

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THESECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2005

OR

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

Commission file number 1-13165

**CRYOLIFE, INC.**

(Exact name of registrant as specified in its charter)

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

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

1655 Roberts Boulevard N.W., Kennesaw, GA 30144  
(Address of principal executive offices) (zip code)

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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, 2005, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was \$167,489,023, computed using the closing price of \$7.76 per share of Common Stock on June 30, 2005, the last trading day of the registrant's most recently completed second fiscal quarter, as reported by NYSE, based on the assumption that directors and executive officers are affiliates.

As of February 17, 2006 the number of outstanding shares of Common Stock of the registrant was 24,751,421.

**Documents Incorporated By Reference**

**Document**  
Proxy Statement for the Annual Meeting of Shareholders  
to be filed within 120 days after December 31, 2005. (Proxy Statement).

**Parts Into Which Incorporated**  
Part III

## Item 1. Business.

### Overview

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, vascular, and orthopaedic transplant applications. The implantable devices include BioGlue® Surgical Adhesive (“BioGlue”), porcine heart valves, and grafts of bovine tissue processed using the Company’s proprietary SynerGraft® technology.

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 can distribute BioGlue throughout the U.S. and 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 several other countries in Central and South America, Asia, and Australia. The 2 and 5 ml version of a syringe delivery system, which provides BioGlue without a separate delivery system, was approved by the FDA and CE Marked in May 2004. The syringe was approved in Canada in November 2004. The 10 ml version of the syringe was CE Marked for distribution in the EEA in November 2005, approved by the FDA in December 2005, and approved in Canada in February 2006. The syringe spreader tip, which allows for a wider application of the 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.

CryoLife distributes preserved human cardiovascular, vascular, and orthopaedic tissue to implanting institutions throughout the U.S., Canada, and Europe. 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.

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, vascular, and orthopaedic 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 tissue preservation services were developed based on work done some years before. 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 BioGlue technology as a potential replacement for spinal disc nuclei and in trauma surgery. Another derivative of the BioGlue technology, BioLastic™, might potentially be used for reducing adhesions. Potential product line extensions include modifications to the BioGlue delivery system.

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.

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The Company’s products are often marketed internationally several years before they can be marketed in the U.S. In 2005 international revenues were 15% of total revenues.

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 ongoing product liability, securities, and other litigation, regulatory action, 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

The Company amended and restated its Rights Agreement, which was entered into on November 27, 1995, to extend its expiration date to November 23, 2015, and make other non-substantive changes.

On December 9, 2005 the Company made the final \$3.75 million payment due pursuant to the previously announced settlement of the securities class action lawsuit. The Company paid the settlement amount with a combination of approximately \$1.8 million in cash and 500,000 shares of CryoLife common stock.

On December 12, 2005, the Company declared a dividend of approximately \$0.75 on its 6% convertible preferred stock payable on January 3, 2006, to shareholders of record at the close of business on December 23, 2005.

On December 27, 2005 the Board of Directors of the Company approved an increase in the size of the board to nine directors and filled the vacant director position by appointing James S. Benson. Mr. Benson was also appointed to the Company’s Regulatory Affairs and Quality Assurance Committee. The Company’s Nominating and Corporate Governance Committee identified Mr. Benson during a candidate search initiated to fill the position, which was

agreed to as part of the previously announced settlement of a shareholder derivative lawsuit.

On December 28, 2005 the Company announced that its Board of Directors had amended the Company's bylaws in order to affirmatively opt out of the Control Share Acquisition Statute contained in the Florida Business Corporation Act. The Board believes that the Company no longer has "substantial assets" in the State of Florida and therefore the Control Share Acquisition Statute does not apply to CryoLife. The Board took this action to clarify that this anti-takeover statute does not apply to the Company. In addition the Board removed a provision of the bylaws relating to special meetings that was inconsistent with the Company's articles of incorporation. The articles of incorporation provide that shareholders owning not less than 50% of the Company's voting shares may call a special meeting of the stockholders.

On January 12, 2006 the Company announced that it has received approval from the FDA for a new 10 ml disposable syringe for BioGlue. Currently available in Europe, the 10 ml BioGlue Syringe will be introduced to the U.S. market late in the first quarter of 2006.

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. No assurance can be given that this process will lead to any specific action or transaction.

On January 24, 2006 the Company announced that President George W. Bush recently signed into law a Department of Defense ("DoD") Appropriations Bill that includes \$2.3 million for the continued development of protein hydrogel and bio-foam sealant in this fiscal year. CryoLife's BioFoam™, now in preclinical studies, is included in this product category, making CryoLife eligible to apply for funding under this bill.

On February 8, 2005 the Company announced that it has received approval from the FDA for two new spreader tips for its BioGlue Syringe applicators. The new 12 mm and 16 mm fan-like extensions deliver a thinner, wider band of BioGlue designed to more quickly seal suture lines.

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## **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.

On September 5, 2002 the Company entered into an agreement with the FDA (the "FDA Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to the recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company had completed specified steps.

In addition pursuant to the FDA Agreement, the Company agreed to perform additional processing procedures and to establish a corrective action plan. The corrective actions taken have been reviewed by the FDA during subsequent inspections.

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***

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 response to the July 2005 483 the Company has implemented new 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 and will continue to work with the FDA to review process improvements and address any outstanding observations.

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 others through administrative procedures. The FDA requested further additional information in January 2006. The FDA may still require that additional studies be undertaken and may never clear the 510(k) premarket notification. 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 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 cardiovascular 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 clearances are granted. The Company is evaluating whether it will file and seek a premarket approval for CryoVein SG or discontinue the CryoVein SG.

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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 will employ its traditional processing methods on these tissues. During the year ended December 31, 2004 the Company wrote down \$353,000 in SynerGraft processed cardiovascular and vascular tissues. As of December 31, 2005 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Consolidated Balance Sheets.

## Strategy

The Company's primary objective is to increase revenue and return to profitability. The Company's strategy to generate revenue growth is based on increasing market penetration for its existing products and services, increasing tissue procurement and throughput, increasing yields of implantable tissue per donor, increasing the use of cryopreserved tissues as an alternative to mechanical and synthetic implantable products, developing new markets for existing products and technologies, and developing new products and technologies for new and existing markets. The Company also selectively considers strategic acquisitions of complementary technologies and businesses to supplement its internal growth. The key elements of the Company's business and growth strategy are to:

- o *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, either directly or through strategic alliances, additional indications or product line extensions for the BioGlue technology in either the U.S. or internationally, (iii) pursuing, either directly or through strategic alliances, 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.
- o *Expand Distribution of Preserved Human Tissue.* The Company intends to increase the market penetration of its CryoLife preserved human heart valves, non-valved conduits, vascular grafts, and orthopaedic tissues 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 75 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.
- o *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.
- o *Expand Distribution of Bioprosthetic SynerGraft Vascular Devices.* The Company intends to increase the market penetration of its SynerGraft Model 100 vascular graft that is presently being marketed in the EMEA as an A-V access graft.
- o *Develop and Commercialize Other Technologies.* The Company intends to leverage its current distribution channel and its expertise in the cardiovascular, vascular, and orthopaedic medical specialties by selectively pursuing the potential distribution or licensing of additional technologies that complement existing services and products.

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. No assurance can be given that this process will lead to any specific action or transaction.

## 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 bioadhesive 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"). PHT is based on a bovine protein that mirrors an array of amino acids that perform complex functions in the human body that together with glutaraldehyde 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 pilot clinical trial for BioDisc™ to determine its clinical utility as a durable

nucleus pulposus replacement in spinal disc repair. The Company is conducting preclinical research with BioFoam in trauma surgery. Another PHT product, BioLastic, might potentially be used for reducing adhesions.

The Company estimates that the number of procedures where tissue sealants could be used was approximately 3.6 million in 2005. CryoLife can 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 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 several other countries in Central and South America, Asia, and Australia. 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 the 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. Revenues from BioGlue represented 55%, 57%, and 47% of total revenues, respectively, in 2005, 2004, and 2003.

#### *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.

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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, vascular, and orthopaedic 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 60,400 cryopreserved human heart valves and conduits from 1984 through 2005, including approximately 1,900 shipments in 2005. Revenues from human heart valve and conduit preservation services accounted for 20%, 20%, and 29% of total revenues, respectively, in 2005, 2004, and 2003. 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 antigen reduction technology. 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 2005 was in excess of \$400 million. Management believes that approximately 89,000 heart valve surgeries were conducted in the U.S. in 2005. Of this total number of heart valve and conduit surgeries, approximately 23,000 or 26%, involved mechanical heart valves, and approximately 66,000 or 74%, 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 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.

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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:

	Porcine				
	Cryopreserved Human	Stented	Stentless	Mechanical	Bovine Pericardium
Materials:	human tissue	glutaraldehyde-fixed pig tissue and synthetic sewing ring	glutaraldehyde-fixed pig tissue	pyrolytic 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 peripheral 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 42,800 human vascular tissues from 1986 through 2005, including approximately 2,100 shipments in 2005. Revenues from human vascular preservation services accounted for 17%, 16%, and 21% of total revenues, respectively, in 2005, 2004, and 2003.

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 fields 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 patients do not have suitable autologous tissue available.

*Human Orthopaedic Tissue.* The Company suspended processing orthopaedic tissues in August 2002 and began limited processing of orthopaedic tissues in late February 2003. The Company began shipment of these orthopaedic tissues processed since February 2003 with the shipment of non-boned orthopaedic tissues in May 2003 and boned orthopaedic tissues in August 2003. During September 2003, in response to a reported infection, the Company 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. In December 2003 the Company resumed shipment of boned orthopaedic tissues after the completion of its review. The Company provides 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. The Company has historically provided preservation services for surgical replacements for osteochondral grafts used for the repair of cartilage defects in the knee. The Company resumed shipment of osteochondral grafts in February 2005. The current processing method for osteochondral grafts includes cryopreservation. Cryopreserving the osteochondral grafts will extend the life of these grafts that were not previously cryopreserved. 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. CryoLife shipped approximately 29,300 human connective tissues for the knee through the end of 2005, including approximately 1,400 shipments in 2005. Revenues from human orthopaedic preservation services accounted for 7%, 5%, and 2% of total revenues, respectively, in 2005, 2004, and 2003.

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. The Company estimates that in 2005 approximately 750,000 U.S. patients underwent partial or total meniscectomies. The Company believes a portion of these patients could become candidates for meniscal replacement within five years.

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. The Company estimates that in 2005 approximately 375,000 cruciate ligament reconstruction surgeries were performed in the U.S.

In 1999 the Company began preserving osteoarticular grafts used to aid in the repair of damaged knee cartilage. Prior to the FDA Order, the orthopaedic surgical community had accepted these grafts. The Company resumed shipment of cryopreserved osteochondral grafts in February 2005. The success of transplanted osteoarticular grafts is attributed to the presence of viable chondrocytes (cells of the cartilage). The Company estimates that in 2005 the cartilage repair market was approximately \$33 million of which the osteoarticular allograft market represented approximately \$10 million with approximately 1,500 procedures.

#### *Bioprosthetic Cardiovascular and Vascular Devices*

The Company developed and commercialized its bioprosthetic cardiovascular and vascular devices based on its experience with cryopreserved human tissue implants. Like human heart valves, the Company's porcine heart valve is stentless with the valve opening, or annulus, retaining a more natural flexibility. 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. Revenues from bioprosthetic cardiovascular and vascular devices represented 1% of total revenues in 2005, 2004, and 2003.

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 \$900 million in 2005.

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The CryoLife O'Brien aortic valve is a stentless porcine valve with design features that contains a matched composite leaflet design that approximates human heart valve blood flow characteristics and requires only a single suture line for surgical implantation. Management believes these features provide advantages over certain other stentless porcine and bovine heart valves. 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.

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 antigen reduction technology involves the removal of cells from the structure of animal tissue, leaving a collagen matrix that has the potential to repopulate *in vivo* 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 vivo* 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.

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 the Company's wholly owned European subsidiary, CryoLife Europa Ltd.'s ("Europa") direct technical representatives and other existing 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 will be responsible for applications and clearances with the Japanese Ministry of Health and Welfare.

##### *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 75 tissue banks and organ procurement agencies throughout the U.S. Management believes

these relationships are critical in the preservation services industry and that the breadth of these existing relationships provides the Company with a significant advantage over potential new entrants to this market. The Company employs approximately 28 individuals in donor services to work with organ procurement agencies and tissue banks, five of which are stationed throughout the country. 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(Degree)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 1,200 cardiovascular, vascular, and 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 33 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 has approximately 115 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 schools. In addition the Company coordinates laboratory sessions that utilize animal tissue to demonstrate surgical techniques. Members of the Company's Medical Advisory Board often lead the surgery demonstrations and laboratory sessions. 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 porcine heart valve and the SynerGraft Model 100 Vascular Graft in the EMEA region. Marketing efforts for the CryoLife O'Brien 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 region through its European subsidiary, Europa, based in Guildford, England. Europa, with its team of approximately ten employees, provides customer service, logistics, marketing, and clinical support to cardiovascular, vascular, thoracic, and general surgeons throughout the EMEA region. Europa markets and distributes the Company's complete range of products through its direct sales representatives in England and Wales and a network of independent agents and distributors in the EMEA region.

### *Backlog*

The limited supply of tissue that is donated and available for processing typically results in a backlog of orders in the Company's human tissue business. The amount of backlog fluctuates based on the tissues available for shipment and varies based on the surgical needs of specific cases. The Company's backlog is generally not considered firm and must be confirmed with the customer before shipment. The Company currently does not have a backlog of orders related to BioGlue or CryoLife O'Brien heart valves. The Company had a minor backlog of SynerGraft bovine vascular grafts due to a manufacturing



slow down earlier in the year.

## Research and Development

The Company uses its expertise in biochemistry and cell biology, and its understanding of the needs of the cardiovascular, vascular, and orthopaedic 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 21 people in its research and development department, including six PhDs with specialties in the fields of molecular biology, protein chemistry, organic chemistry, 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 and 2006 Defense Appropriations Conference Reports included \$926,000 and \$2.3 million, respectively, for the development of BioFoam. CryoLife is currently involved in the initial animal trial with the U.S. Army's Institute for Surgical Research.

BioDisc, a derivative of the PHT, is in a pilot clinical trial to determine its clinical utility as a durable nucleus pulposus replacement in spinal disc repair. The nucleus pulposus is surrounded by fibrous tissue (annulus) and is located in the center of the vertebral disc. The nucleus pulposus is composed of a gelatinous-like material that 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 prevent reherniation and maintain disc height. Currently there are nine patients enrolled in the study.

BioLastic, another derivative of the PHT may have the potential to be used as a pericardial replacement device to serve as a protective membrane and physical barrier to limit post-operative tissue attachment.

Currently under final development is a tissue based surgical mesh product utilizing an adaptation of the SynerGraft technology applied to bovine pericardium. The acellular sheet material will be supplied sterile in a ready to use format, and is designed to be used in the reinforcement of soft tissue repairs where weaknesses in the tissues exist, and more specifically in the repair of various orthopedic injuries such as rotator cuff and tendon ruptures. Derived from animal sourced materials, the tissue repair matrix is designated as a medical device, and will require a 510(k) premarketing notification to FDA prior to launch.

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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, such as it did with Clearant, Inc. in December 2003. Under that arrangement, CryoLife licensed a patented technology based on gamma irradiation designed to inactivate microorganisms, including bacteria, viruses, and fungi from tissue obtained from human donors, while maintaining tissue integrity. The license allows CryoLife to use the Clearant technology on certain orthopaedic tissues and requires that CryoLife pay a royalty on revenues from tissues distributed with this technology. Working with Clearant representatives, CryoLife has further developed this technology and began employing it in processing certain human orthopaedic tissue in early 2005. The Company began shipping its first orthopaedic tissue processed with Clearant technology during the second quarter of 2005.

The Company's research and development strategy is to allocate available resources among the Company's core market areas of preservation services, implantable biomaterials, and bioprosthetic cardiovascular 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 2005, 2004, and 2003 the Company spent approximately \$3.7 million, \$3.9 million, and \$3.6 million respectively, on research and development activities on new and existing products. These amounts represented approximately 5%, 6%, and 6% of the Company's revenues for the years 2005, 2004, and 2003, 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(Degree)C. Two back-up emergency generators assure continuity of Company operations. Additionally, the Company's corporate complex has a 3,600 square foot Learning Center which includes a 225 seat auditorium 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 Learning Center provides visiting cardiovascular, vascular, and orthopaedic 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, vascular, and orthopaedic tissue for transplant. This laboratory contains approximately 15,600 square feet with a suite of eight clean rooms. Currently there are approximately 60 technicians employed in this area, and the laboratory is staffed for 24 hours per day, 365 days per year. In 2005 the laboratory packaged approximately 13,700 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 third shift, and add equipment.

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### *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 14 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 porcine heart valve and the SynerGraft bovine 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.

### *Other Facilities*

The Company maintains a 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 and pharmaceutical manufacturing industries. The quality assurance department, in conjunction with the Company's research and development department and select university research staffs, 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 of measuring devices used for manufacturing and inspection to obtain appropriate accuracy and precision. Records are maintained as to the consignees of products to track product performance and to facilitate product removals or corrections, if necessary.

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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 courses 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 procurement 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 serologic tests to screen 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 proprietary antimicrobial solutions and aseptically packaged. Each tissue must be free of detectable microbial contaminants by two independent tests before being distributed.

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 as required of the facilities 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 38 U.S. patents and 59 foreign patents, including patents relating to its technology for human cardiovascular, vascular, and orthopaedic tissue preservation; tissue revitalization prior to freezing; tissue transport; BioGlue; ACT; and packaging. The Company has approximately 17 pending U.S. patent applications and 65 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. The Company has licensed from third parties certain technologies that call for the payment of both developmental milestones and 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.

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.

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In August 2002 the Company settled litigation with Colorado State University Research Foundation ("CSURF") over the ownership of the Company's SynerGraft technology. The settlement extinguished CSURF's claims to the Company's SynerGraft technology. The settlement payment terms included a nonrefundable prepaid royalty of \$400,000 to be applied to earned royalties as they accrue through March 2011. As of December 31, 2005 the remaining balance of the prepaid royalty was \$69,000. The Company does not expect to pay any additional royalties to CSURF.

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, pharmaceutical, and biopharmaceutical companies. In the surgical adhesive and surgical sealant area, the Company competes primarily with Baxter Healthcare's Tisseel, FloSeal, and CoSeal products. Additionally, Closure Medical, a subsidiary of 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 Related to CryoLife and Its Industry—Rapid Technological Change Could Cause Services And Products To Become Obsolete."

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

The Company faces competition from at least one for-profit company and several non-profit tissue banks that cryopreserve and distribute human tissue, as well as from 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 since 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 the tissue processing and release times and reducing the yield of implantable tissue per donor, have made it difficult for the Company to regain a profitable level of revenues.

