing facilities for compliance with those requirements. See FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices Other FDA Correspondence and Notices above for a discussion of recent inspections.

### **Patents, Licenses, and Other Proprietary Rights**

The Company relies on a combination of patents, trademarks, confidentiality agreements and security procedures to protect its proprietary products, processing technology, trade secrets, and know-how. The Company believes that its patents, trade secrets, trademarks, and technology licensing rights provide it with important competitive advantages. The Company owns or has licensed rights to 37 U.S. patents and 69 foreign patents, including patents relating to its technology for human cardiovascular and vascular tissue preservation, tissue revitalization prior to freezing, tissue transport, BioGlue, ACT, and packaging. The Company has approximately 12 pending U.S. patent applications and 73 pending foreign applications that relate to areas including the Company's cryopreservation, Protein Hydrogel Technologies, 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 or could be required to obtain licenses from the owners of such patents or 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 licensed from third parties certain technologies related to its SynerGraft and ACT technologies that call for the payment of royalties based on revenues, when and if such products or services are approved for marketing. The loss of these licenses could adversely affect the Company's ability to successfully develop certain technologies.

The Company has entered into confidentiality agreements with its employees and 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.

## **Competition**

### *Implantable Biomedical Devices for Use as Surgical Adhesives and Sealants*

The Company competes with many domestic and foreign 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 and Surgifoam, and Tyco Healthcare'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' 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. Furthermore, if the Company commences significant commercial sales of its products, it will also be competing 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.

### *Cryopreserved Human Tissues and Bioprosthetic Cardiovascular Devices*

The Company currently faces competition from at least three 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 cryopreserved human tissue. Management believes that it competes with other entities that cryopreserve human tissue on the basis of technology, customer service, and quality assurance. Following the FDA Order in 2002, the Company experienced a decrease in the procurement and processing of human tissue, a decrease in cardiovascular, vascular, and orthopaedic tissue shipments, and the lack of orthopaedic tissue shipments for a period of time. The Company's competitors have been favorably impacted and the Company believes it has lost some market share following the FDA Order in 2002. The interruption in the Company's services, and the changes made to the Company's preservation services, which have had the effect of substantially increasing tissue processing and release times and reducing the yield of implantable tissue per donor, have had an adverse impact on our profitability.

Management believes that the human heart valves cryopreserved 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. Generally, for each procedure that may utilize vascular human tissue that the Company cryopreserves, 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 will also compete with the use of tissue cryopreserved by the Company.

*Human and Stentless Porcine Heart Valves.* Alternatives to human heart valves cryopreserved 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 cryopreserved 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 three 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 five other companies that offer porcine and bovine pericardial heart valves.

*Human Vascular Tissue.* There are a number of providers of synthetic alternatives to veins cryopreserved by the Company and those alternatives are available primarily in medium and large diameters. Currently, management believes that there are at least two other non-profit tissue banks that cryopreserve and distribute human vascular tissue in competition with the Company. Companies offering either synthetic or allograft products may enter this market in the future.

*Human Orthopaedic Tissue.* In December 2006 CryoLife entered into the RTI Agreement, discussed above, respecting procurement, processing, and distribution activities for cardiovascular and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife. According to the RTI Agreement, CryoLife ceased accepting for processing donated human orthopaedic tissue on January 1, 2007 and will work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise on January 1, 2007, RTI ceased accepting donated human cardiovascular and vascular tissues for processing and will work to transition its arrangements for recovery of these tissues to CryoLife. Certain physical assets relating to the tissues that are the subject of the agreement will also be transferred between the parties. 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 cardiovascular and vascular tissue inventory, through June 30, 2008. After that date, CryoLife will become entitled to distribute RTI's remaining cardiovascular and vascular tissue inventory, and RTI will become entitled to distribute CryoLife's remaining orthopaedic tissue inventory, for a fee. 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 Company's historic competition in the area of orthopaedic tissue has varied according to the tissue involved. When transplantation is indicated, the historic principal competition for tendons and meniscus cryopreserved by the Company has been either freeze-dried or twice frozen human connective tissues. More than ten tissue banks process these alternative allografts.

## **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 U.S. Food and Drug Administration ( 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) ( 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 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, to enjoin and/or to impose civil penalties on manufacturers and distributors marketing non-complying medical devices, to criminally prosecute violators, and to 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 cardiovascular 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 subject to that rule.

As discussed in *FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices*, the Company has filed a 510(k) premarket notification with the FDA for the CryoValve SG and has received three letters from the FDA requesting that additional information be provided to support the 510(k) submission. CryoLife has responded to some of the requests, anticipates responding to some of the additional requests, and has initiated an appeal of others through administrative procedures.

*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. See *FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices* *Other FDA Correspondence and Notices* regarding correspondence from the FDA about cardiovascular and vascular tissues processed with the SynerGraft technology.

However, the FDA does regulate these products pursuant to Section 361 of the Public Health Services 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 Final 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 excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ. The current regulations applicable to human tissues include requirements for donor suitability (discussed above), processing standards, establishment registration, and product listing.

On January 19, 2001 the FDA published a final rule that requires 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 and 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 a new final rule 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 a new final rule 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 expenses or may not be possible, any of which may have a material adverse effect on the Company.

As discussed in "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices", the Company filed an administrative appeal on an RFD submitted in October 2004 regarding SynerGraft processed cardiovascular tissue, including the CryoVein SG. On October 20, 2005 CryoLife was informed that the FDA had denied the appeal and that CryoLife will be unable to distribute CryoVein tissues with the SynerGraft technology until further submissions and FDA approvals are granted. The Company is evaluating whether it will file and seek FDA approvals for CryoVein SG or discontinue the CryoVein SG.

#### *Possible Other FDA Regulation*

Other products and processes under development by the Company are likely to be subject to regulation by the FDA. Some may be classified as medical devices or human cells and tissue products, while others may be classified as drugs or biological products or subject to a regulatory scheme 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 is likely to be a time consuming and expensive process, and there can be no assurance that any of these products will ever receive FDA approval, if required, to be marketed.

#### *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 its CryoLife O'Brien aortic heart valve, BioGlue, and SynerGraft Model 100 vascular grafts. The Company's porcine heart valves and SynerGraft Model 100 vascular graft 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 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, 2006 the Company had approximately 388 employees. These employees included seven persons with Ph.D. degrees, one 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**

**Overview**

We have faced extraordinary challenges since we received, on August 13, 2002, an FDA Order calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by us since October 3, 2001. 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. During the same year we were the subject of intense adverse media attention in connection with allegations that tissue that we processed had infected a man in Minnesota and caused his death. We were also the subject of shareholders' class action and derivative shareholder suits, which were not resolved until the last half of 2005. Product liability cases and claims increased to unprecedented numbers for us, using all of our related 2002/2003 insurance policy year insurance coverage and taxing our other resources. The SEC has initiated a formal investigation which, to our knowledge, is ongoing.

These challenges have affected our revenues, increased our costs to process tissues and our operating expenses, and strained management resources. 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, the foregoing factors will continue to challenge us to some degree in our operations.

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

Due principally to factors mentioned above, we have 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.

Our long term earnings, liquidity, and capital requirements will depend upon numerous factors, including:

The success of BioGlue and other products using related technology,

Our ability to increase the level of tissue procurement and demand for our tissue preservation services,

Our ability to maintain sufficient margins on our tissue preservation services,

Our spending levels on research and development activities, including research studies, to develop and support our service and product pipeline,

The timing and cost of resolving our remaining outstanding product liability lawsuits and other claims,

Whether we will be able to successfully transition to us the cardiovascular and vascular tissue procurement that was previously received by RTI,

To a lesser degree, our success at resolving issues with the FDA regarding processing of human tissue using the SynerGraft technology, and

Our success in implementing recently identified strategic initiatives.

**If We Are Unable To Address The Causes Of Our Operating Losses And Negative Cash Flows, We Will Need To Raise Additional Capital Which May Not Be Available On Acceptable Terms Or At All.**

If we are unable to address the issues facing us, and continue to experience negative cash flows, we anticipate that we will require additional financing or need to seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements. We may not be able to obtain additional funds when needed or on acceptable terms, which could materially and adversely affect our ability to finance and operate our business. If we issue equity capital, this may dilute the holdings of existing shareholders.

**Key Growth Strategies Identified As A Result of Our Strategic Review May Not Generate the Anticipated Benefits.**

In January 2006 we engaged Piper Jaffray & Co. 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.

**The RTI Agreement May Not Generate The Anticipated Benefits.**

As part of our strategic plan, we entered into the RTI Agreement under which we agreed to cease processing orthopaedic tissues starting January 1, 2007 in exchange for, among other things, a non-compete agreement from RTI with respect to cardiovascular tissues and the potential for us to receive additional cardiovascular and vascular procurement which was previously being received by RTI. We may not receive the additional cardiovascular and vascular procurement that we anticipate to receive. Additionally, we may be unable to increase our cardiovascular and vascular revenues sufficiently to compensate for the loss of the orthopaedic revenues resulting from the RTI Agreement.

**We May Be Unable To Comply with the Covenants Of Our Credit Facility, Which Would Limit Our Borrowing Capacity And Potentially Result In A Default Under The Credit Facility, And Our Credit Facility Limits Our Ability To Issue Additional Debt Or Pay Cash Dividends.**

Our credit agreement places limitations on the amount that we may borrow, and includes various affirmative and negative covenants. In particular, we are uncertain whether we can comply with the adjusted earnings test. In the event that we do not reach the necessary level of quarterly adjusted earnings, and were required to spend our qualifying cash and cash equivalents, we anticipate that our borrowing capacity would be limited to \$2.5 million.

Further, if we fail to meet this and other covenants under the facility, we may be in breach of the credit agreement, our outstanding borrowings may be accelerated, and we may lose our borrowing capacity under the credit agreement.

The credit agreement also includes conditions on incurring new indebtedness and limitations on cash dividends. These restrictions and conditions could make it more difficult or more expensive for us to borrow money.

**There Are Limitations On Our Net Operating Loss Carryforwards.**

We estimate that at December 31, 2006, we had approximately \$48.5 million in U.S. Federal net operating loss carryforwards to offset future taxable income. These carryforwards begin to expire in the 2023 tax year. The availability of these net operating loss carryforwards is limited 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 could substantially reduce the benefit of our operating loss carryforwards. In addition, we may be unable to generate enough profits, if any, prior to the expiration of the operating loss carryforwards, to utilize our carryforwards.

**We Are Significantly Dependent On Our Revenues From BioGlue And Are Subject To A Variety Of Risks Affecting This Product.**

BioGlue has become 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 Continue To Feel The Adverse Impacts Of The FDA Order And Subsequent FDA Activity.**

The FDA Order, subsequent FDA activity, and resulting adverse publicity materially and adversely affected our business, financial condition, results of operations, and cash flows. As a result, our revenues decreased, and we have incurred losses and negative cash flows.

In addition, as a result of the FDA Order, subsequent FDA activity, and changes in our processing, the costs of such processing have increased and are likely to remain high as compared to cost levels prior to the FDA Order. These high costs have had a material adverse effect on our business, results of operations, cash flows, and financial position and may continue to do so for some time.

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, and financial condition. 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. Because of the adverse publicity associated with the FDA Order and subsequent FDA activity and uncertainty regarding future tissue processing, some procurement agencies stopped sending tissue to us for processing. As a result, our processing has been constrained in part due to lower availability of tissue. If we are unable to obtain tissues from procurement agencies that have ceased sending tissue to us for processing, to develop new sources, or to increase the tissues shipped from our current suppliers, we may be unable to obtain adequate supplies of donated tissues to operate profitably.

**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 they 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 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 and financial position.

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. For

example, during September 2003, in response to a reported infection, we halted the shipment of boned orthopaedic tissues in order to conduct an additional review of the systems in place to process and release boned orthopaedic 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 Be Unable To Address The Concerns Raised By The FDA In Its Form 483 Notices Of Observations.**

The FDA issued Form 483 Notices of Observations in February and October 2003, in February 2004, and in August 2005. Among the issues raised in the most recent 483 were the process validations associated with the CryoValve SG, complaint handling and reporting, and root cause analysis of certain microbial testing results. If the FDA deems our responses to the most recent 483, or any future notices, 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.

**The FDA Has Notified Us Of Its Belief That Marketing Of CryoValve SG And CryoVein SG Require Additional Regulatory Submissions And/Or Approvals.**

During 2003 the FDA notified us that it considers the application of the SynerGraft technology to allograft heart valves (CryoValve SG) to be a major manufacturing change and required us to submit a 510(k). We submitted a 510(k) for CryoValve SG and have received three requests for additional information from the FDA. While we have provided most of the requested information, we are still compiling additional information, including bench-testing and clinical data. We are also seeking to resolve certain other requests through administrative procedures at the FDA. It could be time-consuming and expensive to resolve this matter, depending in large part on the success of our efforts through the FDA's administrative processes. We can give no assurance that the FDA will agree with us or that it will clear the CryoValve SG 510(k) in the foreseeable future, if at all. If we are unable to resolve this issue, we may not be able to offer our SynerGraft process for human heart valves.

The FDA has also determined that non-valved cardiovascular CryoVein SG tissues processed using our SynerGraft technology should be regulated as medical devices and that it will require additional approvals for continued distribution of these tissues. Our appeal of this designation was denied. We cannot be certain that the designation of SynerGraft cardiovascular tissue will be resolved favorably. If we are unable to resolve this matter, we may not be able to offer our SynerGraft process for non-valved cardiac tissues.

**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 \$572,000, \$193,000 and \$421,000 for the years ended December 31, 2006, 2005 and 2004, respectively. We also offer BioGlue and other products for use in other countries.

**Our Violation Of Government Regulations Could Result In Loss Of Revenues And Customers As Well As Additional Compliance Expense.**

The FDA and some states regulate the facilities and processes that we use. Our facilities are also subject to periodic inspection by the FDA and state regulatory authorities to ensure our compliance with applicable laws and regulations. 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, and financial condition. We cannot be certain that the FDA or state 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.

**We Are The Subject Of An SEC Investigation.**

The SEC notified us in July 2003 that its informal inquiry became a formal investigation in June 2003. We have cooperated with this investigation both before and after issuance of the formal order of investigation in June 2003, and intend to continue doing so. We voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife shares on August 14, 2002 before trading was halted pending our press release reporting the FDA Order. These individuals were not then and are not currently executive officers of our Company. The formal order of investigation indicates that the SEC's scope includes whether, during 2002, among other things, we or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate controls. The investigation could also encompass matters not specifically identified in the formal order. On September 15, 2005, the SEC announced that it had commenced proceedings in federal district court against certain of the above-referenced former and current employees (and certain of their spouses) for alleged illegal insider trading arising out of their August 14, 2002 trading activities. Those proceedings resulted in settlements with the SEC. As of the date hereof, the SEC has had no discussions with our representatives as to whether the SEC will seek relief against us, or the nature of any relief that it may seek. At present, we are unable to predict the ultimate focus or outcome of the investigation, what the current status of the investigation may be, or when the SEC will complete it. An unfavorable outcome could result in monetary or other penalties and could materially and adversely affect our reputation, business, financial position, results of operations, and cash flows.

**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 16, 2007, we were aware of three pending product liability lawsuits against us. Two of these lawsuits are not covered by insurance because the claimed loss date was prior to the effective coverage date for the insurance policy. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against us that have not resulted in lawsuits. We are monitoring these claims.

Our December 31, 2006 Consolidated Balance Sheet reflects a liability in the amount 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 \$6.6 million liability included as a component of accrued expenses and other current liabilities of \$3.3 million and other long-term liabilities of \$3.3 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. These lawsuits, which named us as a nominal defendant, alleged that the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in certain inappropriate practices that caused the Company to suffer damages. 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. In September 2006 we 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 that we paid in 2005 in settlement of outstanding claims. No party admitted any liability as part of the September 2006 settlement. The \$2.1 million is included as a component of general, administrative, and marketing expenses on the Consolidated Statements of Operations as of December 31, 2006. We received the net proceeds of \$2.1 million in October 2006.

If we are unsuccessful in arranging acceptable settlements of product liability, 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. The 2004/2005 products liability policy was a two-year claims-made policy, covering claims arising since the commencement of the 2003/2004 policy year. The 2005/2006 products liability policy was a three-year claims-made policy, covering claims arising since the commencement of the 2003/2004 policy year. Our current products liability insurance policy is a four-year claims-made policy covering claims since the commencement of the 2003/2004 policy year and expires in March 2007. 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 five-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 2007. 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 that process human tissue, as well as companies that market mechanical valves and synthetic and animal tissue for implantation, and companies that market surgical adhesives and surgical sealants. Management believes that at least three domestic tissue banks offer preservation services for allograft heart valves and many companies offer processed porcine heart valves and mechanical heart valves. A few companies dominate portions of the mechanical, porcine and bovine heart valve markets, 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 and Surgifoam, and Tyco Healthcare's U.S. Surgical Division's Duraseal products. We are also aware that a few companies have surgical adhesive products under development. For example, Closure Medical is in clinical trials 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. 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, 2007. This increase may provide an opportunity for our competitors to gain market share. If we are unable to increase prices as planned and retain or improve our market share, our revenue and return to profitability may be adversely affected.

Our cryopreserved tissues compete with other entities that cryopreserve human tissue on the basis of technology, customer service, and quality assurance. Our competitors have been favorably impacted and we believe we have lost some market share because our procurement and processing yields of human tissue and our cardiovascular and vascular tissue shipments decreased following the FDA Order in 2002.

