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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2004

OR

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

For the transition period from to

Commission file number 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida (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:

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

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

None

Indicate by check mark 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 an accelerated filer (as defined in Rule 12b-2 of the Act). ☒ Yes No

As of June 30, 2004, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $109,259,179 computed using the closing price of $5.27 per share of Common Stock on June 30, 2004, 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 18, 2005 the number of outstanding shares of Common Stock of the registrant was 23,442,897.

Documents Incorporated By Reference

Inapplicable.

PART I

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 50 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 including countries within Latin America and Asia. The recently available syringe delivery system provides BioGlue without a separate delivery system. This syringe design configuration was approved by the FDA, was added to the CE Mark approval in May 2004, and is currently under review in Canada.

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.

CryoLife's BioGlue is the base for several potential products in development. Potential product line extensions include modifications to the BioGlue delivery system. CryoLife is researching the use of derivatives of the BioGlue technology as a potential replacement for spinal disc nuclei and for use in addressing endovascular graft leaks and in trauma surgery. Another derivative of the BioGlue technology, BioLastic™, might potentially be used for reinforcing or patching vascular tissue and reducing adhesions.

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.

The Company's products are often marketed internationally several years before they can be marketed in the U.S. In 2004 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 "Risk Factors" below.

Recent Events

CryoLife is a nominal defendant in a purported shareholder derivative action against the individuals who were directors of the Company at the time of the FDA Order as discussed below in Part I, Item 3 "Legal Proceedings". In early December 2004, the court denied the defendant's motion to dismiss. See "Risk Factors—CryoLife's Insurance Coverage Has Been and May Be Either Unavailable or Insufficient—Shareholder Derivative Action" below for more details.

Effective November 3, 2004 the Company promoted D. Ashley Lee from Vice President, Finance and Chief Financial Officer to Executive Vice President, Chief Operating Officer, and Chief Financial Officer.

On December 14, 2004 CryoLife announced that Albert E. Heacox, Ph.D. had assumed the position of Senior Vice President of Research and Development of CryoLife, Inc. He replaces Kirby S. Black, Ph.D. Reporting to Dr. Heacox are CryoLife's Research and Development Laboratory, Product and Process Engineering, and AuraZyme Pharmaceuticals' Research Department.

On December 17, 2004 the Company announced that it had filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission ("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. As of February 21, 2005 no offering of securities had been commenced in accordance with this registration statement.

On January 10, 2005 CryoLife and Endologix, Inc. announced the signing of a development and marketing agreement for the precutaneous or endovascular delivery of CryoLife's BioFoam as a self-expanding sealant for addressing endovascular graft leaks. Under the agreement, Endologix will be responsible for preclinical, clinical, and regulatory activities and costs, and CryoLife will manufacture BioFoam for clinical use and commercial sale and receive a royalty on potential future product sales. See "Research and Development" below.

On February 1, 2005 the Company announced that it received accreditation from the American Association of Tissues Banks ("AATB"). The AATB is a scientific, not-for-profit peer group organization that facilitates the provision of transplantable human tissues in quantities sufficient to meet national needs.

On February 8, 2005 CryoLife and its subsidiaries entered into a new credit agreement with Wells Fargo Foothill, Inc. as lender. 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 million) or a borrowing base determined in accordance with the terms of the credit agreement. See Part I, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" for further information.

FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices

FDA Order

The FDA inspected the Company's tissue processing operations in December 2001, after it was reported that a Minnesota man had died after receiving an implant of orthopedic tissue processed by the Company. The FDA conducted another inspection in March 2002. In April 2002 the FDA issued a Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter was issued, dated June 17, 2002 ("Warning Letter"). 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 steps to ensure that the tissue was used for approved purposes and that patients were notified of risks associated with tissue use. The FDA Agreement had a renewable 45-business day term and the final renewal expired on September 5, 2003. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). A renewal of the FDA Agreement that expired on September 5, 2003 was not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

In addition, pursuant to the FDA Agreement, the Company agreed to perform additional procedures in the processing of non-valved cardiac and vascular tissues and subsequently resumed processing these tissues. The Company also agreed to establish a corrective action plan within 30 days from September 5, 2002 with steps to validate processing procedures. The corrective action plan was submitted on October 5, 2002, and executed thereafter. The corrective actions taken have been reviewed by the FDA during three subsequent inspections as discussed in "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices—Other FDA Correspondence and Notices" below.

See Note 2 to the consolidated financial statements for a discussion of the accounting treatment resulting from the FDA Order.

Other FDA Correspondence and Notices

FDA Form 483 Notices of Observations ("483") were issued in connection with the FDA inspections of the Company's facilities in February 2003, October 2003, and February 2004. The Company responded to the February 2003 483 in March 2003, responded to the October 2003 483 in October 2003, November 2003, and April 2004, and responded to the February 2004 483 in March 2004, April 2004, and June 2004. On September 24, 2004 CryoLife received an inquiry from the FDA Atlanta District Office seeking additional information on four items submitted by CryoLife in response to the February 2004 483 to which CryoLife responded on November 8, 2004. In response to the Form 483 Notice of Observations, the Company has implemented new and revised existing processing, preservation, and testing procedures. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information. The Company continues 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. CryoLife anticipates responding to some of these additional requests and has initiated an appeal of others through administrative procedures. 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 is currently subject to an administrative appeal. Unless this appeal is successful, CryoLife will be unable to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted. In the event that the Company is not successful in appealing the FDA's decision to regulate SynerGraft cardiovascular tissue as a medical device, the Company will evaluate whether it will file and seek a premarket approval for CryoVein SG or discontinue the CryoVein SG product.

In 2003 the Company has 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 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, 2004 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Consolidated Balance Sheet.

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

Strategy

The Company's primary objective is to grow 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:

- *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.

- *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, prospective tissue recipients, and tissue procurement agencies, (iii) improving and expanding its relationships with the approximately 70 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.

- *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.

- *Develop and Commercialize Bioprosthetic SynerGraft Vascular Devices*. The Company intends to leverage its expertise with human vascular grafts and bioprosthetic devices as a platform for the development and commercialization of its SynerGraft processed bovine vascular grafts. In July of 2001 the Company received CE Mark approval for its SynerGraft Model 100 vascular graft that is presently being marketed outside the U.S. as an A-V access graft.

- *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 compliment existing services and products.

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. Other potential product line extensions include a new syringe and additional applicator tips.

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 preclinical research into whether PHT could be used as a replacement for spinal disc nuclei and for use in addressing endovascular graft leaks and in trauma surgery. Another PHT product, the Company is conducting preclinical research on, BioLastic™, might potentially be used for reinforcing or patching vascular tissue and reducing adhesions.

The Company estimates that the number of procedures where tissue sealants could be used was approximately 3.4 million in 2004. CryoLife can distribute BioGlue throughout the U.S. and more than 50 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 including countries within Latin America and Asia. In mid-2004 the Company introduced the 2 ml and the 5 ml syringe delivery system, which provides BioGlue without a separate delivery system. Prior to the release of the syringe delivery system, BioGlue was only available for use with a two-part applicator system. This newly introduced syringe design configuration was approved by the FDA and added to the CE Mark approval in May 2004, and is currently under review in Canada. Revenues from BioGlue represented 27%, 47%, and 57% of total revenues, respectively, in 2002, 2003, and 2004.

Preservation of Human Tissue for Transplant

The Company's proprietary preservation process involves the recovery of tissue from deceased human donors by tissue bank and organ procurement organizations, the timely and controlled delivery of such tissue to the Company, the screening, dissection, disinfection, and preservation of the tissue by the Company, the storage and shipment of the cryopreserved tissue, and the controlled thawing of the tissue. Thereafter, the tissue is surgically implanted into a human recipient.

The transplant of human tissue that has not been preserved must be accomplished within extremely short time limits (for example less than eight hours for transplants of the human heart). Prior to the advent of human tissue cryopreservation, these time constraints resulted in the inability to use much of the tissue donated for transplantation. The application of the Company's cryopreservation technologies to donated tissue expands the amount of human tissue available to physicians for transplantation. Cryopreservation also expands the treatment options available to physicians and their patients by offering alternatives to implantable mechanical, synthetic, and animal-derived devices. The tissues presently cryopreserved by the Company include human heart valves, non-valved conduits, 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 58,500 cryopreserved human heart valves and conduits from 1984 through 2004, including approximately 2,200 shipments in 2004. Revenues from human heart valve and conduit preservation services accounted for 30%, 29%, and 20% of total revenues, respectively, in 2002, 2003, and 2004. Based on CryoLife's records of documented implants, management believes that the acceptance of the Company's cryopreserved allograft heart valve is due in part to physicians' recognition of the longevity and natural functionality of the Company's cryopreserved human tissues, the Company's documented clinical data, and the Company's technical representation, which includes its direct technical service representatives and customer service department. Management believes the Company offers advantages in the area of clinical data and technical service representatives as compared to other allograft processors and that the Company's allograft tissues offer advantages in certain areas over mechanical, porcine, and bovine heart valve alternatives. The Company currently applies its preservation services to human aortic and pulmonary heart valves for implantation by cardiac surgeons. In addition, the Company provides cryopreserved human non-valved conduit and patch tissue to surgeons who wish to perform certain specialized cardiac repair procedures. Each of these cryopreserved human heart valves, non-valved conduits, and patches maintains a tissue structure which more closely resembles and performs like the patient's own tissue than non-human tissue alternatives.

In February 2000 the Company began distributing in the U.S. cryopreserved human heart valves and conduits utilizing its SynerGraft 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 2004 was in excess of $400 million. Management believes that approximately 86,000 heart valve surgeries were conducted in the U.S. in 2004. Of this total number of heart valve and conduit surgeries, approximately 24,000, or 28%, involved mechanical heart valves, and approximately 62,000, or 72%, 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.

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:

	Cryopreserved Human	Porcine		Mechanical	Bovine Pericardium
		Stented	Stentless		
Materials:	human tissue	glutaraldehyde-fixed pig tissue and synthetic sewing ring	glutaraldehyde-fixed pig tissue	pyrolitic carbon bi-leaflet and synthetic sewing ring	glutaraldehyde-fixed cow tissue and synthetic sewing ring
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	low	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 (3mm to 6mm), 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 40,700 human vascular tissues from 1986 through 2004, which includes 2,400 shipments in 2004. Revenues from human vascular preservation services accounted for 23%, 21%, and 16% of total revenues, respectively, in 2002, 2003, and 2004.