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 or orthopaedic human tissue that the Company cryopreserves, there are alternative treatments. Often, as in the case of veins and ligaments, 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 pericardium 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 pericardium heart valves. The Company is aware of at least five other companies that offer porcine and bovine pericardium 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 three other providers, Northwest Tissue Centers, Regeneration Technologies, Inc., and LifeNet, of cryopreserved 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.* The Company ceased processing orthopaedic tissue in August 2002 as a result of the FDA Order and began limited processing of orthopaedic tissue in late February 2003. The Company began shipment of these orthopaedic tissues processed since February 2003 with the shipment of non-boned orthopaedic tissues in May 2003 and boned orthopaedic tissues in August 2003. During September 2003, in response to a reported infection, the Company 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. In December 2003 the Company resumed shipment of boned orthopaedic tissues after the completion of its review. 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. These alternative allografts are distributed by more than ten tissue banks.

## **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. 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.

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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. By statute and regulation, the FDA may take 180 days to review a PMA application although such time may be extended. Furthermore, there can be no

assurance that a PMA application will be reviewed within 180 days or that a PMA application will be approved by the FDA.

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. 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”). HDE’s are granted by the FDA 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’s medical device tracking regulation requires the adoption of a method of device tracking by manufacturers of life-sustaining or implantable products, the failure of which would be reasonably likely to have serious adverse health consequences, if the FDA issues an order to do so. The manufacturer must adopt methods to ensure that such devices can be traced from the manufacturing facility to the ultimate user, the patient. The FDA further requires that certain medical devices not cleared for marketing 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.

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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, do not conflict with the laws of and are approved by the country to which they will be exported, and the FDA determines that their exportation is not contrary to the public health and safety.

*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.

#### *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. 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.

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

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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 clearances are granted. The Company is evaluating whether it will file and seek a premarket approval 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 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 approval, called a CE Mark, which allows for distribution of an approved product throughout the EEA (28 member state countries; 25 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 porcine 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.

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## **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 January 17, 2006 the Company had approximately 363 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, and current reports on Form 8-K, 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.

## Forward-Looking Statements

This Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act 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," "estimate," "plan," "future," and other similar expressions generally identify forward-looking statements, including, in particular, statements regarding future products and 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.

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## Item 1A. Risk Factors.

### Risks Relating to the Company's Business

#### Overview

CryoLife has faced extraordinary challenges since it received, on August 13, 2002, the FDA Order calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife since October 3, 2001. The recall resulted in the destruction of much of CryoLife's tissue, required that it adjust revenue for tissue recall returns, curtailed its processing activities, subjected it to intense FDA scrutiny and additional regulatory requirements that increased costs while CryoLife suffered decreased revenues due to lack of processing ability, and decreased market demand for its services. During the same year CryoLife was the subject of intense adverse media attention in connection with allegations that tissue processed by CryoLife had infected a man in Minnesota and caused his death. CryoLife also became 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 CryoLife, using all of its related 2002/2003 insurance policy year insurance coverage and taxing its other resources. While many cases and claims have been settled, several remain unresolved. The SEC has initiated and continues to pursue a formal investigation. These challenges have affected Company revenues, increased its costs to process tissues and its operating expenses, and strained management resources. Although CryoLife resumed processing and distribution of the types of tissues subject to the FDA recall and resolved many of the product liability suits pending against it, the foregoing factors will continue to challenge CryoLife in its efforts to increase revenues and return to profitability. No assurances can be made that CryoLife will succeed in those efforts in a timely fashion.

#### The Company Has Experienced Operating Losses And Negative Cash Flow. The Company Must Address The Underlying Causes.

Due principally to factors mentioned above the Company has suffered net losses and generated negative operating cash flow each year in the three year period ended December 31, 2005 and anticipates net losses and negative cash flow from operations for the full year of 2006.

The Company expects that the following factors will continue to have an adverse effect on earnings and cash flows during 2006:

- o The anticipated lower preservation service revenues as compared to preservation service revenues prior to the FDA Order, subsequent FDA activity, and related events,
- o The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which increased the cost of processing human tissue and decreased yields of implantable tissue per donor,
- o An expected use of cash related to the defense and resolution of lawsuits and claims, and
- o The legal and professional costs related to ongoing FDA compliance.

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

- o The success of BioGlue and other products using related technology,
- o The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,

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- o The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,
  - o The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,

- o The timing and cost of resolving the remaining outstanding product liability lawsuits and other claims,
- o To a lesser degree, the Company's success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft technology.

**If The Company Is Unable To Address The Causes Of Its Operating Losses And Negative Cash Flows, It Will Need To Raise Additional Capital Which May Not Be Available Or May Not Be Available On Acceptable Terms.**

If the Company is unable to address these issues and continues to experience negative cash flows, the Company anticipates that it will 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. 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 position, results of operations, and cash flows. Issuance of equity capital may be dilutive to existing shareholders.

**The Company's Review Of Potential Strategies May Not Be Productive And The Outcome Of This Process Is Uncertain.**

CryoLife recently retained Piper Jaffray & Co. to assist the Company's management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. The Company is uncertain as to what impact any particular strategy may have on its operating results or stock price, if accomplished, or whether any material changes or transactions will even occur as a result of this review. Other uncertainties and risks relating to the review of potential strategies include:

- o The review of potential strategies may disrupt the Company's operations and divert management's attention, which could have a material adverse effect on CryoLife's business, financial position, or results of operations;
- o The perceived uncertainties as to the Company's future direction may result in the loss of, or failure to attract, customers, employees or business partners;
- o The process of reviewing potential strategies may be more time consuming and expensive than currently anticipated; and
- o CryoLife may not be able to identify new potential strategies, or variations of existing strategies, that are worth pursuing, and even if strategies are identified that are believed to be worth pursuing, the Company may not successfully execute any strategy or strategies undertaken. Even if CryoLife is successful, the effort may not enhance shareholder value.

**The Company's Revolving Credit Facility Imposes Restrictions On Its Ability To Borrow, Which Could Make It More Difficult To Borrow Needed Funds.**

The credit agreement places limitations on the amount that the Company may borrow, and includes various affirmative and negative covenants. Among these financial covenants is a requirement that CryoLife maintain quarterly either:

- o Minimum aggregate borrowing capacity plus cash and cash equivalents in excess of \$12.5 million (the "cash test") or

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- o Achieve an increasing level of earnings before interest, taxes and depreciation, as defined in the credit agreement ("EBITDA"), a BioGlue gross margin greater than 70% for the preceding twelve months as calculated quarterly, and cash and cash equivalents (defined as cash and low risk marketable securities that are held in an account in which the lender has a perfected security interest) and borrowing capacity (defined below) in excess of \$5.0 million (the "EBITDA Test");

Borrowing capacity is defined as the following:

- o The lesser of
  - o \$15 million or
  - o 20% of the appraised value of the business of CryoLife reduced by the lender's reserves for credit exposure associated with other bank products provided by the lender to CryoLife;
- o *Minus* all outstanding obligations under the credit agreement including outstanding letters of credit;
- o *Minus* the aggregate amount of any trade payables of the Company aged in excess of their historical levels and all book overdrafts of the Company in excess of their historical practices.

Current forecasts of Company EBITDA, coupled with the uncertainties inherent in the Company's operating cash flows, make compliance with the EBITDA test uncertain. Accordingly, the Company anticipates that compliance with this financial covenant will be dependent on its ability to satisfy the cash test.

Judgments and settlements arising out of product liability or other claims, negative operating cash flow, and other factors, which adversely affect available cash resources may adversely affect compliance with the cash test. Failure to meet this and other covenants may result in breach of the credit agreement, acceleration of payment of outstanding borrowings, and loss of 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 to borrow money.

#### **The Company Is Significantly Dependent On Its Revenues From BioGlue And Is Subject To A Variety Of Risks Affecting This Product.**

BioGlue has become a significant source of the Company's revenues. Should the product be the subject of adverse developments with regard to its safety or efficacy, reimbursement practices, or if a competitor's product obtains greater acceptance, or the Company's rights to manufacture and market this are challenged, the result could be a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. Furthermore, the Company has only two suppliers of bovine serum albumen, which is necessary for the manufacture of BioGlue. The Company presently has only one supplier for its new syringe. The loss of one or more of these suppliers could have an adverse impact on its ability to manufacture and sell BioGlue. There can be no assurance that CryoLife would be able to replace any such loss on a timely basis, if at all.

#### **The FDA Order And Subsequent FDA Activity Continue To Adversely Impact CryoLife's Business, Including Reducing Demand For Its Services And Increasing Processing Costs.**

On August 13, 2002 CryoLife received an order from the FDA calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife at its headquarters since October 3, 2001 based upon allegations that CryoLife violated FDA regulations in its handling of such tissue and alleged contamination through CryoLife's processing of such tissue that resulted in 14 post-transplant infections including one death. A significant portion of CryoLife's current revenues is derived from the preservation of human tissues. Revenues from human tissue preservation services for the six months ended June 30, 2002, the last period ending prior to the issuance of the FDA Order, were 78% of CryoLife's revenues, or approximately \$37.8 million. During 2005 these revenues were approximately \$30.3 million or 44% of 2005 revenues.

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The FDA Order, subsequent FDA activity, and resulting adverse publicity had a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. CryoLife has experienced decreases in revenues and incurred losses and CryoLife may not generate sufficient cash from operations, to fund its capital requirements over the long-term.

CryoLife has continued to experience a reduced demand for its tissues due to the adverse publicity generated from the recall and from decisions by implanting physicians or risk managers at implanting institutions to use human tissue services provided by CryoLife's competitors. In addition, as a result of the FDA Order, subsequent FDA activity, and changes in CryoLife's 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 CryoLife's business, results of operations and financial position and will continue to do so.

The success of CryoLife's tissue preservation services depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. Any material reduction in the supply of donated human tissue would restrict CryoLife's growth and adversely affect its business, results of operations and financial conditions. CryoLife relies primarily upon the efforts of third party procurement agencies and 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 CryoLife for processing. As a result, the Company's processing has been constrained in part due to availability of tissue. If CryoLife is unable to obtain tissues from procurement agencies that have ceased sending tissue to CryoLife for processing, to develop new sources, or to increase the tissues shipped from its current suppliers, CryoLife may be unable to obtain adequate supplies of donated tissues to operate profitably.

#### **Revenue From Orthopaedic Tissue Preservation Services May Not Return To Acceptable Levels.**

CryoLife has received much lower revenues from the preservation of orthopaedic tissue since August 14, 2002. For the year ended December 31, 2001, human tissue preservation service revenues for orthopaedic tissue were \$22.5 million, which represented 26% of CryoLife's revenues. For the six months ended June 30, 2002, (the last period ending prior to the FDA Order) revenues for preservation services for orthopaedic tissue were \$11.5 million, which represented 24% of CryoLife's revenues. For the year ended December 31, 2005, revenues from preservation services for orthopaedic tissue were \$5.1 million, which represented 7% of CryoLife's revenues.

The demand for orthopaedic tissue from CryoLife may not reach acceptable levels, even though CryoLife has resumed processing after altering the Company's procedures, has introduced a process for sterilizing such tissue, and has begun offering osteochondral tissue. As a result, this portion of CryoLife's business may only continue at substantially reduced levels or may be discontinued. Either of these results could result in a continued significant decrease in CryoLife's preservation service revenues and have an adverse impact on its ability to return to profitability.

#### **Physicians Have Been And May Continue To Be Reluctant To Implant CryoLife's Preserved Tissues.**

Some physicians or implanting institutions have been reluctant to choose CryoLife's 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 CryoLife's tissues are used. In addition, for similar reasons, some hospital risk managers have not allowed implanting surgeons to utilize CryoLife's tissues where alternatives are available. Several risk managers and physicians have refused to use the Company's products due to these concerns. These conditions have materially and adversely affected demand for CryoLife's processed human tissues. If these conditions persist CryoLife's results of operations and cash flow will continue to be adversely affected. If additional implanting hospitals or physicians representing significant revenues refuse to use tissues preserved by the Company, and the Company is unable to replace the revenues lost, preservation service revenues and profits would be materially adversely affected.

#### **CryoLife's Products And The Tissues It Processes Allegedly Have Caused And May In The Future Cause Injury To Patients Using Its Products Or Tissues And The Company Has 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 the Company. Plaintiffs have asserted that the Company's tissue or medical devices have caused a variety of injuries including death. When patients are injured, die or have adverse results following procedures using the Company's tissue or medical devices, the Company has been and may be sued and its insurance coverage has been and may be inadequate. Adverse judgments and settlements in excess of the Company's available insurance coverage could have a material adverse

effect on the Company's financial position, results of operations and cash flows.

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As a result of medical complications that are alleged to have been caused by or occur in connection with medical procedures involving the Company's tissue or medical devices, the Company has 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 CryoLife's heart valve preservation services. As a result, some surgeons and hospitals decided not to use CryoLife's heart valves. Cautionary statements from the FDA or other regulators regarding the Company's tissue services or products, or negative reviews from the FDA or regulators of the Company's processing and manufacturing facilities has and may decrease demand for the Company's tissue services or products and could have a material adverse effect on the Company's business, results of operations and financial position.

In addition to the recall resulting from the FDA Order, the Company has 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 its tissues. For example, during September 2003, in response to a reported infection, the Company 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, the Company's tissue services or medical products could have a material adverse effect on the Company's revenues and profits.

#### **Adverse Publicity May Reduce Demand For Products And Services Not Affected By The FDA Recall.**

Even though CryoLife's heart valve tissues, BioGlue and bioprosthetic devices were not included in the FDA Order, there is a possibility that surgeons or risk managers at institutions that use such products may be reluctant to use such products because of the adverse publicity associated with the FDA Order. Decreased demand for such products, particularly BioGlue, could have a material adverse effect on CryoLife's business, results of operations and financial position.

#### **CryoLife 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 CryoLife's responses to the FDA's observations contained in these notices, or any future notices, are deemed unsatisfactory, the FDA could take further action, which could have a material adverse effect on the Company's business, results of operations, financial position, or cash flows. Further action by the FDA could include additional recalls of products, requiring the Company to do additional testing, beginning to require prescriptions for products where they are not currently required, halting the shipping or processing of products, or requiring additional approvals for marketing the Company's products or services.

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

During 2003 the FDA notified CryoLife that the application of the SynerGraft technology to allograft heart valves (CryoValve SG) was considered to be a major manufacturing change requiring a 510(k) submission. CryoLife submitted a 510(k) for CryoValve SG and has received three requests for additional information from FDA. While most of the requested information has been provided, CryoLife is seeking to resolve certain other requests, involving bench-testing, animal testing, and additional clinical trials, through administrative procedures at the FDA. Resolution of this matter could be time-consuming and expensive, depending in large part on the success of the Company's efforts through the FDA's administrative processes. There can be no assurance that the FDA will agree with CryoLife or that the CryoValve SG 510(k) will be cleared in the foreseeable future, if at all. If the Company is unable to resolve this issue, it may not be able to offer the services.

The FDA has also determined that non-valved cardiovascular "CryoVein" tissues processed using CryoLife's SynerGraft technology should be regulated as medical devices and will require additional premarket approval authorization for continued distribution of these tissues. CryoLife's appeal of this the designation was denied. There can be no assurance that the designation of SynerGraft cardiovascular tissue will be resolved favorably. If CryoLife is unable to resolve this matter, it may not be able to offer these services.

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#### **Regulatory Action Outside Of The U.S. Has Affected CryoLife's Business In The Past And May Also Affect CryoLife's Business In The Future.**

After the issuance of the FDA Order, Health Canada also issued a recall on the same types of tissue. In addition other countries have inquired as to the tissues exported by the Company, although these inquiries are now, to CryoLife's knowledge, complete. In the event other countries raise additional regulatory concerns, CryoLife may be unable to export tissues to those countries. Revenue from international human tissue preservation services was \$193,000, \$421,000 and \$721,000 for the years ended December 31, 2005, 2004 and 2003, respectively. CryoLife also offers BioGlue and other products for use in other countries.

#### **Violation Of Government Regulations Could Result In Loss Of Revenues And Customers And Additional Expense To Attain Compliance.**

The facilities and processes used by the Company are subject to regulation by the FDA and some states. CryoLife's facilities are also subject to periodic inspection by the FDA and state regulatory authorities to ensure their compliance with applicable laws and regulations. Failure to comply with these laws and regulations can lead to sanctions, such as written observations of deficiencies made following inspections, warning letters, product recalls, fines, product seizures and consent decrees, which would be made available to the public. Such actions and publicity could affect the Company's ability to sell its products and services. In the past, CryoLife has received notifications and warning letters from the FDA relating to deficiencies in its compliance with FDA requirements. The Company was required to take measures to respond. CryoLife also was subject to the FDA Order, which had a material adverse effect on its business, results of operations and financial condition. There can be no assurance that the FDA or state regulatory authorities will not request that it take additional steps to correct deficiencies in compliance raised by the FDA or state regulatory authorities in the future. Correction of any such deficiencies could have a material adverse effect on CryoLife's business.

### **CryoLife Is The Subject Of An Ongoing SEC Investigation.**

As previously disclosed, there is an ongoing SEC investigation. 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 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 against several of the former and current employees CryoLife had reported (and certain of their spouses) for alleged illegal insider trading arising out of their August 14, 2002 trading activities. Certain of those proceedings resulted in settlements with the SEC, while other proceedings remain pending. Other than receiving a report of that activity, the SEC has had no discussions with CryoLife representatives as to whether or against whom it will seek additional relief, or the nature of any relief that may be sought. At present, CryoLife is unable to predict the ultimate focus or 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.

### **CryoLife's Insurance Coverage Has Been And May Be Either Unavailable Or Insufficient.**

The Company's products and the tissues it processes allegedly have caused and may in the future cause injury to patients using the Company's products or tissues and the Company has been and may be exposed to product liability claims.

Following the FDA Order, product liability lawsuits increased to unprecedented numbers for CryoLife. These claims involved assertions that infections and related morbidity, including death, were the result of inadequacies in CryoLife's procedures. CryoLife 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.

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As of February 20, 2006 the Company had two outstanding product liability lawsuits against the Company that are covered by the 2004/2005 insurance policy. The Company believes its insurance policy to be adequate to defend against the covered lawsuits in this time period. Additionally, the Company has four outstanding product liability lawsuits against the Company that are not covered by insurance policies as the claims were asserted against the Company in periods after the coverage in the related incident year had lapsed. 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. The Company is monitoring these claims.

CryoLife's December 31, 2005 Consolidated Balance Sheet reflects a liability in the amount of approximately \$1.5 million 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. CryoLife's December 31, 2005 Consolidated Balance Sheet also reflects a \$7.5 million liability, 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 Consolidated Balance Sheet, for the estimated cost of resolving unreported product liability claims. CryoLife's 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 the Company's accounting treatment for product liability claims.