We believe that the human heart valves cryopreserved by us, as compared to mechanical, porcine, and bovine heart valves, compete on the factors set forth above. We also believe that our cryopreserved human heart valves compete by providing a tissue that is the preferred replacement alternative with respect to certain medical conditions, including:

Pediatric cardiac reconstruction,

Valve replacements for women in their child-bearing years, and

Valve replacements for patients with endocarditis.

Our BioGlue product competes on the basis of its high tensile strength and ease of use.

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. The FDA Order, related adverse publicity, and subsequent FDA activity have adversely affected our competitive position and may continue to do so in the future. 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 and applications applying our SynerGraft 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. For example, if we are unable to resolve the issues we are addressing with the FDA with regard to tissues processed using SynerGraft, we may incur significant costs over a lengthy period of time to meet the FDA's requirements. We may not be able to meet the FDA's requirements, and we may not be able to offer a commercially successful product.

Although we have conducted pre-clinical 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, BioLastic and BioDisc, 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 Or Distribution Rights May Not Be Successful.**

We may invest in new technology licenses 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 or purchasing initial inventory. Inability to recover our initial investment may adversely impact our profitability.

**We May Be Unable To Fund Our ACT Technology.**

The ACT is a reversible linker technology that has potential uses in the areas of fibrinolysis (blood clot dissolving) and other drug delivery applications. In February 2001 we formed AuraZyme, a wholly-owned subsidiary, in order to seek a corporate collaboration or to complete a potential private placement of equity or equity-oriented securities to fund the commercial development of the ACT. We have been seeking such funding since 1998 to allow us to continue developing this technology without incurring additional research and development expenditures, other than through AuraZyme. We cannot guarantee that we can obtain such funding on acceptable terms, if at all. Even if we can obtain such financing, we cannot guarantee that the ACT will in fact prove to be effective in the above applications. In addition, any new financing may dilute the ownership interests of our current shareholders, or may include restrictive covenants that could adversely affect us or our business.

**SynerGraft Processed Tissues May Not Demonstrate Expected Benefits.**

We process bovine tissues with the SynerGraft technology and market these services outside the U.S. The process involves antigen reduction, which is the depopulation of the cells of the tissue to be implanted, leaving a matrix of protein fibers that has the potential to be repopulated with the recipient's cells. If successful, we believe that such repopulation may increase graft longevity and improve the biocompatibility and functionality of such tissue, resulting in the implanted tissue behaving more like the recipient's own tissue. Studies on animals have shown that explanted SynerGraft processed heart valves will repopulate with the recipient's cells. However, should such tissues implanted in humans not consistently and adequately repopulate with the human host cells, the higher priced SynerGraft processed tissues may not demonstrate benefits over other alternatives. If this happens, it could materially and adversely affect our future expansion plans and could limit our future growth.

**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;

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 who would be difficult to replace. 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. Our key employees include our management team, consisting of:

Steven G. Anderson, President, Chief Executive Officer, and Chairman;

D. Ashley Lee, CPA, Executive Vice President, Chief Operating Officer, and Chief Financial Officer;

Albert E. Heacox, Ph.D., Senior Vice President, Research and Development;

Gerald B. Seery, Senior Vice President Sales and Marketing; and

David M. Fronk, Vice President, Regulatory Affairs and Quality Assurance.

We do not have key life insurance on these individuals. 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 EEA, 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 Public Health Services 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, and we believe that our ACT may be regulated as a biologic or drug by the FDA. The ACT has not been approved for commercial distribution in the U.S. or elsewhere. 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 required regulatory approvals from the FDA normally involves clinical trials as well as an extensive premarket approval application and often takes many years. The process 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 law, regulatory agency policy, 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. As noted above, the FDA Order and subsequent FDA activity had, and may continue to have, such an effect.

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 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 cryopreserved 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 cryopreserved 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 cryopreserved 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.

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 and preferred 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 and preferred stock would likely decline, perhaps substantially. Changes in the trading price of our common and preferred 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, 2004 to February 16, 2007 has ranged from a high of \$9.35 to a low of \$2.99. Our closing preferred stock price in the period March 15, 2005, the date of our first preferred stock issuance, to February 16, 2007 has ranged from a high of \$67.00 to a low of \$35.00.

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 And Contractual 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 our preferred shareholders whose preferential rights are superior to those receiving the distribution.

Under our new credit agreement, cash dividends on common stock are prohibited, and cash dividends on preferred stock may be paid only so long as we maintain at least \$7.5 million, in the aggregate, of borrowing capacity under the credit agreement plus cash, and specified cash equivalents, see **Risks Factors Risks Relating To Our Business We May be Unable to Comply with the Covenants of Our Credit Facility, Which Would Limit Our Borrowing Capacity and Potentially Result in a Default Under the Credit Facility, And Our Credit Facility Limits Our Ability To Issue Additional Debt Or Pay Cash Dividends**. Increased borrowings under the credit agreement and judgments or settlements arising out of product liability or other claims, negative operating cash flow and other factors which adversely affect available cash resources, will also adversely affect our ability to make cash dividend payments both generally and under the credit agreement. In addition, 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, including, in particular, statements regarding future products or services, market expansion, revenues, cost savings, procurement, tissue processing yields, regulatory activity, available funds and capital resources, and pending litigation. 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 as of their respective dates. 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 adequacy of product liability insurance to defend against lawsuits;

Increases in product liability insurance coverage costs, retention, and claims years covered;

The outcome of lawsuits filed against the Company, and of the SEC investigation;

The impact of the FDA Order and subsequent FDA activity, including the FDA's letters regarding the SynerGraft process and measures taken by the Company as a result, on future revenues, profits, and business operations;

The impact of the FDA's Form 483 Notices of Observation;

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

The Company's ability to increase yields and reduce its costs of tissue preservation services;

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

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The receipt of governmental grants for BioFoam development;

The results of patient studies and their use in applying for governmental approval for products and services;

The outcome of the Company's regulatory applications regarding its SynerGraft process;



Future increases in research and development expenses;

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

Product demand and market growth;

The success of the RTI Agreement, including anticipated cost savings and increased procurement of cardiovascular and vascular tissues;

The potential of the ACT for use in fibrinolysis (blood clot dissolving) and other drug delivery applications;

Expected revenue and earnings growth from recently announced strategic agreements;

Expected impact of adoption of new accounting pronouncements;

The impact on the Company of adverse publicity or negative surgical outcomes from products or services provided by the Company;

Anticipated future revenues and expenses;

Expected seasonality trends;

Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2006;

Anticipated impact of changes in interest rates;

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

The success of distribution, supplier and development agreements with third parties to distribute, supply and develop various Company, as well as third party, products and services;

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

The Company's ability to implement its strategic plans;

The adequacy of the Company's financial resources and its ability to borrow under its credit facility; and

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Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including the risk factors discussed in 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, 2006 (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 20% 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***

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 16, 2007 the Company was aware of three pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, two allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges a product liability claim arising from the Company's allograft orthopaedic tissue services.

Two of the outstanding product liability lawsuits against the Company are not covered by insurance, as the claimed loss date was prior to the effective coverage date for its insurance policy. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits as of February 16, 2007. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2006 of the settled but unpaid claims and the pending product liability claims based on settlement negotiations to date and advice from counsel. As of December 31, 2006 the Company had accrued a total of approximately \$330,000 for pending product liability. The \$330,000 accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2006 Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses related to one of the three pending product liability claims. The Company has not recorded an accrual for the remaining two product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. As of December 31, 2005 the Company had accrued a total of approximately \$1.5 million for settled but unpaid claims and pending product liability claims and recorded \$244,000 representing amounts to be recovered from the Company's insurance carriers. The \$1.5 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2005 Consolidated Balance Sheet.

If the Company is unable to settle one or more of the product liability lawsuits in which the Company is a defendant, and if any such lawsuit should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available liquid assets. Additionally, the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury with respect to any lawsuit that it is unable to settle prior to trial, and the Company's product liability insurance policies do not include coverage for any punitive damages. Failure by the Company to resolve the outstanding product liability claims within its ability to pay would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2006 the Company bound coverage for the 2006/2007 insurance policy year. This policy is a four-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2007 and reported during the period April 1, 2006 through March 31, 2007 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 2007 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2006. 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 2006 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 40% lower than non-BioGlue claims per million dollars of revenue. The 40% 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, including the Company's increased litigation activity following the FDA Order, the Company's low volume of pre-FDA Order historical claims, 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 2007 as of December 31, 2006, the Company estimated that its liability for unreported product liability claims was \$6.6 million as of December 31, 2006. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued \$6.6 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to December 31, 2006. The \$6.6 million



balance is 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. Further analysis indicated that the liability could be estimated to be as high as \$12.3 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, 2006, \$2.3 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.3 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.2 million on the December 31, 2006 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, 2006. Actual results may differ from this estimate.

As of December 31, 2005 the Company accrued \$7.5 million for unreported product liability claims and recorded a receivable of \$2.5 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$7.5 million accrual is included as a component of accrued expenses and other current liabilities of \$3.8 million and other long-term liabilities of \$3.7 million on the December 31, 2005 Consolidated Balance Sheet. The \$2.5 million insurance recoverable is included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.4 million on the December 31, 2005 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.

#### ***SEC Investigation***

On August 19, 2002 the Company issued a press release announcing that on August 17, 2002, the Company received a letter from the Atlanta District Office of the SEC inquiring about certain matters relating to the Company's August 14, 2002 announcement of the FDA Order. The SEC notified the Company in July 2003 that the inquiry became a formal investigation in June 2003. CryoLife cooperated with this investigation both before and after the issuance of the formal order of investigation in June 2003 and intends to continue doing so. CryoLife voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife shares on August 14, 2002, before trading was halted pending CryoLife's press release reporting the FDA Order. These individuals were not and are not executive officers of CryoLife. The formal order of investigation indicates that the SEC's scope includes whether, during 2002, among other things, CryoLife or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate controls. The investigation could also encompass matters not specifically identified in the formal order. On September 15, 2005 the SEC announced that it had commenced proceedings in federal district court against certain of the above-referenced former and current employees (and certain of their spouses) for alleged illegal insider trading arising out of their August 14, 2002 trading activities. Those proceedings resulted in settlements with the SEC. As of the date hereof, the SEC has had no discussions with CryoLife as to whether the SEC will seek relief against CryoLife, or the nature of any relief that may be sought. At present, CryoLife is unable to predict the ultimate focus, its current status, outcome of the investigation, or when it will be completed. An unfavorable outcome could have a material adverse effect on CryoLife's reputation, business, financial position, results of operations, and cash flows.

**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	68	President, Chief Executive Officer, and Chairman
David M. Fronk	Since 1998	43	Vice President, Regulatory Affairs and Quality Assurance
Albert E. Heacox, Ph.D.	Since 1989	56	Senior Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	42	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Gerald B. Seery	Since 2005	50	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.

**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 both cardiovascular 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. Mr. Lee is responsible for the financial affairs of the Company, as well as investor and corporate communications, legal affairs, manufacturing operations, information technology, human resources, and risk management. 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 cardiovascular medical devices. Mr. Seery received his BA in International Economics at The Catholic University of America in Washington, D.C. in 1978 and completed his MBA 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>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
<b>2005</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 8.60	\$ 5.86
Second quarter	8.28	5.70
Third quarter	8.05	6.41
Fourth quarter	7.20	3.10

As of February 16, 2007 the Company had 503 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. The holders of any outstanding shares of 6% convertible preferred stock issued by the Company have a preference as to the payment of dividends over the holders of shares of common stock. The holders of other shares of preferred stock that the Company may choose to issue could also have a preference as to the payment of dividends over the holders of common stock. See discussions of the Company's debt and limitations on the payment of dividends in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources and Item 8, Note 6 of the Notes to Consolidated Financial Statements.

The following table provides information about purchases by the Company during the quarter ended December 31, 2006 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

**Issuer Purchases of Equity Securities***Common Stock*

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Common Shares That May Yet Be Purchased Under the Programs
10/01/06 - 10/31/06		\$		
11/01/06 - 11/30/06	1,518	6.30		
12/01/06 - 12/31/06				
Total	1,518	\$ 6.30		

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



**6% Convertible Preferred Stock**

The Company did not repurchase any shares of its 6% convertible preferred stock in the quarter ended December 31, 2006.

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

The following table provides information as of December 31, 2006 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 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.

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants, and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Plans approved by shareholders	2,129,570	\$ 6.98	1,901,336
Plans not approved by shareholders	58,925	\$ 18.62	
<b>Total</b>	<b>2,188,495</b>	<b>\$ 7.29</b>	<b>1,901,336</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 or incorporated herein by reference.

**Selected Financial Data**

(in thousands, except percentages and per share data)

	2006	2005	December 31, 2004	2003	2002
<b>Operations</b>					
Revenues	\$ 81,311	\$ 69,282	\$ 62,384	\$ 59,532	\$ 77,795
Net income (loss)	365	(19,535)	(18,749)	(32,294)	(27,761)
Net loss applicable to common shareholders	(608)	(20,312)	(18,749)	(32,294)	(27,761)
Research and development as a percentage of revenues	4.4%	5.4%	6.3%	6.1%	5.9%
<b>Loss Per Common Share</b>					
Basic	\$ (0.02)	\$ (0.85)	\$ (0.81)	\$ (1.64)	\$ (1.43)
Diluted	\$ (0.02)	\$ (0.85)	\$ (0.81)	\$ (1.64)	\$ (1.43)
<b>Year-End Financial Position</b>					
Total assets	\$ 79,865	\$ 76,809	\$ 73,261	\$ 75,027	\$ 106,414
Working capital	26,472	23,922	19,689	14,790	39,385
Long term liabilities	4,864	4,909	5,629	5,716	4,552
Convertible preferred stock	3	3			
Shareholders' equity	52,088	50,621	49,660	48,338	79,800
Current ratio <sup>1</sup>	2:1	2:1	2:1	2:1	3:1

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<u>Shareholders</u> equity per diluted common share	\$ 2.10	\$ 2.11	\$ 2.16	\$ 2.46	\$ 4.11
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<sup>1</sup> Current assets divided by current liabilities.

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

**Overview**

For CryoLife Inc., (CryoLife or the Company), the year ended December 31, 2006 brought a return to profitability as CryoLife reported net income for the year ended December 31, 2006. The fourth quarter of 2006 was a strong quarter for the Company, as product and preservation services revenues for the quarter reached a four-year high and BioGlue quarterly revenues reached an all time high for the Company. For the year ended December 31, 2006 revenues increased for each of CryoLife's three tissue types, cardiovascular, vascular, and orthopaedic and also for BioGlue, resulting in an increase in product and preservation services revenues of 17% over 2005.

The year ended December 31, 2006 also brought the resolution of some legal matters still outstanding as a result of the FDA Order as defined in Part I, Item I, Business and other FDA activity. During the third quarter of 2006 the Company recognized a net \$2.1 million gain related to the settlement of insurance coverage disputes. The Company also recorded favorable adjustments during 2006 to reduce the levels of its legal reserves for unreported product liability claims in accordance with new actuarial valuations, as the amount of new product liability claims brought against the Company and the expense related to product liability claims continued to decline from the levels experienced in 2002 and 2003.

During the fourth quarter of 2006 the Company began focusing its efforts on new strategic initiatives. On November 2, 2006 the Company announced the successful conclusion of its strategic review begun in January 2006 at the request of the Company's Board of Directors and with the assistance of Piper Jaffray & Co. As a result of this review, the Board of Directors 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. Subsequent to conclusion of this strategic review, the Company has announced several initiatives which management believes will benefit the Company with future revenue and earnings growth. Agreements reached with BioForm Medical, Inc., Regeneration Technologies Inc. (RTI), Cleveland Clinic, and MAST Biosurgery, Inc. are discussed in more detail in Part I, Item I, Business. The Company is continuing to review opportunities to implement its three key strategies and enhance the Company's performance in the coming years.

See Part I, Item 1, Business, for further discussion of the Company's business and activities during 2006.

**Recent Events**

On December 19, 2006 CryoLife announced that they had entered into an exchange and service agreement with Regeneration Technologies, Inc., and certain of its affiliates, (collectively, RTI), respecting procurement, processing, and distribution activities for cardiovascular and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife (RTI Agreement). According to the RTI Agreement, CryoLife ceased accepting for processing donated human orthopaedic tissue commencing January 1, 2007 and will work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise, on January 1, 2007 RTI ceased accepting donated human cardiovascular and vascular tissues for processing and will work to transition its arrangements for recovery of these tissues to CryoLife. Certain physical assets relating to the tissues that are the subject of the agreement may also be transferred between the parties. 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 cardiovascular and vascular tissue inventory, through June 30, 2008. After that date CryoLife will become entitled to distribute RTI's remaining cardiovascular and vascular tissue inventory, and RTI will become entitled to distribute CryoLife's remaining orthopaedic tissue inventory, for a fee. 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.

**Critical Accounting Policies**

A summary of the Company's significant accounting policies is included in 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 16, 2007 the Company was aware of three pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, two allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges a product liability claim arising from allograft orthopaedic tissue services.