A surgeon's first choice for replacing diseased or damaged vascular tissue is generally the patient's own tissue. However, in cases of advanced vascular disease, the patient's tissue is often unusable, and the surgeon may consider using synthetic grafts or transplanted human vascular tissue. Small diameter synthetic vascular grafts are generally not suitable for below-the-knee surgeries because they have a tendency to occlude over time. Cryopreserved human vascular tissues tend to remain open longer and as such are used in indications where synthetics fail. In addition, synthetic grafts are not suitable for use in infected 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 anticipates reintroducing osteochondral grafts in early 2005. Additionally, the Company expects to offer a service, which includes a process for gamma irradiation of certain orthopaedic tissues. 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 bacteria, viruses, and fungi. CryoLife shipped approximately 27,800 human connective tissues for the knee through the end of 2004, which includes approximately 900 shipments in 2004. Revenues from human orthopaedic preservation services accounted for 18%, 2%, and 5% of total revenues, respectively, in 2002, 2003, and 2004.

Human menisci provide orthopaedic surgeons with an alternative treatment in cases where a patient's meniscus has been completely removed (meniscectomy). When a patient has a damaged meniscus, the current surgical alternatives are to repair, partially remove, or completely remove the patient's meniscus, with partial removal being the most common procedure. Meniscal removal increases the risk of premature knee degeneration and arthritis, and typically results in the need for knee replacement surgery at some point during the patient's life. Management believes that there are no synthetic total menisci on the market. The Company estimates that in 2004 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 2004 approximately 350,000 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 anticipates reintroducing osteochondral grafts in early 2005. The success of transplanted osteoarticular grafts is attributed to the presence of viable chondrocytes (cells of the cartilage). The Company estimates that in 2004 the cartilage repair market was approximately $30 million of which the osteoarticular allograft market represented approximately $9 million with approximately 1,300 procedures.

Bioprosthetic Cardiovascular and Vascular Devices

The Company is developing 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 2002, 2003, and 2004.

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 $850 million in 2004.

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.

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. 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, 35, and 50 cm. The SynerGraft Model 100 vascular graft can be stored at room temperature.

See "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 Footnote 18 to the consolidated financial statements regarding segment and geographic information.

Procurement, Sales, Distribution, and Marketing

BioGlue

The Company markets and distributes BioGlue in the U.S. 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 70 tissue banks and organ procurement agencies throughout the U.S. Management believes these relationships are critical for a growing business 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 20 individuals to work with organ procurement agencies and tissue banks, six 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°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 315 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 35 persons as technical service representatives 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 100 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 Fareham, England. Europa, with its team of 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, CryoLife O'Brien heart valves, SynerGraft bovine vascular grafts, or certain orthopaedic tissues.

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 14 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, additional applications of its SynerGraft technology, its Protein Hydrogel Technology used in BioGlue, and its Activation Control Technology ("ACT"). The Company is conducting preclinical research into whether PHT could be used as a replacement for spinal disc nuclei and for use in addressing endovascular graft leaks and in trauma surgery. Another PHT product the Company is conducting preclinical research on, BioLastic™, might potentially be used for reinforcing or patching vascular tissue and reducing adhesions.

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 plans to employ it in processing certain human orthopaedic tissue. The Company anticipates shipping its first orthopaedic tissue processed with Clearant technology during the first quarter of 2005.

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 provide hemostatsis in penetrating wounds and severe trauma. The 2005 Defense Appropriations Conference Report included $1 million for the development of BioFoam. CryoLife plans to submit a proposal to the Department of Defense for the use of these funds by the end of February 2005. In January 2005 CryoLife entered into a development and marketing agreement with Endologix, Inc. for the percutaneous or endovascular delivery of CryoLife's BioFoam as a self-expanding sealant for addressing endovascular graft leaks. Under the agreement, CryoLife granted Endologix an exclusive right to BioFoam for this use and Endologix will be responsible for preclinical, clinical, and regulatory activities and costs, and CryoLife will manufacture BioFoam for clinical use and commercial sale and receive a royalty on potential future product sales.

BioDisc™, a derivative of the PHT, is in preclinical development, and may be used 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 it 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.

BioLastic™, a derivative of the PHT, is in preclinical development. BioLastic 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.

The Company's research and development strategy is to allocate available resources among the Company's core market areas of preservation services, bioprosthetic cardiovascular devices, and implantable biomaterials, 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 2002, 2003, and 2004 the Company spent approximately $4.6 million, $3.6 million, and $3.9 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 6% of the Company's revenues for each of the years 2002, 2003, and 2004. 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 campus-style setting in suburban Atlanta, Georgia. Approximately 20,000 square feet are dedicated to thirty-one class 10,000 clean rooms. An additional 5,500 square feet are dedicated as class 100,000 clean rooms. The extensive clean room environment provides a controlled environment for tissue dissection and processing, manufacturing, and packaging. Approximately 55 liquid nitrogen storage units maintain cryopreserved tissue at or below -135°C. Two back-up emergency generators assure continuity of Company 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 54 technicians employed in this area, and the laboratory is staffed for three shifts, 365 days per year. In 2004 the laboratory packaged approximately 12,250 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.

BioGlue

BioGlue is presently manufactured at the Company's headquarters facility. The laboratory contains approximately 13,500 square feet, including a suite of six clean rooms. Currently, there are 16 technicians employed in this area. The laboratory has a potential annual capacity of approximately 2 million cartridges or syringes of BioGlue. The current processing level is about 5% of total capacity. To produce at full capacity levels, the Company would need to increase the number of employees, add work shifts, and install automated filling and pouching equipment.

Bioprosthetic Cardiovascular and Vascular Devices

The bioprosthesis laboratory at the Company's headquarters facility is responsible for the manufacturing of the CryoLife-O'Brien stentless 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 four technicians.

Other Facilities

The Company maintains a separate facility, located in Marietta, Georgia, that is approximately 20,000 square feet with about 2,100 square feet of laboratory space and a suite of six clean rooms. The Company is currently seeking to sublease this facility. In addition, the Company maintains a facility located in Fareham, United Kingdom for its European subsidiary Europa that contains approximately 5,600 square feet of office, warehousing, and training laboratory space. The Company is seeking to move its European operations closer to London, United Kingdom by mid 2005.

Quality Assurance

The Company's operations encompass the provision of 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 ensure 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. This approval is issued by Lloyd's Register Quality Assurance Limited ("LRQA"). LRQA is a Notified Body officially recognized by the EEA to perform assessments of compliance with ISO 9001 and its derivative standards. LRQA performs periodic on-site inspections 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.

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 Quality System Regulations, additional FDA 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 donor sites. 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 Company's tissue processing facilities are annually licensed by the States of Georgia, New York, Florida, Maryland, and California 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. In addition the Company's human heart valve processing operations are regulated by the FDA and periodically inspected for compliance with Quality System Regulations. Human tissue processed by the Company must also comply with FDA regulations for determining the suitability of human tissue for implantation. 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 34 U.S. patents and 65 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 63 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 2 to 17 years. The Company has licensed from third parties certain technologies that call for the payment of both development 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.

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. The earned royalty rate is a maximum of 0.75% of net revenues from products or tissue services utilizing the SynerGraft technology. Through December 31, 2004 $60,000 of this prepaid royalty had been applied to earned royalties. During 2004 CryoLife recorded an additional $260,000 as royalty expense related to the impairment of the prepaid asset due to the uncertainty regarding future SynerGraft royalties. As of December 31, 2004 the remaining balance of the prepaid royalty was $80,000.

The Company has entered into confidentiality agreements with all of 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 is in clinical trials 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 "Risk Factors—Risks Related to CryoLife and The Company's Industry—Rapid Technological Change Could Cause Services And Products To Become Obsolete."

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.

As compared to mechanical, porcine, and bovine heart valves, management believes that the human heart valves cryopreserved by the Company 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 selection of treatment choices is made by the attending physician in consultation with the patient. 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 human tissues 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 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. In addition, various foreign countries in which the Company's products are or may be distributed impose additional regulatory requirements.

The FDCA provides that, unless exempted by regulation, medical devices may not be distributed in the U.S. unless they have been approved or cleared for marketing by the FDA. There are two review procedures by which medical devices can receive such approval or clearance. Some products may qualify for clearance to be marketed under a Section 510(k) ("510(k)") procedure, in which the manufacturer provides a premarket notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed 510(k) product (i.e., that it has the same intended use, it is as safe and effective as a legally marketed 510(k) device, and it does not raise different questions of safety and effectiveness than does a legally marketed device). In some cases, the submission must include data from clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence.

If the product does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed 510(k) device or because it is a Class III device required by the FDCA and implementing regulations to have an approved application for premarket approval, ("PMA"), the FDA must approve a PMA application before marketing can begin. PMA applications must demonstrate, among other matters, that the medical device is safe and effective. A PMA application is typically a complex submission, usually including the results of human clinical studies, and preparing an application is a detailed and time-consuming process. Once a PMA application has been submitted, the FDA's review may be lengthy and may include requests for additional data. 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 are 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 premarket approval.

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.

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 allows the Company to distribute such valves to cardiovascular surgeons throughout the U.S.

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 two 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. BioGlue is regulated as a Class III medical device by the FDA. 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. Heart valves are one of a small number of processed human tissues over which the FDA has 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 ("CGTPs"). The Company had already implemented many of the new requirements and plans to have the remaining requirements implemented by April 2005. Both the new donor eligibility rule and the CGTP rule become effective on May 25, 2005, at which time, human heart valves are currently scheduled to be designated as human tissue rather than medical devices. CryoLife does not anticipate incurring significant additional expenses in order to comply with the requirements of the donor eligibility rule and the CGTPs in a timely manner.

It is likely that the FDA's regulation of processed human tissue will continue to evolve in the future. For example, the FDA may determine that the vascular and orthopaedic tissues that are processed by the Company are medical devices, but the FDA has not done so at this time. 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. In addition, the U.S. Congress may consider legislation that would regulate human tissue for transplant or the FDA could impose a separate regulatory scheme for human tissue. Such legislation or regulation could have a material adverse effect on the Company.