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) 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 the Company 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 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. A settlement was also reached in those cases and became final in 2005. The Company's insurance proceeds were insufficient to fund the costs of defending and settling the securities class action and derivative lawsuits.

If CryoLife is unsuccessful in arranging acceptable settlements of product liability claims, securities class action, or derivative claims, there may not be sufficient insurance coverage and liquid assets to meet these obligations. Additionally, if one or more claims in which CryoLife is 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 CryoLife's available insurance coverage and liquid assets. If CryoLife is unable to meet required future cash payments to resolve the outstanding or any future claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of CryoLife. Further, if the costs of pending or unreported but incurred product liability claims exceed CryoLife's current estimates, its business, financial condition and results of operations may be materially adversely affected.

### **Satisfactory Levels Of Insurance Coverage May Be Difficult Or Impossible To Obtain In The Future And If Obtained, It Could Be Very Expensive.**

Due in part to the current litigation, the FDA Order and subsequent FDA activity, CryoLife may be unable to obtain satisfactory insurance coverage in the future, causing CryoLife to be subject to additional future exposure from product liability claims. Additionally, if insurance coverage is obtained, the insurance rates may be significantly higher than in the past, and may provide less coverage, which may adversely impact CryoLife's profitability. For example, CryoLife paid a higher fee for its 2003/2004 policy year product liability insurance coverage, which also had a higher retention level and a lower overall limit. Unlike the prior year's policy, the 2003/2004 policy did not cover any claims, which arose prior to the insurance policy year. The 2004/2005 policy was a two-year claims-made policy, covering claims arising since the commencement of the 2003/2004 policy year. The Company's current insurance policy is a three-year claims-made policy covering claims since the commencement of the 2003/2004 policy year and expires in March 2006. The Company is currently evaluating with prospective insurers available coverage and cost. The Company presently expects that there could be increases in both cost and retention, although it also expects coverage to be a four-year claims-made policy. There is no assurance the Company will be successful in obtaining satisfactory coverage upon expiration of its current coverage.

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### **Intense Competition Affects CryoLife's Ability To Recover From The FDA Order.**

CryoLife faces 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. CryoLife's BioGlue product competes with other surgical adhesives and surgical sealants, including Baxter Healthcare's Tisseel, FloSeal, and CoSeal products. CryoLife is 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 competitive products may also be under development by other large medical device, pharmaceutical, and biopharmaceutical companies. Many of CryoLife's competitors have greater financial, technical, manufacturing, and marketing resources than CryoLife and are well established in their markets. CryoLife increased fees and prices on a number of its services and products effective January 1, 2006. The increase may provide an opportunity for CryoLife's competitors to gain market share. If the Company is unable to increase prices as planned and retain or improve its market share, its revenue and return to profitability may be adversely affected.

The Company's cryopreserved tissues compete with other entities that cryopreserve human tissue on the basis of technology, customer service, and quality assurance. As a result of the decrease in CryoLife's procurement and processing yields of human tissue since the FDA Order in 2002, the decrease in cardiovascular, vascular, and orthopaedic tissue shipments, and the lack of orthopaedic tissue shipments for a period of time, CryoLife competitors have been favorably impacted and CryoLife believes it has lost some market share. CryoLife believes that the human heart valves cryopreserved by CryoLife, as compared to mechanical, porcine, and bovine heart valves, compete on the factors set forth above, as well as by providing a tissue that is the preferred replacement alternative with respect to certain medical conditions, such as pediatric cardiac reconstruction, valve replacements for women in their child-bearing years, and valve replacements for patients with endocarditis. The Company's BioGlue product competes on the basis of its high tensile strength and ease of use.

There can be no assurance that CryoLife's products and services will be able to compete successfully. Any products developed by CryoLife that gain regulatory clearance or approval then have to compete for market acceptance and market share. Failure of CryoLife to compete effectively could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. The FDA Order, related adverse publicity, and subsequent FDA activity had and may continue to have an adverse effect on CryoLife's competitive position. CryoLife's competitors may gain competitive advantages that may be difficult to overcome.

### **CryoLife May Not Be Successful In Obtaining Necessary Clinical Results And Regulatory Approvals For Products And Services In Development, And Such Products And Services May Not Achieve Market Acceptance.**

CryoLife's growth and profitability will depend, in part, upon its ability to complete development of and successfully introduce new products and services, including new applications of its BioGlue and related technology and applications applying its SynerGraft technology. Developing new products and services to a commercially acceptable form is uncertain, and obtaining required regulatory approval is time consuming and costly. For example, if the Company is unable to resolve the issues it is addressing with the FDA with regard to tissues processed using SynerGraft, it may incur significant costs over a lengthy period of time to meet the FDA's requirements, and it may not be successful in meeting them or in offering a commercially successful product.

Although CryoLife has conducted pre-clinical studies on certain products under development which indicate that such products may be effective in a particular application, there can be no assurance that the results obtained from expanded clinical studies will be consistent with earlier trial results or be sufficient for CryoLife to obtain any required regulatory approvals or clearances. There can be no assurance that CryoLife will not experience difficulties that could delay or prevent the successful development, introduction and marketing of new products, that regulatory clearance or approval of these or any new products will be granted on a timely basis, if ever, or that the new products will adequately meet the requirements of the applicable market or achieve market acceptance.

The completion of the development of any of CryoLife's products is subject to all of the risks associated with the commercialization of new products based on innovative technologies, including unanticipated technical or other problems, manufacturing difficulties, and the possible insufficiency of the funds allocated for the completion of such development. Consequently, CryoLife's products under development may not be successfully developed or manufactured or, if developed and manufactured, such products may not meet price or performance objectives, be developed on a timely basis, or prove to be as effective as competing products.

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The inability to successfully complete the development of a product, application or service, or a determination by CryoLife, for financial, technical or other reasons, not to complete development or obtain regulatory approval of any product, application or service, particularly in instances in which CryoLife has made significant capital expenditures, could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. Research and development efforts are time consuming and expensive and there can be no assurance 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 the Company's 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.**

CryoLife may invest in new technology licenses or distribution rights that may not succeed in the marketplace. For example, in February 2003 CryoLife entered into an arrangement with Curasan AG for the distribution of its Cerasorb Ortho, a resorbable bone graft substitute. That arrangement was terminated. In such cases, CryoLife may be unable to recover its initial investment, which investment could include acquisition of license or distribution rights or the purchase of initial inventory, all of which may adversely impact CryoLife's profitability.

### **Funding For The ACT Technology May Not Be Available.**

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 CryoLife 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. CryoLife has been seeking such funding since 1998 to allow CryoLife to continue development of this technology without incurring additional research and development expenditures, other than through AuraZyme. There can be no guarantee that such funding can be obtained on acceptable terms, if at all. Even if such financing is obtained, there is no guarantee that the ACT will in fact prove to be effective in the above applications. In addition any new financing may cause dilution to the ownership interests of current CryoLife shareholders, or may include restrictive covenants that could adversely affect CryoLife or its business.

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

CryoLife processes bovine tissues with the SynerGraft technology and markets 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, CryoLife believes 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. In animal studies, explanted SynerGraft processed heart valves have been shown to 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. This could have a material adverse effect on future expansion plans and could limit future growth.

#### **If CryoLife Is Not Successful In Expanding Its Business Activities In International Markets, It Will Not Be Able To Pursue One Of Its Strategies For Increasing Its Revenues.**

CryoLife's international operations are subject to a number of risks which may vary from the risks it faces in the U.S., including:

- o Unexpected changes in regulatory requirements and tariffs;

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- o Difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships;
  - o Longer accounts receivable collection cycles in certain foreign countries;
  - o Adverse economic or political changes;
  - o More limited protection for intellectual property in some countries;
  - o Changes in the Company's international distribution network and direct sales force;
  - o Changes in currency exchange rates;
  - o Potential trade restrictions, exchange controls and import and export licensing requirements; and
  - o Potentially adverse tax consequences of overlapping tax structures.

#### **CryoLife Is Dependent On Its Key Personnel.**

CryoLife's business and future operating results depend in significant part upon the continued contributions of its key technical personnel and senior management, many of who would be difficult to replace. CryoLife's business and future operating results also depend in significant part upon its ability to attract and retain qualified management, processing, technical, marketing, sales, and support personnel for its operations. Competition for such personnel is intense and there can be no assurance that CryoLife will be successful in attracting and retaining such personnel. CryoLife's key employees include its 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. Other than a \$1.5 million life insurance policy on Mr. Anderson, CryoLife does not have key life insurance on these individuals. The loss of key employees, the failure of any key employee to perform adequately, or CryoLife's inability to attract and retain skilled employees as needed could have a material adverse effect on CryoLife's business, financial condition, results of operations and cash flows.

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### **Risks Related To CryoLife And Its Industry**

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

Government regulation in the U.S., the EEA, and other jurisdictions can determine the success of CryoLife's efforts to market and develop its services and products and those of its competitors. Allograft tissues processed and distributed by CryoLife are currently regulated as "human tissue" under rules promulgated by the FDA pursuant to the Public Health Services Act. 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, 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 CryoLife and its 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 CryoLife believes that its 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. CryoLife may not obtain the FDA approval required to distribute its porcine heart valve products in the U.S. Distribution of these products within the EEA is dependent upon CryoLife maintaining the CE Mark for this product and its ISO 13485 certifications, of which there can be no assurance.

Most of CryoLife's products and services in development and those of CryoLife's 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 ("PMA") application and often takes many years. The process is expensive and can vary significantly based on the type, complexity, and novelty of the product. There can be no assurance that any products developed by CryoLife or its 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 a company's competitive position. The FDA may also place conditions on product approvals that could restrict commercial applications of such products. Product marketing approvals or clearances may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Delays imposed by the governmental clearance process may materially reduce the period during which a company such as CryoLife has the exclusive right to commercialize patented products.

Delays or rejections may also be encountered during any stage of the regulatory approval process based upon the failure of the clinical or other data to satisfactorily demonstrate compliance with, or upon the failure of the product to meet, the regulatory agency's requirements for safety, efficacy and quality, and 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 regulatory approval is obtained for any products or services offered by CryoLife or one of its competitors, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. The unapproved use of the Company's products or tissues preserved by CryoLife could adversely affect the reputation of such 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. Failure to comply with applicable FDA requirements, which may be ambiguous, could result in civil and criminal enforcement actions, warnings, citations, product recalls or detentions and other penalties and could have a material adverse effect on CryoLife's 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.

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In addition the National Organ Transplant Act ("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. There can be no assurance that restrictive interpretations of NOTA will not be adopted in the future that will challenge one or more aspects of industry methods of charging for preservation services. Laboratory operations of CryoLife and its 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 governing the processing, transportation and storage of human organs and tissue.

More restrictive laws or regulations may be adopted in the future and they could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows.

#### **Uncertainties Related To Patents And Protection Of Proprietary Technology May Adversely Affect The Value Of Intellectual Property.**

CryoLife owns several patents, patent applications, and licenses relating to its technologies, which it believes provide important competitive advantages. There can be no assurance that CryoLife's pending patent applications will issue as patents or that challenges will not be instituted concerning the validity or enforceability of any patent owned by CryoLife, or, if instituted, that such challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of a patent could be substantial. Furthermore, there can be no assurance that competitors will not independently develop similar technologies or duplicate CryoLife's technologies or design around the patented aspects of such technologies. There can be no assurance that CryoLife's proposed technologies will not infringe patents or other rights owned by others.

In addition under certain of CryoLife's license agreements, if CryoLife fails to meet certain contractual obligations, including the payment of minimum royalty amounts, such licenses may become nonexclusive or terminable by the licensor, which could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. CryoLife protects its proprietary technologies and processes in part by confidentiality agreements with its collaborative partners, employees and consultants. There can be no assurance that these agreements will not be breached, that CryoLife will have adequate remedies for any breach, or that CryoLife's trade secrets will not otherwise become known or independently discovered by competitors, any of which could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows.

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

Even though CryoLife does not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand for CryoLife's cryopreserved tissue and other services and products. CryoLife's preservation services with respect to its 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. CryoLife is 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 CryoLife.

Changes in the reimbursement methods and policies utilized by third-party health care payors, including Medicare, with respect to cryopreserved tissues

provided for implant by CryoLife and other Company services and products, could have a material adverse effect on CryoLife. 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 CryoLife to maintain price levels sufficient for realization of an appropriate return on its 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 and by refusing in some cases to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval. If adequate coverage and reimbursement levels are not provided by government and other third-party payors for uses of CryoLife's new products and services, market acceptance of these products would be adversely affected, which could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows.

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

The technologies underlying products and services offered by CryoLife and its competitors are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. There can be no assurance that others will not develop products or processes with significant advantages over the products and processes that CryoLife or a competitor offers or is seeking to develop. Any such occurrence could have a material adverse effect on the business, financial condition, results of operations, and cash flows of CryoLife.

### **Risks Related To CryoLife's Capital Stock**

#### **Securities Prices For CryoLife Shares Have Been, And May Continue To Be, Volatile.**

The trading price of CryoLife's 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 CryoLife or its 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 CryoLife's control. If CryoLife's revenues or operating results in future quarters fall below the expectations of securities analysts and investors, the price of CryoLife's common and preferred stock would likely decline, perhaps substantially. Changes in the trading price of CryoLife's common and preferred stock may bear no relation to CryoLife's actual operational or financial results. If CryoLife's share prices do not meet the requirements of the New York Stock Exchange, CryoLife's shares may be delisted. CryoLife's closing common stock price in the period January 1, 2003 to February 20, 2006 has ranged from a high of \$10.71 to a low of \$3.20. CryoLife's closing preferred stock price in the period March 15, 2005 (date of first preferred stock issuance) to February 20, 2006 has ranged from a high of \$58.50 to a low of \$38.00.

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 experience 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 the Company could result in substantial costs, divert the Company's management's attention and resources and harm its financial condition and results of operations.

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

CryoLife's 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 CryoLife, 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 CryoLife is subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of CryoLife's 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 CryoLife on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. These provisions could potentially deprive the Company's stockholders of opportunities to sell shares of the Company's stock at above-market prices.

#### **Common Stock Dividends Are Not Likely To Be Paid In The Foreseeable Future.**

CryoLife has not paid, and does not presently intend to pay, cash dividends on its common stock.

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### **CryoLife May Not Be Able To Pay Cash Dividends On Its Capital Stock Due To Legal And Contractual Restrictions And Lack Of Liquidity.**

Under Florida law and under the restrictions set forth in the Company's credit agreement, the Company may not be able to pay cash dividends on the Company's capital stock. Under Florida law, no distributions may be paid on capital stock, if after giving it effect: (a) the corporation would not be able to pay its debts as they become due in the usual course of business; or (b) the corporation's total assets would be less than the sum of its total liabilities plus (unless the articles of incorporation permit otherwise) the amount that would be needed, if the corporation were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of shareholders whose preferential rights are superior to those receiving the distribution.

Under the Company's new credit agreement, cash dividends on its common stock are prohibited, and cash dividends on its preferred stock may be paid only so long as the Company maintains at least \$7.5 million, in the aggregate, of borrowing capacity under the credit agreement, cash and cash equivalents, each as more fully described above under "Risks Factors—Risks Related To The Company's Business—The Company's Revolving Credit Facility Imposes Restrictions On Its Ability To Borrow, Which Could Make It More Difficult To Borrow Needed Funds." 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 the Company's ability to make cash dividend payments both generally and under the credit agreement. In addition the

terms of any future financing arrangements entered into by the Company may also restrict its 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 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,” “estimate,” “plan,” “future,” and other 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:

- o The adequacy of product liability insurance to defend against lawsuits;
- o The outcome of lawsuits filed against the Company, and of the SEC investigation;
- o 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;
- o The effect of the FDA Order and subsequent FDA activity on sales of BioGlue;
- o The impact of the FDA’s Form 483 Notices of Observation;
- o The estimates of the amounts accrued for the Company’s product liability lawsuits, as well as the estimates of the amounts accrued for product liability claims incurred but not reported;
- o Future costs of human tissue preservation services, including the Company’s ability to increase yields and reduce its costs of tissue preservation services;

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- o The Company’s competitive position, including the impact of price increases;
  - o Product demand and market growth;
  - o The potential of the ACT for use in fibrinolysis (blood clot dissolving) and other drug delivery applications;
  - o The impact on the Company of adverse results of surgery utilizing tissue processed by it;
  - o The adequacy of the Company’s financial resources; and
  - o 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, 2005 (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 office, manufacturing, 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 eight 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 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 office and warehousing space.

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### 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. Following the FDA Order, a greater number of lawsuits was filed. As of February 20, 2006 the Company was aware of six 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 orthopaedic tissue services, three allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges a product liability claim arising from BioGlue.

As of February 20, 2006 there were two outstanding product liability lawsuits against the Company that are covered by the 2004/2005 insurance policy. The Company believes its insurance policy to be adequate to defend against the covered lawsuits in this time period. Additionally, there are four outstanding product liability lawsuits against the Company that are not covered by insurance policies, as either the Company has used all of its insurance coverage related to that policy year, or the claims were asserted against the Company in periods after the coverage in the related incident year had lapsed. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company, which have not resulted in lawsuits. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2005 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, 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. This amount represents the Company's estimate of the probable losses related to one settled but unpaid claim and three of the six pending product liability claims. The Company has not recorded an accrual for the remaining three 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, 2004 the Company had accrued a total of approximately \$2.8 million for settled but unpaid claims and pending product liability claims and recorded \$1.1 million representing amounts to be recovered from the Company's insurance carriers. The \$2.8 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2004 Consolidated Balance Sheet.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as most of the claims do not specify the damages sought and 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. Additionally, 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 insurance coverage and 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.

On April 1, 2005 the Company bound coverage for the 2005/2006 insurance policy year. This policy is a three-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2006 and reported during the period April 1, 2005 through March 31, 2006 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 2006 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2005. 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:

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- o 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,
  - o The future claim reporting lag time would be a blend of the Company's experiences and industry data,
  - o The frequency of unreported claims for accident years 2001 through 2005 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,

- o 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,
- o 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
- o The number of BioGlue claims per million dollars of BioGlue revenue would be 35% lower than non-BioGlue claims per million dollars of revenue. The 35% 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 actual developments could differ materially from the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions, including the FDA Order, the Company's recent levels of litigation activity, 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 amounts accrued.

Based on the actuarial valuation performed in January 2006 as of December 31, 2005, the Company estimated that its liability for unreported product liability claims was \$7.5 million as of December 31, 2005. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued \$7.5 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, 2005. The \$7.5 million balance 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. Further analysis indicated that the liability could be estimated to be as high as \$13.4 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, 2005, \$2.5 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.5 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.4 million on the December 31, 2005 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, 2005. Actual results may differ from this estimate.