Two of the outstanding product liability lawsuits against the Company are not covered by insurance policies, as the claimed loss date was prior to the effective coverage date for the insurance policy. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits as of February 16, 2007. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2006 of the settled but unpaid claims and the pending product liability claims based on settlement negotiations to date and advice from counsel. As of December 31, 2006 the Company had accrued a total of approximately \$330,000 for pending product liability claims. The \$330,000 accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2006 Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses related to one of the three pending product liability claims. The Company has not recorded an accrual for the remaining two product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. As of December 31, 2005 the Company had accrued a total of approximately \$1.5 million for settled but unpaid claims and pending product liability claims and recorded \$244,000 representing amounts to be recovered from the Company's insurance carriers. The \$1.5 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2005 Consolidated Balance Sheet.

If the Company is unable to settle one or more of the product liability lawsuits in which the Company is a defendant, and if any such lawsuit should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available liquid assets. Additionally, the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury with respect to any lawsuit that it is unable to settle prior to trial, and the Company's product liability insurance policies do not include coverage for any punitive damages. Failure by the Company to resolve the outstanding product liability claims within its ability to pay would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2006 the Company bound coverage for the 2006/2007 insurance policy year. This policy is a four-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2007 and reported during the period April 1, 2006 through March 31, 2007 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 2007 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2006. 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 2006 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 40% lower than non-BioGlue claims per million dollars of revenue. The 40% 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, including the Company's increased litigation activity following the FDA Order, the Company's low volume of pre-FDA Order historical claims, 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 2007 as of December 31, 2006, the Company estimated that its liability for unreported product liability claims was \$6.6 million. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued \$6.6 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to December 31, 2006. The \$6.6 million balance is 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. Further analysis indicated that the liability could be estimated to be as high as \$12.3 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, 2006, \$2.3 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.3 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.2 million on the December 31, 2006 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, 2006. Actual results may differ from this estimate.

As of December 31, 2005 the Company accrued \$7.5 million for unreported product liability claims and recorded a receivable of \$2.5 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$7.5 million accrual is included as a component of accrued expenses and other current liabilities of \$3.8 million and other long-term liabilities of \$3.7 million on the December 31, 2005 Consolidated Balance Sheet. The \$2.5 million insurance recoverable is included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.4 million on the December 31, 2005 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 laboratory expenses, tissue procurement fees, freight-in charges, and fringe benefits) 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.

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. The Company 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 RTI Agreement discussed above. This write-down is based on the Company's 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 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.

The Company also recorded \$1.2 million in the year ended December 31, 2006 and \$1.8 million in the year ended December 31, 2005 as an increase to cost of preservation services to write-down the value of certain deferred tissue 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 regularly evaluates its deferred preservation costs to determine if an impairment in the value of the deferred preservation costs is required when the value of these tissues is not expected to be fully recoverable. A write-down of \$588,000 was recorded for the year ended December 31, 2006 due to the impairment of certain 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 tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when it is more likely than not that the full value of a deferred tax asset will not be recovered.

The Company assesses the recoverability of its deferred tax assets on an annual basis, and on an interim basis, 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, 2006 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, at December 31, 2006 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, 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 realizability of the Company's deferred tax assets could be limited in future periods as mandated by Internal Revenue Service Section 382.



**Valuation of Long-lived and Intangible Assets and Goodwill:** The Company assesses the impairment of its long-lived, identifiable intangible assets and related goodwill annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that management considers important 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, and

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

Statement of Financial Accounting Standards (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. In applying SFAS 144 the Company defined the specific asset groups used to perform the cash flow analysis. The Company defined the asset groups at the lowest level possible, by identifying the cash flows from groups of assets that could be segregated from the cash flows of other assets and liabilities. Using this methodology the Company determined that its asset groups consisted of the long-lived assets related to the Company's two reporting segments. As the Company does not segregate assets by segment the Company allocated assets to the two reporting segments based on factors including facility space and revenues. The undiscounted future cash flows related to these asset groups exceeded their carrying values as of December 31, 2006 and 2005 and, therefore, management concluded that there was not an impairment of the Company's long-lived intangible assets and tangible assets related to the tissue preservation business or medical device business. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142), requires that goodwill resulting from business acquisitions and other intangible assets be subject to periodic impairment testing. The Company's intangible assets consist of patents and trademarks. In addition, during 2006, the Company acquired customer lists, non-compete agreements, procurement contracts and access to the procurement of cardiovascular and vascular human tissues previously received by RTI as a result of the RTI Agreement discussed in Recent Events above. The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. As of December 31, 2006 and 2005 the Company did not believe that an impairment existed related to its intangible assets.

**Derivative Instruments:** The terms of the Company's first quarter 6% convertible Preferred Stock offering include a Dividend Make-Whole Payment. If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock. The Dividend Make-Whole Payment is 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. In accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities (SFAS 133), the Company is required to separate and account for, as an embedded derivative, the Dividend Make-Whole Payment feature of the Preferred Stock, (the Derivative). As an embedded derivative instrument, the Dividend Make-Whole Payment feature must be measured at fair value and reflected as a current liability on the Company's Consolidated Balance Sheets. Changes in the fair value of the Derivative are recognized as the line item change in valuation of derivative as non-operating income/expense on the Company's Consolidated Statements of Operations.

The accounting for derivatives is complex, and requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the Dividend Make-Whole Payment feature is based on various assumptions, including the estimated market volatility and discount rates. The use of different assumptions may have a material effect on the estimated fair value amount, which is reflected in the Company's results of operations and financial position.

### **New Accounting Pronouncements**

The Company will be required to adopt Financial Accounting Standards Board ( FASB ) Interpretation No. 48 Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 ( FIN 48 ) for the fiscal year beginning January 1, 2007. 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. The cumulative effect of adoption of this interpretation will be reported as an adjustment to the opening balance of retained earnings. The Company does not anticipate that the adoption of FIN 48 will have a material affect on its results of operations or financial position, although the Company is continuing to evaluate the full impact of the adoption of FIN 48.

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 is in the process of evaluating the impact of SFAS 157 on its results of operations and financial position.

The Company was required to adopt Staff Accounting Bulletin ( SAB ) No. 108, codified as SAB Topic 1.N, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements ( SAB 108 ) for the year ended December 31, 2006. SAB 108 requires the use of both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. Adjustment to the financial statements is required if either approach results in quantifying a misstatement that is material. The adoption of SAB 108 did not have an impact on the Company's results of operations and financial position.

**Results of Operations**

(In thousands)

*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 BioGlue revenues and in preservation service revenues for each of the three major tissue types processed by the Company is presented below.

**BioGlue**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2006	2005	2006	2005
Revenues	\$ 10,491	\$ 9,645	\$ 40,025	\$ 37,985
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.

The Company anticipates that BioGlue revenues in 2007 will continue to increase due in part to domestic price increases that went into effect on July 1, 2006 and January 1, 2007 and due to projected unit growth in domestic and international markets.



**Cardiovascular 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
Cardiovascular revenues as a percentage of total revenue	21%	19%	20%	20%

Revenues from cardiovascular 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 cardiovascular tissues, which increased revenues by 14%.

Revenues from cardiovascular 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 cardiovascular 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 cardiovascular 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 cardiovascular revenues due to a shift in product mix, as the increases were primarily experienced in products with smaller per unit revenues than the average cardiovascular 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.

The Company anticipates that cardiovascular service revenues in 2007 will increase due in part to the continuing effect of price increases that went into effect in 2006, price increases on certain non-valved cardiac tissues as of January 1, 2007, and projected growth in cardiovascular tissue shipments during 2007, primarily as a result of expected increases in procurement. The Company anticipates that procurement of cardiac tissues during 2007 will be favorably impacted by the RTI Agreement discussed in Recent Events above as a result of the anticipated transition of some or all of the tissue procurement previously received by RTI to the Company.

**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.

The Company anticipates that vascular service revenues in 2007 will increase due in part to the continuing effect of the price increase that went into effect in 2006, price increases as of January 1, 2007, and projected growth in vascular tissue shipments during 2007, as a result of expected increases in procurement. The Company anticipates that procurement of vascular tissues during 2007 will be favorably impacted by the RTI Agreement discussed in Recent Events above as a result of the anticipated transition of some or all of the tissue procurement previously received by RTI to the Company.

#### *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.

The Company anticipates that orthopaedic service revenues in 2007 will decrease significantly from 2006 due to the Company's cessation of processing orthopaedic tissues on January 1, 2007 in accordance with the RTI Agreement discussed in Recent Events above. Although under the RTI Agreement CryoLife will continue to ship its existing orthopaedic tissues through June 30, 2008, the volume of orthopaedic tissue shipments is expected to decrease each quarter beginning with the first quarter of 2007 as the higher demand tissues and sizes are exhausted from the existing tissue inventories.

#### ***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 \$926,000 for the development of protein hydrogel technology for use on the battlefield. The Company applied for and was awarded the full \$926,000 allocated under the 2005 DOD Grant in connection with its development of BioFoam®. The Company has received advances totaling \$926,000 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.

The Company anticipates that other revenues in 2007 will increase over 2006 due to continuing recognition of the Company's licensing revenues during 2007 and an anticipated increase in grant revenues related to spending on BioFoam research.

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

##### ***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.

The Company anticipates that in 2007 cost of products will increase to reflect volume increases.

##### ***Cost of Human Tissue Preservation Services***

Cost of human tissue 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 tissue preservation service revenues during

such periods. Cost of human tissue 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 human tissue 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 human tissue 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 tissue preservation service revenues during such periods. Cost of human tissue 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 discussed above, 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 human tissue 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 tissue preservation costs as a result of the RTI Agreement during 2006 is 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 Item 8, Note 3 of the Notes to Consolidated Financial Statements for further discussion of the RTI Agreement and its financial impact.

The write-down of deferred tissue 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 current year periods as compared to the prior year periods is 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 is 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 human tissue preservation services for the three and twelve months ended December 30, 2006 is primarily due to increased tissue preservation service volume as compared to the same period in 2005. After considering the effects of the write-downs discussed above, cost of human tissue preservation services as a percentage of total tissue preservation service revenues decreased. The decrease is primarily due to improvements in tissue 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.

The Company anticipates that aggregate cost of human tissue preservation services in 2007 will be similar to 2006. The Company anticipates that cost of human tissue preservation services as a percentage of tissue preservation service revenues will decrease in 2007 as compared to 2006 as a result of a mix shift as the percentage of shipments of lower margin orthopaedic tissues decrease and shipments of cardiovascular and vascular tissues increase. Cardiovascular and vascular tissue shipments are expected to increase during 2007 as a result of anticipated increases in procurement. The Company expects that procurement of cardiovascular and vascular tissues during 2007 will be favorably impacted by the RTI Agreement discussed in Recent Events above.

#### ***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 a \$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 \$2.1 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 decrease in legal and professional fees.

The Company anticipates that general, administrative, and marketing expenses will increase in 2007 when compared to 2006, due to the expected increases in marketing expenses and in personnel related expenses to support expected revenue growth and personnel increases, although several important components are difficult to estimate or control. For example the Company will continue to evaluate the level of accruals for product liability claims and make adjustments as required based on periodic actuarial analyses and product liability claim status. Adjustments to these accruals may be required during 2007, and the effect of these adjustments may be favorable or unfavorable to general, administrative, and marketing expenses.

#### ***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 and discussed in the Recent Events section above. 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 cardiovascular 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 Item 8, Note 3 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 Soft Tissue Repair Matrix, and Protein Hydrogel Technologies ( PHT ), which include BioGlue, BioFoam, BioDisc, and related products.

The Company anticipates that research and development expenses will increase in 2007 when compared to 2006, primarily due to increased spending on research related to PHT, particularly BioFoam and BioDisc, as well as continuing spending on research related to SynerGraft products and tissues, and human tissue preservation. The BioFoam spending increase is expected to be due in part to funds the Company has obtained or expects to obtain pursuant to the 2005 and 2006 Defense Appropriation Conference Report discussed in Revenues Other Revenues above.

**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 is primarily due to higher borrowings under the Company's February 2005 credit agreement with Wells Fargo Foothill, Inc. (the Credit Agreement) as compared to the same period in 2005 and higher interest rates on these borrowings, as the bank's prime lending rate has increased since the prior year 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 is unable to estimate the change in valuation of the Derivative for 2007, as this amount is subject to numerous variables including the market value of the Company's common stock, the number of preferred stock shares converted during 2007, and the general level of U.S. interest rates. The change in valuation of the Derivative in 2007 could significantly differ from the levels experienced in 2006.

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 of for the three months ended December 31, 2006 was primarily due to alternative minimum tax on the Company'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 of 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 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.

**Year Ended December 31, 2005 Compared to Year Ended December 31, 2004**

Revenues

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2005	2004	2005	2004
Revenues	\$ 17,961	\$ 15,866	\$ 69,282	\$ 62,384

Revenues increased 13% for the three months ended December 31, 2005 as compared to the three months ended December 31, 2004. This increase was primarily due to an increase in sales of BioGlue and an increase in preservation service revenues for each of the Company's three major tissue types as compared to the prior year period.

Revenues increased 11% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004. This increase was primarily due to an increase in sales of BioGlue and an increase in preservation service revenues for each of the Company's three major tissue types as compared to the prior year.

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

**BioGlue**

	Three Months Ended		Twelve Months Ended	
	December 31, 2005	December 31, 2004	December 31, 2005	December 31, 2004
Revenues	\$ 9,645	\$ 9,226	\$ 37,985	\$ 35,745
BioGlue revenues as a percentage of total revenue	54%	58%	55%	57%

Revenues from the sale of BioGlue increased 5% for the three months ended December 31, 2005 as compared to the three months ended December 31, 2004. BioGlue revenues for the three months ended December 31, 2005 included an increase in average selling prices, which increased revenues by 7%, partially offset by a decrease in BioGlue sales volume, which decreased revenues by 1% and the effect of foreign currency exchange, which decreased revenues by 1%.

Revenues from the sale of BioGlue increased 6% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004. The 6% increase in revenues for the twelve months ended December 31, 2005 was due to an increase in average selling prices, which increased revenues.

The increase in average selling prices for the quarter and year to date periods was primarily due to list price increases that went into effect on January 1, 2005 domestically. BioGlue volume for the three months ended December 31, 2005 was 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 (a variety of optional applicator tips are available for the BioGlue syringe). Primarily as a result of these lost accessory sales, BioGlue volume decreased slightly for the three months ended December 31, 2005 compared to the three months ended December 31, 2004, despite an increase in the milliliters of BioGlue sold during that the same period. Domestic revenues accounted for 76% of total BioGlue revenues in 2005 and 78% of total BioGlue revenues in 2004.

**Cardiovascular Preservation Services**

	Three Months Ended		Twelve Months Ended	
	December 31, 2005	December 31, 2004	December 31, 2005	December 31, 2004
Revenues	\$ 3,355	\$ 2,767	\$ 13,762	\$ 12,504
Cardiovascular revenues as a percentage of total revenue	19%	17%	20%	20%

Revenues from cardiovascular preservation services increased 21% for the three months ended December 31, 2005 as compared to the three months ended December 31, 2004. The 21% increase in revenues for the three months ended December 31, 2005 was due to an increase in average service fees, which increased revenues by 14%, and an increase in cardiovascular volume, which increased revenues by 7%.

Revenues from cardiovascular preservation services increased 10% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004. The 10% increase in revenues for the twelve months ended December 31, 2005 was due to an increase in average service fees, which increased revenues by 20%, partially offset by a decrease in cardiovascular volume, which reduced revenues by 10%.

The increase in average service fees reflected the fee increases that went into effect in July 2004 and January 2005. The fee increases primarily increased revenues for traditionally processed pulmonary valves and aortic valves. The increase in cardiovascular volume for the three month period ended December 31, 2005 was primarily due to increases in aortic valve shipments and to a lesser extent shipments of non-valved conduits and patch material due in part to improved cardiac procurement in the latter part of 2005. The decrease in cardiovascular volume for the twelve months ended December 31, 2005 was largely due to a reduced level of pulmonary valve shipments, primarily due to the reduced amount of tissues available for implantation as a result of a decline in procurement levels, particularly in the first half of 2005. See the additional discussion of procurement below.

The Company's procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, increased 10% during second half of 2005 as compared to the first six months of 2005. The Company's procurement of cardiac tissues decreased 11% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004.

#### *Vascular Preservation Services*

	Three Months Ended		Twelve Months Ended	
	December 31, 2005	December 31, 2004	December 31, 2005	December 31, 2004
Revenues	\$ 3,172	\$ 2,522	\$ 11,453	\$ 10,293
Vascular revenues as a percentage of total revenue	18%	16%	17%	16%

Revenues from vascular preservation services increased 26% for the three months ended December 31, 2005 as compared to the three months ended December 31, 2004. The 26% increase in revenues for the three months ended December 31, 2005 was due to an increase in average service fees, which increased revenues by 16% and an increase in vascular volume, which increased revenues by 10%.

Revenues from vascular preservation services increased 11% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004. The 11% increase in revenues for the twelve months ended December 31, 2005 was due to an increase in average service fees, which increased revenues by 20%, partially offset by a decrease in vascular volume, which reduced revenues by 9%.

The increase in average service fees reflected the fee increases that went into effect in July 2004 and January 2005 on all vascular tissues. The increase in vascular volume for the three months ended December 31, 2005 is primarily due to increases in shipments of saphenous veins, due in part to improved vascular procurement in the second half of 2005. The decrease in vascular volume for the twelve months ended December 31, 2005 is primarily due to decreases in shipments of saphenous veins, due in part to a decline in procurement levels in the fourth quarter of 2004 and the first quarter of 2005, which had a negative impact on vascular revenues for the year ended December 31, 2005. See the additional discussion of procurement below.