As discussed in "—FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices", the Company filed an administrative appeal on an RFD submitted in October 2004 regarding SynerGraft processed cardiovascular tissue, including the CryoVein SG. Unless this appeal is successful CryoLife will be unable to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted. In the event that the Company is not successful in appealing the FDA's decision to regulate SynerGraft cardiovascular tissue as a medical device, the Company will evaluate whether it will file and seek a premarket approval for the 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, while others may be classified as drugs or biological products or subject to a regulatory scheme for human tissue 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 may be exported to specified developed nations, including countries in the EEA, Australia, Canada, Israel, United Arab Emirates, Turkey, and Switzerland. The Company's SynerGraft Model 100 vascular graft may also be exported to Switzerland, Turkey, and Israel.

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 25, 2005 the Company had approximately 349 employees. These employees included eight persons with Ph.D. degrees and two with M.D. degrees. 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*, on the day of filing. All of such filings made on or after November 15, 2002 have been made available on the website.

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, both of which remain pending. 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. The combined effect of these challenges has been to reduce Company revenues, increase its costs to process tissues and its operating expenses, and strain management resources. Although CryoLife has now 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, 2004 and anticipates net losses and negative cash flow from operations for the full year of 2005.

The Company expects that the following factors will continue to have an adverse effect on earnings and cash flows during 2005:

- The anticipated lower preservation service revenues as compared to preservation service revenues prior to the FDA Order, subsequent FDA activity, and related events,
- 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 have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,
- An expected use of cash related to the defense and resolution of lawsuits and claims, and
- The legal and professional costs related to ongoing FDA compliance.

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

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

- The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,
- The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- The amount and timing of the resolution of the remaining outstanding product liability lawsuits and other claims,
- The outcome of other litigation against the Company, and
- To a lesser degree, the Company's success at resolving the issues with the FDA regarding SynerGraft processing of human tissue.

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 Terms Acceptable To The Company Or Dilutive To Existing Shareholders.

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 condition, results of operations, and cash flows. Issuance of equity capital may be dilutive to existing shareholders.

The Company's New 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:

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

- the lesser of
  - $15 million or
  - 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;
- *minus* all outstanding obligations under the credit agreement including outstanding letters of credit;
- *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 borrowing 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 Increasingly Dependent On Its Revenues From BioGlue And Is Subject To A Variety Of Risks Affecting This Product.

BioGlue has become an increasingly important 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 2004 these revenues were approximately $25.7 million or 41% of 2004 revenues.

The FDA Order, subsequent FDA activity, and resulting adverse publicity have 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 there is a possibility that CryoLife may not generate sufficient cash from operations, to fund its operations 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 effect 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 improve its relationships with those procurement agencies and CryoLife is unable to obtain tissues from procurement agencies that have ceased sending tissue to CryoLife for processing, 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, 2004, revenues from preservation services for orthopaedic tissue were $2.9 million, which represented 5% of CryoLife's revenues.

The demand for orthopaedic tissue from CryoLife may not return to the levels in existence before the FDA Order, even though CryoLife has resumed processing after altering the Company's procedures. Furthermore, there can be no assurance that CryoLife's anticipated offering of osteochondral tissue will be successful. As a result, this portion of CryoLife's business may be discontinued or may only continue at substantially reduced levels. Either of these results would 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 not been and may not be adequate to cover the amounts owed by the Company under those claims. 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.

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 new Form 483 Notices of Observations in February and October 2003, and another in February 2004. Among the issues raised in the February 2004 483 were the validation and effectiveness of the antimicrobial solution the company uses in processing tissue; the validation of the company's rinse-recovery method; and the company's monitoring and reporting of providers/suppliers' non-compliance with company procedures for obtaining, handling, and transporting tissue. 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), currently regulated as Class II medical devices, was considered to be a major manufacturing change requiring a 510(k) submission. CryoLife submitted a 510(k) for CryoValve SG and has received two 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 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 appealed the designation of SynerGraft-processed cardiovascular tissue as medical devices. Discussions with the FDA to resolve this issue are ongoing. Resolution of this matter could be time-consuming and expensive, depending in large part on the success of the Company's efforts under the FDA's administrative processes. 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.

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 additional regulatory concerns are raised by other countries, CryoLife may be unable to export tissues to those countries. Revenue from international human tissue preservation services was $721,000 and $421,000 for the years ended December 31, 2003 and 2004, 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. As of the date hereof, the SEC has had no discussions with CryoLife representatives as to whether or against whom it will seek 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.

Product Liability Claims

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 have 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.

As of February 21, 2005 the Company had three outstanding product liability lawsuits against the Company that are covered by three separate insurance policies, beginning with the policy year 2000/2001. The Company believes its insurance policies to be adequate to defend against the covered lawsuits in each of these time periods. Additionally, the Company has five 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 that have not resulted in lawsuits. The Company is monitoring these claims.

CryoLife's December 31, 2004 Consolidated Balance Sheet reflects a liability in the amount of approximately $2.8 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, 2004 Consolidated Balance Sheet also reflects an $8.2 million liability, 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 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 I, 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.

If CryoLife is unsuccessful in arranging acceptable settlements of product liability claims, there may not be sufficient insurance coverage and liquid assets to meet these obligations. Additionally, if one or more of the product liability 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 product liability 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.

Class Action Lawsuit

Several putative class action lawsuits were filed in July through September 2002 against CryoLife and certain officers of CryoLife, 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, which principally alleges that CryoLife made misrepresentations and omissions relating to product safety and CryoLife's alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. CryoLife 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. At present, discovery in the case has closed, and the Court has instructed the parties to serve their dispositive motions, if any, by March 11, 2005. Although CryoLife carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment in excess of CryoLife's available insurance coverage could have a material adverse effect on CryoLife's financial position, results of operations, and cash flows. At this time, CryoLife is unable to predict the outcome of this litigation.

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 names the Company as a nominal defendant, alleges 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 seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of the Company. As previously disclosed, the Company's Board of Directors established a committee it determined to be independent to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel, evaluated the consolidated amended complaint and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of the Company. Based on the report of the independent committee, the Company moved to dismiss the derivative action in May 2004. In an order dated December 1, 2004, the Court denied the motion to dismiss, such that the case will proceed into the discovery phase. At this time, the Company is unable to predict the outcome of this litigation. Although the derivative suit is brought nominally on behalf of the Company, the Company expects to continue to incur defense costs and other expenses in connection with the derivative litigation.

Insurance Coverage May Be Difficult Or Impossible To Obtain In The Future And If Obtained, The Cost Of Insurance Coverage Is Likely To Be Much More Expensive Than In The Past.

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 is a two-year claims-made policy, covering claims arising since the commencement of the 2003/2004 policy year. The Company's current insurance policy expires in March 2005. The Company is currently evaluating with prospective insurers available coverage and cost. The Company presently expects increases in both cost and retention, although it also expects coverage to be a three-year claims-made policy. There is no assurance the Company will be successful in obtaining satisfactory coverage upon expiration of its current coverage.

Intense Competition May Affect 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 four 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 recently updated its plans to launch an absorbable surgical sealant 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, 2005. 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. As compared to mechanical, porcine, and bovine heart valves, CryoLife believes that the human heart valves cryopreserved by CryoLife 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 with the products of these or other companies. Any products developed by CryoLife that gain regulatory clearance or approval would 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 and related adverse publicity had an adverse effect on CryoLife's competitive position, which had a material adverse effect on CryoLife's results of operations. The FDA Order and subsequent FDA activity may continue to have an adverse effect on CryoLife's competitive position, which may continue to have a material adverse effect on CryoLife's results of operations. As a result, 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 its 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 remains 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.

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 has now been 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 (Activation Control Technology) 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:

- unexpected changes in regulatory requirements and tariffs;
- difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships;
- longer accounts receivable collection cycles in certain foreign countries;
- adverse economic or political changes;
- unexpected changes in regulatory requirements;
- more limited protection for intellectual property in some countries;
- changes in the Company's international distribution network and direct sales force;
- changes in currency exchange rates;
- potential trade restrictions, exchange controls and import and export licensing requirements; and
- potentially adverse tax consequences of overlapping tax structures.

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; Sidney B. Ashmore, Vice President, Marketing; David M. Fronk, Vice President, Clinical Research; Albert E. Heacox, Ph.D., Senior Vice President, Research and Development; and Thomas J. Lynch, J.D., Ph.D., Vice President, Regulatory Affairs and Quality Assurance. CryoLife has employment agreements with these key personnel. Mr. Anderson's employment agreement, which expires September 3, 2005, provides for payment of $900,000 if his employment is terminated other than for cause, death, disability, or by him for good reason. Mr. Anderson and the Compensation Committee of CryoLife's Board of Directors are currently negotiating a new agreement. The others expire in August 2005 or September 2005, except for Mr. Lynch's, which expires in August 2006. They provide for payments ranging from $240,000 to $360,000 if employment is terminated other than for cause, death, disability, or by the employee for good reason. 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.

Risks Related To CryoLife And The Company's 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 heart valves such as those processed by CryoLife are currently regulated as Class II medical devices by the FDA and are subject to significant regulatory requirements, including Quality System Regulations and record keeping requirements. Changes in regulatory treatment or the adoption of new statutory or regulatory requirements are likely to occur, which could adversely impact the marketing or development of these products or could adversely affect market demand for these products. Other 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 a regulation that will implement good tissue practices, akin to good manufacturing practices, followed by tissue banks and processors of human tissue. It is anticipated that these good tissue practice regulations, when made effective, 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 EC 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 and the preparation of 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 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. 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.

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, transplantation, 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 state 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. Additionally, 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.

Uncertainties Regarding Future Health Care Reimbursement May Affect The 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.

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 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 regulatory actions such as the FDA Order, recent product liability claims, variations in operating results, 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 stock would likely decline further, perhaps substantially. Changes in the trading price of CryoLife's common 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, 2002 to February 21, 2005 has ranged from a high of $31.31 to a low of $1.89.

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. For example, the Florida Business Corporation Act imposes a requirement that a two-thirds vote of the stockholders is required to approve certain transactions with certain 10% stockholders unless the transaction is approved by disinterested directors. Further, pursuant to the terms of a shareholder rights plan adopted in 1995, 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.