As of December 31, 2004 the Company accrued \$8.2 million for unreported product liability claims and recorded a receivable of \$1.9 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. The \$8.2 million balance is included as a component of accrued expenses and other current liabilities of \$4.2 million and other long-term liabilities of \$4.0 million on the December 31, 2004 Consolidated Balance Sheet. The \$1.9 million insurance recoverable is included as a component of other current receivables of \$800,000 and other long-term assets of \$1.1 million on the December 31, 2004 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 alleges 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. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the U.S. District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003 the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. On March 11, 2005 defendants moved for summary judgment on all of plaintiffs' claims, and plaintiffs moved for partial summary judgment as to some of their claims against certain defendants. On June 17, 2005 the court denied plaintiffs' motion for partial summary judgment and granted in part and denied in part defendants' motion for summary judgment.

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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 include 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. The Company and the individual defendants have denied any wrongdoing and liability whatsoever, and the settlement does not contain any admission of liability.

The Company has filed a request for mediation under its insurance policies to assert a claim against two of its insurance carriers. The claim is for recovery of monetary losses of approximately \$11.25 million paid by the Company in excess of policy limits to settle the securities class action lawsuit. The claim alleges that the loss resulted from the carriers' bad faith failure to settle. There can be no assurance that the claim will be successful. The Company will not record a gain related to this claim prior to final settlement.

#### ***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 123 Revised "Share-Based Payment" ("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. Certain of those proceedings resulted in settlements with the SEC, while other proceedings remain pending. Other than receiving a report of that activity, the SEC has had no discussions with CryoLife representatives 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 or 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.

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### **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	67	President, Chief Executive Officer, and Chairman
David M. Fronk	Since 1998	42	Vice President, Regulatory Affairs and Quality Assurance
Albert E. Heacox, Ph.D	Since 1989	55	Senior Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	41	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Gerald B. Seery	Since 2005	49	Senior Vice President Sales and Marketin

**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 biopharmaceutical 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 has 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.

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**D. Ashley Lee, CPA**, has served as Executive Vice President, Chief Operating Officer, and Chief Financial Officer since November 2004. Mr. Lee has been with the Company since December 1994 serving as Vice President of Finance, Chief Financial Officer, and Treasurer from December 2002 to November 2004; as Vice President Finance and Chief Financial Officer from April 2000 to December 2002; and as Controller of the Company from December 1994 until

April 2000. Mr. Lee is responsible for the financial affairs of the Company, as well as all manufacturing operations, information technology, human resources, risk management, and contract administration. 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.

2005	High	Low
First quarter	\$ 8.60	\$ 5.86
Second quarter	8.28	5.70
Third quarter	8.05	6.41
Fourth quarter	7.20	3.10
2004	High	Low
First quarter	\$ 8.25	\$ 5.48
Second quarter	6.40	4.43
Third quarter	7.49	4.43
Fourth quarter	8.50	5.68

As of February 17, 2006 the Company had 517 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 5 of the Notes to Consolidated Financial Statements".

The following table provides information about purchases by the Company during the quarter ended December 31, 2005 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
10/01/05 - 10/31/05	—	\$ —	—	—
11/01/05 - 11/30/05	—	—	—	—
12/01/05 - 12/31/05	333	3.96	—	—
Total	333	\$ 3.96	—	—

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, 2005.

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

The following table provides information as of December 31, 2005 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	Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Plans approved by shareholders	1,625,080	\$ 10.43	2,629,362
Plans not approved by shareholders	128,925	\$ 25.67	—
<b>Total</b>	<b>1,754,005</b>	<b>\$ 11.55</b>	<b>2,629,362</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)

	December 31,				
	2005	2004	2003	2002	2001
<b>Operations</b>					
Revenues	\$ 69,282	\$ 62,384	\$ 59,532	\$ 77,795	\$ 87,671
Net (loss) income	(19,535)	(18,749)	(32,294)	(27,761)	9,166
Net (loss) earnings applicable to common shareholders	(20,312)	(18,749)	(32,294)	(27,761)	9,166
Research and development as a percentage of revenues	5.4%	6.3%	6.1%	5.9%	5.4%
<b>(Loss)/Earnings Per Share</b>					
Basic	\$ (0.85)	\$ (0.81)	\$ (1.64)	\$ (1.43)	\$ 0.49
Diluted	\$ (0.85)	\$ (0.81)	\$ (1.64)	\$ (1.43)	\$ 0.47
<b>Year-End Financial Position</b>					
Total assets	\$ 76,809	\$ 73,261	\$ 75,027	\$ 106,414	\$ 129,310
Working capital	23,922	19,689	14,790	39,385	66,668
Long term liabilities	4,909	5,629	5,716	4,552	10,071
Shareholders' equity	50,621	49,660	48,338	79,800	101,439
Current ratio <sup>1</sup>	2:1	2:1	2:1	3:1	5:1
Shareholders' equity per diluted common share	\$ 2.11	\$ 2.16	\$ 2.46	\$ 4.11	\$ 5.16

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

#### 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, 2005 brought the resolution of several outstanding legal matters. The Company reached an agreement and completed its settlement of the class action lawsuit for \$23.25 million, of which approximately half was paid from insurance proceeds. In addition the Company's insurers paid \$3.5 million for the settlement of the shareholder derivative lawsuit, and settlements or dismissals were reached on several other product liability lawsuits during 2005.

The year ended December 31, 2005 brought continued revenue growth and improved margins over the prior year. The Company's preservation and product revenues increased by 11% in 2005 over 2004, led by a rebounding tissue preservation services business and strong international BioGlue sales. The growth in the tissue preservation services business was due in large part to increases in average service fees in July 2004 and January 2005 for most of the Company's cardiovascular and vascular tissues. The Company's efforts to grow revenues in 2005 were hampered by some vacant sales territories and by reduced tissue procurement in the first half of 2005, which caused the Company's quarter over quarter revenues to decline slightly in the second and third quarters of the year. The Company made efforts in the second half of the year to address these issues, and as a result, quarter over quarter growth of BioGlue revenues in the fourth quarter was 8% and quarter over quarter growth of tissue preservation services revenues in the fourth quarter was 10%.

CryoLife continued to experience the ongoing effects of the August 13, 2002 order from the Atlanta district office of the U.S. Food and Drug Administration ("FDA") (the "FDA Order"), which resulted in the recall of certain tissues processed by the Company between October 3, 2001 and September 5, 2002, and subsequent FDA activity. As a result of the FDA Order the Company continues to experience low margins on its tissue preservation services and net losses as a result of higher operating costs and lower processing throughput than that experienced in the pre-FDA Order period. The Company continues to implement programs designed to improve safety, increase tissue yields, and decrease costs of processing. In addition CryoLife instituted price increases for most tissue preservation services and for BioGlue on January 1, 2005 and 2006 to reflect its increased operating costs.

On January 18, 2006 the Company issued a press release announcing it has engaged Piper Jaffray & Co. to assist the Company's management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. No assurance can be given that this process will lead to any specific action or transaction.

See Part I, Item 1, "Business," for further discussion of the Company's business and activities during 2005.

### Critical Accounting Policies

A summary of the Company's significant accounting policies is included in Item 8, "Note 1 of 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. Following the FDA Order a greater number of lawsuits than historically was filed. As of February 20, 2006 the Company was aware of six 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 orthopaedic tissue services, three allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges a product liability claim arising from BioGlue.

As of February 20, 2006 there were two outstanding product liability lawsuits against the Company that are covered by the 2004/2005 insurance policy. The Company believes its insurance policy to be adequate to defend against the covered lawsuits in this time period. Additionally, there are four outstanding product liability lawsuits against the Company that are not covered by insurance policies, as either the Company has used all of its insurance coverage related to that policy year, or the claims were asserted against the Company in periods after the coverage in the related incident year had lapsed. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company, which have not resulted in lawsuits. The Company is monitoring these claims.

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The Company performed an analysis as of December 31, 2005 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, 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. This amount represents the Company's estimate of the probable losses related to one settled but unpaid claim and three of the six pending product liability claims. The Company has not recorded an accrual for the remaining three 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.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as most of the claims do not specify the damages sought and 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. Additionally, 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 insurance coverage and 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.

On April 1, 2005 the Company bound coverage for the 2005/2006 insurance policy year. This policy is a three-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2006 and reported during the period April 1, 2005 through March 31, 2006 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 2006 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2005. 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:

- o 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,
- o The future claim reporting lag time would be a blend of the Company's experiences and industry data,
- o The frequency of unreported claims for accident years 2001 through 2005 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,
- o 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,

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- o 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
  - o The number of BioGlue claims per million dollars of BioGlue revenue would be 35% lower than non-BioGlue claims per million dollars of revenue. The 35% factor was selected based on BioGlue claims experience to-date and the actuary's judgment.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but actual developments could differ materially from the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions, including the FDA Order, the Company's recent levels of litigation activity, 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 amounts accrued.

Based on the actuarial valuation performed in January 2006 as of December 31, 2005, the Company estimated that its liability for unreported product liability claims was \$7.5 million as of December 31, 2005. In accordance with Emerging Issues Task Force Issue 03-8 the Company has accrued \$7.5 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, 2005. The \$7.5 million balance 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. Further analysis indicated that the liability could be estimated to be as high as \$13.4 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, 2005, \$2.5 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.5 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.4 million on the December 31, 2005 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, 2005. Actual results may differ from this estimate.

**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 and preservation. 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 #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 affect the deferred preservation costs per tissue, which could 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.

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During 2002 the Company recorded impairment write-downs of deferred preservation costs totaling \$32.7 million as a result of the FDA Order. The amount of these write-downs reflected management's estimates based on information available to it at the time the estimates were made and actual results did differ from these estimates. The write-down created a new cost basis, which cannot be written back up if and when these tissues become available for distribution. The cost of human tissue preservation services in the twelve months ended December 31, 2004 was favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services was not materially affected by these write-downs in the twelve months ended December 31, 2005 and is not expected to be materially affected by these write-downs in future periods.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company recorded \$499,000 and \$1.8 million, respectively, in the three and twelve months ended December 31, 2005 and \$511,000 and \$6.6 million,

respectively, in the three and twelve months ended December 31, 2004 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 twelve months ended December 31, 2004 also included \$353,000 in costs related to the write-down of SynerGraft processed 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.

**Deferred Income Taxes:** Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses, reflecting reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activities, and related events. The Company continued to generate deferred tax assets for the twelve months ended December 31, 2005 primarily as a result of operating losses. The Company periodically assesses the recoverability of its deferred tax assets and provides a valuation allowance when 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, the Company reviewed its historic operating results, including the reasons for its operating losses, uncertainties regarding projected future operating results due to the effects of the FDA Order and subsequent FDA activity, and the uncertainty of the outcome of litigation. Based on the results of this analysis, at December 31, 2005 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, 2005 the Company had a total of \$26.4 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

**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:

- o Significant underperformance relative to expected historical or projected future operating results,
- o Significant negative industry or economic trends,
- o Significant decline in the Company's stock price for a sustained period, and
- o 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, 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. 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, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

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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 patent costs, which are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method, and trademarks, which are non-amortizing. As of December 31, 2005 the Company did not believe that an impairment existed related to the other intangible assets that were assessed in accordance with SFAS 144.

**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 a 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 early adopted SFAS 123 Revised "Share-Based Payment" ("SFAS 123R") as amended by SEC Rule 2005-57 "Commission Amends Compliance Dates For FASB Statement No. 123R on Employee Stock Options" 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 Item 8, "Note 9 of the Notes to Consolidated Financial



Statements". 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. Prior to its adoption of SFAS 123R the Company elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for its employee stock options.

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 an additional pro forma expense of \$1.4 million in the third quarter of 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. The decision to initiate the accelerated vesting, which the Company believes 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 will be required to adopt SFAS 151 "Inventory Costs" ("SFAS 151") for the fiscal year ending December 31, 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 Company is still evaluating the impact of the adoption of SFAS 151.

The Company was required to adopt FIN 47, "Accounting for Conditional Asset Retirement Obligations" ("FIN 47") for the year ending December 31, 2005. FIN 47 provides interpretation which clarifies that the term conditional asset retirement obligation as used in FASB Statement No. 143, "Accounting for Asset Retirement Obligations", refers to a legal obligation to perform an asset retirement activity in which the timing and (or) method of settlement are conditional on a future event that may or may not be within the control of the entity. The adoption of FIN 47 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

### Results of Operations (In thousands)

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

#### Revenues

	Three Months Ended December 31,		Twelve Months Ended 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 December 31,		Twelve Months Ended December 31,	
	2005	2004	2005	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%.

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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.

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

#### **Cardiovascular Preservation Services**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2005	2004	2005	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.

The Company anticipates that cardiovascular service revenues in 2006 will increase due in part to a domestic price increase that went into effect on January 1, 2006 and due to projected growth in cardiovascular tissue shipments during 2006, if and to the extent tissues available for implantation increase due to expected improvements in procurement and in the Company's tissue processing yields. Process changes were implemented during 2005 and additional process changes were implemented in January 2006, which are expected to have a favorable impact on the Company's tissue processing yields during 2006 as compared to 2005.

As discussed in Part I, Item 1, "Business," the Company suspended the use of the SynerGraft technology in the processing of allograft cardiovascular tissue and in late September 2003 suspended the distribution of tissues on hand that were processed with the SynerGraft technology until the regulatory status of the CryoValve SG is resolved. At this time the Company cannot estimate when or if it will resume processing allograft cardiovascular tissue using the SynerGraft technology.

#### **Vascular Preservation Services**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2005	2004	2005	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 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.

The Company anticipates that vascular service revenues in 2006 will increase due in part to a domestic price increase that went into effect on January 1, 2006 and due to projected growth in vascular tissue shipments during 2006, if and to the extent tissues available for implantation increase due to expected improvements in procurement and in the Company's tissue processing yields. Process changes were implemented during 2005 and additional process changes were implemented in January 2006, which are expected to have a favorable impact on the Company's tissue processing yields during 2006 as compared to 2005.

### ***Orthopaedic Preservation Services***

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2005	2004	2005	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%.

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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 is 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.

The Company anticipates that orthopaedic service revenues in 2006 will increase significantly over 2005 due to projected growth in orthopaedic tissue shipments during 2006, if and to the extent tissues available for implantation increase due to expected improvements in procurement and in the Company's tissue processing yields. Process changes were implemented during 2005 and additional process changes were implemented in January 2006, which are expected to have a favorable impact on the Company's tissue processing yields during 2006 as compared to 2005. Additional increases in service revenues are expected due to a domestic price increase that went into effect on January 1, 2006.

### ***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.

The 2005 Defense Appropriations Conference Report included \$926,000 for the development of BioFoam™, the ("DOD Grant"). The Company began receiving advances under the grant during the second half of 2005, and is currently 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. The terms of the DOD Grant require that the Company use the grant proceeds to fund the development of BioFoam.

The 2006 Defense Appropriations Conference Report included approximately \$2.3 million for the continued development of protein hydrogel and bio-foam sealants. CryoLife plans to apply for funding under this bill in the second quarter of 2006. The Company anticipates that grant revenues will increase in 2006 related to the 2005 and 2006 Department of Defense funding.

### ***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.

The Company anticipates that in 2006 cost of products will increase to reflect volume increases.

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### **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. See "Critical Accounting Policies—Deferred Preservation Costs" above.

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.

The Company anticipates that aggregate cost of human tissue preservation services will increase if volume increases in 2006. The Company anticipates that cost of human tissue preservation services as a percentage of tissue preservation service revenues will decrease in 2006 as compared to 2005 as a result of increases in yields of implantable tissue per donor, increases in average service fees due to fee increases implemented in January 2006, and increases in the amount of tissues expected to be processed, due to increased procurement. The cost of human tissue preservation services as a percentage of revenue will likely continue to be high compared to pre-FDA Order levels as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue.

### **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 by \$193,000 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 tradeshow.

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 9 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 by \$455,000 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.

The Company anticipates that general, administrative, and marketing expenses will be lower in 2006 than in 2005, due to the expense recorded in 2005 related to the resolution of the Company's class action and derivative lawsuits, 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 2006, and the effect of these adjustments may be favorable or unfavorable to general, administrative, and marketing expenses.

### **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 ("PHT"), which include BioGlue and related products.

The Company anticipates that research and development expenses will increase in 2006 when compared to 2005, due to increased spending on research related to PHT, which is used in BioGlue, BioFoam, and BioDisc, SynerGraft, and tissue preservation. The BioFoam spending increase will be due in part to the 2005 and 2006 Defense Appropriation Conference Report discussed in "Revenues — Grant Revenues" above.

### **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.

The Company is unable to estimate the change in valuation of derivative for 2006, 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 2006, and the general level of U.S. interest rates. The change in valuation of derivative in 2006 could significantly differ from the levels experienced in 2005.

The Company's income tax benefit of \$618,000 and \$428,000 for the three and twelve months ended December 31, 2005, respectively, is primarily related to carrybacks of the Company's product liability expenses in 2005 and 2004 which are expected to generate income tax refunds of approximately \$453,000 in 2006, the adjustment of previously estimated product liability carrybacks, foreign taxes on income of the Company's wholly owned European subsidiary, and adjustments of the Company's net operating loss carryforwards. The Company's income tax benefit of \$1.6 million and \$3.0 million for the three and twelve months ended December 31, 2004, respectively, was primarily due to the receipt of tax refunds related to product liability expenses incurred in 2004 and 2003.

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**Year Ended December 31, 2004 Compared to Year Ended December 31, 2003**

**Revenues**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Revenues	\$ 15,866	\$ 12,802	\$ 62,384	\$ 59,532

Revenues increased 24% for the three months ended December 31, 2004 as compared to the three months ended December 31, 2003. This increase was primarily due to an increase in sales of BioGlue and orthopaedic and vascular tissue preservation service revenues as compared to the prior year period.

Revenues increased 5% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. This increase was primarily due to an increase in sales of BioGlue, partially offset by decreases in cardiovascular and vascular tissue preservation service revenues 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 December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Revenues	\$ 9,226	\$ 7,757	\$35,745	\$27,784
BioGlue revenues as a percentage of total revenue	58%	61%	57%	47%

Revenues from the sale of BioGlue increased 19% for the three months ended December 31, 2004 as compared to the three months ended December 31, 2003. The increase in revenues consisted of a 13% increase due to volume, a 5% increase due to price, and a 1% increase due to foreign exchange. The volume increase was primarily due to demand for the new BioGlue syringe product, which was introduced in mid 2004, partially offset by decreases in other BioGlue products as customers transitioned to the syringe product. The price increase was primarily due to an increase in average selling prices, due to list price increases that went into effect on December 1, 2003 domestically and in early 2004 internationally.