The Company's procurement of vascular tissues increased 41% during the second half of 2005 as compared to the first six months of 2005. The Company's procurement of vascular tissues increased 9% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004.

#### *Orthopaedic Preservation Services*

	Three Months Ended		Twelve Months Ended	
	December 31, 2005	December 31, 2004	December 31, 2005	December 31, 2004
Revenues	\$ 1,561	\$ 1,153	\$ 5,092	\$ 2,879
Orthopaedic revenues as a percentage of total revenue	9%	7%	7%	5%

Revenues from orthopaedic preservation services increased 35% for the three months ended December 31, 2005 as compared to the three months ended December 31, 2004. The 35% increase in revenues for the three months ended December 31, 2005 was largely due to an increase in orthopaedic volume, which increased revenues by 37%.

Revenues from orthopaedic preservation services increased 77% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004. The 77% increase in revenues for the twelve months ended December 31, 2005 was due to an increase in orthopaedic volume, which increased revenues by 77%.

The volume increase was primarily due to an increase in shipments of osteochondral grafts and non-boned tendons for the three and twelve months ended December 31, 2005. The increase in orthopaedic tissue shipments was directly related to an increase in demand for the Company's orthopaedic tissues through the introduction of the new cryopreserved osteochondral graft in the first quarter of 2005, the reestablishment of the Company's presence in the orthopaedic tissue business, and the rebuilding of the Company's supply of tissues available for shipment. To a lesser degree, the Company's orthopaedic tissue business was favorably impacted in 2005 by the introduction of tissues terminally sterilized with gamma irradiation.

The Company's procurement of orthopaedic tissues increased 30% during the second half of 2005 as compared to the first six months of 2005. The Company's procurement of orthopaedic tissues decreased 25% for the twelve months ended December 31, 2005 as compared to the twelve months ended December 31, 2004.

#### ***Grant Revenues***

Grant revenues were \$43,000 and zero, respectively, for the three months ended December 31, 2005 and 2004. Grant revenues were \$43,000 and \$71,000, respectively, for the twelve months ended December 31, 2005 and 2004.

Grant revenues in 2005 are related to funding received under the 2005 DOD Grant, which included \$926,000 for the development of protein hydrogel technology for use on the battlefield. The Company applied for and was awarded the full \$926,000 allocated under the 2005 DOD Grant in connection with its development of BioFoam. The Company began receiving advances under the grant during the second half of 2005, and was involved in the initial animal trial with the U.S. Army's Institute for Surgical Research. As a result the Company began recognizing revenues for expenses incurred related to this grant during the fourth quarter of 2005.

#### **Costs and Expenses**

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

Cost of products was \$1.9 million for the three months ended December 31, 2005 as compared to \$2.0 million for the three months ended December 31, 2004, representing 20% and 21%, respectively, of total product revenues during such periods. Cost of products was \$8.1 million for the twelve months ended December 31, 2005 as compared to \$7.8 million for the twelve months ended December 31, 2004, representing 21% of total product revenues during each such period. Cost of products as a percentage of total product revenues remained at consistent levels from period-to-period.

##### ***Cost of Human Tissue Preservation Services***

Cost of human tissue preservation services was \$6.4 million for the three months ended December 31, 2005 as compared to \$6.0 million for the three months ended December 31, 2004, representing 79% and 94%, respectively, of total tissue preservation service revenues during such periods. Cost of human tissue preservation services for the three months ended December 31, 2005 and 2004 includes the write-down of \$499,000 and \$511,000, respectively, of certain deferred preservation costs that exceeded market value.

Cost of human tissue preservation services was \$24.4 million for the twelve months ended December 31, 2005 as compared to \$29.8 million for the twelve months ended December 31, 2004, representing 80% and 116%, respectively, of total tissue preservation service revenues during such periods. Cost of human tissue preservation services for the twelve months ended December 31, 2005 and 2004 includes the write-down of \$1.8 million and \$6.6 million, respectively, reflecting current period processing costs that exceeded market value based on recent average service fees. The twelve months ended December 31, 2004 also included \$353,000 in costs related to the write-down of SynerGraft processed tissues.

The write-down of deferred tissue preservation costs in both the three and twelve months ended December 31, 2005 and 2004 is primarily due to higher overhead cost allocations per unit associated with lower tissue processing volumes and

changes in processing methods subsequent to the FDA Order, resulting in costs which exceed market value for certain tissues. The decrease in cost of human tissue preservation services for the twelve month period ended December 31, 2005 and the decrease in cost of human tissue preservation services as a percentage of tissue preservation service revenues for the three and twelve month period ended December 31, 2005 is primarily due to improvements in the Company's tissue processing yields and, to a lesser extent, an increase in the number of tissues processed. Cost of human tissue preservation services as a percentage of tissue preservation service revenues was favorably affected by shipments of tissue with a zero cost basis for which revenues were recognized but costs, estimated to be \$549,000 for the twelve months ended December 31, 2004, had already been recorded in previous periods primarily related to write-downs of deferred preservation costs in 2002. The write-downs of deferred preservation costs during 2002 created a new cost basis, which cannot be written back up when these tissues are shipped or become available for shipment.

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

General, administrative, and marketing expenses decreased 2% to \$10.5 million for the three months ended December 31, 2005, compared to \$10.7 million for the three months ended December 31, 2004, representing 59% and 67%, respectively, of total revenues during such periods. 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 and unfavorable adjustments/expenses of approximately \$89,000 related to the expensing of stock options in accordance with the provisions of SFAS 123R and \$150,000 to accrue post employment benefits related to the signing of a compensation agreement by one of the Company's senior executives. Excluding these items, general, administrative, and marketing expenses decreased due to a decrease in insurance costs, largely offset by increases in marketing fees primarily due to increased marketing expenses to support revenue growth including increased commissions and expenses related to tradeshows.

General, administrative, and marketing expenses increased 25% to \$53.2 million for the twelve months ended December 31, 2005, compared to \$42.6 million for the twelve months ended December 31, 2004, representing 77% and 68%, respectively, of total revenues during such periods. 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 as discussed in Item 8, Note 10 of the Notes to Consolidated Financial Statements, and approximately \$851,000 in post employment benefits related to the signing of a compensation agreement by one of the Company's senior executives, partially offset by a reversal of approximately \$961,000 in previously accrued legal expenses and settlement accruals. General, administrative, and marketing expenses for the twelve months ended December 31, 2004 includes an accrual of approximately \$1.5 million in additional legal expenses and settlement accruals. Excluding these items, general, administrative, and marketing expenses decreased due to lower professional fees and \$269,000 in lower insurance costs in 2005 as compared to 2004, largely offset by increases in marketing fees primarily due to increased marketing expenses to support revenue growth including increased commissions.

#### ***Research and Development Expenses***

Research and development expenses were \$980,000 for the three months ended December 31, 2005, compared to \$1.2 million for the three months ended December 31, 2004, representing 6% and 8%, respectively, of total revenues during such periods. Research and development expenses were \$3.7 million for the twelve months ended December 31, 2005 compared to \$3.9 million for the twelve months ended December 31, 2004, representing 5% and 6%, respectively, of total revenues during such periods. Research and development spending in 2005 and 2004 was primarily focused on the Company's tissue preservation, SynerGraft, and Protein Hydrogel Technologies, which include BioGlue and related products.

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

Interest expense increased to \$126,000 for the three months ended December 31, 2005, compared to \$40,000 for the three months ended December 31, 2004. Interest expense increased to \$346,000 for the twelve months ended December 31, 2005, compared to \$196,000 for the twelve months ended December 31, 2004. Interest expense for the three and twelve months ended December 31, 2005 included interest incurred related to the Credit Agreement, short term notes payable, and capital leases. Interest expense for the three and twelve months ended December 31, 2004 included interest incurred related to the Company's short term notes payable and capital leases.

Interest income increased to \$123,000 for the three months ended December 31, 2005, compared to \$61,000 for the three months ended December 31, 2004. Interest income increased to \$531,000 for the twelve months ended December 31, 2005, compared to \$262,000 for the twelve months ended December 31, 2004. Interest income in both periods was primarily due to interest earned on the Company's cash, cash equivalents, and marketable securities.

The change in valuation of the derivative was income of \$512,000 for the three months ended December 31, 2005 and \$140,000 for the twelve months ended December 31, 2005. The change in valuation of derivative in the three and twelve months ended December 31, 2005 reflects the amount of the Dividend Make-Whole Payment on preferred shares converted during the period and the amount of the change in valuation of the derivative. The change in valuation of the derivative was zero for the three and twelve months ended December 31, 2004, as the Derivative was first established in March 2005.

### **Seasonality**

The demand for BioGlue appears to experience seasonality, 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 cardiovascular tissue preservation services has historically been seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiovascular 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 cardiovascular tissues. This seasonal trend has been obscured in recent years by the impact of the FDA Order and related events. The Company expects that this seasonal trend will be apparent in future years.

The demand for the Company's human vascular and orthopaedic tissue preservation services and bioprosthetic cardiovascular and vascular devices does not appear to experience seasonal trends.

### **Liquidity and Capital Resources**

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

At December 31, 2006 net working capital (current assets of \$49.4 million less current liabilities of \$22.9 million) was \$26.5 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$23.9 million, with a current ratio of 2 to 1 at December 31, 2005.

The Company's primary capital requirements for the twelve months ended December 31, 2006 arose out of general working capital needs, capital expenditures for facilities and equipment, and funding of research and development projects. In recent years the Company's operating activities have failed to generate sufficient cash to fund its business due to the increasing costs of operations, primarily costs related to the Company's tissue preservation services business, increases in general, administrative, and marketing costs over pre-FDA Order levels, and increased legal, professional, and litigation expenses. For the twelve months ended December 31, 2006 the Company funded its operating cash requirements primarily through existing cash, cash equivalents, and marketable securities, and through bank credit facilities.

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

The Company believes that the Company's existing cash, cash equivalents, marketable securities, and availability under the Credit Agreement will enable the Company to meet its liquidity needs through at least December 31, 2007.

The Company could experience an adverse impact on revenues and cash flows during 2007 from decreases in orthopaedic revenue as a result of the RTI Agreement, which will need to be offset by increases in cardiovascular and vascular revenues derived as a result of the RTI Agreement.

The Company believes the following should continue to have a favorable impact on cash flow from operations during 2007, although there can be no assurance that these events will occur as and when currently anticipated:

Expected increases in BioGlue revenues over levels experienced in 2006 due to increases in BioGlue list prices implemented in July 2006 and January 2007 and anticipated volume increases,

Expected increases in total preservation service revenues over levels experienced in 2006 due to fee increases for certain tissues implemented in July 2006 and January 2007, to reflect the higher cost of processing these tissues, and anticipated volume increases for cardiovascular and vascular tissues,

Anticipated net benefits of the RTI Agreement in reducing general, administrative, and marketing costs related to orthopaedic tissues, and

Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2006.

However, the Company's long term liquidity and capital requirements will depend upon numerous factors, including:

The success of BioGlue and other products using related technology,

The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,

The Company's ability to maintain sufficient margins on its tissue preservation services,

The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,

The timing and cost of resolving product liability lawsuits and other claims (as discussed in Item 8, Note 10 of the Notes to Consolidated Financial Statements ),

The successful transition of cardiovascular and vascular tissue procurement previously received by RTI to the Company (as discussed in Item 8, Note 3 of the Notes to Consolidated Financial Statements ),

To a lesser degree, the Company's success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft technology (as discussed in Item 8, Note 2 of the Notes to Consolidated Financial Statements ), and

The Company's success in implementing its recently identified strategic initiatives.

If the Company is unable to address these issues and continues to experience negative operating cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond December 31, 2007. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. as lender (the Credit Agreement ) to address some of its liquidity needs. As of December 31, 2006 the outstanding balance of the Credit Agreement was \$4.5 million and the remaining borrowing availability was \$10.5 million. The Company's borrowing availability is subject to various limitations as discussed in Item 8, Note 6 of the Notes to Consolidated Financial Statements that may restrict future borrowings.



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In January 2006 the Company engaged Piper Jaffray & Co. 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.

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*Product Liability Claims*

As discussed in Item 8, Note 10 of the Notes to Consolidated Financial Statements, as of December 31, 2006 the Company had accrued a total of \$330,000 for pending product liability lawsuits. The \$330,000 accrual is an estimate of the Company's portion of the costs required to resolve one of three outstanding claims, and does not reflect actual settlement arrangements or actual judgments for all open claims, including punitive damages, which may be assessed by the courts. The \$330,000 accrual is not a cash reserve. The timing and amount of actual future payments is dependent on when and if judgments are rendered, and/or settlements are reached. Should payments related to the accrual 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 these outstanding claims in order to minimize the potential cash payout.

If the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available liquid assets. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

As discussed in Item 8, Note 10 of the Notes to Consolidated Financial Statements, at December 31, 2006 the Company had accrued a total \$6.6 million for the estimated costs of unreported product liability claims related to services performed and products sold prior to December 31, 2006 and had recorded a receivable of \$2.3 million representing amounts to be paid by the Company's insurance carriers. Further analysis indicated that the liability could be estimated to be as high as \$12.3 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The \$6.6 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.

*Net Cash from Operating Activities*

Net cash used in operating activities was \$1.1 million for the twelve months ended December 31, 2006 as compared to \$18.5 million for the twelve months ended December 31, 2005. The \$1.1 million in current year cash used was primarily due to the Company's working capital needs, as reflected in the increases in deferred preservation costs, inventory, and accounts receivable on the Company's Consolidated Balance Sheet.

The Company uses the indirect method to prepare its cash flow statement, and as such the operating cash flows are based on the Company's net income, which is then adjusted to remove non-cash items included that generated a book gain or loss during the period and for changes in operating assets and liabilities. For the twelve months ended December 31, 2006 the Company's \$365,000 net income included significant non-cash items that generated favorable and unfavorable adjustments to net income. These adjustments included a favorable \$4.8 million in depreciation and amortization, a favorable \$1.8 million in write-downs for impairment of deferred preservation costs, a favorable \$1.6 million in non-cash compensation, primarily related to the SFAS 123R expense for new and existing stock options and stock awards to the Company's board of directors and certain employees, and a favorable \$426,000 for the loss on disposal of assets. 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, 2006 these changes included an unfavorable \$10.4 million due to the buildup of deferred preservation costs and inventories, an unfavorable \$2.4 million due to the timing differences between the recording of receivables and the actual receipt of cash, and a favorable \$1.9 million due to the timing differences between the recording of accounts payable and other accruals and the actual payment of cash.

*Net Cash from Investing Activities*

Net cash used by investing activities was \$557,000 for the twelve months ended December 31, 2006, as compared to \$2.0 million for the twelve months ended December 31, 2005. The \$557,000 in current year cash used was primarily due to \$17.4 million in purchases of marketable securities and \$1.6 million in capital expenditures, partially offset by \$18.6 million in proceeds from sales and maturities of marketable securities.

**Net Cash from Financing Activities**

Net cash used by financing activities was \$968,000 for the twelve months ended December 31, 2006, as compared to \$22.7 million in cash provided for the twelve months ended December 31, 2005. The \$968,000 in current year cash used was primarily due to \$2.3 million in principal payments on notes payable, \$973,000 in payments of Preferred Stock dividends, \$570,000 in principal payments on capital leases, and \$553,000 in debt principal payments. These unfavorable effects were partially offset by \$2.3 million in proceeds from the financing of insurance policies, \$710,000 in proceeds from issuance of debt, including borrowing on the Company's line of credit and issuance of new capital leases, and \$468,000 in proceeds from exercises of options and issuance of stock.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments are as follows (in thousands):

	Total	2007	2008	2009	2010	2011	Thereafter
Operating leases	\$ 19,833	\$ 2,459	\$ 2,360	\$ 2,226	\$ 2,119	\$ 2,145	\$ 8,524
Revolving line of credit	4,507		4,507				
Capital lease obligations	193	53	52	53	35		
Purchase commitments	255	254	1				
Other obligations	1,239	992	192	55			

Total contractual obligations \$ 26,027 \$ 3,758 \$ 7,112 \$ 2,334 \$ 2,154 \$ 2,145 \$ 8,524

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 Credit Agreement. The timing of the obligation in the above table is based on the February 7, 2008 Credit Agreement expiration date, at which time the outstanding principal balance will be due. Due to the terms of the Credit Agreement, and due to the net losses and negative cash flows experienced by the Company since the FDA Order, the Company has classified amounts due under the Credit Agreement as short-term debt on the December 31, 2006 Consolidated Balance Sheet in accordance with the provisions of FASB Technical Bulletin No. 79-3 (As Amended). Assuming the Company's level of borrowings and the interest rate on the line of credit remain the same, the Company would have additional contractual obligations for interest expense and fees of \$486,000, and \$56,000 for 2007 and 2008, respectively, which are not included in the table above.

The Company's capital lease obligations result from the financing of certain of the Company's equipment.

The Company's purchase commitments generally result from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production.

The Company's other obligations contain various items including minimum required royalty payments, payments to support research and development activities, and other items as appropriate.

**Preferred Stock**

Dividends on the Company's Preferred Stock are 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 must be declared by the Company's board of directors and must come from funds that are legally available for dividend payments. Dividends of approximately \$243,000 were paid on January 2, 2007 to shareholders of record on December 22, 2006.