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 New 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 services, market expansion, revenues, cost savings, 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 "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:

- adequacy of product liability insurance to defend against lawsuits;
- the outcome of lawsuits filed against the Company, and of the SEC investigation;
- the impact of the FDA Order and subsequent FDA activity, including the FDA's letters regarding the SynerGraft process and measures taken by the Company as a result, on future revenues, profits and business operations;
- the effect of the FDA Order and subsequent FDA activity on sales of BioGlue;
- the impact of the FDA's Form 483 Notices of Observation;
- the estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies, as well as the estimates of the amounts accrued for product liability claims incurred but not reported;
- future costs of human tissue preservation services, including the Company's ability to increase yields and reduce its costs of tissue preservation services;
- the Company's competitive position, including the impact of price increases;
- product demand and market growth;
- the potential of the ACT for use in fibrinolysis (blood clot dissolving) and other drug delivery applications;

- the impact on the Company of adverse results of surgery utilizing tissue processed by it; and
- other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including the risk factors discussed in this Form 10-K and other factors, many of which are beyond the control of CryoLife. Consequently, all of the forward-looking statements made in this Form 10-K are qualified by these cautionary statements and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

Item 2. Properties.

The Company's facilities are located in suburban Atlanta, Georgia, and in Fareham, United Kingdom. The Atlanta facilities consist of two separate locations totaling approximately 220,000 square feet of leased office, manufacturing, laboratory, and 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 BioGlue manufacturing laboratory contains approximately 13,500 square feet with a suite of six clean rooms. 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. One additional facility contains approximately 20,000 square feet, with about 2,100 square feet of laboratory space and a suite of six clean rooms. The Europa facility located in Fareham, United Kingdom contains approximately 5,600 square feet of office, warehousing, and training laboratory space. Subsequent to the sale of the Ideas for Medicine, Inc. ("IFM") assets, the Company continues to lease the 30,000 square foot IFM facility in St. Petersburg, Florida from the former principal shareholder of IFM. A wholly owned subsidiary of LeMaitre Vascular, Inc. currently subleases the IFM facility from the Company. The Company's lease and sublease on its IFM facility expires in 2007.

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 than has historically been experienced have been filed. As of February 21, 2005 the Company was aware of eight pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, three 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, one alleges product liability claims arising from BioGlue, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, Inc. when it was a subsidiary of the Company.

As of February 21, 2005 the Company had three outstanding product liability lawsuits against the Company that are covered by three separate insurance policies, beginning with the policy year 2000/2001. The Company believes its insurance policies to be adequate to defend against the covered lawsuits in each of these time periods. Additionally, the Company has five 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 that have not resulted in lawsuits. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2004 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, 2004 the Company had accrued a total of $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. This amount represents the Company's estimate of the probable losses related to two settled but unpaid claims and three of the eight pending product liability claims. The Company has not recorded an accrual for the remaining five 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 amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. Prior to 2004, the Company recorded accruals for the uninsured portion of product liability claims for which the amount of probable loss was reasonably estimable. Had the Company recorded the total amounts of the reasonably estimable probable losses as a liability and recorded an asset for the estimated amount recoverable from the insurance carrier, the impact on the financial statements as of December 31, 2003 would not have been material. 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 many 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, 2004 the Company bound coverage for the 2004/2005 insurance policy year. This policy is a two-year claims made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2005 and reported during the period April 1, 2004 through March 31, 2005 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 sold. In January 2005 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2004. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby, projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- A ceiling of $5 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of $5 million,
- The future claim reporting lag time would be a blend of the Company's experiences and industry data,
- The frequency of unreported claims for accident years 2001 through 2004 would be lower than the Company experienced during the 2002/2003 policy year, but higher than the Company's historical claim frequency in prior policy years,
- The average cost per claim would be lower than the Company experienced during the 2002/2003 policy year, but higher than the Company's historical cost per claim in prior policy years,
- The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
- The number of BioGlue claims per million dollars of BioGlue revenue would be 20% lower than non-BioGlue claims per million dollars to adjust for the increase of BioGlue revenue as a percentage of total revenues since 2002 and the BioGlue claims history to date.

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 and 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.

Beginning April 1, 2004 and concurrent with signing the claims-made insurance policy for the policy year from April 1, 2004 to March 31, 2005, the Company implemented the provisions of Emerging Issues Task Force Issue 03-8, Accounting for Claims-Made Insurance and Retroactive Contracts by the Insured Entity ("EITF 03-8"). Pursuant to EITF 03-8, the Company continues to record an estimated liability for unreported product liability claims and has begun to record a related recoverable from insurance. Prior to the effective date of EITF 03-8, the Company did not record a recoverable from insurance related to the unreported product liability claims.

Based on the actuarial valuation performed in January 2005 as of December 31, 2004, the Company estimated that its liability for unreported product liability claims was $8.2 million as of December 31, 2004. In accordance with EITF 03-8, the Company has accrued $8.2 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, 2004. 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. Further analysis indicated that the liability could be estimated to be as high as $14.6 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, 2004, $1.9 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. 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. These amounts represent management's estimate of the probable losses and anticipated recoveries related to unreported product liability claims related to services performed and products sold prior to December 31, 2004. Actual results may differ from this estimate.

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 seeks 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. At present, discovery in the case has closed, and the Court has instructed the parties to serve their dispositive motions, if any, by March 11, 2005. Although the Company carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment 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. At this time, the Company is unable to predict the outcome of this litigation. Therefore, the Company has not recorded any accruals for future expenses related to this case, as the Company is currently unable to estimate these amounts. As of December 31, 2004 the Company had accrued $632,000 for legal fees incurred but unpaid related to this case and recorded an asset of $632,000 representing the anticipated recovery of these fees from the Company's insurance carrier. The $632,000 accrual is included as a component of accrued expenses and other current liabilities and the $632,000 insurance receivable is included as a component of other receivables on the December 31, 2004 Consolidated Balance Sheet. The Company believes that the receivable will be fully collectible.

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 names the Company as a nominal defendant, alleges 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 seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of the Company. As previously disclosed, the Company's Board of Directors has established an independent committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel, evaluated the consolidated amended complaint and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of the Company. Based on the report of the independent committee, the Company moved to dismiss the derivative action in May 2004. In an order dated December 1, 2004, the Court denied the motion to dismiss, such that the case will proceed into the discovery phase. At this time, the Company is unable to predict the outcome of this litigation. Although the derivative suit is brought nominally on behalf of the Company, the Company expects to continue to incur defense costs and other expenses in connection with the derivative litigation.

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 regarding 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 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. As of the date hereof, the SEC has had no discussions with CryoLife representatives as to whether or against whom it will seek 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.

Other Litigation

In October 2003 an action was filed against multiple defendants, including the Company, titled Donald Payne and Candace Payne v. Community Blood Center, et al., in the Circuit Court of the State of Oregon, County of Multnomah, seeking noneconomic damages of $9.0 million and other damages of $4.7 million. The suit alleged that Mr. Payne received a tissue implant processed by one of the other defendants, and that he was subsequently diagnosed with an infection attributed to the implant. The claim against the Company asserted that CryoLife had processed tissue from the same donor and been notified that a recipient of that tissue had contracted the same virus, and further that the Company had a duty to notify governmental authorities and the other defendants. A second action, titled L.L.R. and W.C.R. v. Community Blood Center, et al., was filed in October 2003 in the same court as the Payne case, against the same defendants, seeking the same amounts of damages. In this case the plaintiffs alleged the recipient received an implant processed by the same co-defendant tissue processor, from the same donor as Mr. Payne, and contracted an infection. In late July 2004 a third action was filed against multiple defendants, including the Company, titled Anthony F. Spadaro v. Community Blood Center, et al., in the same court as the other two cases, seeking noneconomic damages of $6.0 million, $1.7 million in economic damages, and punitive and exemplary damages. This suit alleged that Mr. Spadaro received a tissue implant processed by the same defendant tissue processor that was named in the other two suits, and that he was subsequently diagnosed with an infection attributed to the implant. This claim also asserted that the Company had processed tissue from the same donor and been notified that a recipient of the tissue had contracted the same virus, and that the Company had a duty to notify governmental authorities and the other defendants.

The trial for the Payne and L.L.R. cases began on October 18, 2004. CryoLife reached a settlement agreement with the plaintiffs on October 25, 2004 concerning the Payne, L.L.R. and Spadaro cases totaling $3.0 million in the aggregate, which CryoLife paid on November 5, 2004. The Company did not have insurance coverage for these claims. The $3.0 million is included in the Company's general, administrative, and marketing expenses for the year ended December 31, 2004. A cross-claim for indemnification by another defendant was dismissed earlier in the lawsuit because the claim is subject to a contractual obligation to arbitrate. As of the date of this filing, the arbitration clause has not been invoked by either party and CryoLife has not accrued any amounts for any potential loss. Although the Company believes there are defenses it can and would assert against such a claim, such a claim, if successfully brought, would not be insured and could have a material impact on the Company's liquidity and financial condition.

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

Inapplicable.

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.

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

2003	High	Low
First quarter	$ 9.79	$ 4.44
Second quarter	10.94	6.25
Third quarter	10.98	4.00
Fourth quarter	6.60	5.00

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 growth and, therefore, does not anticipate paying any cash dividends on its Common Stock in the foreseeable future. The holders of any shares of Preferred Stock issued by the Company may have a preference as to the payment of dividends over the holders of shares of Common Stock. No shares of Preferred Stock are currently issued and outstanding.

As of February 7, 2005 the Company had 557 shareholders of record.

Certain federal and state withholding taxes related to an employee stock grant were paid by individual employees through 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 in the fourth quarter of 2004.