Revenues from the sale of BioGlue increased 29% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The increase in revenues consisted of an 18% increase due to volume, a 10% increase due to price, and a 1% increase due to foreign exchange. The volume increase was primarily due to demand for the new BioGlue syringe product, which was introduced in mid 2004 and contributed 11% of total sales of BioGlue. Approximately 19% of the 2004 volume increase in BioGlue was due to customers that did not purchase BioGlue in 2003 or 2002. Smaller volume increases were noted in all other BioGlue products. The price increase was primarily due to an increase in average selling prices, due to the list price increases discussed above. Domestic revenues accounted for 78% of total BioGlue revenues in 2004 and 77% of total BioGlue revenues in 2003.

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### Cardiovascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Revenues	\$ 2,767	\$ 2,751	\$12,504	\$17,059
Cardiovascular revenues as a percentage of total revenue	17%	21%	20%	29%

Revenues from cardiovascular preservation services increased 1% for the three months ended December 31, 2004 as compared to the three months ended December 31, 2003. The increase in revenues consisted of a 14% increase due to price, largely offset by a 13% decrease due to volume. The price increase reflected the fee increase that went into effect in July 2004. The fee increase primarily increased revenues for traditionally processed pulmonary valves and aortic valves. The volume decrease was primarily due to a decrease in shipments of aortic and pulmonary valves. The decrease in heart valve shipments reflected the continuing impact of the FDA Order and subsequent FDA activity, as reflected in the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2004, the exhaustion of much of the Company's supply of heart valve tissue processed prior to October 3, 2001, increased tissue processing and release times, and lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order.

Revenues from cardiovascular preservation services decreased 27% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The decrease in revenues consisted of a 35% decrease due to volume, partially offset by an 8% increase due to price. The volume decrease was primarily due to a decrease in shipments of aortic and pulmonary valves, including SynerGraft processed valves, which demand higher service fees than traditionally processed valves. The decrease in heart valve shipments reflects the continuing impact of the FDA Order and subsequent FDA activity, as discussed above. The price increase reflected the fee increase as discussed above. Revenues from cardiovascular preservation services for the twelve months ended December 31, 2003 include \$85,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

The Company's procurement of cardiac tissues during the twelve months ended December 31, 2004, from which heart valves and non-valved cardiac tissues are processed, decreased 8% as compared to twelve months ended December 31, 2003. Procurement levels of cardiac tissues remained significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

As discussed in Part I, Item 1, "Business", the Company suspended the use of the SynerGraft technology in the processing of allograft cardiovascular tissue and in late September 2003 suspended the distribution of tissues on hand that were processed with the SynerGraft technology until the regulatory status of the CryoValve SG is resolved. The suspension had an adverse effect on revenues and margins for the Company's tissue preservation services.

### Vascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Revenues	\$ 2,522	\$ 2,018	\$10,293	\$12,655
Vascular revenues as a percentage of total revenue	16%	16%	16%	21%

Revenues from vascular preservation services increased 25% for the three months ended December 31, 2004 as compared to the three months ended December 31, 2003. The increase in revenues consisted of a 19% increase due to price and a 6% increase due to volume. The price increase reflects the fee increase that went into effect in July 2004 on all vascular tissues. The volume increase was primarily due to an increase in shipments of saphenous veins, due to improvements in availability of tissue as a result of improved yields during the second half of 2004, partially offset by decreases in femoral vein shipments.

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Revenues from vascular preservation services decreased 19% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The decrease in revenues consisted of a 26% decrease due to volume, partially offset by a 7% increase due to price. The volume decrease was primarily due to a decrease in shipments of saphenous veins. Decreases were also experienced in SynerGraft processed femoral veins and arteries and traditional processed femoral veins, partially offset by increases in shipments of femoral arteries. The decrease in vein shipments also reflects the impact of the FDA Order and subsequent FDA activities, as reflected in the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2004, the exhaustion of much of the Company's supply of vascular tissue processed prior to October 3, 2001, the suspension of shipments of SynerGraft processed femoral veins and arteries, and increased tissue processing and release times and lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order. The price increase reflects the fee increase as discussed above. Revenues from vascular preservation services for the twelve months ended December 31, 2003 include \$752,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

The Company's procurement of vascular tissues during the twelve months ended December 31, 2004 decreased 21% as compared to twelve months ended December 31, 2003. Procurement levels of vascular tissues remained significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

### Orthopaedic Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Revenues	\$1,153	\$ 166	\$2,879	\$1,063
Orthopaedic revenues as a percentage of total revenue	7%	1%	5%	2%

The Company's orthopaedic preservation services were most affected by the FDA Order and subsequent FDA activity.

Revenues from orthopaedic preservation services increased 595% for the three months ended December 31, 2004 as compared to the three months ended December 31, 2003. The increase in revenues consisted primarily of an increase due to volume. The volume increase was primarily due to an increase in shipments of boned and non-boned tendons. Increases were also experienced in shipments of menisci. The increase in orthopaedic tissue shipments is directly related to the low volumes of shipments in 2003 due to temporary suspensions of orthopaedic tissue processing and shipments in 2003 and low levels of orthopaedic tissues available for shipment due to the disposal of much of the Company's supply of orthopaedic tissue processed prior to October 3, 2001, increased tissue processing and release times, and lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order.

Revenues from orthopaedic preservation services increased 171% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The increase in revenues consisted primarily of an increase due to volume, partially offset by a 3% decrease due to price. The volume increase was primarily due to an increase in shipments of boned tendons. Increases were also experienced in non-boned tendons and menisci. The increase in orthopaedic tissue shipments is directly related to the low volumes of shipments in 2003 as discussed above. The increase in average service fees that went into effect in July 2004 for cardiovascular and vascular tissues did not include an increase in orthopaedic tissue processing fees. Revenues from orthopaedic preservation services for the twelve months ended December 31, 2003 include \$63,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

The Company's procurement of orthopaedic tissues during the twelve months ended December 31, 2004 increased 68% as compared to twelve months ended December 31, 2003. Procurement levels of orthopaedic tissues remained significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

#### **Grant Revenues**

Grant revenues decreased to \$71,000 in 2004 from \$492,000 in 2003. Grant revenues in 2004 and 2003 were attributable to the Activation Control Technology ("ACT") research and development programs through AuraZyme Pharmaceuticals, Inc. ("AuraZyme") and the SynerGraft research and development programs. In February 2001 the Company formed the wholly owned subsidiary AuraZyme to foster the commercial development of ACT, a reversible linker technology that has potential uses in the areas of cancer therapy, fibrinolysis (blood clot dissolving), and other drug delivery applications.

The 2005 Defense Appropriations Conference Report included \$926,000 for the development of BioFoam.

#### **Costs and Expenses**

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

Cost of products aggregated \$7.8 million in 2004 compared to \$7.5 million in 2003. The increase in cost of products was primarily due to higher BioGlue sales levels during 2004 when compared to 2003.

Cost of products as a percentage of total product revenues was 21% in 2004 compared to 27% in 2003. The decrease was primarily due to a favorable product mix driven by an increase in revenues from BioGlue, which carries higher gross margins than bioprosthetic devices. Gross margins related to BioGlue improved in 2004 as compared to 2003 as a result of increasing manufacturing efficiencies, higher throughput, and an increase in average selling prices.

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

Cost of human tissue preservation services increased to \$29.8 million in 2004 as compared to \$24.0 million in 2003. Cost of human tissue preservation services for 2004 and 2003 includes the increases to cost of preservation services of \$6.6 million and \$6.9 million, respectively, reflecting the write-down of certain deferred tissue preservation costs to market value. See "Critical Accounting Policies—Deferred Preservation Costs" above. The increase in cost of human tissue preservation services was primarily due to increasing tissue processing costs due to process changes implemented subsequent to the FDA Order. The write-down of deferred tissue preservation costs in both 2004 and 2003 was primarily due to higher overhead cost allocations per unit associated with lower tissue processing volumes, changes in processing methods subsequent to the FDA Order, and a decrease in shipments of tissues processed with the higher margin SynerGraft process as compared to traditional processing.

Cost of human tissue preservation services as a percentage of tissue preservation service revenues was 116% in 2004 as compared to 78% in 2003. 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 in 2004 and \$4.3 million in 2003, 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 20% to \$42.6 million in 2004, compared to \$53.6 million in 2003, representing 68% and 90%, respectively, of total revenues during such periods. General, administrative, and marketing costs include net expenses related to litigation of \$1.5 million in 2004 and \$12.0 million in 2003. (See Legal Proceedings at Part I, Item 3 and "Critical Accounting Policies—Product Liability Claims" for further information.) Excluding the effect of litigation expenses, general, administrative, and marketing expenses in 2004 decreased slightly from 2003. The

remaining decrease is primarily due to a reduction in legal and consulting fees related to product liability and regulatory issues of \$2.7 million, partially offset by an increase of approximately \$1.1 million in insurance premiums, separation costs related to the departure of two members of Company management of \$557,000, and an increase of approximately \$478,000 in accounting and audit fees related to efforts to comply with the Sarbanes-Oxley Act of 2002. General, administrative, and marketing expenses in both periods were impacted by increased insurance costs, legal costs, and professional fees as compared to pre-FDA Order levels.

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

Research and development expenses increased 8% to \$3.9 million in 2004, compared to \$3.6 million in 2003, representing 6% of total revenues during these periods. Research and development spending in 2004 and 2003 was primarily focused on the Company's tissue preservation, SynerGraft, and Protein Hydrogel Technologies, which include BioGlue and related products.

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

Interest expense decreased 53% to \$196,000 in 2004, compared to \$415,000 in 2003. The decrease was due to the Company's reduced average debt balances in 2004 as compared to 2003, as a result of the Company's pay off of the outstanding balance of its term loan in the third quarter of 2003. Interest expense in 2004 and 2003 included interest on the financing of insurance premiums associated with the yearly renewal of certain of the Company's insurance policies.

Interest income decreased 38% to \$262,000 in 2004, compared to \$425,000 in 2003. The decrease was due to the Company's reduced average balances of cash and marketable securities during 2004 as compared to 2003, as the Company used cash to support ongoing operations and resolve product liability claims.

The Company's income tax benefit of \$3.0 million in 2004 was primarily due to the receipt of tax refunds of \$1.4 million and anticipated refunds of \$1.3 million related to product liability expenses incurred in 2003 and 2004. The Company did not record a receivable for the \$1.4 million carryback of 2003 expense in prior periods due to uncertainty regarding its realizability. The Company recorded a full valuation allowance against the tax benefit on the other losses generated in 2004. The Company's income tax expense of \$3.1 million in 2003 was primarily due to the expense related to the establishment of a full valuation allowance against its net deferred tax assets. The effective income tax rate was 34% in 2004 and 2003, excluding the effects of the valuation allowances.

### ***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, 2005 net working capital (current assets of \$45.2 million less current liabilities of \$21.3 million) was \$23.9 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$19.7 million, with a current ratio of 2 to 1 at December 31, 2004. The Company's primary capital requirements historically arose out of general working capital needs, capital expenditures for facilities and equipment, and funding of research and development projects, and the Company funded those requirements through cash generated by operations, equity offerings, and bank credit facilities.

In recent years the Company's primary requirements for capital have arisen out of working capital needs created by increasing costs of operations and settlements of litigation combined with losses incurred in the Company's tissue preservation services business. Operating results have also been negatively impacted by increases in general, administrative, and marketing costs over pre-FDA Order levels, as a result of legal and professional fees and litigation costs. For the twelve months ended December 31, 2005 the Company funded these requirements primarily through existing cash, cash equivalents, and marketable securities, through the proceeds from its equity financing, and by drawing down on its Credit Agreement as discussed below.

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

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, depository 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.

As of December 31, 2005 the Company has outstanding 324,500 shares of preferred stock. If no shares are converted and the Company continues to pay a



6% dividend on them, the dividends will equal \$243,000 per quarter.

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. as lender (the "Credit Agreement"). The Credit Agreement 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 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 quarterly (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. As of December 31, 2005 the outstanding balance of the Credit Agreement was \$4.5 million and the remaining borrowing availability was \$10.5 million. 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, 2005 Consolidated Balance Sheet in accordance with the provisions of FASB Technical Bulletin No. 79-3 (As Amended).

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 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 to pay employee federal and state withholding taxes related to these stock grants.

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.

The Company expects that the following factors will continue to have an adverse impact on earnings and cash flows during 2006:

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- o The anticipated lower preservation services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activities, and related events (discussed in Item 8, "Note 2 of the Notes to Consolidated Financial Statements"),
  - o The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which increased the cost of processing human tissue and decreased yields of implantable tissue per donor,
  - o An expected use of cash related to the defense and resolution of lawsuits and claims, and
  - o The legal and professional costs related to ongoing FDA compliance.

The Company believes the following factors should have a favorable impact on cash flow from operations during 2006, although there can be no assurance that these factors will be successful:

- o Expected increases in revenues due to increases in BioGlue list prices implemented in January 2006,
- o Expected increases in the service fees for cardiovascular and vascular tissues due to fee increases implemented in January 2006, to reflect the higher cost of processing these tissues,
- o Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2005 through process changes and process directives,
- o Expected increases in procurement of human tissues for processing over the levels experienced in 2005, and
- o Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2005.

The Company believes that the Company's existing cash, cash equivalents, marketable securities, and availability on the Credit Agreement will enable the Company to meet its liquidity needs through December 31, 2006.

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

- o The success of BioGlue and other products using related technology,
- o The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,

- o The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,
- o The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- o The timing and cost of resolving the remaining outstanding product liability lawsuits and other claims (see Item 8, "Note 9 of the Notes to Consolidated Financial Statements"),
- o 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 previously noted the Company has engaged Piper Jaffray & Co. to assist the Company's management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. No assurance can be given that this process will lead to any specific action or transaction.

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, 2006. 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.

#### *Product Liability Claims*

As discussed in Item 8, "Note 9 of the Notes to Consolidated Financial Statements", as of December 31, 2005 the Company had accrued a total of \$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 an estimate of the Company's portion of the costs required to resolve 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 \$1.5 million 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 insurance coverage and 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 9 of the Notes to Consolidated Financial Statements", at December 31, 2005 the Company had accrued a total \$7.5 million for the estimated costs of unreported product liability claims related to services performed and products sold prior to December 31, 2005 and had recorded a receivable of \$2.5 million representing amounts to be paid by the Company's insurance carriers. The \$7.5 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 \$18.5 million, \$19.6 million, and \$8.4 million for the twelve months ended December 31, 2005, 2004, and 2003, respectively. The \$18.5 million in cash used in the twelve months ended December 31, 2005 was primarily due to the \$19.5 million net loss generated by the Company during the period. Included in this net loss is an expense of \$11.6 million for the settlement of the Company's class action lawsuit and related legal fees, of which approximately \$9.6 million was paid out in cash and the remaining \$2.0 million was paid in stock. The stock payment is listed as part of other non-cash adjustments to income as discussed below. The Company's net loss is also due to the Company's preservation services business, which has failed to generate margins sufficient to cover its operating expenses since the second half of 2002 as a result of the FDA Order, subsequent FDA activity, and related events, as discussed in Item 8, "Note 2 of the Notes to Consolidated Financial Statements," "FDA Order on Human Tissue Preservation," and "Other FDA Correspondence and Notices".

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 loss, 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, 2005, the Company's \$19.5 million net loss included significant recurring non-cash items that generated favorable and unfavorable adjustments to the net loss. For the twelve months ended December 31, 2005 these adjustments included a favorable \$5.0 million in depreciation and amortization, a favorable \$1.8 million in write-downs for impairment of deferred preservation costs, a favorable \$1.8 million in other non-cash adjustments to income, primarily related to the payment of stock to satisfy \$2.0 million in legal settlement costs, and a favorable \$322,000 in non-cash employee compensation, primarily related to the implementation of SFAS 123R and the vesting of employee stock awards granted in 2004. 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, 2005 these changes included an unfavorable \$1.9 million due to the timing differences between the recording of receivables and the actual receipt of cash, a favorable \$1.0 million due to the receipt of an income tax refund recorded in the previous year, an unfavorable \$6.9 million due to the buildup of deferred preservation costs for which vendors and employees have already been paid, a favorable \$2.5 million due to timing differences between making cash payments and the expensing of assets, and a favorable \$361,000 due to the timing differences between the recording of accounts payable and other accruals and the actual payment of cash. In addition the Company's operating cash flows were unfavorably affected by \$2.5 million in payments on short-term notes payable used to finance certain of the Company's insurance policies.

The Company expects that its operations will continue to generate negative cash flows from operating activities during 2006 due to its anticipated net losses.

### **Net Cash from Investing Activities**

Net cash used by investing activities was \$2.0 million for the twelve months ended December 31, 2005, as compared to cash provided of \$457,000 and \$15.8 million for the twelve months ended December 31, 2004 and 2003, respectively. The \$2.0 million in current year cash used was primarily due to \$21.7 million in purchases of marketable securities and \$989,000 in capital expenditures, partially offset by \$20.8 million in sales and maturities of marketable securities. Investments were purchased using the proceeds of the equity offering discussed below.

### **Net Cash from Financing Activities**

Net cash provided by financing activities was \$22.7 million for the twelve months ended December 31, 2005, as compared to \$18.9 million for the twelve months ended December 31, 2004 and net cash used of \$5.6 million for the twelve months ended December 31, 2003. The \$22.7 million in current year cash provided was primarily due to \$19.1 million in net proceeds from the Company's offering of Preferred Stock in March and April of 2005, a net \$4.5 million in proceeds from drawing down on the Company's Credit Agreement, and \$372,000 in proceeds from the exercise of stock options, partially offset by \$741,000 in principal payments on capital leases, and \$533,000 in payments of Preferred Stock dividends.

### **Scheduled Contractual Obligations and Future Payments**

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

	<b>Total</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>Thereafter</b>
Operating leases	\$21,461	\$2,244	\$2,217	\$2,166	\$2,061	\$2,103	\$10,670
Revolving line of credit	4,530	—	—	4,530	—	—	—
Capital lease obligations	570	570	—	—	—	—	—
Purchase commitments	365	363	1	1	—	—	—
Other obligations	1,319	755	397	167	—	—	—
<b>Total contractual obligations</b>	<b>\$28,245</b>	<b>\$3,932</b>	<b>\$2,615</b>	<b>\$6,864</b>	<b>\$2,061</b>	<b>\$2,103</b>	<b>\$10,670</b>

The Company's operating lease obligations result from the lease of land and buildings that comprise the Company's corporate headquarters and manufacturing facilities, leases related to additional office and warehouse space rented by the Company, leases on Company vehicles, and leases on a variety of office equipment.

The 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, 2005 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 \$442,000, \$442,000, and \$47,000 in 2006, 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 and leasehold improvements primarily purchased during the renovation of the corporate headquarters and manufacturing facilities in previous years.

The Company's purchase commitments 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, litigation settlement obligations, and other items as appropriate.

### **Stock Repurchases**

During 2004 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 on November 2, 2004. Repurchases of stock from employees in 2004 related to these stock grants totaled \$54,000. No further purchases will be made related to these employee stock grants.