**Stock Repurchases**

In the first quarter of 2006 the Company's Board of Directors authorized the purchase of shares of its common stock from employees to fund the payment of employee federal and state withholding taxes in association with the grant of stock to employees in February 2006. These repurchases of stock from employees totaled \$50,000. No further purchases will be made related to these employee stock grants.



### *Capital Expenditures*

The Company expects that its capital expenditures in 2007 will be similar to its expenditures in 2006, which were approximately \$1.6 million. Planned capital expenditures for 2007 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.

### **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, including, in particular, statements regarding future products or services, market expansion, revenues, cost savings, procurement, tissue processing yields, regulatory activity, available funds and capital resources, and pending litigation. 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 as of their respective dates. 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 adequacy of product liability insurance to defend against lawsuits;

Increases in product liability insurance coverage costs, retention, and claims years covered;

The outcome of lawsuits filed against the Company, and of the SEC investigation;

The impact of the FDA Order and subsequent FDA activity, including the FDA's letters regarding the SynerGraft process and measures taken by the Company as a result, on future revenues, profits, and business operations;

The impact of the FDA's Form 483 Notices of Observation;

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

The Company's ability to increase yields and reduce its costs of tissue preservation services;

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

The receipt of governmental grants for BioFoam development;

The results of patient studies and their use in applying for governmental approval for products and services;

The outcome of the Company's regulatory applications regarding its SynerGraft process;

Future increases in research and development expenses;

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

Product demand and market growth;

The success of the RTI Agreement, including anticipated cost savings and increased procurement of cardiovascular and vascular tissues;

The potential of the ACT for use in fibrinolysis (blood clot dissolving) and other drug delivery applications;

Expected revenue and earnings growth from recently announced strategic agreements;

Expected impact of adoption of new accounting pronouncements;

The impact on the Company of adverse publicity or negative surgical outcomes from products or services provided by the Company;

Anticipated future revenues and expenses;

Expected seasonality trends;

Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2006;

Anticipated impact of changes in interest rates;

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

The success of distribution, supplier and development agreements with third parties to distribute, supply and develop various Company, as well as third party, products and services;

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

The Company's ability to implement its strategic plans;

The adequacy of the Company's financial resources and its ability to borrow under its credit facility; and

Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including the risk factors discussed in 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 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 United States interest rates. In this regard, changes in United States interest rates affect the interest earned on the Company's cash and cash equivalents of \$4.1 million and the interest incurred on the line of credit balance of \$4.5 million as of December 31, 2006. The Company's short-term investments in marketable securities of \$4.0 million as of December 31, 2006 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 affecting the Company's cash equivalents and short-term investments or borrowings under the Company's Credit Agreement would not have a material impact on the Company's financial position, results of operations, or cash flows.

***Derivative Valuation Risk***

The terms of the Company's March 18, 2005 6% convertible preferred stock offering include a Dividend Make-Whole Payment feature. This feature is considered an embedded derivative instrument. Due to the quarterly revaluation of the derivative liability, the Company recorded other expense of \$121,000 for the twelve months ended December 31, 2006. At December 31, 2006 the derivative liability was valued at \$235,000. The fair value of this derivative is based on various factors, including the market price of the Company's common stock and discount rates used in determination of fair value. Changes in these factors could cause the fair value of this derivative to fluctuate significantly from period to period. These resulting changes in valuation may have a significant impact on the Company's results of operations.

***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 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, 2006, 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, 2006, 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 and Executive Officers of the Registrant.**

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 30, 2007, with the exception of information concerning executive officers, which is included in Part I, Item 4A 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 30, 2007.

**Item 12. Security Ownership of Certain Beneficial Owners and Management.**

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 30, 2007.

**Item 13. Certain Relationships and Related Transactions.**

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 30, 2007.

**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 30, 2007.

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**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	Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended March 31, 2003.)
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of CryoLife, Inc., classifying and designating Series A Junior Participating Preferred Stock.. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on November 3, 2005.)
3.3	Preferred Stock Articles of Amendment to the Articles of Incorporation of the Registrant. (Incorporated herein by reference to Exhibit 3.4 to the Registrant's Form 8-A/A filed on March 15, 2005.)
3.4	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed December 28, 2005.)
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	Form of Specimen Convertible Preferred Stock Certificate. (Incorporated herein by reference to Exhibit 4.1 to the Registrant's Form 8A/A filed March 15, 2005.)
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.)
10.1(a)	The Stipulation of Settlement of securities class action litigation dated August 29, 2005. (Incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005.)

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- 10.2+ Credit Agreement by and between CryoLife, Inc., Certain Subsidiaries of CryoLife, Inc., and Wells Fargo Foothill, Inc., dated February 8, 2005. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.)
- 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 dated and filed on September 27, 2005.)

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Exhibit Number	Description
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.
10.3	Reserved.
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.
10.6	Reserved.
10.7	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.)
10.8	Reserved.
10.9(a)	Employment Agreement, by and between the Company and Steven G. Anderson, dated September 5, 2005. (Incorporated herein by reference to Exhibit 10.1 to Form 8-K dated September 5, 2005 and filed September 9, 2005.)
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)*	Commission Arrangement with Gerald B. Seery, Effective January 1, 2006.
10.9(f)	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.)
10.10	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.
10.12	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, 1995.)
10.13	Reserved.
10.14	Amended and Restated Technology Acquisition Agreement between the Company and Nicholas Kowanko, Ph.D., dated March 14, 1996. (Incorporated herein by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.)
10.15	CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated herein by reference to Appendix 2 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.16	Lease Agreement between the Company and Aml Land Development I Limited Partnership, dated April 18, 1995. (Incorporated herein by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 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*	Description of CryoLife, Inc. Performance-Based Bonus Plan.
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. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 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	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.)
10.29*	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
10.30(a)*	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
10.30(b)*	Form of Director Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
10.31*	Form of Non-Employee Directors Stock Option Agreement and Grant pursuant to the Amended and Restated Non-Employee Directors Stock Option Plan.
10.32*	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
10.33*	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
10.34*	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.

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<b>Exhibit Number</b>	<b>Description</b>
10.35*	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan.
10.36*	Form of Grant of Non-Qualified Stock Option to Directors.
10.37*	Grant of Incentive Stock Option to Stephen G. Anderson, dated May 4, 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.)
10.44-10.49	Reserved.
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.

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\* 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 Stock Option Agreement and Grant under the Incentive Stock Option and Employee Stock Incentive Plans (Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
2. Employment Agreement, by and between the Company and Steven G. Anderson, dated September 5, 2005. (Incorporated herein by reference to Exhibit 10.1 to Form 8-K dated September 5, 2005 and filed September 9, 2005.)
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.\* Commission Arrangement with Gerald B. Seery Effective January 1, 2006
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.
10. CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated herein by reference to Appendix 2 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
11. CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Appendix 2 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
12. CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.)
13. CryoLife, Inc. 2004 Employee Stock Incentive Plan, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)

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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.\* Description of CryoLife, Inc. Performance-Based Bonus Plan.
  
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.
- 24.\* Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
- 25.\* Form of Director Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
- 26.\* Form of Non-Employee Directors Stock Option Agreement and Grant pursuant to the Amended and Restated Non-Employee Directors Stock Option Plan.
- 27.\* Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
- 28.\* Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
- 29.\* Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
- 30.\* Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan.
- 31.\* Form of Grant of Non-Qualified Stock Option to Directors.
- 32.\* Grant of Incentive Stock Option to Stephen G. Anderson, dated May 4, 2006.

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\* 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.



**SIGNATURES**

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

CRYOLIFE, INC.

February 22, 2007

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ STEVEN G. ANDERSON <b>Steven G. Anderson</b>	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	February 22, 2007
/s/ D. ASHLEY LEE <b>D. Ashley Lee</b>	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 22, 2007
/s/ AMY D. HORTON <b>Amy D. Horton</b>	Chief Accounting Officer (Principal Accounting Officer)	February 22, 2007
/s/ THOMAS F. ACKERMAN <b>Thomas F. Ackerman</b>	Director	February 22, 2007
/s/ JAMES S. BENSON <b>James S. Benson</b>	Director	February 22, 2007
/s/ DAN BEVEVINO <b>Dan Bevevino</b>	Director	February 22, 2007
/s/ JOHN M. COOK <b>John M. Cook</b>	Director	February 22, 2007
/s/ RONALD CHARLES ELKINS, M.D. <b>Ronald Charles Elkins, M.D.</b>	Director	February 22, 2007

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/s/ VIRGINIA C. LACY

Director

February 22, 2007

**Virginia C. Lacy**

/s/ RONALD D. McCALL

Director

February 22, 2007

**Ronald D. McCall**

/s/ BRUCE J. VAN DYNE, M.D.

Director

February 22, 2007

**Bruce J. Van Dyne, M.D.**

**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, 2006. 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, 2006, 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 22, 2007

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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 management's assessment, included in the accompanying Management's Report on Internal Controls over Financial Reporting under Sarbanes-Oxley Section 404, that CryoLife, Inc. and subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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 the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006 of the Company and our report dated February 22, 2007 expressed an unqualified opinion on those financial statements and financial statement schedule.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 22, 2007



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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, 2006 and 2005, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2006. 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, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, 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, present fairly, in all material respects, the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, effective October 1, 2005, the Company changed its method of accounting for share based payments to conform to Statement of Financial Accounting Standards No. 123R Share Based Payment.

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, 2006, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 22, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

DELOITTE & TOUCHE LLP

Atlanta, Georgia

February 22, 2007

## CRYOLIFE, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31,	
	2006	2005
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 4,133	\$ 6,631
Marketable securities, at market	3,965	4,968
Restricted cash and securities	571	560
<b>Receivables:</b>		
Trade accounts, less allowance for doubtful accounts of \$130 in 2006 and \$105 in 2005	12,553	10,153
Income taxes	148	371
Other	1,255	1,563
<b>Total receivables</b>	<b>13,956</b>	<b>12,087</b>
Deferred preservation costs, net	19,278	13,959
Inventories	5,153	4,609
Prepaid expenses and other assets	2,329	2,387
<b>Total current assets</b>	<b>49,385</b>	<b>45,201</b>
<b>Property and equipment:</b>		
Equipment	19,911	23,227
Furniture and fixtures	5,196	5,112
Leasehold improvements	28,937	29,754
Construction in progress	30	1
Total property and equipment	54,074	58,094
Less accumulated depreciation and amortization	32,684	33,719
<b>Net property and equipment</b>	<b>21,390</b>	<b>24,375</b>
<b>Other assets:</b>		
Patents, less accumulated amortization of \$1,372 in 2006 and \$1,691 in 2005	4,226	4,877
Trademarks and other intangibles	3,362	425
Other	1,502	1,931
<b>Total assets</b>	<b>\$ 79,865</b>	<b>\$ 76,809</b>

See accompanying notes to consolidated financial statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31,	
	2006	2005
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,475	\$ 2,239
Accrued compensation	2,599	1,467
Accrued procurement fees	4,734	3,797
Accrued expenses and other current liabilities	7,074	8,154
Deferred income	1,223	424
Deferred income taxes	26	
Derivative liability	235	114
Line of credit	4,507	4,530
Current maturities of capital lease obligations	40	554
<b>Total current liabilities</b>	<b>22,913</b>	<b>21,279</b>
Capital lease obligations, less current maturities	124	
Deferred income taxes	200	
Other	4,540	4,909
<b>Total liabilities</b>	<b>27,777</b>	<b>26,188</b>
<b>Shareholders' equity:</b>		
Preferred stock \$.01 par value per share; authorized 5,000 shares Series A junior participating preferred stock; 2,000 shares authorized; no shares issued		
Convertible preferred stock; 460 shares authorized; 325 issued and outstanding in 2006 and 2005	3	3
Common stock \$.01 par value per share; authorized 75,000 shares; issued 25,813 shares in 2006 and 25,582 shares in 2005	258	256
Additional paid-in capital	115,678	113,507
Retained deficit	(59,177)	(58,569)
Deferred compensation	(73)	
Accumulated other comprehensive income	160	123
Treasury stock at cost; 906 shares in 2006 and 892 shares in 2005	(4,761)	(4,699)
<b>Total shareholders' equity</b>	<b>52,088</b>	<b>50,621</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 79,865</b>	<b>\$ 76,809</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,		
	2006	2005	2004
<b>Revenues:</b>			
Products	\$ 41,037	\$ 38,932	\$ 36,637
Human tissue preservation services	40,078	30,307	25,676
Other	196	43	71
<b>Total revenues</b>	<b>81,311</b>	<b>69,282</b>	<b>62,384</b>
<b>Costs and expenses:</b>			
Products	7,463	8,065	7,818
Human tissue preservation services (including write-downs of \$4,537 in 2006, \$1,797 in 2005, and \$6,905 in 2004)	29,958	24,357	29,807
General, administrative, and marketing	41,545	53,225	42,640
Gain on exit activities	(2,620)		
Research and development	3,547	3,724	3,938
Interest expense	657	346	196
Interest income	(409)	(531)	(262)
Change in valuation of derivative	121	(140)	
Other expense, net	399	199	13
<b>Total costs and expenses</b>	<b>80,661</b>	<b>89,245</b>	<b>84,150</b>
<b>Income (loss) before income taxes</b>	<b>650</b>	<b>(19,963)</b>	<b>(21,766)</b>
Income tax expense (benefit)	285	(428)	(3,017)
<b>Net income (loss)</b>	<b>\$ 365</b>	<b>\$ (19,535)</b>	<b>\$ (18,749)</b>
Effect of preferred stock dividends	(973)	(777)	
<b>Net loss applicable to common shares</b>	<b>\$ (608)</b>	<b>\$ (20,312)</b>	<b>\$ (18,749)</b>
<b>Loss per common share:</b>			
Basic	\$ (0.02)	\$ (0.85)	\$ (0.81)
Diluted	\$ (0.02)	\$ (0.85)	\$ (0.81)
<b>Weighted average common shares outstanding:</b>			
Basic	24,829	23,959	23,043
Diluted	24,829	23,959	23,043

See accompanying notes to consolidated financial statements.



**CRYOLIFE, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Year Ended December 31,		
	2006	2005	2004
<b>Net cash flows from operating activities:</b>			
Net income (loss)	\$ 365	\$ (19,535)	\$ (18,749)
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	426	108	30
Depreciation of property and equipment	4,560	4,759	5,202
Amortization	284	277	281
Provision for doubtful accounts	65	57	53
Write-down of deferred preservation costs and inventories	1,758	1,797	7,105
Net non-cash gain on exit activities	(31)		
Deferred income taxes	226		
Non-cash compensation	1,620	322	358
Change in valuation of derivative	121	(140)	
Other non-cash adjustments to income	(182)	1,771	10
Changes in operating assets and liabilities:			
Trade and other receivables	(2,431)	(1,854)	(2,159)
Income taxes	213	1,024	665
Deferred preservation costs	(9,800)	(6,934)	(6,916)
Inventories	(600)	158	(517)
Prepaid expenses and other assets	397	27	(2,060)
Accounts payable	155	(712)	342
Accrued expenses and other liabilities	1,783	361	(3,256)
<b>Net cash flows used in operating activities</b>	<b>(1,071)</b>	<b>(18,517)</b>	<b>(19,611)</b>
<b>Net cash flows from investing activities:</b>			
Capital expenditures	(1,642)	(989)	(950)
Net proceeds from sale of assets	13	12	26
Purchases of marketable securities	(17,385)	(21,690)	(563)
Sales and maturities of marketable securities	18,562	20,841	2,000
Other	(105)	(208)	(56)
<b>Net cash flows (used in) provided by investing activities</b>	<b>(557)</b>	<b>(2,034)</b>	<b>457</b>
<b>Net cash flows from financing activities:</b>			
Principal payments of debt	(553)	(317)	
Proceeds from debt issuance	710	4,847	
Principal payments on obligations under capital leases	(570)	(741)	(717)
Proceeds from financing of insurance policies	2,349	2,482	3,385
Principal payments on short-term note payable	(2,349)	(2,482)	(3,385)
Proceeds from exercise of options and issuance of stock	468	372	443
Payment of preferred stock dividend and make whole payments	(973)	(533)	
Proceeds from equity offering		19,098	19,265
Purchase of treasury stock	(50)		(54)
<b>Net cash flows (used in) provided by financing activities</b>	<b>(968)</b>	<b>22,726</b>	<b>18,937</b>

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<b>(Decrease) increase in cash</b>	<b>(2,596)</b>	<b>2,175</b>	<b>(217)</b>
Effect of exchange rate changes on cash	98	(257)	33
Cash and cash equivalents, beginning of year	6,631	4,713	4,897
<b>Cash and cash equivalents, end of year</b>	<b>\$ 4,133</b>	<b>\$ 6,631</b>	<b>\$ 4,713</b>

See accompanying notes to consolidated financial statements.