The following table provides information about purchases by the Company during the quarter ended December 31, 2004 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares That May Yet Be Purchased Under the Programs
10/01/04 - 10/31/04	—	$ —	—	—
11/01/04 - 11/30/04	5,000	7.12	—	—
12/01/04 - 12/31/04	2,968	7.30	—	—
Total	7,968	$ 7.19	—	—

The Company currently has no stock repurchase program, publicly announced or otherwise. All shares shown were tendered to the Company in payment of the exercise price of outstanding options or to pay federal and state withholding taxes related to stock grants awarded to Company employees as discussed in Part I, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

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,				
	2004	2003	2002	2001	2000
Operations					
Revenues	$ 62,384	$ 59,532	$ 77,795	$ 87,671	$ 77,096
Net (loss) income	(18,749)	(32,294)	(27,761)	9,166	7,817
Research and development as a percentage of revenues	6.3%	6.1%	5.9%	5.4%	6.8%
(Loss)/Earnings Per Share[1]					
Basic	$ (0.81)	$ (1.64)	$ (1.43)	$ 0.49	$ 0.42
Diluted	$ (0.81)	$ (1.64)	$ (1.43)	$ 0.47	$ 0.41
Year-End Financial Position					
Total assets	$ 73,261	$ 75,027	$ 106,414	$ 129,310	$ 112,009
Working capital	19,689	14,790	39,385	66,668	69,063
Long term liabilities	5,629	5,716	4,552	10,071	12,192
Shareholders' equity	49,660	48,338	79,800	101,439	89,395
Current ratio[2]	2:1	2:1	3:1	5:1	8:1
Shareholders' equity per diluted common share[1]	$ 2.16	$ 2.46	$ 4.11	$ 5.16	$ 4.65

1 Reflects adjustment for 3-for-2 stock split effected December 27, 2000.

2 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, 2004 was a period of continued growth of BioGlue® Surgical Adhesive ("BioGlue"). For the year ended December 31, 2004 BioGlue revenues accounted for 57% of total revenue and for the first time supplanted preservation service revenues as the top component of Company revenue. BioGlue revenues were enhanced by the BioGlue syringe product, which was introduced in 2004, and a list price increase that went into effect on December 1, 2003 domestically and in early 2004 internationally. An additional list price increase on BioGlue was implemented on January 1, 2005.

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. Preservation service revenue in 2004 was negatively impacted by a shortage of high demand tissues available for shipment. Tissue scarcity was a direct result of 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 exhaustion of much of the Company's supply of tissue processed prior to October 3, 2001, and a reduction in procurement levels during 2004. The Company experienced improvements in yields of implantable tissues per donor and margins for its tissue business during 2004 over the levels experienced in 2003, and is taking steps intended to further improve its yields through process changes and process directives. The Company is also working to increase procurement of human tissues for processing over the levels experienced in 2004. The Company instituted list fee increases for its cardiovascular and vascular tissues in July 2004 and January 2005, to reflect the higher cost of processing these tissues subsequent to the FDA Order.

CryoLife continued to actively monitor its cash flows in an effort to reduce the operating cash shortfall experienced by the Company since the FDA Order. The Company focused its research and development spending on key opportunities, limited its capital expenditures, and targeted spending on regulatory filings to projects with strong market potential. BioGlue margins continued to be in excess of 80%, and BioGlue revenues provided operating cash flows to support the tissue business. Tissue margins are expected to improve as the Company works to increase yields of implantable tissues per donor and to increase service fees to support higher tissue processing costs. The Company is also closely monitoring expenses related to the defense and resolution of lawsuits, in an effort to reduce selling, general, and administrative costs from the levels seen in 2003 and 2004.

See Item 1. Business. for further discussion of the Company's business and activities during 2004.

Critical Accounting Policies

A summary of the Company's significant accounting policies is included in Note 1 to the 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 has historically been experienced have been 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 2005 as of December 31, 2004. 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.

Based on the information included in the actuarial valuation, management has included an accrual of $8.2 million as of December 31, 2004 for estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2004. This accrual reflected management's estimate based on information available to it at the time the estimate was made. Actual results may differ from this estimate. Further analysis indicated that the liability could be estimated to be as high as $14.6 million, after including a reasonable margin for statistical fluctuations based on actuarial simulation techniques. 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.

As of February 21, 2005 the Company had three outstanding product liability lawsuits against the Company that are covered by three separate insurance policies, beginning with the policy year 2000/2001. The Company believes its insurance policies to be adequate to defend against the covered lawsuits in each of these time periods. Additionally, the Company has five 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 that have not resulted in lawsuits. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2004 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, 2004 the Company had accrued a total of $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. This amount represents the Company's estimate of the probable losses related to two settled but unpaid claims and three of the eight pending product liability claims. The Company has not recorded an accrual for the remaining five 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 amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims, and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. 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. If the Company is unable to meet required future cash payments to resolve the outstanding product liability claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of the Company. See Legal Proceedings at Part I, Item 3 for further discussion of the Company's product liability claims.

Deferred Preservation Costs: 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 related to tissue held by the Company are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities. Deferred 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. Deferred preservation costs are stated on a first-in, first-out basis at the lower of cost or estimated market value.

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 balance sheet and the cost of preservation services, including the lower of cost or market write-down, described below, on the Company's Consolidated Statement 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 2003 and 2004 was favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services 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. Based on those evaluations, the Company recorded expenses of $6.6 million and $6.9 million, respectively, for 2004 and 2003 as an increase to cost of preservation services on its Consolidated Statements of Operations. These charges reflect the write-down of the value of certain deferred tissue preservation costs that exceeded management's estimates of the tissue's market value based on recent average service fees. Actual results may differ from these estimates.

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.

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 significant 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 activity, and reported tissue infections. The Company continued to generate deferred tax assets for the twelve months ended December 31, 2004 and 2003 primarily as a result of operating losses. The Company periodically assesses the recoverability of 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.

The Company evaluated several factors to determine if a valuation allowance relative to its deferred tax assets was necessary during 2003. The Company reviewed its historic operating results, including the reasons for its operating losses in 2003 and 2002, uncertainties regarding projected future operating results due to the effects of the adverse publicity resulting from the FDA Order, subsequent FDA activity, and reported tissue infections, the changes in processing methods resulting from the FDA Order, and the uncertainty of the outcome of 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, 2003 the Company had a total of $14.4 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

As of December 31, 2004 the Company updated the evaluation of its deferred tax assets. The Company reviewed its historic operating results, including the operating losses which continued in 2004, 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, 2004 the Company had a total of $18.8 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

New Accounting Pronouncements

The Company was required to adopt Emerging Issues Task Force ("EITF") issue 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("EITF 03-1"). The Company adopted the recognition and measurement guidance of EITF 03-1 for the interim period ending September 30, 2004 and the annual disclosure requirements for its year ended December 31, 2004. EITF 03-1 clarifies the definition of and accounting treatment for other-than-temporary losses on debt and equity investments. The adoption of the recognition and measurement guidance of EITF 03-1 did not have a material effect on the results of operations or financial position of the Company. The Financial Accounting Standards Board has delayed implementation of certain requirements under EITF 03-1. Until the requirements are finalized the Company cannot determine the effect of fully adopting EITF 03-1 on the results of operations or financial position.

The Company adopted EITF 03-8 "Accounting for Claims-Made Insurance and Retroactive Insurance Contracts by the Insured Entity" ("EITF 03-8") for the interim period ended June 30, 2004. EITF 03-8 clarifies reporting for insurance policies, including providing guidance in accounting for prospective and retroactive insurance policies and guidance for situations when a company's fiscal year and insurance policy period do not coincide. The adoption of EITF 03-8 resulted in the Company recording additional legal accruals and offsetting amounts recoverable from insurance as discussed in Part I, Item 3 "Legal Proceedings".

The Company will be required to adopt SFAS 123 Revised "Share-Based Payment" ("SFAS 123-R") for the interim period ending September 30, 2005. SFAS 123-R requires companies to recognize the cost of all share-based payments in the financial statements using a fair-value based measurement method. Based on its preliminary analysis, the Company anticipates that the effect of implementing SFAS 123-R on its results of operations will be less than the amounts in the pro-forma footnote disclosures currently required, but will have a significant impact on the Company's results of operations, assuming that the Company's stock price, option terms, and amounts of 2005 option grants are comparable with 2004. The Company anticipates it will adopt SFAS 123-R using the modified version of prospective application, as defined in SFAS 123-R. However, the Company is continuing to evaluate the adoption of SFAS 123-R.

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 currently evaluating the impact of the adoption of SFAS 151 on its results of operations and financial position.

Results of Operations
(In thousands)

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 continues in the detailed sections below.

BioGlue

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
BioGlue 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.

The Company anticipates that revenues from BioGlue will continue to grow in 2005 as compared to 2004. On January 1, 2005 the Company initiated list price increases for BioGlue products. The Company anticipates that this price increase will favorably affect revenues in 2005, in addition to anticipated growth in BioGlue domestic and international sales volume.

Cardiovascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2004	2003	2004	2003
Cardiovascular 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 reflects 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 remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that cardiovascular service revenues will benefit in 2005 if and to the extent tissues available for implantation increase due to expected improvements in the Company's tissue processing yields. Process changes were implemented during 2004 and others are expected to be implemented in 2005. Cardiac revenues for 2005 should also be favorably affected by the fee increases implemented in July 2004 and January 2005, reflecting increased tissue processing costs.

As discussed in 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, which historically yielded a higher price and margin than processing without SynerGraft. 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
Vascular 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.

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 remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that vascular service revenues will also benefit in 2005 if and to the extent tissues available for implantation increase through expected improvements in the Company's tissue processing yields, as well as from the fee increases implemented in July 2004 and January 2005.

Orthopaedic Preservation Services

	December 31,		December 31,	
	2004	2003	2004	2003
Orthopaedic 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 remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that orthopaedic service revenues will also benefit in 2005 if and to the extent tissues available for implantation increase through expected improvements in procurement and in the Company's tissue processing yields. In addition, the Company anticipates reintroducing osteochondral grafts in early 2005, which have not been part of the Company's service offerings since the FDA Order was issued in August 2002.

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 $1 million for the development of BioFoam. CryoLife plans to submit a proposal to the Department of Defense for the use of these funds by the end of February 2005. These funds are expected to result in an increase in grant revenues in 2005.

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 is 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.

The Company anticipates aggregate cost of products will increase in 2005 to reflect volume increases. The cost of products as a percentage of product revenues for 2005 is expected to be lower than 2004 due to favorable product mix, reflecting anticipated increased BioGlue revenues relative to other product revenues.

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 is 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 is 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.

The Company anticipates that the aggregate cost of human tissue preservation services will increase if volume increases in 2005. The Company anticipates that cost of human tissue preservation services as a percentage of tissue preservation service revenues will benefit in 2005 from any increases in the amount of tissues processed, or any increases in yields of implantable tissue per donor, as well as increases in average service fees due to fee increases implemented in July 2004 and January 2005. 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 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.

The Company anticipates that insurance costs, legal costs, and professional fees will continue to be higher in 2005 than those experienced prior to the FDA Order. The Company presently expects general, administrative, and marketing expenses to be comparable to 2004, excluding the effect of implementing SFAS 123-R as discussed in "New Accounting Pronouncements" above, 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 2005, 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 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.