### **Capital Expenditures**

The Company expects that its capital expenditures in 2006 will be somewhat higher than its expenditures in 2005, which were approximately \$1.0 million. Planned capital expenditures for 2006 are primarily related to the upgrade of the Company's accounting software and related hardware purchases, and 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**

The Company's statements addressing events or developments which will or may occur in the future, including those regarding its ability to address its negative cash flows from operations, the impacts of the FDA Order and subsequent activity on the Company's business, its expectation regarding future revenues and expenses, and trends factors influencing those items, the future developments of its products and services, its ability to increase prices, future

demand for BioGlue, the expectations regarding the impact of estimates required by U.S. generally accepted accounting principles, product demand and market size and growth, the impact of product liability lawsuits and claims, adequacy of financing, and other statements regarding future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts are forward-looking statements. These statements are based on assumptions and analyses made by the Company in light of historical trends, current conditions and expected future developments as well as other factors it considers appropriate. However, whether actual developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties, including the "Risk Factors" discussed in Part I, Item 1A. to this Form 10-K and other factors, many of which are beyond the control of the Company, and which could cause actual results to differ materially from the Company's expectations. 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 that they will have the expected results. The Company assumes no obligation to update publicly any such forward-looking statements.

#### **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 \$6.6 million and the interest incurred on the line of credit balance of \$4.5 million as of December 31, 2005. The Company's short-term investments in marketable securities of \$5.0 million as of December 31, 2005 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, and the Company determined the fair value of this derivative to be \$1.0 million on March 18, 2005, the date of issuance. Due to voluntary conversions and the quarterly revaluation of the derivative liability, the Company recorded other income of \$512,000 for the three months ended December 31, 2005 and \$140,000 for the twelve months ended December 31, 2005. At December 31, 2005 the derivative liability was valued at \$114,000. 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.

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#### **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 on 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, 2005, 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, 2005, 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.

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The management of CryoLife, Inc. and subsidiaries (“CryoLife”) 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, 2005. In making this assessment, it used the criteria set forth in 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, 2005, 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 23, 2006

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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 Sec. 404, that CryoLife, Inc. and subsidiaries (the “Company”) maintained effective internal control over financial reporting as of December 31, 2005, 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, 2005, 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, 2005, 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 schedules as of and for the year ended December 31, 2005 of the Company and our report dated February 23, 2006 expressed an unqualified opinion on those financial statements and financial statement schedules and included an explanatory paragraph regarding the Company's change in method of accounting for share based payments to conform to Statement of Financial Accounting Standards No. 123R "Share Based Payment", which was adopted by the Company as of October 1, 2005.

DELOITTE & TOUCHE LLP  
Atlanta, Georgia  
February 23, 2006

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**Item 9B. Other Information.**

None.

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**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, 2006, 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, 2006.

**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, 2006.

**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, 2006.

**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, 2006.

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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:

<u>Exhibit</u> <u>Number</u>	<u>Description</u>
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- 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 Rights Agreement between the Company and Chemical Mellon Shareholder Services, L.L.C., as Rights Agent, dated as of November 27, 1995. (Incorporated herein by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
- 4.4 First Amendment to Rights Agreement, effective June 1, 1997, executed by the Company and American Stock Transfer & Trust Company, as successor Rights agent. (Incorporated herein by reference to Exhibit 4.4 to the Registrant's Form S-3 (File No. 333-112673) filed February 10, 2004.)
- 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 Form 8-K dated August 1, 2005 and filed August 5, 2005.)
- 10.2+ Credit Agreement by and between CryoLife, Inc., Certain Subsidiaries of CryoLife, Inc., and Wells Fargo Foothill, Inc., dated February 8, 2005. (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.)

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<u>Exhibit Number</u>	<u>Description</u>
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.)
10.3	1993 Employee Stock Incentive Plan adopted on July 6, 1993. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
10.4	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.)
10.5	Reserved.
10.6	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).)
10.7	CryoLife, Inc. Profit Sharing 401(k) Plan, as adopted on December 17, 1991. (Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
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)	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(d)*	Summary of annual base salaries for named executive officers.
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	Reserved.
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	Option Agreement, by and between the Company and Duke University, dated July 9, 1990, as amended by that Option Agreement Extension, by and between the parties, dated July 9, 1991. (Incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
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 Amlı 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.)
10.16(a)	First Amendment to Lease Agreement, dated April 18, 1995, between the Company and Amlı 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 Amlı 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.)

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<u>Exhibit Number</u>	<u>Description</u>
10.18	CryoLife, Inc. Employee Stock Purchase Plan (Incorporated herein by reference to Exhibit "A" of the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 10, 1996.)
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. 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	Reserved.
10.26	Reserved.
10.27	Reserved.
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.)
10.29-10.36	Reserved.



- 10.37 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.)
- 10.38-10.40 Reserved.
- 10.41 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.)
- 10.43-10.48 Reserved.
- 10.49 Form of Stock Purchase Agreement between the Company and each PIPE investor dated January 27, 2004. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Form 8-K dated January 26, 2004.)
- 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.

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### 3. B. Executive Compensation Plans and Arrangements.

1. 1993 Employee Stock Incentive Plan adopted on July 6, 1993. (Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
2. Form of Stock Option Agreement and Grant under the Incentive Stock Option and Employee Stock Incentive Plans (Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
3. CryoLife, Inc. Profit Sharing 401(k) Plan, as adopted on December 17, 1991 (Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
4. 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.)
5. Summary of annual base salaries for named executive officers. (Incorporated herein by reference to Exhibit 10.9(d) to this Form 10-K.)
6. 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.)
7. 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.)
8. CryoLife, Inc. Employee Stock Purchase Plan. (Incorporated herein by reference to Exhibit "A" of the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 10, 1996.)
9. 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. 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.)
11. 2002 Stock Incentive Plan (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.)

12. CryoLife, Inc. 2004 Employee Stock Incentive Plan, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
13. CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
14. 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.)
15. 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.)
16. 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.)

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**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 23, 2006

By /s/ STEVEN G. ANDERSON  
 Steven G. Anderson  
 President, Chief Executive  
 Officer and Chairman of  
 the Board of Directors

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

Signature	Title	Date
<u>/s/ STEVEN G. ANDERSON</u> <b>Steven G. Anderson</b>	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	February 23, 2006
<u>/s/ D. ASHLEY LEE</u> <b>D. Ashley Lee</b>	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2006
<u>/s/ THOMAS F. ACKERMAN</u> <b>Thomas F. Ackerman</b>	Director	February 23, 2006
<u>/s/ JAMES S. BENSON</u> <b>James S. Benson</b>	Director	February 23, 2006
<u>/s/ DAN BEVEVINO</u> <b>Dan Bevevino</b>	Director	February 23, 2006
<u>/s/ JOHN M. COOK</u> <b>John M. Cook</b>	Director	February 23, 2006
<u>/s/ RONALD CHARLES ELKINS, M.D.</u> <b>Ronald Charles Elkins, M.D.</b>	Director	February 23, 2006
<u>/s/ VIRGINIA C. LACY</u> <b>Virginia C. Lacy</b>	Director	February 23, 2006
<u>/s/ RONALD D. MCCALL</u> <b>Ronald D. McCall</b>	Director	February 23, 2006
<u>/s/ BRUCE J. VAN DYNE, M.D.</u> <b>Bruce J. Van Dyne, M.D.</b>	Director	February 23, 2006

## 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, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedules 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, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedules, 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, 2005, 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 23, 2006 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 23, 2006

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### CryoLife, Inc. Consolidated Balance Sheets (in thousands)

	December 31,	
	2005	2004
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 6,631	\$ 4,713
Marketable securities, at market	4,968	3,956
Restricted cash and securities	560	563
<b>Receivables:</b>		
Trade accounts, less allowance for doubtful accounts of \$105 in 2005 and \$85 in 2004	10,153	8,293
Income taxes	371	1,203
Other	1,563	2,754
<b>Total receivables</b>	<b>12,087</b>	<b>12,250</b>
Deferred preservation costs, net	13,959	8,822
Inventories	4,609	4,767
Prepaid expenses and other assets	2,387	2,590
<b>Total current assets</b>	<b>45,201</b>	<b>37,661</b>
<b>Property and equipment:</b>		
Equipment	23,227	23,383
Furniture and fixtures	5,112	5,011
Leasehold improvements	29,754	33,026
Construction in progress	1	20
Total property and equipment	58,094	61,440
Less accumulated depreciation and amortization	33,719	32,716
<b>Net property and equipment</b>	<b>24,375</b>	<b>28,724</b>

**Other assets:**

Patents, less accumulated amortization of \$1,692 in 2005 and \$1,414 in 2004	4,877	4,978
Trademarks and other intangibles	425	393
Other	1,931	1,505
	<u>          </u>	<u>          </u>
<b>Total assets</b>	<b>\$76,809</b>	<b>\$73,261</b>

See accompanying notes to consolidated financial statements.

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**CryoLife, Inc.**  
**Consolidated Balance Sheets**  
**(in thousands)**

	December 31,	
	2005	2004
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,239	\$ 2,569
Accrued expenses and other current liabilities	8,578	9,615
Accrued compensation	1,467	1,835
Accrued procurement fees	3,797	2,634
Derivative liability	114	—
Line of credit	4,530	—
Current maturities of capital lease obligations	554	1,319
	<u>          </u>	<u>          </u>
<b>Total current liabilities</b>	<b>21,279</b>	<b>17,972</b>
	<u>          </u>	<u>          </u>
Capital lease obligations, less current maturities	—	530
Other long-term liabilities	4,909	5,099
	<u>          </u>	<u>          </u>
<b>Total liabilities</b>	<b>26,188</b>	<b>23,601</b>
	<u>          </u>	<u>          </u>
<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, and 325 issued and outstanding in 2005	3	—
Common stock \$.01 par value per share; authorized 75,000 shares; issued 25,582 shares in 2005 and 24,805 shares in 2004	256	248
Additional paid-in capital	113,507	94,846
Retained deficit	(58,569)	(38,257)
Deferred compensation	—	(222)
Accumulated other comprehensive income, net of tax	123	361
Treasury stock; 892 shares in 2005 and 1,390 shares in 2004, at cost	(4,699)	(7,316)
	<u>          </u>	<u>          </u>
<b>Total shareholders' equity</b>	<b>50,621</b>	<b>49,660</b>
	<u>          </u>	<u>          </u>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 76,809</b>	<b>\$ 73,261</b>

See accompanying notes to consolidated financial statements.

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**CryoLife, Inc.**  
**Consolidated Statements of Operations**  
**(in thousands, except per share data)**

Year Ended December 31,		
2005	2004	2003

<b>Revenues:</b>			
Products	\$ 38,932	\$ 36,637	\$ 28,263
Human tissue preservation services	30,307	25,676	30,777
Research grants	43	71	492
	<u>69,282</u>	<u>62,384</u>	<u>59,532</u>
<b>Costs and expenses:</b>			
Products	8,065	7,818	7,506
Human tissue preservation services (including write-down of \$1,797 in 2005, \$6,905 in 2004, and \$6,861 in 2003)	24,357	29,807	23,976
General, administrative, and marketing	53,225	42,640	53,630
Research and development	3,724	3,938	3,644
Interest expense	346	196	415
Interest income	(531)	(262)	(425)
Change in valuation of derivative	(140)	—	—
Other expense, net	199	13	12
	<u>89,245</u>	<u>84,150</u>	<u>88,758</u>
<b>Loss before income taxes</b>	<b>(19,963)</b>	<b>(21,766)</b>	<b>(29,226)</b>
Income tax (benefit) expense	(428)	(3,017)	3,068
	<u>(19,535)</u>	<u>(18,749)</u>	<u>(32,294)</u>
<b>Net loss</b>	<b>\$(19,535)</b>	<b>\$(18,749)</b>	<b>\$(32,294)</b>
Effect of preferred stock dividends	(777)	—	—
	<u>(20,312)</u>	<u>(18,749)</u>	<u>(32,294)</u>
<b>Net loss applicable to common shares</b>	<b>\$(20,312)</b>	<b>\$(18,749)</b>	<b>\$(32,294)</b>
<b>Loss per share:</b>			
Basic	\$ (0.85)	\$ (0.81)	\$ (1.64)
Diluted	\$ (0.85)	\$ (0.81)	\$ (1.64)
<b>Weighted average shares outstanding:</b>			
Basic	23,959	23,043	19,684
Diluted	23,959	23,043	19,684

See accompanying notes to consolidated financial statements.

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**CryoLife, Inc.**  
**Consolidated Statements of Cash Flows**  
**(in thousands)**

	Year Ended December 31,		
	2005	2004	2003
<b>Net cash flows from operating activities:</b>			
Net loss	\$(19,535)	\$(18,749)	\$(32,294)
Adjustments to reconcile net loss to net cash from operating activities:			
Gain on sale of marketable equity securities	(3)	—	(19)
Loss (gain) on sale of assets	108	30	(65)
Depreciation of property and equipment	4,759	5,202	5,191
Amortization	277	281	316
Provision for doubtful accounts	57	53	29
Write-down of deferred preservation costs and inventories	1,797	7,105	6,861
Other non-cash adjustments to income	1,771	10	347
Deferred income taxes	—	—	5,726
Non-cash employee compensation	322	358	—
Change in valuation of derivative	(140)	—	—
Changes in operating assets and liabilities:			
Trade and other receivables	(1,854)	(2,159)	954
Income taxes	1,024	665	9,620
Deferred preservation costs	(6,934)	(6,916)	(11,340)

Inventories	158	(517)	135
Prepaid expenses and other assets	2,509	1,325	2,281
Accounts payable	(712)	342	(1,717)
Accrued expenses and other liabilities	361	(3,256)	8,043
Principal payments on financing of insurance premiums	(2,482)	(3,385)	(2,443)
<b>Net cash flows used in operating activities</b>	<b>(18,517)</b>	<b>(19,611)</b>	<b>(8,375)</b>
<b>Net cash flows from investing activities:</b>			
Capital expenditures	(989)	(950)	(955)
Net proceeds from sale of assets	12	26	1,093
Other assets	(208)	(56)	155
Purchases of marketable securities	(21,690)	(563)	(15,430)
Sales and maturities of marketable securities	20,841	2,000	30,889
<b>Net cash flows (used in) provided by investing activities</b>	<b>(2,034)</b>	<b>457</b>	<b>15,752</b>
<b>Net cash flows from financing activities:</b>			
Principal payments of debt	(317)	—	(5,600)
Proceeds from debt issuance	4,847	—	—
Principal payments on obligations under capital leases	(741)	(717)	(651)
Proceeds from exercise of options and issuance of stock	372	443	660
Payment of preferred stock dividend and make whole payments	(533)	—	—
Proceeds from equity offering	19,098	19,265	—
Purchase of treasury stock	—	(54)	—
<b>Net cash flows provided by (used in) financing activities</b>	<b>22,726</b>	<b>18,937</b>	<b>(5,591)</b>
<b>Increase (decrease) in cash</b>	<b>2,175</b>	<b>(217)</b>	<b>1,786</b>
Effect of exchange rate changes on cash	(257)	33	9
Cash and cash equivalents, beginning of year	4,713	4,897	3,102
<b>Cash and cash equivalents, end of year</b>	<b>\$ 6,631</b>	<b>\$ 4,713</b>	<b>\$ 4,897</b>

See accompanying notes to consolidated financial statements.

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**CryoLife, Inc.**  
**Consolidated Statements of Shareholders' Equity**  
(in thousands)

	Preferred Stock		Common Stock		Additional Paid In Capital	Retained Earnings (Deficit)	Accumulated Deferred Compensation	Other Comprehensive (Loss) Income	Treasury Stock		Total Shareholders' Equity
	Shares	Amount	Shares	Amount					Shares	Amount	
<b>Balance at December 31, 2002</b>	--	\$ --	20,935	\$ 209	\$ 73,630	\$ 12,786	\$ (21)	\$ 282	(1,361)	\$(7,086)	\$ 79,800
Net loss	--	--	--	--	--	(32,294)	--	--	--	--	(32,294)
Other comprehensive income, net of taxes	--	--	--	--	--	--	--	83	--	--	83
Comprehensive loss											(32,211)
Exercise of options	--	--	58	1	272	--	--	--	(10)	(95)	178
Employee stock purchase plan	--	--	137	1	558	--	--	--	--	--	559
Amortization of deferred compensation	--	--	--	--	--	--	12	--	--	--	12
<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
Stock grants	--	--	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>	<b>--</b>	<b>--</b>	<b>24,805</b>	<b>\$ 248</b>	<b>\$ 94,846</b>	<b>\$(38,257)</b>	<b>\$ (222)</b>	<b>\$ 361</b>	<b>(1,390)</b>	<b>\$(7,316)</b>	<b>\$ 49,660</b>
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)
Stock grants	--	--	(3)	--	(20)	--	222	--	--	--	202
Exercise of options	--	--	36	--	111	--	--	--	(2)	(17)	94
Employee equity compensation	--	--	--	--	120	--	--	--	--	--	120
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>	<b>325</b>	<b>\$ 3</b>	<b>25,582</b>	<b>\$ 256</b>	<b>\$ 113,507</b>	<b>\$(58,569)</b>	<b>\$ --</b>	<b>\$ 123</b>	<b>(892)</b>	<b>\$(4,699)</b>	<b>\$ 50,621</b>

See accompanying notes to consolidated financial statements.

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**CRYOLIFE, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies**

***Nature of Business***

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

CryoLife can distribute BioGlue throughout the United States and 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 several other countries in Central and South America, Asia, and Australia. CryoLife distributes preserved human cardiovascular, vascular, and orthopaedic tissue to implanting institutions throughout the United States, 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 expects that the following factors will continue to have an adverse impact on earnings and cash flows during 2006:

- o The anticipated lower preservation services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activities, and related events (discussed in Note 2),
- o The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which increased the cost of processing human tissue and decreased yields of implantable tissue per donor,
- o An expected use of cash related to the defense and resolution of lawsuits and claims, and
- o The legal and professional costs related to ongoing FDA compliance.

The Company believes the following factors should have a favorable impact on cash flow from operations during 2006, although there can be no

assurance that these factors will be successful:

- o Expected increases in revenues due to increases in BioGlue list prices implemented in January 2006,
- o Expected increases in the service fees for cardiovascular and vascular tissues due to fee increases implemented in January 2006, to reflect the higher cost of processing these tissues,
- o Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2005 through process changes and process directives,
- o Expected increases in procurement of human tissues for processing over the levels experienced in 2005, and
- o Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2005.

The Company believes that the Company's existing cash, cash equivalents, marketable securities, and availability on the Credit Agreement will enable the Company to meet its liquidity needs through December 31, 2006.

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

- o The success of BioGlue and other products using related technology,
- o The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,
- o The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,
- o The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- o The timing and cost of resolving the remaining outstanding product liability lawsuits and other claims (see Note 9),
- o To a lesser degree, the Company's success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft technology.