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## CRYOLIFE, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands)

	Accumulated										
	Preferred		Common		Additional	Retained	Deferred	Other	Treasury		Total
	Stock	Stock	Paid In	Capital	Deficit	Compensation	Comprehensive	Stock	Stock	Shareholders	
	Shares	Amount	Shares	Amount			Income	Shares	Amount	Equity	
<b>Balance at December 31, 2003</b>	\$	21,130	\$ 211	\$ 74,460	\$ (19,508)	\$ (9)	\$ 365	(1,371)	\$ (7,181)	\$ 48,338	
Net loss					(18,749)					(18,749)	
Other comprehensive loss, net of taxes							(4)			(4)	
Comprehensive loss										(18,753)	
Equity offering		3,444	34	19,231						19,265	
Equity Compensation		84	1	579		(222)		(7)	(54)	304	
Exercise of options		72	1	221				(12)	(81)	141	
Employee stock purchase plan			75	1	355					356	
Amortization of deferred compensation						9				9	
<b>Balance at December 31, 2004</b>		24,805	\$ 248	\$ 94,846	\$ (38,257)	\$ (222)	\$ 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 stock and dividend make whole payments	(92)	(1)	694	7	779					785	
Dividend payments						(777)				(777)	
Exercise of options			36		111			(2)	(17)	94	
Equity compensation			(3)		100		222			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						(973)				(973)	
Exercise of options			101	1	227			(2)	(12)	216	
Equity compensation			54		1,693		(73)	(12)	(50)	1,570	
Employee stock purchase plan			76	1	251					252	
<b>Balance at December 31, 2006</b>	325	\$ 3	25,813	\$ 258	\$ 115,678	\$ (59,177)	\$ (73)	\$ 160	(906)	\$ (4,761)	\$ 52,088



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 or the Company), incorporated January 19, 1984 in Florida, develops and commercializes implantable medical devices and preserves and distributes human tissues for cardiovascular and vascular transplant applications. The Company's biomaterials and implantable devices include BioGlue® Surgical Adhesive (BioGlue), porcine heart valves, and vascular grafts of bovine tissue processed using the Company's proprietary SynerGraft® technology. 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 distribute its existing orthopaedic tissues through June 30, 2008.

CryoLife is authorized to distribute BioGlue throughout the United States and in more than 60 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 cardiovascular, pulmonary, and additional soft tissue repair procedures). CryoLife has also received approval and distributes BioGlue for soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in Australia and several other countries in Central and South America, and Asia. CryoLife distributes preserved human cardiovascular, vascular, and orthopaedic tissue to implanting institutions throughout the U.S., Canada, and Europe. CryoLife also distributes its SynerGraft processed bovine vascular graft and a porcine heart valve, the CryoLife O'Brien® aortic heart valve, in Europe, the Middle East, and Africa.

The Company believes that its existing cash, cash equivalents, marketable securities, and availability under the Credit Agreement, as defined in Note 6, will enable the Company to meet its liquidity needs through at least December 31, 2007.

The Company could experience an adverse impact on revenues and cash flows during 2007 from decreases in orthopaedic revenue as a result of the exchange and service agreement with Regeneration Technologies, Inc., and certain of its affiliates (collectively RTI), (the RTI Agreement), which will need to be offset by increases in cardiovascular and vascular revenues derived as a result of the RTI Agreement. See Note 3 for a discussion of the RTI Agreement.

The Company believes the following should continue to have a favorable impact on cash flow from operations during 2007, although there can be no assurance that these events will occur as and when currently anticipated:

Expected increases in BioGlue revenues over levels experienced in 2006 due to increases in BioGlue list prices implemented in July 2006 and January 2007 and anticipated volume increases,

Expected increases in total preservation service revenues over levels experienced in 2006 due to fee increases for certain tissues implemented in July 2006 and January 2007, to reflect the higher cost of processing these tissues, and anticipated volume increases for cardiovascular and vascular tissues,

Anticipated net benefits of the RTI Agreement in reducing general, administrative, and marketing costs related to orthopaedic tissues, and

Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2006.

However, the Company's long term liquidity and capital requirements will depend upon numerous factors, including:

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The success of BioGlue and other products using related technology,

The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,

The Company's ability to maintain sufficient margins on its tissue preservation services,

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The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,

The timing and cost of resolving product liability lawsuits and other claims (as discussed in Note 10),

The successful transition of cardiovascular and vascular tissue procurement previously received by RTI to the Company (as discussed in Note 3),

To a lesser degree, the Company's success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft technology (as discussed in Note 2), and

The Company's success in implementing its recently identified strategic initiatives.

If the Company is unable to address these issues and continues to experience negative cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond December 31, 2007. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

#### ***Certain Reclassifications of Prior Year Amounts***

Certain prior year amounts have been reclassified to conform to current year presentation. In 2006 the Company determined that its presentation of payments on notes payable to finance insurance policy premiums in the operating section of the cash flow statement are more appropriately classified as a change in operating assets in the operating cash outflows and both a proceed and principal payment in the financing cash outflows. Therefore, a total of \$2.5 million and \$3.4 million was reclassified from the financing section of the cash flow statement to the operating section of the cash flow statement as of December 31, 2005 and 2004, respectively. The Company had previously disclosed the existence and the nature of these financing agreements in the Notes to Consolidated Financial Statements included in the CryoLife Form 10-K for the year ended December 31, 2005.

In 2006 the Company revised its presentation of income tax expense (benefit) by showing a separate disclosure for foreign current and foreign deferred taxes. In addition the Company revised its disclosures of temporary tax differences to show subtotals for total deferred tax assets and total deferred tax liabilities. As a result of these changes, the Company revised the presentation of comparative amounts in 2005 and 2004 to conform with the new presentation.

#### ***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances are eliminated.

#### ***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, 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 human tissue 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

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shipped, at which time title passes to the customer. 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 and complete the earnings process.

#### *Shipping and Handling Charges*

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

#### *Cash and Cash Equivalents*

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

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

	2006	2005	2004
<b>Cash paid during the year for:</b>			
Interest	\$ 635	\$ 276	\$ 127
Income taxes	34	216	200
<b>Non-cash investing and financing activities:</b>			
Non-cash acquisition of intangibles	\$ 2,909	\$	\$
Assets acquired under capital leases	180		77
Payment of legal settlement in stock		1,973	
Payment of make whole payments in common stock		786	
Purchase of property and equipment in accounts payable and accrued expenses		21	70

#### *Marketable Securities*

The Company maintains cash equivalents and investments in several large, well-capitalized financial institutions, and the Company's policy disallows 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 positive 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 investment income. Debt securities not classified as held-to-maturity or trading and 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 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 investment income (loss). The cost of securities sold is based on the specific identification method.

As of December 31, 2006 and 2005 \$4.0 million and \$5.0 million, respectively, of marketable securities were designated as available-for-sale, and \$571,000 and \$560,000, respectively, of marketable securities were designated as held-to-maturity. These securities were designated as held-to-maturity due to a contractual commitment to pledge and hold the securities as collateral under one of the Company's product liability insurance policies; accordingly, such securities are reported as restricted securities on the December 31, 2006 and 2005 Consolidated Balance Sheets.

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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 laboratory expenses, tissue procurement fees, freight-in charges, and fringe benefits) 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.

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 Sheet 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. The Company 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 RTI Agreement discussed in Note 3 below. This write-down is based on the Company's 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.

The Company also recorded \$1.2 million in the year ended December 31, 2006 and \$1.8 million in the year ended December 31, 2005 as an increase to cost of preservation services to write-down the value of certain deferred tissue 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 regularly evaluates its deferred preservation costs to determine if an impairment in the value of the deferred preservation costs is required when the value of these tissues is not expected to be fully recoverable. A write-down of \$588,000 was recorded for the year ended December 31, 2006 due to the impairment of certain 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. As of December 31, 2005 deferred preservation costs consisted of \$3.4 million for allograft heart valve tissues, \$566,000 for non-valved cardiac tissues, \$6.0 million for vascular tissues, and \$4.0 million for orthopaedic tissues.

***Inventories***

Inventories are comprised of implantable surgical adhesives and bioprosthetic products and are valued at the lower of cost (first-in, first-out) or market.

The Company was required to adopt Statements of Financial Accounting Standards ( SFAS ) 151 Inventory Costs ( SFAS 151 ) effective January 1, 2006. SFAS 151 requires current period expensing of items such as 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. The adoption of SFAS 151 did not have a material impact on the Company s results of operations and financial position.

**Property and Equipment**

Property and equipment are 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.

**Long-Lived Assets**

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. In applying SFAS 144 the Company defined the specific asset groups used to perform the cash flow analysis. The Company defined the asset groups at the lowest level possible, by identifying the cash flows from groups of assets that could be segregated from the cash flows of other assets and liabilities. Using this methodology the Company determined that its asset groups consisted of the long-lived assets related to the Company s two reporting segments. As the Company does not segregate assets by segment, the Company allocated assets to the two reporting segments based on factors including facility space and revenues. The undiscounted future cash flows related to these asset groups exceeded their carrying values as of December 31, 2006 and 2005, therefore, management concluded that there was not an impairment of the Company s long-lived intangible assets and tangible assets related to the tissue preservation business or medical device business. However, depending on the Company s ability to rebuild demand for its tissue preservation services and the future effects of events surrounding the FDA Order as defined in Note 3 below, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

**Intangible Assets**

SFAS No. 142, Goodwill and Other Intangible Assets ( SFAS 142 ), requires that goodwill resulting from business acquisitions and other intangible assets be subject to periodic impairment testing. The Company s intangible assets consist of patents and trademarks. In addition, during 2006, the Company acquired customer lists, non-compete agreements, procurement contracts and access to the procurement of cardiovascular and vascular human tissues previously received by RTI as a result of the RTI Agreement discussed in Note 3 below. The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. As of December 31, 2006 and 2005 the Company did not believe that an impairment existed related to its intangible assets.

As of December 31, 2006 and 2005 gross values, accumulated amortization, and amortization periods of the Company s definite lived intangible assets are as follows (in thousands):

	<b>Gross</b>		
	<b>Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Amortization Period</b>
<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
<b><u>December 31, 2005</u></b>			
Patents	\$ 6,568	\$ 1,691	17 Years



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As of December 31, 2006 and 2005 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	2006	2005
Trademarks	\$ 453	\$ 425
Procurement contracts	2,013	

As of December 31, 2006 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2007	2008	2009	2010	2011	Total
Amortization expense	\$ 498	\$ 498	\$ 496	\$ 321	\$ 315	\$ 2,128

### *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. The Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed in January 2007 as of December 31, 2006. 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 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.

### *Deferred Income Taxes*

Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when it is more likely than not that the full value of a deferred tax asset will not be recovered.

### *Earnings (Loss) Per Common Share*

Earnings (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 the dilutive effect of outstanding stock options, computed using the treasury stock method, and the dilutive effect of outstanding convertible preferred stock, computed using the if converted method.



### ***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 early adopted SFAS 123 Revised Share-Based Payment ( SFAS 123R ) on October 1, 2005. The Company's decision to early adopt SFAS 123R was pursuant to a shareholder derivative action settlement, as discussed in Note 10. 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 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 deferred compensation in the equity section of the Company's Consolidated Balance Sheets, and was expensed over the vesting period.

Pro forma information regarding net income (loss) and income (loss) per common share is required by SFAS 123R, which requires that the information be determined as if the Company has 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. All revenue and expense accounts are translated as transactions occur at exchange rates in effect at the time of each transaction. Translation adjustments are recorded as a separate component of other comprehensive income in shareholders' equity.

### ***Derivative Instruments***

In accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities ( SFAS 133 ), the Company is required to separate and account for the Dividend Make-Whole Payment feature, as defined in Note 8, of its 6% convertible preferred stock as an embedded derivative. The Company determines the fair value of its derivative and records the value as a current liability on the Company's Consolidated Balance Sheets. Changes in the fair value of the derivative are recognized in the 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 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, 2006 and 2005.

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

The Company will be required to adopt Financial Accounting Standards Board ( FASB ) Interpretation No. 48 Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 ( FIN 48 ) for its year beginning January 1, 2007. 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. The cumulative effect of adoption of this interpretation will be reported as an adjustment to the opening balance of retained earnings. The Company does not anticipate that the adoption of FIN 48 will have a material affect on its results of operations or financial position, although the Company is continuing to evaluate the full impact of the adoption of FIN 48.

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 is in the process of evaluating the impact of SFAS 157 on its results of operations and financial position.

The Company was required to adopt SAB No. 108, codified as SAB Topic 1.N, Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements ( SAB 108 ) for the year ended December 31, 2006. SAB 108 requires the use of both a balance sheet approach and an income statement approach when quantifying and evaluating the materiality of a misstatement. Adjustment to the financial statements is required if either approach results in quantifying a misstatement that is material. The adoption of SAB 108 did not have a material impact on the Company's results of operations and financial position.

## **2. FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices**

### ***FDA Order***

On August 13, 2002 the Company 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, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order (i.e. 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 the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues.

The FDA allowed non-valved cardiac and vascular tissues covered by the recall to be distributed beginning in late September 2002, subject to specified conditions. The Company changed its processing procedures and took other actions intended to address the FDA's concerns, and now processes non-valved cardiac and vascular tissues. The Company processed orthopaedic tissues through December 31, 2006 when it ceased processing orthopaedic tissue pursuant to the RTI Agreement discussed below in Note 3.

See Note 10 for a discussion of certain material legal proceedings relating to the FDA Order and other matters.

### ***Other FDA Correspondence and Notices***

#### July 2005 483

An FDA Form 483 Notice of Observations ( 483 ) was issued in August 2005 in connection with the FDA inspections of the Company's facilities in July 2005 ( July 2005 483 ). The Company responded to the July 2005 483 in August 2005, in September 2005, and in October 2005. In April 2006 the FDA responded on the adequacy of the Company's responses. The Company responded to the FDA in June 2006. In response to the July 2005 483 the Company has implemented new systems and procedures and revised existing systems and procedures. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information related to the inspections, and has the authority to take other actions, which may be more burdensome. The Company has cooperated and will continue to cooperate with the FDA to review process improvements and address any outstanding observations.

#### SynerGraft

On February 20, 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company's SynerGraft processed human cardiac tissues ( CryoValve SG ) and that premarket approval marketing authorization should be obtained for the Company's SynerGraft processed human vascular tissues ( CryoVein SG ) when marketed or labeled as an arteriovenous ( A-V ) access graft. The agency's position is that use of the SynerGraft technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On February 4, 2004 the Company received a letter from the FDA requesting additional information. On August 24, 2004 the Company submitted an amendment to its original 510(k) submission providing clarification and additional information. The FDA requested further additional information in November 2004. On June 8, 2005 CryoLife responded to some of these additional requests. CryoLife also has initiated an appeal of other requests through administrative procedures. The FDA requested further additional information in January 2006. Since March 2006 the Company has had discussions with the FDA to address the outstanding requests for additional information and seek clearance for the CryoValve SG pulmonary valve. On July 21, 2006 the Company submitted an amendment to its 510(k) application addressing information requested by the FDA. The Company has undertaken further clinical and preclinical evaluations in response to requests by the FDA. These evaluations were submitted to the FDA in an additional 510(k) amendment on February 20, 2007. The FDA may still require that additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed CryoValve SG.

On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that certain additional cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On September 14, 2004 the Company met with the FDA to discuss the data to be used to support a formal Request for Designation ( RFD ) filing for SynerGraft processed non-valved cardiac and vascular tissue, including the CryoVein SG. An RFD submission establishes the regulatory status of the tissue. The Company submitted the RFD on October 5, 2004. The FDA affirmed its original decision in letters received in December 2004. That decision was subject to an administrative appeal. On October 20, 2005 CryoLife was informed that the FDA had denied the appeal and that CryoLife will be unable to distribute CryoVein tissues with the SynerGraft technology until further submissions and FDA approvals are granted. The Company is evaluating whether it will file and seek FDA approvals for CryoVein SG or discontinue the CryoVein SG.

As a result of these FDA communications, in 2003 the Company suspended the use of the SynerGraft technology in the processing of allograft tissue and the distribution of tissues on hand previously processed with the SynerGraft technology until the regulatory issues associated with these tissues are resolved. Additionally, the Company discontinued labeling its vascular grafts for use as A-V access grafts. Until such time as the issues surrounding SynerGraft are resolved, the Company is employing its traditional processing methods on these tissues. As of December 31, 2006 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Consolidated Balance Sheets.

### 3. Exchange and Service Agreement

On December 19, 2006 the Company announced that it had entered into the RTI Agreement, an exchange and service agreement with Regeneration Technologies, Inc., and certain of its affiliates (collectively, RTI ), respecting procurement, processing, and distribution activities for cardiovascular and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife. According to the RTI Agreement, CryoLife ceased accepting for processing donated human orthopaedic tissue commencing January 1, 2007 and will work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise, on January 1, 2007 RTI ceased accepting donated human cardiovascular and vascular tissues for processing and will work to transition its arrangements for recovery of these tissues to CryoLife. Certain physical assets relating to the tissues that are the subject of the agreement may also be transferred between the parties. 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 cardiovascular and vascular tissue inventory, through June 30, 2008. After that date CryoLife will become entitled to distribute RTI's remaining cardiovascular and vascular tissue inventory, and RTI will become entitled to distribute CryoLife's remaining orthopaedic tissue inventory, for a fee. 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, which is composed of a write-down of \$2.8 million in cost of human tissue preservation services and a \$2.6 million gain on exit activities included in general, administrative, and marketing expense and disclosed on the face of 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 is 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. The write-down of processing materials was based on the book value of certain raw materials that would not be used in future periods.

The \$2.6 million gain on exit activities 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 cardiovascular 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 based upon a valuation study prepared by an independent valuation consultant.