The Company anticipates research and development expenses will increase in 2005 when compared to 2004, due to increased spending on research related to the Protein Hydrogel Technology used in BioGlue, including BioFoam, BioLastic™, BioDisc™, and new product line extensions for BioGlue, SynerGraft, and tissue preservation. The BioFoam spending increase will be due in part to the 2005 Defense Appropriations Conference Report discussed in Grant Revenues above.

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. See additional discussion of the Company's cash position in the Liquidity and Capital Resources section below.

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.

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Revenues

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2003	2002	2003	2002
Revenues as reported	$ 12,802	$ 12,171	$ 59,532	$ 77,795
Estimated tissue recall returns	—	—	—	3,466
Adjustment to estimated tissue recall returns	—	—	(900)	—
Adjusted revenues[a]	$ 12,802	$ 12,171	$ 58,632	$ 81,261

a The measurement "adjusted revenues" is defined as revenues prior to estimated tissue recall returns and adjustments made to estimated tissue recall returns. This measurement may be deemed to be a "non-GAAP" financial measure as that term is defined in Regulation G and Item 10(e) of Regulation S-K and is included for informational purposes to provide comparable disclosure in the current and prior periods of revenues derived from services provided with respect to tissues and products shipped in the normal course of business.

The GAAP number revenue as reported in the prior year periods was calculated by deducting the amount of estimated tissue recall returns for subsequent returns of FDA recalled tissues from revenue related to tissues and products shipped in the normal course of business. In order to compute revenues as adjusted this unfavorable item from the prior periods was added back to show a clearer comparison to current year periods and to illustrate the magnitude of the decrease in current year revenues. The adjustment to estimated tissue recall returns was recorded during the current year periods to reduce the original estimate of the effect of returns of FDA recalled tissues based on revised estimates. In order to compute revenues as adjusted this item from the current year periods was added back for the reasons discussed above with respect to estimated tissue returns. The presentation of revenue as reported without the presentation of adjusted revenues might mislead investors with respect to the magnitude of the decrease in the Company's current year revenues relative to the prior year.

Revenues as reported increased 5% for the three months ended December 31, 2003 as compared to the three months ended December 31, 2002. This increase was primarily due to continued growth in sales of BioGlue, partially offset by a decrease in tissue service revenues.

Revenues as reported decreased 23% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. Revenues as reported for the twelve months ended December 31, 2003 include $900,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated. Revenues as reported for the twelve months ended December 31, 2002 were adversely affected by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of $3.5 million in preservation service revenues. As of December 31, 2003 there was no remaining accrual for estimated return of tissues subject to recall by the FDA Order. Adjusted revenues decreased 28% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. This decrease in adjusted revenues for the twelve months ended December 31, 2003 was primarily due to a decrease in cryopreservation services revenues for cardiac, vascular, and orthopaedic tissues when compared to the prior year period, partially offset by an increase in sales of BioGlue.

Further discussion of the decrease in cryopreservation service revenues for each of the three major tissue types processed by the Company and the increase in BioGlue revenues continues in the detailed sections below.

BioGlue

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2003	2002	2003	2002
Revenues as reported	$ 7,757	$ 5,590	$ 27,784	$ 20,898
BioGlue revenues as reported as a percentage of total revenue as reported	61%	46%	47%	27%
BioGlue revenues as reported as a percentage of total adjusted revenues[a]	61%	46%	47%	26%

Revenues as reported from the sale of BioGlue increased 39% and 33%, respectively, for the three and twelve months ended December 31, 2003 as compared to the three and twelve months ended December 31, 2002. The 39% increase in revenues as reported for the three months ended December 31, 2003 was primarily due to an increase in BioGlue sales volume due to an increase in demand in both foreign and domestic markets which increased revenues by 36%, and an increase in average selling prices which increased revenues by 3%. The 33% increase in revenues as reported for the twelve months ended December 31, 2003 was due to an increase in BioGlue sales volume due to an increase in demand in both foreign and domestic markets which increased revenues by 31%, and by an increase in average selling prices which increased revenues by 2%.

Volume increases in both the three and twelve months ended December 31, 2003 were led by large percentage increases in the BioGlue 2ml and 5ml product sizes. The BioGlue 10ml size continued to generate the largest amount of BioGlue revenue, accounting for 69% and 72%, respectively, of total BioGlue revenues during the three and twelve months ended December 31, 2003. Domestic revenues accounted for 77% of total BioGlue revenues for both the three and twelve months ended December 31, 2003, and 81% and 79%, respectively, of total BioGlue revenues for the three and twelve months ended December 31, 2002. Domestic and international revenue growth continued to be strong, however, foreign revenues in 2003 benefited from the stronger British Pound, which yielded higher sales in U.S. dollars due to the favorable effects of currency translation. Foreign BioGlue revenues increased 46% in 2003 over 2002 of which 9% was due to favorable foreign exchange rates in 2003.

Cardiovascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2003	2002	2003	2002
Revenues as reported	$ 2,751	$ 3,283	$ 17,059	$ 23,413
Estimated tissue recall returns	—	—	—	511
Adjustment to estimated tissue recall returns	—	—	(85)	—
Adjusted revenues[a]	$ 2,751	$ 3,283	$ 16,974	$ 23,924
Cardiovascular revenues as reported as a percentage of total revenue as reported	21%	27%	29%	30%
Cardiovascular adjusted revenues as a percentage of total adjusted revenues[a]	21%	27%	29%	29%

Revenues as reported from cardiovascular preservation services decreased 16% for the three months ended December 31, 2003 as compared to the three months ended December 31, 2002. The 16% decrease in revenues for the three months ended December 31, 2003 was due to a decrease in average service fees, which reduced revenues by 15%, and a slight decrease in cardiovascular volume, which reduced revenues by 1%. The decrease in average service fees was largely driven by a change in product mix as shipments of heart valves decreased, while shipments of lower fee cardiac tissues such as non-valved conduits and patch material increased. The decrease in heart valve shipments is directly related to the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2003, the disposal of much of the Company's heart valve tissue processed prior to October 3, 2001 and increased tissue processing times and lower yields of implantable tissue per donor as a result of process changes implemented in the latter half of 2002 and during 2003. In addition average service fees were negatively impacted by the Company's suspension of shipments of SynerGraft processed cardiac tissues, which usually demand higher average service fees for heart valves and for non-valved cardiac tissues.

Revenues as reported from cardiovascular preservation services decreased 27% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. Cardiovascular revenues as reported for the twelve months ended December 31, 2003 include $85,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were estimated in the prior year. Cardiovascular revenues as reported for the twelve months ended December 31, 2002 were adversely affected by the estimated effect of the non-valved cardiac tissues returned subject to the FDA Order, which resulted in an estimated decrease of $511,000 in service revenues.

Adjusted revenues from cardiovascular preservation services decreased 29% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. The 29% decrease in adjusted revenues for the twelve months ended December 31, 2003 was due to a decrease in cardiovascular volume primarily due to the decrease in cardiac shipments in 2003 as a result of the effects of the FDA Order, subsequent FDA activity, and related events as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices", which reduced revenues by 31%, partially offset by an increase in average service fees which increased revenues by 2%.

As a result of effects of the FDA Order, subsequent FDA activity, and related events as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices", the Company's procurement of cardiac tissues during the twelve months ended December 31, 2003, from which heart valves and non-valved cardiac tissues are processed, decreased 13% as compared to twelve months ended December 31, 2002. The Company's procurement of cardiac tissues remained relatively steady during the second, third, and fourth quarters of 2003 from its low in the first quarter of 2003. However, these procurement levels remained approximately 19% below procurement levels prior to the FDA Order in the second quarter of 2002.

Vascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2003	2002	2003	2002
Revenues as reported	$ 2,018	$ 2,908	$ 12,655	$ 17,826
Estimated tissue recall returns	—	—	—	2,547
Adjustment to estimated tissue recall returns	—	—	(752)	—
Adjusted revenues[a]	$ 2,018	$ 2,908	$ 11,903	$ 20,373
Vascular revenues as reported as a percentage of total revenue as reported	16%	24%	21%	23%
Vascular adjusted revenues as a percentage of total adjusted revenues[a]	16%	24%	20%	25%

Revenues as reported from vascular preservation services decreased 31% for the three months ended December 31, 2003 as compared to the three months ended December 31, 2002. The 31% decrease in revenues for the three months ended December 31, 2003 was due to a decrease in volume, which reduced revenues by 34%, partially offset by a slight increase in average service fees, which increased revenues by 3%. The decrease in volume was largely driven by fewer shipments of saphenous veins, which represented 67% and 75%, respectively, of vascular preservation service revenues for the three months ended December 31, 2003 and 2002. The decrease in saphenous vein shipments is directly related to the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2003, the disposal of much of the Company's tissues processed prior to October 1, 2001 in accordance with the FDA Order, and increased tissue processing times and lower yields of implantable tissue per donor as a result of process changes implemented in the latter half of 2002 and during 2003. The increase in average service fees was primarily due to a lower percentage of discounted multi-tissue heart and limb packs being shipped in 2003 compared to 2002. Heart and limb packs generally have reduced fees when compared to similar amounts of tissues shipped individually.

Revenues as reported from vascular preservation services decreased 29% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. Vascular revenues as reported for the twelve months ended December 31, 2003 include $752,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were estimated in the prior year. Vascular revenues as reported for the twelve months ended December 31, 2002 were adversely affected by the estimated effect of the vascular tissues returned subject to the FDA Order, which resulted in an estimated decrease of $2.5 million in service revenues.

Adjusted revenues from vascular preservation services decreased 42% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. The 42% decrease in adjusted revenues for the twelve months ended December 31, 2003 was due to a decrease in vascular volume primarily due to the decrease in vascular shipments in 2003 as a result of the effects of the FDA Order, subsequent FDA activity, and related events as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices", which reduced revenues by 40%, and a decrease in average service fees which decreased revenues by 2%.

As a result of effects of the FDA Order, subsequent FDA activity, and related events as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices", the Company's procurement of vascular tissues during the twelve months ended December 31, 2003 decreased 30% as compared to twelve months ended December 31, 2002. The Company's procurement of vascular tissues increased quarter over quarter in 2003 with a slight decline in the fourth quarter of 2003 as compared to the third quarter of 2003. However, these procurement levels remained approximately 48% below procurement levels prior to the FDA Order in the second quarter of 2002.