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, 2006. 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.

#### ***Prior Year Amounts***

Certain prior year amounts have been reclassified to conform to current year presentation. In 2005 the Company determined that its presentation of payments on notes payable to finance insurance policy premiums in the financing section of the cash flow statement are more appropriately classified as operating cash outflows. Therefore, a total of \$3.4 million and \$2.4 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, 2004 and 2003, 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, 2004.

#### ***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 and 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, 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 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 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.

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### ***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):

	2005	2004	2003
<b>Cash paid during the year for:</b>			
Interest	\$ 276	\$ 127	\$ 358
Income taxes	216	200	169
<b>Non-cash investing and financing activities:</b>			
Payment of legal settlement in stock	\$ 1,973	\$ —	\$ —
Payment of make whole payments in common stock	786	—	—
Non-cash employee compensation	322	358	—
Purchase of property and equipment in accounts payable and accrued expenses	21	70	—
Establishment of capital lease obligation	—	77	—

### ***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. The cost of securities sold is based on the specific identification method.

As of December 31, 2005 \$5.0 million of marketable securities were designated as available-for-sale, and \$560,000 of marketable securities were designated as held-to-maturity. These securities were designated held-to-maturity due to a contractual commitment to hold the securities as pledged collateral relating to one of the Company's product liability insurance policies, and, therefore, they are reported as restricted securities on the December 31, 2005 Consolidated Balance Sheet. As of December 31, 2004 \$4.0 million of marketable securities were designated as available-for-sale, and \$563,000 of marketable securities were designated as held-to-maturity.

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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 and preservation. 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 #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 affect the deferred preservation costs per tissue, which could 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.

During 2002 the Company recorded impairment write-downs of deferred preservation costs totaling \$32.7 million as a result of the FDA Order. The amount of these write-downs reflected management's estimates based on information available to it at the time the estimates were made and actual results did differ from these estimates. The write-down created a new cost basis, which cannot be written back up if and when these tissues become available for distribution. The cost of human tissue preservation services in the twelve months ended December 31, 2004 and 2003 was favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services was not materially affected by these write-downs in the twelve months ended December 31, 2005 and is not expected to be materially affected by these write-downs in future periods.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company recorded \$499,000 and \$1.8 million, respectively, in the three and twelve months ended December 31, 2005 and \$511,000 and \$6.6 million, respectively, in the three and twelve months ended December 31, 2004 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 twelve months ended December 31, 2004 also included \$353,000 in costs related to the write-down of SynerGraft processed 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. As of December 31, 2004 deferred preservation costs consisted of \$3.1 million for allograft heart valve tissues, \$280,000 for non-valved cardiac tissues, \$2.8 million for vascular tissues, and \$2.6 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.

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### ***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***

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, 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. 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, 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 patent costs, which are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method, and trademarks, which are non-amortizing. As of December 31, 2005 the Company did not believe that an impairment existed related to the other intangible assets that were assessed in accordance with SFAS No. 144.

Scheduled amortization of intangible assets for the next five years is as follows (in thousands):

2006	\$	277
2007		277
2008		277
2009		274
2010		271
Total	\$	<u>1,376</u>

### ***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 and preservation. 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. Following the FDA Order a greater number of lawsuits than historically were filed. 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 sold. The Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed in January 2006 as of December 31, 2005. 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.

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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.

### ***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 Share***

Earnings (loss) per 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 which provide for grants of shares to employees and grants of options to employees and directors 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") as amended by SEC Rule 2005-57 "Commission Amends Compliance Dates For FASB Statement No. 123R on Employee Stock Options" 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 9. 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 equals 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 loss and loss per share is required by SFAS 123, 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.

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### ***Comprehensive Income***

The Company follows the provisions of SFAS No. 130, "Reporting Comprehensive Income" ("SFAS 130") for the reporting and display of comprehensive income and its components. Comprehensive income is defined in SFAS 130 as net income plus other comprehensive income, which under existing accounting standards, includes foreign currency items, minimum pension liability adjustments, and unrealized gains and losses on certain investments in debt and equity securities.

### ***Translation of Foreign Currencies***

Assets and liabilities are translated at the exchange rate as of the balance sheet date. All revenue and expense accounts are translated as transactions

occur at exchange rates in effect during the year. Translation adjustments are recorded as a separate component of other comprehensive income in shareholders' equity.

### ***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 approximated fair value at December 31, 2005 and 2004.

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

The Company early adopted SFAS 123 Revised "Share-Based Payment" ("SFAS 123R") as amended by SEC Rule 2005-57 "Commission Amends Compliance Dates For FASB Statement No. 123R on Employee Stock Options" 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 9. 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.

The Company will be required to adopt SFAS 151 "Inventory Costs" ("SFAS 151") for the fiscal year ending December 31, 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 Company is still evaluating the impact of the adoption of SFAS 151.

The Company was required to adopt FIN 47, "Accounting for Conditional Asset Retirement Obligations" ("FIN 47") for the year ending December 31, 2005. FIN 47 provides interpretation which clarifies that the term conditional asset retirement obligation as used in FASB Statement No. 143, "Accounting for Asset Retirement Obligations", refers to a legal obligation to perform an asset retirement activity in which the timing and (or) method of settlement are conditional on a future event that may or may not be within the control of the entity. The adoption of FIN 47 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

## **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.

On September 5, 2002 the Company entered into an agreement with the FDA (the "FDA Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to the recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company had completed specified steps.

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In addition pursuant to the FDA Agreement, the Company agreed to perform additional processing procedures and to establish a corrective action plan. The corrective actions taken have been reviewed by the FDA during subsequent inspections.

### ***Accounting Treatment***

As a result of the FDA Order the Company recorded a reduction in revenues during the year ended December 31, 2002 for the estimated return of the tissues subject to recall by the FDA Order. During the year ended December 31, 2003 the Company recorded a favorable adjustment of \$900,000 to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002. The adjustment increased cardiac tissue revenues by \$85,000, vascular tissue revenues by \$752,000, and orthopaedic tissue revenues by \$63,000. Management determined that no additional accruals were necessary for tissue returns under the FDA Order. Therefore, as of December 31, 2003 there was no accrual for estimated return of tissues subject to recall by the FDA Order.

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

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 response to the July 2005 483 the Company has implemented new 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 and will continue to work with the FDA to review process improvements and address any outstanding observations.

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 others through administrative procedures. The FDA requested further additional information in January 2006. The FDA may still require that additional studies be undertaken and may never clear the 510(k) premarket notification. 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 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 cardiovascular 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 clearances are granted. The Company is evaluating whether it will file and seek a premarket approval for CryoVein SG or discontinue the CryoVein SG.

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 will employ its traditional processing methods on these tissues. During the year ended December 31, 2004 the Company wrote down \$353,000 in SynerGraft processed cardiovascular and vascular tissues. As of December 31, 2005 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Consolidated Balance Sheets.

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### 3. Cash Equivalents and Marketable Securities

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

	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
US Treasury debt securities	1,990	—	1,990
Total marketable securities	\$ 4,970	\$ (2)	\$ 4,968
Restricted securities:			
Government entity sponsored debt securities	\$ 560	\$ —	\$ 560
<b>December 31, 2004</b>			
Cash equivalents:			
Money market funds	\$ 2,290	\$ —	\$ 2,290
Marketable securities:			
Municipal obligations	\$ 3,138	\$ 43	\$ 3,181
Variable rate demand notes	775	—	775
Total marketable securities	\$ 3,913	\$ 43	\$ 3,956
Restricted securities:			
Government entity sponsored debt securities	\$ 563	\$ —	\$ 563

Gross realized gains on sales of available-for-sale securities totaled \$3,000 for the twelve months ended December 31, 2005 and zero for the twelve months ended December 31, 2004. Differences between cost and market listed above, consisting of a net unrealized holding loss of \$2,000 less deferred taxes of zero at December 31, 2005 and a net unrealized holding gain of \$43,000 less deferred taxes of \$11,000 at December 31, 2004, are included as a separate component of other comprehensive income in the shareholders' equity section of the Consolidated Balance Sheets.

At December 31, 2005 the Company's \$5.0 million in marketable securities had a maturity date within 90 days. At December 31, 2004 approximately \$2.2 million of the Company's marketable securities had a maturity date between 90 days and 1 year, approximately \$1.0 million had a maturity date between 1 and 5 years, and approximately \$775,000 had a maturity date of greater than 5 years.

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### 4. Inventories

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

	2005	2004

Raw materials	\$	3,083	\$	2,780
Work-in-process		415		246
Finished goods		1,111		1,741
		<u>          </u>		<u>          </u>
Total Inventories	\$	4,609	\$	4,767
		<u>          </u>		<u>          </u>

## 5. 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 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 quarterly (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, 2005 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 8.25% as of December 31, 2005. During the year-ended December 31, 2005 CryoLife borrowed approximately \$4.8 million against the \$15.0 million available under the Credit Agreement. As of December 31, 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, 2005 the Company entered into two agreements to finance approximately \$1.7 million and \$761,000, respectively, in insurance premiums associated with the yearly renewal of certain Company insurance policies. The amounts financed accrue interest at a 4.98% and 5.01% rate, respectively, and are 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 April 2004 the Company entered into two agreements to finance approximately \$1.9 million and \$1.5 million, respectively, in insurance premiums associated with the yearly renewal of certain Company insurance policies. The amounts financed accrue interest at a 3.25% rate and are payable in equal monthly payments over a nine month period and an eight month period, respectively. As of December 31, 2004 the outstanding balance under the agreements was zero.

Total interest expense was \$346,000, \$196,000, and \$415,000 in 2005, 2004, and 2003, respectively.

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## 6. 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.

## 7. 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. On June 2, 2005 the Company declared a dividend of \$0.8667 per share on its 6% convertible preferred stock. The dividend of approximately \$290,000 was paid on July 1, 2005 to shareholders of record on June 20, 2005. On September 12, 2005 the Company declared a dividend of \$0.75 per share on its 6% convertible preferred stock. The dividend of approximately \$243,000 was paid on October 1, 2005 to shareholders of record on September 22, 2005. On December 12, 2005 the Company declared a dividend of \$0.75 per share on its 6% convertible preferred stock. The dividend of approximately \$244,000 was paid on January 1, 2006 to shareholders of record on December

23, 2005.

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. At December 31, 2005 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, 2005 the Company had issued 119,000 shares of common stock to converting holders in satisfaction of 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, 2005, before the payment of the January 2006 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.

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

## **8. Derivatives**

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

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 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 voluntary conversions, which took place during the period from March 18, 2005 through December 31, 2005, and due to the quarterly revaluation of the derivative liability, the Company recorded other income of \$140,000 for the year ended December 31, 2005. At December 31, 2005 the derivative liability was valued at \$114,000.

### ***Interest Rate Swap Agreement***

On April 25, 2000 the Company entered into a loan agreement permitting the Company to borrow up to \$8.0 million under a line of credit during the expansion of the Company's corporate headquarters and manufacturing facilities. On March 16, 2000 the Company entered into a \$4.0 million notional amount forward-starting interest swap agreement. This swap agreement was designated as a cash flow hedge to effectively convert a portion of the Term Loan balance to a fixed rate basis, thus reducing the impact of interest rate changes on future income.

In conjunction with the payoff of the outstanding balance of the Term Loan in 2003, the Company paid \$199,000 to terminate the swap agreement. This \$199,000 payment represents the estimated fair value of the interest rate swap, as estimated by the bank based on its internal valuation models, as of the day of the termination of the agreement. For the year ended December 31, 2003 the Company recorded a total expense of \$168,000 related to the interest rate swap.

## **9. Commitments and Contingencies**

### ***Leases***

The Company's capital lease obligations result from the financing of certain of the Company's equipment and leasehold improvements primarily those purchased during the renovation of the corporate headquarters and manufacturing facilities in previous years.

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

Certain leases contain escalation clauses and renewal options for additional periods. Rent expense is computed on the straight-line method over the term of the lease with the offsetting accrual recorded in other long-term liabilities.

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Future minimum lease payments under noncancelable leases as of December 31, 2005 are as follows (in thousands):

	Leases	
	Capital	Operating
2006	\$ 570	\$ 2,244
2007	—	2,217
2008	—	2,166
2009	—	2,061
2010	—	2,103
Thereafter	—	10,670
	<hr/>	<hr/>
Total minimum lease payments	\$ 570	\$ 21,461
Less amount representing interest	16	
	<hr/>	
Present value of net minimum lease payments	554	
Less current maturities	554	
	<hr/>	
Capital lease obligations, less current maturities	\$ —	
	<hr/>	

Property acquired under capital leases included in the Consolidated Balance Sheet dated December 31, 2005 consists of the following (in thousands):

Equipment	\$	480
Furniture and fixtures		890
Leasehold improvements		1,212
		<hr/>
Total	\$	2,582
		<hr/>

Total rental expense for operating leases was \$2.4 million, \$2.5 million, and \$2.6 million, for 2005, 2004, and 2003, respectively. Total rental income under a sublease that terminated during 2005 was \$258,000, \$310,000, and \$310,000 in 2005, 2004, and, 2003, 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. Following the FDA Order, a greater number of lawsuits was filed. As of February 20, 2006 the Company was aware of six 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 orthopaedic tissue services, three allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges a product liability claim arising from BioGlue.

As of February 20, 2006 there were two outstanding product liability lawsuits against the Company that are covered by the 2004/2005 insurance policy. The Company believes its insurance policy to be adequate to defend against the covered lawsuits in this time period. Additionally, there are four outstanding product liability lawsuits against the Company that are not covered by insurance policies, as either the Company has used all of its insurance coverage related to that policy year, or the claims were asserted against the Company in periods after the coverage in the related incident year had lapsed. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company, which have not resulted in lawsuits. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2005 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, 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. This amount represents the Company's estimate of the probable losses related to one settled but unpaid claim and three of the six pending product liability claims. The Company has not recorded an accrual for the remaining three 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, 2004 the Company had accrued a total of approximately \$2.8 million for settled but unpaid claims and pending product liability claims and recorded \$1.1 million representing amounts to be recovered from the Company's insurance carriers. The \$2.8 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2004 Consolidated Balance Sheet.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as most of the claims do not specify the damages sought and 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. Additionally, 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 insurance coverage and 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.

On April 1, 2005 the Company bound coverage for the 2005/2006 insurance policy year. This policy is a three-year claims-made insurance policy, i.e.



claims incurred during the period April 1, 2003 through March 31, 2006 and reported during the period April 1, 2005 through March 31, 2006 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 2006 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2005. 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:

- o 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,
- o The future claim reporting lag time would be a blend of the Company's experiences and industry data,
- o The frequency of unreported claims for accident years 2001 through 2005 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,
- o 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,
- o 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
- o The number of BioGlue claims per million dollars of BioGlue revenue would be 35% lower than non-BioGlue claims per million dollars of revenue. The 35% 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 actual developments could differ materially from the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions, including the FDA Order, the Company's recent levels of litigation activity, 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 amounts accrued.

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Based on the actuarial valuation performed in January 2006 as of December 31, 2005, the Company estimated that its liability for unreported product liability claims was \$7.5 million as of December 31, 2005. In accordance with Emerging Issues Task Force Issue 03-8, the Company has accrued \$7.5 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, 2005. The \$7.5 million balance 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. Further analysis indicated that the liability could be estimated to be as high as \$13.4 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, 2005, \$2.5 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.5 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.4 million on the December 31, 2005 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, 2005. Actual results may differ from this estimate.

As of December 31, 2004 the Company accrued \$8.2 million for unreported product liability claims and recorded a receivable of \$1.9 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. The \$8.2 million balance is included as a component of accrued expenses and other current liabilities of \$4.2 million and other long-term liabilities of \$4.0 million on the December 31, 2004 Consolidated Balance Sheet. The \$1.9 million insurance recoverable is included as a component of other current receivables of \$800,000 and other long-term assets of \$1.1 million on the December 31, 2004 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 alleges 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. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the U.S. District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003 the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. On March 11, 2005 defendants moved for summary judgment on all of plaintiffs' claims, and plaintiffs moved for partial summary judgment as to some of their claims against certain defendants. On June 17, 2005 the court denied plaintiffs' motion for partial summary judgment and granted in part and denied in part defendants' motion for summary judgment.

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 include 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. The Company and the individual defendants have denied any wrongdoing and liability whatsoever, and the settlement does not contain any admission of liability.

The Company has filed a request for mediation under its insurance policies to assert a claim against two of its insurance carriers. The claim is for recovery of monetary losses of approximately \$11.25 million paid by the Company in excess of policy limits to settle the securities class action lawsuit. The claim alleges that the loss resulted from the carriers' bad faith failure to settle. There can be no assurance that the claim will be successful. The Company will not record a gain related to this claim prior to final settlement.

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### ***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 123 Revised "Share-Based Payment" ("SFAS 123-R") 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. Certain of those proceedings resulted in settlements with the SEC, while other proceedings remain pending. Other than receiving a report of that activity, the SEC has had no discussions with CryoLife representatives 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 or 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.

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

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

The Company has stock option and stock incentive plans which provide for grants of shares to employees and grants of options to employees and directors 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.

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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, 2005 and 2004 there were 2.6 million and 2.4 million, respectively, shares of common stock reserved for future issuance under the Company's stock option and stock incentive plans. 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.

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2004	2,293,000	\$ 11.04		
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
Vested and Expected to Vest	1,718,000	\$ 11.69	2.41	\$ 495,000
Exercisable at December 31, 2005	1,260,000	\$ 14.27	2.20	\$ 337,000

The following table summarizes information concerning outstanding and exercisable options at December 31, 2005:

Options Outstanding				Options Exercisable	
Range of Exercise Price	Average Number Outstanding	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 2.20-2.20	441,000	2.02	\$ 2.20	294,000	\$ 2.20
3.22-5.36	385,000	3.52	5.13	161,000	5.04
6.16-7.74	362,000	3.21	6.87	239,000	7.10
8.00-30.14	360,000	1.92	23.18	360,000	23.18
30.86-31.99	206,000	0.69	31.56	206,000	31.56
\$ 2.20-31.99	1,754,000	2.42	\$ 11.55	1,260,000	\$ 14.27

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

	2005	2004	2003
Weighted average fair value of options granted	\$ 3.51	\$ 2.80	\$ 2.88
Intrinsic value of options exercised	\$ 148,000	\$ 304,000	\$ 215,000

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, vest at a rate of one twelfth per month for the twelve months following the grant date. As of December 31, 2004 the Company had \$222,000 recorded as deferred compensation in the equity section of the Consolidated Balance Sheets representing the unvested portion of employee stock grants. 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 twelve months ended December 31, 2005 and 2004, respectively. 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.