#### 4. Cash Equivalents and Marketable Securities

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

	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value
<b>December 31, 2006</b>			
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

	Cost Basis	Unrealized Holding (Losses) Gains	Estimated Market Value
<b>December 31, 2005</b>			
Cash equivalents:			
Money market funds	\$ 5,595	\$	\$ 5,595
Marketable securities:			
Government entity sponsored debt securities	\$ 2,980	\$ (2)	\$ 2,978
U.S. Treasury debt securities	1,990		1,990
Total marketable securities	\$ 4,970	\$ (2)	\$ 4,968

Restricted securities:			
Government entity sponsored debt securities	\$ 560	\$	\$ 560

Gross realized gains on sales of available-for-sale securities totaled zero for the year ended December 31, 2006 and \$3,000 for the year ended December 31, 2005. Differences between cost and market listed above, consisting of a net unrealized holding gain of \$1,000 at December 31, 2006 and a net unrealized holding loss of \$2,000 at December 31, 2005, are included as a separate component of other comprehensive income in the shareholders' equity section of the Consolidated Balance Sheets.

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At December 31, 2006 and 2005 all of the Company's marketable securities had a maturity date within 90 days.

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## 5. Inventories

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

	2006	2005
Raw materials	\$ 3,048	\$ 3,083
Work-in-process	479	415
Finished goods	1,626	1,111
Total Inventories	\$ 5,153	\$ 4,609

## 6. Debt

On February 8, 2005 CryoLife and its subsidiaries entered into a new credit agreement with Wells Fargo Foothill, Inc. as lender (the Credit Agreement). The Credit Agreement provides for a revolving credit facility in an aggregate amount equal to the lesser of \$15.0 million (including a letter of credit subfacility of up to an aggregate of \$2.0 million) or a borrowing base determined in accordance with the terms of the Credit Agreement. Generally, the borrowing base is 20% of the appraised value of the business of CryoLife, reduced by specified lender reserves. The Credit Agreement places further limitations on the amount that the Company may borrow, and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife maintain on a quarterly basis (i) a minimum aggregate borrowing capacity plus cash and cash equivalents, as defined, of \$12.5 million or (ii) achieve an increasing level of minimum earnings before interest, taxes, depreciation, and amortization ( EBITDA ), BioGlue gross margins greater than 70% for the preceding twelve months, and cash and cash equivalents, as defined, of \$5.0 million. While the Company currently expects that its aggregate borrowing capacity under the Credit Agreement will equal \$15.0 million, there can be no assurance that the capacity will remain at this level. The Credit Agreement also includes customary conditions on incurring new indebtedness and limitations on cash dividends. Cash dividends on any class of capital stock are prohibited; provided that cash dividends on preferred stock may be paid so long as the Company maintains \$7.5 million, in the aggregate, of cash, cash equivalents, and borrowing capacity, as defined. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The Credit Agreement expires on February 7, 2008, at which time the outstanding principal balance will be due. Due to the terms of the Credit Agreement and due to the net losses and negative cash flows experienced by the Company since the FDA Order, the Company has classified amounts due under the Credit Agreement as short-term debt on the December 31, 2006 Consolidated Balance Sheet in accordance with the provisions of FASB Technical Bulletin No. 79-3 (As Amended).

Amounts borrowed under the Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest at the bank's prime rate plus 1%, which was 9.25% as of December 31, 2006 and 8.25% as of December 31, 2005. As of December 31, 2006 and 2005 the outstanding balance of the Credit Agreement was \$4.5 million and the remaining borrowing availability was \$10.5 million.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In the quarter ended June 30, 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 a 6.71% and 6.70% rate, respectively, and were payable in equal monthly payments over a nine month period and an eight month period, respectively. As of December 31, 2006 the outstanding balance under the agreements was zero.

In the quarter ended June 30, 2005 the Company entered into two agreements to finance approximately \$1.7 million and \$761,000 in insurance premiums associated with the yearly renewal of certain Company insurance policies. The amounts financed accrued interest at a 4.98% and 5.01% rate, respectively, and were payable in equal monthly payments over a nine month period and an eight month period, respectively. As of December 31, 2005 the outstanding balance under the agreements was zero.

In September 2006 the Company's European subsidiary obtained a pre-approved credit facility with a bank in the United Kingdom for the financing of vehicles. This credit facility pre-approves the Company to enter into leases to finance vehicles, for which terms and interest rates are set for each individual lease agreement. The Company has accounted for the leases entered into under this credit facility as operating leases. The credit facility allows the Company to have a total exposure on outstanding leases, as defined by the bank, of £180,000 (or approximately \$353,000 as of December 31, 2006). Per the bank, the Company had a total exposure of approximately £90,000 or \$176,000 as of December 31, 2006, and the Company's total payment obligations related to these outstanding leases was \$109,000 as of December 31, 2006.





Total interest expense was \$657,000, \$346,000, and \$196,000 in 2006, 2005, and 2004, respectively.

#### **7. Private Equity Placement**

On January 7, 2004 the Company's Board of Directors authorized an agreement with a financial advisory company to sell shares of the Company's common stock in a private investment in public equity transaction (the PIPE). The PIPE was consummated on January 27, 2004, and resulted in the sale of approximately 3.4 million shares of stock at a price of \$6.25 per share. The sale generated net proceeds of approximately \$19.3 million, after commissions, filing fees, late registration fees, and other related charges, which was used for general corporate purposes. The Company filed a registration statement on Form S-3 with the SEC covering the resale of the shares sold in the PIPE by the investors. The Company paid a total of \$466,000 in late registration penalties to the investors through May 18, 2004, the date the registration statement was declared effective. This amount was deducted from the PIPE proceeds in recording net proceeds from the PIPE in shareholders' equity.

#### **8. Convertible Preferred Stock**

On December 17, 2004 the Company announced that it had filed a shelf registration statement on Form S-3 with the SEC covering the sale from time to time of up to \$50 million of its common stock, preferred stock, depositary shares, or any combination of these securities for its own account in one or more offerings.

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 are 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 must be declared by the Company's board of directors and must come from funds that are legally available for dividend payments. The Company declared dividends of \$973,000 and \$777,000 in the years ended December 31, 2006 and 2005, respectively to shareholders of record. The Company made cash payments of \$973,000 and \$533,000 in the years ended December 31, 2006 and 2005, respectively for dividends declared. Dividends of approximately \$243,000 were paid on January 2, 2007 to shareholders of record on December 22, 2006.

The Preferred Stock is 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 initial conversion price is subject to adjustment in certain events. The Company reserved 4,600,000 shares of common stock for issuance upon conversion. Through December 31, 2006 holders had voluntarily converted 92,000 shares of Preferred Stock into 575,000 shares of common stock.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has 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.

If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock, (the Dividend Make-Whole Payment). The Dividend Make-Whole Payment is 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. At December 31, 2006 the Company had issued 119,000 shares of common stock to converting holders to satisfy this additional payment.

The Preferred Stock has a liquidation preference of \$50 per share, plus accrued and unpaid dividends. The liquidation preference of the Preferred Stock was approximately \$16.5 million as of December 31, 2006, before the payment of the January 2007 dividend.

The Company may elect to redeem the Preferred Stock, in whole or in part, at declining redemption prices on or after April 7, 2008.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

## **9. Derivatives**

### ***Dividend Make-Whole Payments***

In accordance with SFAS 133, the Company is 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 must be measured at fair value and reflected as a current liability on the Company's Consolidated Balance Sheets. Changes in the fair value of the Derivative are 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 upon exercise of the underwriter's over allotment option to be \$32,000 on April 19, 2005, the date of issuance. These amounts were allocated from the proceeds of the Preferred Stock to the derivative liability.

Due to the quarterly revaluation of the derivative liability, the Company recorded other expense of \$121,000 and other income of \$140,000 for the years ended December 31, 2006 and 2005, respectively.

## **10. 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 manufacturing, 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 recorded in other long-term liabilities.

Future minimum lease payments under non-cancelable leases as of December 31, 2006 are as follows (in thousands):

	Leases	
	Capital	Operating
2007	\$ 53	\$ 2,459
2008	52	2,360
2009	53	2,226
2010	35	2,119
2011		2,145
Thereafter		8,524
<b>Total minimum lease payments</b>	<b>\$ 193</b>	<b>\$ 19,833</b>
<b>Less amount representing interest at a weighted average 9% interest rate</b>	<b>29</b>	
<b>Present value of net minimum lease payments</b>	<b>164</b>	
<b>Less current maturities</b>	<b>40</b>	
<b>Capital lease obligations, less current maturities</b>	<b>\$ 124</b>	

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

	2006	2005
Equipment	\$ 937	\$ 730
Furniture and fixtures	765	686
Leasehold improvements	1,244	1,244
<b>Total</b>	<b>\$ 2,946</b>	<b>\$ 2,660</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, \$2.4 million, and \$2.5 million, for 2006, 2005, and 2004, respectively. Total rental income under a sublease that terminated during 2005 was \$258,000 and \$310,000 in 2005 and 2004, respectively.

### ***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 16, 2007 the Company was aware of three pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, two allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges a product liability claim arising from the Company's allograft orthopaedic tissue services.

Two of the outstanding product liability lawsuits against the Company are not covered by insurance, as the claimed loss date was prior to the effective coverage date for the insurance policy. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits as of February 16, 2007. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2006 of the settled but unpaid claims and the pending product liability claims based on settlement negotiations to date and advice from counsel. As of December 31, 2006 the Company had accrued a total of approximately \$330,000 for pending product liability. The \$330,000 accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2006 Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses related to one of the three pending product liability claims. The Company has not recorded an accrual for the remaining two product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that

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loss or the range of losses cannot be made at this time. As of December 31, 2005 the Company had accrued a total of approximately \$1.5 million for settled but unpaid claims and pending product liability claims and recorded \$244,000 representing amounts to be recovered from the Company's insurance carriers. The \$1.5 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2005 Consolidated Balance Sheet.

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If the Company is unable to settle one or more of the product liability lawsuits in which the Company is a defendant, and if any such lawsuit should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available liquid assets. Additionally, the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury with respect to any lawsuit that it is unable to settle prior to trial, and the Company's product liability insurance policies do not include coverage for any punitive damages. Failure by the Company to resolve the outstanding product liability claims within its ability to pay would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2006 the Company bound coverage for the 2006/2007 insurance policy year. This policy is a four-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2007 and reported during the period April 1, 2006 through March 31, 2007 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 2007 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2006. 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 2006 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 40% lower than non-BioGlue claims per million dollars of revenue. The 40% 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, the Company's increased litigation activity following the FDA Order, the Company's low volume of pre-FDA Order historical claims, 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 2007 as of December 31, 2006, the Company estimated that its liability for unreported product liability claims was \$6.6 million as of December 31, 2006. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued \$6.6 million, representing the Company's best estimate of the total liability for



unreported product liability claims related to services performed and products sold prior to December 31, 2006. The \$6.6 million balance is 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. Further analysis indicated that the liability could be estimated to be as high as \$12.3 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, 2006, \$2.3 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.3 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.2 million on the December 31, 2006 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, 2006. Actual results may differ from this estimate.

As of December 31, 2005 the Company accrued \$7.5 million for unreported product liability claims and recorded a receivable of \$2.5 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$7.5 million accrual is included as a component of accrued expenses and other current liabilities of \$3.8 million and other long-term liabilities of \$3.7 million on the December 31, 2005 Consolidated Balance Sheet. The \$2.5 million insurance recoverable is included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.4 million on the December 31, 2005 Consolidated Balance Sheet.

#### ***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 quarter 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.

#### ***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.

#### ***Shareholder Derivative Action***

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which named the Company as a nominal defendant, alleged that the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in certain inappropriate practices that caused the Company to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that the Company's Board of Directors take certain actions in response to her allegations. On January 16, 2003 another purported derivative suit alleging claims similar to those of the Lichtenberger suit was filed in the Superior Court of Fulton County by complainant Robert F. Frailey. As in the Lichtenberger suit, the filing of the complaint in the Frailey action was preceded by a demand letter sent on Frailey's behalf to the Company's Board of Directors. Both complaints sought undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of the Company.



A settlement with respect to the shareholder derivative lawsuit was agreed to by the parties and approved by the board and the court. Pursuant to the settlement, the Company paid \$3.5 million, in the third quarter of 2005, related to the plaintiffs' counsel fees and expenses. The \$3.5 million payment was entirely covered by the Company's insurance carriers.

Additionally, as part of the settlement, the Company and its management have also agreed to several changes in corporate governance, including the identification and appointment of a new director with regulatory experience who was appointed in December 2005, the formation of a regulatory affairs and quality assurance committee, and the adoption of SFAS 123R in the fourth quarter of 2005.

### ***SEC Investigation***

On August 19, 2002 the Company issued a press release announcing that on August 17, 2002, the Company received a letter from the Atlanta District Office of the SEC inquiring about certain matters relating to the Company's August 14, 2002 announcement of the FDA Order. The SEC notified the Company in July 2003 that the inquiry became a formal investigation in June 2003. CryoLife has cooperated with this investigation both before and after the issuance of the formal order of investigation in June 2003 and intends to continue doing so. CryoLife voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife shares on August 14, 2002, before trading was halted pending CryoLife's press release reporting the FDA Order. These individuals were not and are not executive officers of CryoLife. The formal order of investigation indicates that the SEC's scope includes whether, during 2002, among other things, CryoLife or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate controls. The investigation could also encompass matters not specifically identified in the formal order. On September 15, 2005 the SEC announced that it had commenced proceedings in federal district court against certain of the above-referenced former and current employees (and certain of their spouses) for alleged illegal insider trading arising out of their August 14, 2002 trading activities. Those proceedings resulted in settlements with the SEC. As of the date hereof, the SEC has had no discussions with CryoLife as to whether the SEC will seek additional relief against CryoLife, or the nature of any relief that may be sought. At present, CryoLife is unable to predict the ultimate focus, its current status, outcome of the investigation, or when it will be completed. An unfavorable outcome could have a material adverse effect on CryoLife's reputation, business, financial position, results of operations, and cash flows.

## **11. Stock Option and Stock Incentive Plans and Stock Compensation**

### ***Stock Option and Incentive Plans***

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. Options granted to employees typically become exercisable over a five-year vesting period and have a 66 month term. Options granted to directors typically vest immediately and have a 60 month term.

As of December 31, 2006 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
2004 Non-Employee Directors Stock Option Plan	500,000

As of December 31, 2006 and 2005 there were 1.9 million and 2.6 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.

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A summary of Company's stock option transactions under the plans as of and for the year ended December 31, 2006, 2005, and 2004 follows:

	Shares	Exercise Price	Weighted Average Term	Weighted Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2003	2,523,000	\$ 11.48			
Granted	319,000	5.49			
Exercised	(72,000)	2.32			
Forfeited	(123,000)	9.47			
Expired	(354,000)	11.54			
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
Vested and Expected to Vest	2,084,000	\$ 7.41	0.90		\$ 5,053,000
Exercisable at December 31, 2006	1,091,000	\$ 9.69	1.89		\$ 2,318,000

The following table summarizes information concerning outstanding and exercisable options at December 31, 2006:

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	
\$2.20-4.25	595,000	2.65	\$3.11	271,000	\$2.24	
4.78-5.03	450,000	3.94	4.97	155,000	4.92	
5.05-5.80	554,000	4.05	5.43	131,000	5.31	
6.16-27.90	496,000	1.85	12.26	441,000	12.99	
29.15-30.86	93,000	1.16	29.72	93,000	29.72	
\$2.20-30.86	2,188,000	3.03	\$7.29	1,091,000	\$9.69	

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

	2006	2005	2004
Weighted average fair value of options granted	\$ 2.64	\$ 3.51	\$ 2.80
Intrinsic value of options exercised	\$ 362,000	\$ 148,000	\$ 304,000

In August 2006 the Company's Board of Directors authorized the grant of stock to its non-employee directors. The stock grants of 2,500 shares of common stock per non-employee director were valued at a total of \$109,000 based on the

stock price of \$5.47 on the date of grant. The value of this stock grant will be recorded as director compensation over the 12-month vesting period. As of December 31, 2006 the Company recorded \$36,000 in expense related to these stock grants and had deferred compensation recorded of \$73,000. The Company also made cash payments totaling \$38,000 to the non-employee directors to partially offset each individual's income tax liability as a result of the stock grant.

In February 2006 the Company's Board of Directors authorized the grant of stock to recognize the performance of certain Company executives. The stock grants totaled 34,000 shares of common stock, which were valued at \$145,000 based on the

stock price of \$4.25 on the date of grant. The Company purchased \$50,000 of Company stock from employees, based on the closing price on the New York Stock Exchange on the day the stock was transferred to the Company, to pay employee federal and state withholding taxes related to these stock grants. The Company recorded \$145,000 in compensation expense related to these stock grants for the year ended December 31, 2006. As of December 31, 2006 the executive stock grants were fully vested.

On November 2, 2004 the Company's Board of Directors authorized the grant of stock to Company employees in lieu of annual performance based salary increases and to recognize the performance of certain Company executives. The stock grants totaled 84,000 shares of common stock, which were valued at \$580,000 based on the stock price of \$6.91 on the date of grant. Certain of these stock grants, contingent upon future service to the Company, vested at a rate of one twelfth per month for the twelve months following the grant date. Certain federal and state withholding taxes related to the stock grant were paid by individual employees through deduction of 2004 earnings or through payments made in cash or Company stock. The Company purchased \$54,000 in treasury stock from employees, based on the closing price on the day the stock was transferred to the Company, to pay employee federal and state withholding taxes related to these stock grants. The Company recorded \$202,000 and \$358,000 in compensation expense related to these stock grants for the years ended December 31, 2005 and 2004, respectively. The Company reversed \$20,000 of deferred compensation due to stock grants that were cancelled in 2005. As of December 31, 2005 the employee stock grants were fully vested and the Company had zero remaining as deferred compensation in the equity section of the Consolidated Balance Sheet.