Orthopaedic Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2003	2002	2003	2002
Revenues as reported	$ 166	$ 108	$ 1,063	$ 14,134
Estimated tissue recall returns	—	—	—	408
Adjustment to estimated tissue recall returns	—	—	(63)	—
Adjusted revenues[a]	$ 166	$ 108	$ 1,000	$ 14,542
Orthopaedic revenues as reported as a percentage of total revenue as reported	1%	1%	2%	18%
Orthopaedic adjusted revenues as a percentage of total adjusted revenues[a]	1%	1%	2%	18%

Revenues as reported from orthopaedic preservation services increased to $166,000 for the three months ended December 31, 2003 as compared to $108,000 for the three months ended December 31, 2002. Revenues in both periods were minimal due to a severe reduction in processing and shipments of orthopaedic tissues following the FDA Order and subsequent FDA activity as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices." Processing and shipping of orthopaedic tissues throughout 2003 has remained at levels significantly below the levels experienced prior to the FDA Order.

Revenues as reported from orthopaedic preservation services decreased 92% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. Orthopaedic revenues as reported for the twelve months ended December 31, 2003 include $63,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were estimated in the prior year. Orthopaedic revenues as reported for the twelve months ended December 31, 2002 were adversely affected by the estimated effect of the orthopaedic tissues returned subject to the FDA Order, which resulted in an estimated decrease of $408,000 in service revenues.

Adjusted revenues from orthopaedic preservation services decreased 93% for the twelve months ended December 31, 2003 as compared to the twelve months ended December 31, 2002. The 93% decrease in adjusted revenues for the twelve months ended December 31, 2003 was due to a decrease in orthopaedic volume primarily due to the decrease in orthopaedic shipments in 2003 as a result of the effects of the FDA Order, subsequent FDA activity, and related events as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices," which reduced revenues by 91%, and a decrease in average service fees which decreased revenues by 2%.

During 2002 the Company temporarily suspended its processing of orthopaedic tissues as a result of the FDA Order. The Company resumed limited processing of orthopaedic tissues in late February 2003 and began shipments 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 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. These suspensions of processing, combined with the disposal of much of the Company's orthopaedic tissue processed prior to October 1, 2001 in accordance with the FDA Order, resulted in low levels of orthopaedic tissues available for shipment in the latter half of 2002 and much of 2003.

As a result of effects of the FDA Order, subsequent FDA activity, and related events as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices", the Company's procurement of orthopaedic tissues during the twelve months ended December 31, 2003 decreased 73% as compared to twelve months ended December 31, 2002. The Company's procurement of orthopaedic tissues increased quarter over quarter throughout 2003, after recovering somewhat from its low in the fourth quarter of 2002. Procurement of orthopaedic tissues in the fourth quarter of 2003 increased 33% over procurement levels in the third quarter of 2003. However, procurement levels in the fourth quarter of 2003 remained approximately 75% below procurement levels prior to the FDA Order in the second quarter of 2002.

Distribution and Grant Revenues

Grant revenues increased to $492,000 in 2003 from $348,000 in 2002. Grant revenues in 2003 and 2002 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.

Distribution revenues decreased to zero in 2003 from $477,000 in 2002. Distribution revenues consisted of commissions received for the distribution of orthopaedic tissues for another processor.

Cost of Human Tissue Preservation Services

Cost of human tissue preservation services decreased to $24.0 million in 2003 as compared to $55.4 million in 2002. Cost of human tissue preservation services for 2003 includes an increase to cost of preservation services of $6.9 million to adjust the value of certain deferred tissue preservation costs that exceeded market value, and the favorable effect on gross margin of approximately $4.3 million related to shipments of tissue with a zero cost basis due to the prior write-downs of these deferred preservation costs in the second and third quarter of 2002. The cost of human tissue preservation services for 2002 includes $32.7 million in write-downs of deferred preservation costs for tissues subject to the FDA Order. The remaining decrease in costs is largely due to the reduced amount of tissue preservation services and related costs in the first seven months of 2003 as compared to the first seven months of 2002, which was prior to the issuance of the FDA Order.

Cost of human tissue preservation services as a percentage of total human tissue preservation service revenues was 78% in 2003 compared to 100% in 2002. The decrease in cost of human tissue preservation services as a percentage of revenues was also due to the effects of the adjustments and write-downs in 2003 and 2002 discussed above, partially offset by an increase in overhead allocations associated with lower tissue processing volumes, changes in processing methods resulting from the FDA Order, and a decrease in tissue shipments of valves processed with the higher margin SynerGraft process as compared to traditional processing.

Cost of Products

Cost of products aggregated $7.5 million in 2003 compared to $10.3 million in 2002. The decrease in cost of products in 2003 was primarily due to a $3.1 million write-down of bioprosthetic valves, including SynerGraft and non-SynerGraft processed porcine valves, in the third quarter of 2002 due to the Company's decision to stop future expenditures on the development and marketing of these valves and to maintain its focus on its preservation services business and its BioGlue and SynerGraft bovine vascular graft product lines. The remaining increase in cost of products was due to higher BioGlue sales levels during 2003 when compared to 2002.

Cost of products as a percentage of total product revenues was 27% in 2003 compared to 48% in 2002. The decrease is primarily due to the write-down in 2002 discussed above. The remaining decrease was due to a favorable product mix driven by an increase in revenues from BioGlue, which carries higher gross margins than bioprosthetic devices.

General, Administrative, and Marketing Expenses

General, administrative, and marketing expenses increased 13% to $53.6 million in 2003, compared to $47.5 million in 2002, representing 90% and 61%, respectively, of total revenues during such periods. The increase in expenses was primarily due to an accrual of $7.5 million for the estimated and actual expense to resolve ongoing product liability claims in excess of insurance coverage, $4.3 million for estimated unreported product liability claims related to services performed and products sold prior to December 31, 2003, and $200,000 for required insurance retention payments for the Company's product liability insurance policies related to prior policy years (See Legal Proceedings at Part I Item 3 for further discussion of these items.) General, administrative, and marketing costs in 2002 were unfavorably impacted by a $3.6 million accrual for estimated product loss claims incurred but not reported as of December 31, 2002 and a $1.2 million accrual for retention levels under the Company's liability and directors' and officers' insurance policies. Additional increases in costs for 2003 were due to an increase of approximately $1.0 million in professional fees (legal, consulting, and accounting) due to increased litigation and issues surrounding the FDA Order and subsequent FDA activity and an increase of approximately $1.0 million in insurance premiums, offset by a $3.9 million decrease in marketing expenses, including personnel costs and sales commissions. 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 decreased 21% to $3.6 million in 2003, compared to $4.6 million in 2002, representing 6% of total revenues during these periods. The decrease in research and development spending for year ended December 31, 2003 was primarily due to a delay in the timing of several external research studies, which are expected to take place in future periods, due to the Company's focus on process improvements and addressing FDA compliance requirements. Research and development spending in 2003 was primarily focused on the Company's core tissue cryopreservation, SynerGraft, and Protein Hydrogel Technologies. Research and development spending in 2002 was primarily focused on the Company's SynerGraft and Protein Hydrogel Technologies.

Other Costs and Expenses

Goodwill impairment of $1.4 million in 2002 consists of a write-down for impairment of goodwill related to the Company's tissue processing reporting unit. This write-down was taken in accordance with Statement of Accounting Standards No. 142, based on a valuation done by an independent valuation expert.

Interest expense decreased 40% to $415,000 in 2003, compared to $692,000 in 2002. The decrease was due to the Company's reduced average debt balances in 2003 as compared to 2002, as a result of scheduled principal payments which reduced the level of outstanding debt, and the Company's pay off of the outstanding balance of the term loan in the third quarter of 2003. These decreases were partially offset by additional interest expense related to the Company's financing of $2.9 million in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies.

Interest income decreased 53% to $425,000 in 2003, compared to $895,000 in 2002. The decrease was due to the Company's reduced average balances of cash and marketable securities during 2003 as compared to 2002, as the Company sold investments and used cash balances to support ongoing operations and resolve product liability claims.

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 2003, excluding the effects of the valuation allowance, and 33% in 2002.

Seasonality

The demand for BioGlue appears to experience some 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. As BioGlue is in a growth phase generally associated with a recently introduced product that has not fully penetrated the marketplace, the full nature of any seasonal trends in BioGlue sales may be obscured. The Company will continue to evaluate the seasonal nature of BioGlue sales.

The demand for the Company's cardiovascular tissue preservation services is 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.

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

As of December 31, 2004 net working capital (current assets of $37.7 million less current liabilities of $18.0 million) was $19.7 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of $14.8 million, with a current ratio of 2 to 1 at December 31, 2003. 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 periods 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, 2004 the Company funded these requirements primarily through existing cash, cash equivalents, and marketable securities and through the proceeds from its equity financing, as discussed below.

Overall Liquidity and Capital Resources

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, auditor's fees, attorney's fees, late registration fees, and other related charges, for general corporate purposes. The Company filed a Registration Statement on Form S-3 with the Securities and Exchange Commission ("SEC") covering the resale of the shares sold in the PIPE by the investors.

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 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. Depending on market conditions, the Company may sell equity securities pursuant to its Form S-3 shelf registration statement in the first half of 2005. As of February 21, 2005 no offering of securities had been commenced in accordance with this registration statement, and there can be no assurance any offering will be commenced or consummated.

On February 8, 2005 CryoLife and its subsidiaries entered into a new credit agreement with Wells Fargo Foothill, Inc. as lender. 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 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") and 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 expects that its aggregate borrowing availability under the credit agreement will equal $15.0 million, there can be no assurance that the availability 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. Amounts borrowed under the revolving credit facility bear interest at the bank's prime rate plus 1%. Amounts borrowed under the credit facility are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries. On February 8, 2005 CryoLife borrowed approximately $265,000 against the $15.0 million then available under its revolving credit facility, and used such borrowings to pay certain expenses of the transaction.

The Company expects that the following factors will continue to have an adverse impact on cash flows during 2005:

- 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 1. Business.),

- 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 have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,

- An expected use of cash related to the defense and resolution of lawsuits and claims, and

- 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 2005, although there can be no assurance that these factors will be successful:

- Expected increases in revenues due to increases in BioGlue list prices implemented in January 2005,

- Expected increases in the service fees for cardiovascular and vascular tissues due to fee increases implemented in July 2004 and January 2005, to reflect the higher cost of processing these tissues,

- Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2003 and 2004 through process changes and process directives,

- Expected increases in procurement of human tissues for processing over the levels experienced in 2004, and

- Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 and 2004.