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A summary of stock grants under the plans follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2002	—	\$ —
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

—	\$ —
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In September 1999 the Company granted options to a nonemployee to purchase 18,000 shares of common stock at an exercise price of \$8.21 per share. In connection with the issuance of these options the Company recognized \$60,000 as deferred compensation for the estimated fair value of the options. Deferred compensation is amortized ratably over the vesting period of the options in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). As of December 31, 2004 the Company had recorded expense equal to the estimated fair value of the options and the value of deferred compensation recorded on the Company's books related to this option grant was zero.

### **Stock Compensation**

The Company's stock option and stock incentive plans provide for grants of shares to employees and grants of options to employees and directors 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") as amended by SEC Rule 2005-57 "Commission Amends Compliance Dates For FASB Statement No. 123R on Employee Stock Options" 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 9. 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, did not effect 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 an additional pro forma 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 believes 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.

The Company maintains a shareholder approved Employee Stock Purchase Plan (the "ESPP") for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a quarterly basis at the lower of 85% of the market price at the beginning or end of each three-month offering period. 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.

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

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

The modified prospective approach requires that the Company expense over the remaining vesting period the value it previously calculated under the fair value method for stock options issued prior to the adoption of SFAS 123R. As of October 1, 2005, the date of adoption, there was approximately \$593,000 in total unrecognized compensation cost related to unvested stock, before considering estimated forfeitures. That cost is expected to be recognized based on the vesting of the underlying option awards through the quarter ended June 30, 2010.

For the three months ended December 31, 2005 the Company's stock-based compensation expense was approximately \$120,000, of which approximately \$37,000 was capitalized into the Company's 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. 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 three months ended December 31, 2005 as the Company is currently maintaining a full valuation allowance on its deferred tax assets. See Note 16 for additional discussions of the Company's income tax valuation.

As of December 31, 2005 there was approximately \$495,000 in total unrecognized compensation costs related to nonvested share-based compensation arrangements, before considering the effect of expected forfeitures. This expense is expected to be recognized over a weighted average period of 1.5 years.

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The following table outlines the estimated effect of the adoption of SFAS 123R on the Company's key financial disclosures for the three months ended December 31, 2005 (in thousands except per share data):

	As Reported	Effect of the Adoption of SFAS 123R	Excluding the Effect of SFAS 123R
	(unaudited)	(unaudited)	(unaudited)
Loss from operations	\$ (1,820)	\$ 89	\$ (1,731)
Loss before income taxes	\$ (1,299)	\$ 89	\$ (1,210)
Net loss	\$ (681)	\$ 89	\$ (592)
Net loss applicable to common shareholders	\$ (925)	\$ 89	\$ (836)
Net loss per share:			
Basic	\$ (0.04)	\$ 0.01	\$ (0.03)
Diluted	\$ (0.04)	\$ 0.01	\$ (0.03)

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 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.

A summary of stock option transactions during 2004 and 2003 follows:

	Shares	Exercise Price	Weighted Average Exercise Price
Outstanding at December 31, 2002	2,386,000	\$ 2.20-31.99	\$ 12.10
Granted	419,000	4.78-7.74	5.66
Exercised	(58,000)	2.20-9.00	3.37
Canceled	(224,000)	2.20-31.99	9.15
Outstanding at December 31, 2003	2,523,000	\$ 2.20-31.99	\$ 11.48
Granted	319,000	5.27-6.91	5.49
Exercised	(72,000)	2.20-4.88	2.32
Canceled	(477,000)	2.20-30.86	11.01
Outstanding at December 31, 2004	2,293,000	\$ 2.20-31.99	\$ 11.04

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

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The following weighted-average assumptions were used:

	Nine Months Ended September 30, 2005	Twelve Months Ended December 31, 2004      2003	
	(unaudited)		
Expected dividend yield	0%	0%	0%
Expected stock price volatility	.519	.589	.616
Risk-free interest rate	3.36%	3.09%	2.35%
Expected life of options	3.2 Years	3.7 Years	3.6 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, 2005	Twelve Months Ended December 31, 2004      2003	
	(unaudited)		
Basic net loss applicable to common shares—as reported	\$(19,387)	\$(18,749)	\$(32,294)
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	1,715
	<u>\$(22,474)</u>	<u>\$(21,484)</u>	<u>\$(34,009)</u>
Basic net loss applicable to common shares—pro forma			
Basic weighted-average shares	23,839	23,043	19,684
Basic loss per common share:			
As reported	\$ (0.81)	\$ (0.81)	\$ (1.64)
Pro forma	<u>\$ (0.94)</u>	<u>\$ (0.93)</u>	<u>\$ (1.73)</u>
Diluted net loss applicable to common shares—as reported	\$(19,387)	\$(18,749)	\$(32,294)
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	1,715
	<u>\$(22,474)</u>	<u>\$(21,484)</u>	<u>\$(34,009)</u>
Diluted net loss applicable to common shares—pro forma			
Diluted weighted-average shares	23,839	23,043	19,684
Diluted loss per common share:			
As reported	\$ (0.81)	\$ (0.81)	\$ (1.64)
Pro forma	<u>\$ (0.94)</u>	<u>\$ (0.93)</u>	<u>\$ (1.73)</u>

## 11. 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.

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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).

## 12. Stock Repurchases

During 2004 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 on November 2, 2004. Repurchases of stock from employees in 2004 related to these stock grants totaled \$54,000. No further purchases will be made related to these employee stock grants.

## 13. Accumulated Other Comprehensive Loss

Components of comprehensive loss consist of the following, net of tax (in thousands):

	2005	2004	2003
Net loss	\$(19,535)	\$(18,749)	\$(32,294)
Unrealized loss on investments	(34)	(53)	(119)
Change in fair value of interest rate swap	—	—	172
Translation adjustment	(204)	49	30
Comprehensive loss	<u>\$(19,773)</u>	<u>\$(18,753)</u>	<u>\$(32,211)</u>

The tax effect on the change in unrealized (loss) gain on investments is \$11,000, \$28,000, and \$65,000 for the years ended December 31, 2005, 2004, and 2003, respectively. The tax effect on the change in fair value of the interest rate swap is zero, zero, and \$88,000 for the years ended December 31, 2005, 2004, and 2003, respectively. The tax effect of the translation adjustment is \$64,000, \$17,000, and \$167,000, for the years ended December 31, 2005, 2004, and 2003, respectively.

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Components of accumulated other comprehensive income consist of the following, net of tax (in thousands):

	2005	2004
Unrealized gain on investments	\$ (2)	\$ 32
Translation adjustment	125	329
Total accumulated other comprehensive income	<u>\$ 123</u>	<u>\$ 361</u>

## 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 2005 and 2004 and up to 5% of each participant's salary in 2003. Total Company contributions approximated \$296,000, \$312,000, and \$350,000 for 2005, 2004, and 2003, respectively. Additionally, the Company may make discretionary contributions to the Plan that are allocated to each participant's account. No discretionary contributions were made in 2005, 2004, or 2003.

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, 2005 and 2004 there were 281,000 and 331,000, respectively, shares of common stock reserved under the ESPP and there were 619,000 and 569,000, respectively, shares issued under the plan.

## 15. Loss Per Share

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

	2005	2004	2003
Numerator for basic loss per common share:			
Net loss	\$ (19,535)	\$ (18,749)	\$ (32,294)
Effect of preferred stock <sup>a</sup>	(777)	—	—
Net loss applicable to common shares	<u>\$ (20,312)</u>	<u>\$ (18,749)</u>	<u>\$ (32,294)</u>
Denominator for basic loss per common share:			
Basic weighted-average shares	<u>23,959</u>	<u>23,043</u>	<u>19,684</u>
Basic loss per common share	<u>\$ (0.85)</u>	<u>\$ (0.81)</u>	<u>\$ (1.64)</u>

Numerator for diluted loss per common share:			
Net loss	\$ (19,535)	\$ (18,749)	\$ (32,294)
Effect of preferred stock <sup>a, b</sup>	(777)	—	—
Net loss applicable to common shares	<u>\$ (20,312)</u>	<u>\$ (18,749)</u>	<u>\$ (32,294)</u>
Denominator for diluted loss per common share:			
Basic weighted-average shares	23,959	23,043	19,684
Effect of dilutive convertible preferred stock <sup>b</sup>	—	—	—
Effect of dilutive stock options <sup>c</sup>	—	—	—
Adjusted weighted-average shares	<u>23,959</u>	<u>23,043</u>	<u>19,684</u>
Diluted loss per common share	<u>\$ (0.85)</u>	<u>\$ (0.81)</u>	<u>\$ (1.64)</u>

a The amount of the accumulated dividend on the Preferred Stock increases the net loss applicable to common shares by \$777,000 for the year ended December 31, 2005.

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b The adjustment for voluntary conversions of Preferred Stock which took place during the period from March 18, 2005 through December 31, 2005 and the adjustment for the quarterly revaluation of the derivative liability, would have 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 shares by 2.0 million for the year ended December 31, 2005, respectively. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

c The additional stock based compensation expense for unvested options to be recorded in future periods would have increased the net loss applicable to common shares by \$495,000 for the year ended December 31, 2005. Outstanding options to purchase the Company's common stock would have resulted in additional dilutive common shares of 331,000 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.

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

	2005	2004	2003
Current:			
Federal	\$ (428)	\$ (3,017)	\$ (2,502)
State	—	27	(23)
Deferred	(428)	(2,990)	(2,525)
	—	(27)	5,593
	<u>\$ (428)</u>	<u>\$ (3,017)</u>	<u>\$ 3,068</u>

The Company's income tax benefit of \$428,000 in 2005 was primarily related to carrybacks of the Company's product liability expenses in 2005 and 2004 which are expected to generate income tax refunds of approximately \$453,000 in 2006, the adjustment of previously estimated product liability carrybacks, foreign taxes on income of the Company's wholly owned European subsidiary, and adjustments of the Company's net operating loss carryforwards.

Such amounts differ from the amounts computed by applying the U.S. federal income tax rate of 34% in 2005, 2004, and 2003 to pretax income as a result of the following (in thousands):

	2005	2004	2003
Tax benefit at statutory rate	\$ (6,787)	\$ (7,400)	\$ (9,937)
Increase (reduction) in income taxes resulting from:			
Deferred tax valuation	6,493	4,477	13,701
Entertainment expenses	76	67	70
State income taxes, net of federal benefit	(132)	(182)	(218)
Nontaxable interest income	(10)	(27)	(110)
Extraterritorial income exclusion	55	(54)	(20)



Equity compensation	31	—	—
Gain on preferred stock dividend make whole payments	(49)	—	—
Other	(105)	102	(418)
	<u>\$ (428)</u>	<u>\$ (3,017)</u>	<u>\$ 3,068</u>

For the year ended December 31, 2005 and 2004, the Company generated federal income tax losses that can be carried back to offset income taxes paid and are expected to result in approximately \$453,000 in refunds to the Company during 2006.

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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):

	2005	2004
Long-term deferred tax (liabilities) assets:		
Property	\$ (607)	\$ (1,016)
Intangible assets	(142)	(23)
Loss carryforwards	24,790	16,779
Other	—	—
Less valuation allowance	(24,041)	(15,740)
	<u>—</u>	<u>—</u>
Current deferred tax (liabilities) assets:		
Unrealized loss on marketable securities	—	(15)
Allowance for bad debts	36	29
Accrued expenses	2,337	2,929
Prepaid items	(422)	(661)
Deferred preservation costs and inventory reserves	258	533
Other	179	281
Less valuation allowance	(2,388)	(3,096)
	<u>—</u>	<u>—</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2005 the Company updated the evaluation of its deferred tax assets. The Company reviewed its historic operating results, including the operating losses which continued in 2005, uncertainties regarding projected future operating results due to the effects of the FDA Order and subsequent activity, changes in processing methods subsequent to the FDA Order, and the uncertainty of the outcome of the remaining product liability claims. Based on the results of this analysis 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, 2005 the Company had a total of \$26.4 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero. The Company's federal net operating loss carryforwards will begin to expire in the 2024 tax year and its research and development tax credit carryforwards will begin to expire in 2010.

#### 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, 2004, or 2003. In 2004 the Company awarded as a bonus amounts contributed by the Company to policies for two departing executive officers who 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 who 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 \$27,000, \$30,000, and \$83,000 in 2005, 2004, and 2003, respectively, relating to supplies for clinical trials from a company whose CFO and Senior VP is a member of the Company's Board of Directors and a shareholder of the Company. In addition, in 2003 the Company expensed \$101,000 relating to services performed by a law firm whose sole proprietor is a member of the Company's Board of Directors and a shareholder of the Company, \$5,000 relating to consulting services performed by a member of the Company's Board of Directors and a shareholder of the Company, and \$19,000 relating to research performed by the university where the same Director and shareholder holds a significant position.

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#### 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):

	2005	2004	2003
Revenue:			
Implantable Medical Devices	\$ 38,932	\$ 36,637	\$ 28,263
Human Tissue Preservation Services	30,307	25,676	30,777
All Other <sup>a</sup>	43	71	492
	<u>\$ 69,282</u>	<u>\$ 62,384</u>	<u>\$ 59,532</u>
Cost of Products and Preservation Services:			
Implantable Medical Devices	\$ 8,065	\$ 7,818	\$ 7,506
Human Tissue Preservation Services	24,357	29,807	23,976
	<u>\$ 32,422</u>	<u>\$ 37,625</u>	<u>\$ 31,482</u>
Gross Margin (Loss):			
Implantable Medical Devices	\$ 30,867	\$ 28,819	\$ 20,757
Human Tissue Preservation Services	5,950	(4,131)	6,801
All Other <sup>a</sup>	43	71	492
	<u>\$ 36,860</u>	<u>\$ 24,759</u>	<u>\$ 28,050</u>

<sup>a</sup> The All Other designation includes grant revenue.

Net revenues by product for the years ended December 31, 2005, 2004, and 2003 were as follows (in thousands):

	2005	2004	2003
Products:			
BioGlue	\$ 37,985	\$ 35,745	\$ 27,784
Bioprosthetic devices	947	892	479
Total products	38,932	36,637	28,263
Human tissue preservation services:			
Cardiovascular tissue	13,762	12,504	17,059
Vascular tissue	11,453	10,293	12,655
Orthopaedic tissue	5,092	2,879	1,063
Total preservation services	30,307	25,676	30,777
Grant revenue	43	71	492
	<u>\$ 69,282</u>	<u>\$ 62,384</u>	<u>\$ 59,532</u>

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Net revenues<sup>b</sup> by geographic location for the years ended December 31, 2005, 2004, and 2003 were as follows (in thousands):

	2005	2004	2003
U.S.	\$ 58,869	\$ 53,244	\$ 51,949
International	10,413	9,140	7,583
Total	<u>\$ 69,282</u>	<u>\$ 62,384</u>	<u>\$ 59,532</u>

b Net external revenues are attributed to countries based on the location of the customer.

At December 31, 2005, 2004, and 2003, over 95% of the long-lived assets of the Company were held in the U.S., where all Company manufacturing facilities and the corporate headquarters are located.

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**SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**  
(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE:				
2005	\$ 17,665	\$ 17,198	\$ 16,458	\$ 17,961
2004	15,086	15,314	16,118	15,866
2003	15,920	15,713	15,097	12,802
GROSS MARGIN:				
2005	\$ 9,650	\$ 9,049	\$ 8,503	\$ 9,658
2004	4,036	5,877	6,996	7,850
2003	11,836	8,547	5,834	1,833
NET LOSS:				
2005	\$ (1,357)	\$ (14,379)	\$ (3,118)	\$ (681)
2004	(7,026)	(3,352)	(6,008)	(2,363)
2003	(434)	(19,921)	(4,695)	(7,244)
LOSS PER SHARE—DILUTED:				
2005	\$ (0.06)	\$ (0.61)	\$ (0.14)	\$ (0.06)
2004	(0.32)	(0.14)	(0.26)	(0.10)
2003	(0.02)	(1.01)	(0.24)	(0.37)

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SCHEDULE II

**CRYOLIFE, INC. AND SUBSIDIARIES**  
**VALUATION AND QUALIFYING ACCOUNTS**  
Years ended December 31, 2005, 2004, and 2003

Description	Balance Beginning of Period	Additions	Deductions	Balance End of Period
Year ended December 31, 2005				
Allowance for doubtful accounts	\$ 85,000	\$ 57,000	\$ 37,000	\$ 105,000
Deferred preservation costs	—	—	—	—
Year ended December 31, 2004				
Allowance for doubtful accounts	\$ 65,000	\$ 53,000	\$ 33,000	\$ 85,000
Deferred preservation costs	50,000	—	50,000	—
Year ended December 31, 2003				
Allowance for doubtful accounts	\$ 75,000	\$ 38,000	\$ 48,000	\$ 65,000
Deferred preservation costs	50,000	22,000	22,000	50,000

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## SUBSIDIARIES OF CRYOLIFE, INC.

Subsidiary	Jurisdiction
CryoLife Acquisition Corp.	Florida
CryoLife Technology, Inc.	Nevada
CryoLife Europa, LTD.	England and Wales
AuraZyme Pharmaceuticals, Inc.	Florida
CryoLife International, Inc.	Florida

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement Nos. 333-112673, 333-16581, 333-112673 and 333-121406 of CryoLife, Inc. on Form S-3 and Registration Statement Nos. 33-83996, 33-84048, 333-03513, 333-59853, 333-06141, 333-34025, 333-75535, 333-47310, 333-10463 and 333-119137 of CryoLife, Inc on Form S-8 of our reports dated February 23, 2006 relating to the consolidated financial statements and financial statement schedule of CryoLife, Inc. (which i) expresses an unqualified opinion and ii) includes an explanatory paragraph relating to the October 1, 2005 adoption of Statement of Financial Accounting Standards No. 123R "Share Based Payment" which is discussed in Note 1) and management's report of the effectiveness of internal control over financial reporting, appearing in this Annual Report on Form 10-K of CryoLife, Inc. for the year ended December 31, 2005.

DELOITTE & TOUCHE LLP  
Atlanta, Georgia  
February 23, 2006

I, Steven G. Anderson certify that:

1. I have reviewed this annual report on Form 10-K of CryoLife, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 23, 2006

/s/ STEVEN G. ANDERSON  
Chairman, President, and  
Chief Executive Officer

I, David Ashley Lee certify that:

1. I have reviewed this annual report on Form 10-K of CryoLife, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 23, 2006

/s/ DAVID ASHLEY LEE  
Executive Vice President,  
Chief Operating Officer, and  
Chief Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of CryoLife, Inc. (the "Company") on Form 10-K for the year ending December 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Steven G. Anderson, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN G. ANDERSON

STEVEN G. ANDERSON  
Chairman, President, and  
Chief Executive Officer

February 23, 2006

/s/ DAVID ASHLEY LEE

DAVID ASHLEY LEE  
Executive Vice President,  
Chief Operating Officer, and  
Chief Financial Officer

February 23, 2006