A summary of stock grants follows:

	Shares	Weighted Average Grant Date Fair Value \$
Unvested at December 31, 2003		
Granted	84,000	6.91
Vested	(52,000)	6.91
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)	4.70
Unvested at December 31, 2006	13,000	\$ 4.70

### **Stock Compensation**

The Company early adopted SFAS 123R for the period beginning October 1, 2005. The Company's decision to early adopt SFAS 123R was pursuant to the shareholder derivative action settlement, as discussed in Note 10. 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.

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The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP ) for the benefit of its employees. See Note 14 for additional discussions of the 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. Pursuant to the adoption of SFAS 123R the lookback portion of the Company s ESPP constitutes an option and as such issuances of stock under the Company s ESPP must be valued and expensed.

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SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the required effective date or implementation date, as well as to the unvested portion of awards outstanding as of the required effective date or implementation date. 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 as the options vest.

During the fourth quarter of 2006, 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 2006.

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

	Twelve Months Ended December 31, 2006		Three Months Ended December 31, 2005	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	.650	.417	.650	.525
Risk-free interest rate	4.80%	4.39%	4.32%	3.55%
Expected life of options	4.1 Years	.24 Years	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.

For the year ended December 31, 2006 the Company's stock-based compensation expense was approximately \$1.6 million of which approximately \$852,000 was related to stock option grants and ESPP, \$587,000 was related to executive bonuses paid by the issuance of stock during 2007, and \$181,000 was related to common stock grants. The Company capitalized \$75,000 of the stock-based compensation expense into its deferred preservation costs and inventory costs. For the year ended December 31, 2005 the Company's stock-based compensation expense was approximately \$322,000 of which approximately \$120,000 was related to stock option grants and ESPP and \$202,000 was related to common stock grants. The Company capitalized \$37,000 of the stock-based compensation expense into its deferred preservation costs and inventory costs. Included in this total stock-based compensation expense were expenses related to options issued prior and subsequent to the adoption of SFAS 123R and compensation related to the Company's ESPP and common stock grants. This amount was recorded as compensation expense and subject to the Company's normal allocation of expenses to inventory and deferred preservation costs. The Company did not recognize a tax benefit, or a related operating cash outflow and financing cash inflow, related to the additional compensation expense recorded in the years ended December 31, 2006 and 2005 as the Company is maintaining a full valuation allowance on its deferred tax assets. See Note 16 for additional discussions of the Company's income tax valuation.

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As of December 31, 2006 and December 31, 2005 there was approximately \$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, 2006 and 2005 this expense is expected to be recognized over a weighted average period of 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 deferred compensation 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 123R for options accounted for under APB 25. SFAS 123R 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,	Twelve Months Ended December 31,
	2005 (unaudited)	2004
Expected dividend yield	0%	0%
Expected stock price volatility	.519	.589
Risk-free interest rate	3.36%	3.09%
Expected life of options	3.2 Years	3.7 Years

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,	Twelve Months Ended December 31,
	2005 (unaudited)	2004
Basic net loss applicable to common shares as reported	\$ (19,387)	\$ (18,749)
Stock-based employee compensation:		
Add expense included in the determination of net loss	166	358
Deduct expense determined under the fair value based method for all awards	3,253	3,093
Basic net loss applicable to common shares pro forma	\$ (22,474)	\$ (21,484)
Basic weighted-average shares	23,839	23,043
Basic loss per common share:		
As reported	\$ (0.81)	\$ (0.81)
Pro forma	\$ (0.94)	\$ (0.93)

	Nine Months Ended September 30,	Twelve Months Ended December 31,
	2005 (unaudited)	2004
Diluted net loss applicable to common shares as reported	\$ (19,387)	\$ (18,749)
Stock-based employee compensation:		
Add expense included in the determination of net loss	166	358
Deduct expense determined under the fair value based method for all awards	3,253	3,093
Diluted net loss applicable to common shares pro forma	\$ (22,474)	\$ (21,484)
Diluted weighted-average shares	23,839	23,043
Diluted loss per common share:		
As reported	\$ (0.81)	\$ (0.81)
Pro forma	\$ (0.94)	\$ (0.93)

## 12. 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. At the meeting on November 1, 2005, the Board also declared that each share of 6% convertible preferred stock of the Company (a Convertible Share) outstanding on November 23, 2005 is entitled to one Right for each share of common stock into which the Convertible Share is convertible as of the Distribution Date (as defined in the rights agreement), subject to the terms and conditions of the rights agreement. Each Convertible Share that becomes outstanding after November 23, 2005 is also entitled to a Right, subject to the terms and conditions of the rights agreement. The Rights, which expire on November 23, 2015, may be exercised only if certain conditions are met, such as the acquisition of 15% or more of the Company's common stock by a person or affiliated group (together with its affiliates, associates, and transferees, an Acquiring Person). Rights beneficially owned by an Acquiring Person become void from and after the time such persons become Acquiring Persons, and Acquiring Persons have no rights whatsoever under the rights agreement.

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

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



**13. Comprehensive Income (Loss)**

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

	2006	2005	2004
Net income (loss)	\$ 365	\$ (19,535)	\$ (18,749)
Unrealized gain (loss) on investments	3	(34)	(53)
Translation adjustment	34	(204)	49
Comprehensive income (loss)	\$ 402	\$ (19,773)	\$ (18,753)

The tax effect on the change in unrealized gain (loss) on investments is zero, \$11,000, and \$28,000 for the years ended December 31, 2006, 2005, and 2004, respectively. The tax effect of the translation adjustment is a benefit of \$91,000 for the year ended December 31, 2006 and an expense of \$64,000, and \$17,000, for the years ended December 31, 2005 and 2004, respectively.

At December 31, 2006, components of accumulated other comprehensive income consist of the following, (in thousands):

	2006	2005
Unrealized gain (loss) on investments	\$ 1	\$ (2)
Translation adjustment	159	125
Total accumulated other comprehensive income	\$ 160	\$ 123

**14. 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 2006, 2005, and 2004. Total Company contributions approximated \$340,000, \$296,000, and \$312,000 for 2006, 2005, and 2004, respectively. Additionally, the Company may make discretionary contributions to the Plan that are allocated to each participant's account. In 2006 discretionary contributions of \$56,000 were made by the plan administrator on behalf of the Company. No discretionary contributions were made in 2005 or 2004.

On May 16, 1996 the Company's shareholders approved the CryoLife, Inc. Employee Stock Purchase Plan (the 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, 2006 and 2005 there were 205,000 and 281,000, respectively, shares of common stock reserved under the ESPP and there were 695,000 and 619,000, respectively, shares issued under the plan.

**15. Loss Per Common Share**

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

	2006	2005	2004
<b>Numerator for basic income (loss) per common share:</b>			
Net income (loss)	\$ 365	\$ (19,535)	\$ (18,749)
Effect of preferred stock <sup>a</sup>	(973)	(777)	
Net loss applicable to common shares	\$ (608)	\$ (20,312)	\$ (18,749)
<b>Denominator for basic loss per common share:</b>			
Basic weighted-average common shares	24,829	23,959	23,043
Basic loss per common share	\$ (0.02)	\$ (0.85)	\$ (0.81)
<b>Numerator for diluted income (loss) per common share:</b>			
Net income (loss)	\$ 365	\$ (19,535)	\$ (18,749)
Effect of preferred stock <sup>a, b</sup>	(973)	(777)	
Net loss applicable to common shares	\$ (608)	\$ (20,312)	\$ (18,749)
<b>Denominator for diluted income (loss) per common share:</b>			
Basic weighted-average common shares	24,829	23,959	23,043
Effect of dilutive convertible preferred stock <sup>b</sup>			
Effect of dilutive stock options <sup>c</sup>			
Adjusted weighted-average common shares	24,829	23,959	23,043
Diluted loss per common share	\$ (0.02)	\$ (0.85)	\$ (0.81)

<sup>a</sup> The amount of the accumulated dividend on the Preferred Stock increased the net loss applicable to common shares by \$973,000 and \$777,000 for the years ended December 31, 2006 and December 31, 2005, respectively.

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

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 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.

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- <sup>c</sup> Outstanding options to purchase the Company's common stock that would have resulted in additional dilutive common shares of 229,000, 331,000, and 345,000 for the years ended December 31, 2006, 2005, and 2004, respectively, were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

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In future periods the basic and diluted loss per common share are expected to be affected by the declaration of dividends on Preferred Stock, the conversion of Preferred Stock, fluctuations in the fair value of the Company's common stock, and changes in the valuation of the derivative.

## 16. Income Taxes

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

	2006	2005	2004
Domestic	\$ 358	\$ (19,956)	\$ (22,205)
Foreign	292	(7)	439
<b>Income (loss) before income taxes</b>	<b>\$ 650</b>	<b>\$ (19,963)</b>	<b>\$ (21,766)</b>

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

	2006	2005	2004
<b>Current:</b>			
Federal	\$ 85	\$ (557)	\$ (3,120)
State	(58)	70	27
Foreign	(17)	123	103
	10	(364)	(2,990)
<b>Deferred:</b>			
Federal	\$	\$	\$
State			
Foreign	275	(64)	(27)
	275	(64)	(27)
<b>Income tax expense (benefit)</b>	<b>\$ 285</b>	<b>\$ (428)</b>	<b>\$ (3,017)</b>

The Company's income tax expense of \$285,000 for 2006 was primarily due to the recording of deferred tax liabilities related to a foreign jurisdiction and alternative minimum tax on the Company'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.

Such amounts differ from the amounts computed by applying the U.S. federal income tax rate of 34% in 2006, 2005, and 2004 to pretax income as a result of the following (in thousands):

	2006	2005	2004
Tax expense (benefit) at statutory rate	\$ 221	\$ (6,787)	\$ (7,400)
Increase (reduction) in income taxes resulting from:			
Deferred tax valuation	(330)	6,493	5,475
Research and development credit	(126)	(100)	(550)
Extraterritorial income exclusion	(49)	(54)	(54)
Foreign income taxes	258	59	76
Equity compensation	175	30	
Entertainment expenses	81	74	67
Loss (Gain) on preferred stock dividend make whole payments	41	(48)	
State income taxes, net of federal benefit	3	(142)	(604)

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Nontaxable interest income		(10)	(27)
Other	11	57	
	\$ 285	\$ (428)	\$ (3,017)

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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):

	2006	2005
Deferred tax assets:		
Allowance for bad debts	\$ 50	\$ 36
Property	62	
Intangible assets	335	356
Accrued expenses	3,327	2,356
Loss carryforwards	23,603	20,177
Credit carryforwards	5,372	5,134
Deferred preservation costs and inventory reserves	1,467	258
Other	237	11
Less valuation allowance	(32,978)	(26,538)
<b>Net deferred tax assets</b>	<b>1,475</b>	<b>1,790</b>
Deferred tax liabilities:		
Property		(608)
Intangible assets	(574)	(499)
Prepaid items	(441)	(422)
Accrued expenses	(401)	(13)
Other	(285)	(248)
<b>Total gross deferred tax liabilities</b>	<b>(1,701)</b>	<b>(1,790)</b>
<b>Total net deferred tax liabilities</b>	<b>\$ (226)</b>	<b>\$</b>

The Company assesses the recoverability of its deferred tax assets on an annual basis, and on an interim basis, 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, 2006 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, at December 31, 2006 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, 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.

As of December 31, 2006, the Company had approximately \$48.5 million of U.S. federal net operating loss carryforwards that will begin to expire in the 2023 tax year and \$3.1 million in research and development tax credit carryforwards that will begin to expire in 2010. Additionally, at December 31, 2006 the Company had \$2.3 million in alternative minimum tax credit carryforwards that do not expire.

The realizability of the Company's net operating losses could be limited in future periods as mandated by Internal Revenue Code Section 382.

## 17. 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. No contributions were made to the plan in 2005 or 2004. In 2004 the Company awarded as a bonus amounts contributed by the Company to policies for two departing executive officers that had participated in the plan. 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 that had participated in the plan. As a result the Company recorded compensation expense of approximately \$253,000 and \$75,000 related to this plan in 2005 and 2004, respectively.

**18. Transactions with Related Parties**

The Company expensed \$135,000, \$27,000, and \$30,000 in 2006, 2005, and 2004, 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 expensed \$26,000 in 2006 relating to research performed by a company whose former Chief of Thoracic Surgery 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 \$151,000, \$18,000, and \$38,000 in 2006, 2005, and 2004 from a customer whose former Chief of Thoracic Surgery is a member of the Company's Board of Directors and a shareholder of the Company.

**19. Segment and Geographic Information**

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

The Implantable Medical Devices segment includes external revenue from product sales of BioGlue and bioprosthetic devices, including stentless porcine heart valves and SynerGraft processed bovine vascular grafts. The Human Tissue Preservation Services segment includes external services revenue from preservation of cardiac, vascular, and orthopaedic allograft tissues. 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 products and preservation services. The Company does not segregate assets by segment, therefore, asset information is excluded from the segment disclosures below.

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

	2006	2005	2004
Revenue:			
Implantable medical devices	\$ 41,037	\$ 38,932	\$ 36,637
Human tissue preservation services	40,078	30,307	25,676
All other <sup>a</sup>	196	43	71
	\$ 81,311	\$ 69,282	\$ 62,384
Cost of products and preservation services:			
Implantable medical devices	\$ 7,463	\$ 8,065	\$ 7,818
Human tissue preservation services	29,958	24,357	29,807
	\$ 37,421	\$ 32,422	\$ 37,625
Gross margin:			
Implantable medical devices	\$ 33,574	\$ 30,867	\$ 28,819
Human tissue preservation services	10,120	5,950	(4,131)
All other <sup>a</sup>	196	43	71
	\$ 43,890	\$ 36,860	\$ 24,759

<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.

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Net revenues by product for the years ended December 31, 2006, 2005, and 2004 were as follows (in thousands):

	2006	2005	2004
<b>Products:</b>			
BioGlue	\$ 40,025	\$ 37,985	\$ 35,745
Bioprosthetic devices	1,012	947	892
Total products	41,037	38,932	36,637
<b>Human tissue preservation services:</b>			
Cardiovascular tissue	15,988	13,762	12,504
Vascular tissue	16,956	11,453	10,293
Orthopaedic tissue	7,134	5,092	2,879
Total preservation services	40,078	30,307	25,676
All other <sup>a</sup>	196	43	71
	\$ 81,311	\$ 69,282	\$ 62,384

<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, 2006, 2005, and 2004 were as follows (in thousands):

	2006	2005	2004
U.S.	\$ 69,467	\$ 58,869	\$ 53,244
International	11,844	10,413	9,140
Total	\$ 81,311	\$ 69,282	\$ 62,384

At December 31, 2006, 2005, and 2004, over 95% of the long-lived assets of the Company were held in the U.S., where all Company manufacturing facilities and the corporate headquarters are located.



**SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
<b>REVENUE:</b>				
2006	\$ 19,449	\$ 20,754	\$ 20,018	\$ 21,090
2005	17,665	17,198	16,458	17,961
2004	15,086	15,314	16,118	15,866
<b>GROSS MARGIN:</b>				
2006	\$ 10,763	\$ 11,638	\$ 11,488	\$ 10,001
2005	9,650	9,049	8,503	9,658
2004	4,036	5,877	6,996	7,850
<b>NET (LOSS) INCOME:</b>				
2006	\$ (1,780)	\$ 217	\$ 1,978	\$ (50)
2005	(1,357)	(14,379)	(3,118)	(681)
2004	(7,026)	(3,352)	(6,008)	(2,363)
<b>(LOSS) INCOME PER COMMON SHARE DILUTED:</b>				
2006	\$ (0.08)	\$ (0.00)	\$ 0.07	\$ (0.01)
2005	(0.06)	(0.61)	(0.14)	(0.04)
2004	(0.32)	(0.14)	(0.26)	(0.10)

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## CRYOLIFE, INC. AND SUBSIDIARIES

## VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2006, 2005, and 2004

Description	Balance Beginning			Balance End
	of Period	Additions	Deductions	of Period
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
Year ended December 31, 2004:				
Allowance for doubtful accounts	\$ 65,000	\$ 53,000	\$ 33,000	\$ 85,000
Deferred preservation costs	50,000		50,000	

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List of Exhibits Included

<b>Exhibit Number</b>	<b>Description</b>
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.
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.
10.9(e)*	Commission Arrangement with Gerald B. Seery, Effective January 1, 2006.
10.11*	Form of Key Employee Secrecy and Noncompete Agreement, by and between the Company and its Officers and Key Employees.
10.18*	Description of CryoLife, Inc. Performance-Based Bonus Plan.
10.29*	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
10.30(a)*	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
10.30(b)*	Form of Director Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 1998 Long-Term Incentive Plan.
10.31*	Form of Non-Employee Directors Stock Option Agreement and Grant pursuant to the Amended and Restated Non-Employee Directors Stock Option Plan.
10.32*	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
10.33*	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
10.34*	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan.
10.35*	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan.
10.36*	Form of Grant of Non-Qualified Stock Option to Directors.
10.37*	Grant of Incentive Stock Option to Stephen G. Anderson, dated May 4, 2006.
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.