The Company believes that the Company's existing cash, cash equivalents, and marketable securities will enable the Company to meet its liquidity needs through December 31, 2005. Additionally, in February 2005 the Company has entered into a credit agreement, discussed above, and depending on market conditions may sell equity securities pursuant to its Form S-3 shelf registration statement in the first half of 2005. As of February 21, 2005 no offering of securities had been commenced in accordance with this registration statement, and there can be no assurance any offering will be commenced or consummated.

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

- The success of BioGlue and other products using related technology,

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

- The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,

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

- The amount and the timing of the resolution of the remaining outstanding product liability lawsuits and other claims (see Part I. Item 3. Legal Proceedings),

- The outcome of other litigation against the Company (see Part I. Item 3. Legal Proceedings), and

- To a lesser degree, the Company's success at resolving the issues with the FDA regarding SynerGraft processing of human tissue.

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, 2005. 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.

As discussed in Note 8 to the consolidated financial statements, as of December 31, 2004 the Company had accrued a total of $2.8 million for pending product liability claims and $632,000 for other litigation and recorded a receivable for $1.7 million representing the amounts due from insurance companies related to this litigation. The net $1.7 million accrual represents the Company's portion of the estimated costs, net of insurance recoveries, required to resolve outstanding claims and does not reflect actual settlement arrangements or actual judgments, including punitive damages, which may be assessed by the courts. These accruals are not cash reserves. 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 settlements of these outstanding claims in order to minimize the potential cash payout. See additional discussion of these matters in Note 8 to the consolidated financial statements. In addition, the amount and timing of the resolution of the uninsured indemnification claim, if brought (see Part I. Item 3. Legal Proceedings), could have a material impact on the Company's financial condition and liquidity.

If the Company is unable to settle the outstanding product liability claims and other litigation, and any other similar claims that may be brought, for amounts within its ability to pay, or if one or more of the lawsuits in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed the Company's liquid assets. There is a possibility that significant punitive damages could be assessed in one or more lawsuits which would have to be paid out of the liquid assets of the Company, if available.

In addition, as discussed in Note 8 to the consolidated financial statements, as of December 31, 2004 the Company has $8.2 million in an accrual for the estimated costs of unreported product liability claims related to services performed and products sold prior to December 31, 2004. The Company has also recorded a $1.9 million receivable representing an estimate of amounts due from insurance companies related to unreported product liability claims. The $8.2 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 $16.2 million, $5.9 million, and $2.1 million, respectively for the twelve months ended December 31, 2004, 2003, and 2002. The Company has experienced operating cash shortfalls in 2004, 2003, and 2002 due to:

- Decreases in revenues as a result of the FDA Order,
- Overhead costs, including the cost of employees and facilities, which did not decrease in accordance with the reduction in revenues,
- Increases in general and administrative expenditures, primarily due to litigation settlement costs and increased professional fees, and
- Increases in processing costs due to the Company's efforts to address the FDA's concerns.

These adverse factors were partially offset by the substantial increase in revenues from BioGlue, which is a high margin product. Net cash used in 2003 was favorably affected by the receipt of approximately $12.2 million in tax refunds.

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. For the twelve months ended December 31, 2004, the Company's $18.7 million net loss included significant recurring non-cash items that resulted in the Company booking an expense without a corresponding cash payment, thereby generating favorable adjustments to the net loss. These adjustments included $5.5 million in depreciation and amortization, $7.1 million in write-downs for impairment of deferred preservation costs and inventories, and $358,000 in non-cash employee compensation consisting of grants of Company stock. In addition, net losses are adjusted by changes in operating asset and liability balances to reflect the timing difference between recording a revenue or expense item and the actual receipt or disbursement of cash. These adjustments included an unfavorable $2.2 million due to the timing differences between the recording of receivables and the actual receipt of cash, an unfavorable $7.4 million due to the buildup of deferred preservation costs and inventories for which vendors and employees have already been paid, a favorable $1.3 million due to the timing differences associated with prepaid expenses and other assets, and an unfavorable $2.9 million due to the timing differences between the recording of accounts payable, accrued expenses, and other current liabilities and the actual payment of cash. The effect of a receipt of $1.4 million in income tax refunds in the second quarter of 2004 for which a receivable had not previously been recorded was largely offset by the recording of a $1.3 million income tax receivable in the fourth quarter of 2004 which is not expected to be received until 2005.

The Company expects that its operations will continue to generate negative cash flows from operating activities during 2005. Cash used will primarily be a result of the Company's projected net loss for 2005. Significant additional cash payments related to settlements and tissue product costs could have a negative impact on future cash flows.

Net Cash from Investing Activities

Net cash provided by investing activities was $457,000 for the twelve months ended December 31, 2004, as compared to net cash provided of $15.8 million for the twelve months ended December 31, 2003 and net cash used of $394,000 for the twelve months ended December 31, 2002. The $457,000 in current year cash provided was primarily due to $1.4 million in cash generated from sales and maturities of marketable securities, net of purchases, partially offset by $950,000 in capital expenditures.

Net Cash from Financing Activities

Net cash provided by financing activities was $15.6 million for the twelve months ended December 31, 2004, as compared to net cash used of $8.0 million for the twelve months ended December 31, 2003 and net cash used of $1.4 million for the twelve months ended December 31, 2002. The $15.6 million in current year cash provided was primarily due to $19.3 million in proceeds from the Company's PIPE equity offering discussed above and $443,000 in net proceeds from the exercise of stock options, partially offset by $4.1 million in principal payments on short-term notes payable and capital leases. Additionally, $54,000 was used to purchase treasury stock from employees in association with the employee stock grants discussed above.

Scheduled Contractual Obligations and Future Payments

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

	Total	2005	2006	2007	2008	2009	Thereafter
Capital Lease Obligations	$ 2,010	$ 884	$ 860	$ 266	$ —	$ —	$ —
Operating Leases	24,029	2,360	2,107	2,075	2,108	2,149	13,230
Purchase Commitments	733	708	25	—	—	—	—
Litigation Settlement Obligations	600	600	—	—	—	—	—
Total Contractual Obligations	$ 27,372	$ 4,552	$ 2,992	$ 2,341	$ 2,108	$ 2,149	$ 13,230

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. Due to cross default provisions included in the Company's Term loan which was paid in full on August 15, 2003, the Company was in default of certain capital lease agreements maintained with the lender under its then outstanding term loan. Therefore, the $1.0 million due under these capital leases is reflected as a current liability on the Consolidated Balance Sheets as of December 31, 2004 and $1.5 million as of December 31, 2003. Additional capital lease obligations result from the lease of a building related to Company's Ideas for Medicine ("IFM") manufacturing business, which the Company sold in 2000. The Company has a sublease agreement with a wholly owned subsidiary of LeMaitre Vascular, Inc., the current parent of IFM, to sublet the building housing the IFM manufacturing facilities, which effectively reduces the Company's future obligations under this capital lease to zero.

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.

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 litigation settlement obligations result from contractual agreements with plaintiffs to resolve outstanding legal matters through the payment of cash settlements.

Stock Repurchase

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 the employee stock grants.

On July 18, 2002 the Company's Board of Directors authorized the purchase of up to $10 million in shares of its common stock. The purchase of shares was to be made from time-to-time in open market or privately negotiated transactions on such terms as management deemed appropriate. As of December 31, 2002 the Company had repurchased 68,000 shares of its common stock for an aggregate purchase price of $663,000 and an average price of $9.69 per share. This purchase authorization expired during 2003, therefore no further purchases will be made under this authorization.

On March 27, 2002 the Company's Board of Directors authorized the Company to purchase up to 1.0 million shares of its common stock. As of December 31, 2004, the Company had made no purchases under this authorization. This purchase authorization was rescinded in 2004, therefore no further purchases will be made under this authorization.

Capital Expenditures

The Company expects that its capital expenditures in 2005 will approximate its expenditures in 2004, which were approximately $1.0 million. Planned capital expenditures for 2005 are primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment needed to support the Company's business. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to generate cash flows.

Forward Looking Statements

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 Item 1 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.

The Company's interest income and expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents of $5.3 million and short-term investments in municipal obligations of $4.0 million as of December 31, 2004. A 10% adverse change in interest rates affecting the Company's cash equivalents and short-term investments would not have had a material impact on the Company's financial position, results of operations, and cash flows for 2004.

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's management, including the Company's President and Chief Executive Officer ("CEO") and the Company's Executive Vice President of Finance, Chief Operating Officer, and Chief Financial Officer ("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, 2004, 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, 2004, 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.

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

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, 2004. 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, 2004, 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.
March 2, 2005

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, 2004, 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, 2004, 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, 2004, 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, 2004 of the Company and our report dated March 2, 2005 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 goodwill and other intangible assets to conform to Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets", which was adopted by the Company as of January 1, 2002.

DELOITTE & TOUCHE LLP
Atlanta, Georgia
March 2, 2005

Item 9B. Other Information.

On February 18, 2005, the Compensation Committee of the Board of Directors increased the salaries of Dr. Heacox and Mr. Fronk. On November 2, 2004, concurrently with his appointment to the position of Executive Vice President, Chief Operating Officer, and Chief Financial Officer, Mr. Lee's salary was increased. See Exhibit 10.9(d) to this Form 10-K, which is incorporated herein by reference.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The following table lists the executive officers and directors of CryoLife and their ages, positions with CryoLife, and the dates from which they have continually served as directors or 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. Directors of CryoLife hold office until the next Annual Meeting or until their successors are elected and qualified. CryoLife's Board of Directors is comprised of eight Directors.

Name	Service as Director or Executive	Age	Position
Steven G. Anderson	Since 1984	66	President, Chief Executive Officer, and Chairman
Sidney B. Ashmore	Since 2001	46	Vice President, Marketing
David M. Fronk	Since 1998	41	Vice President, Clinical Research
Albert E. Heacox, Ph.D.	Since 1989	54	Senior Vice President, Research and Development
D. Ashley Lee, CPA	Since 2000	40	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
Thomas J. Lynch, J.D., Ph.D.	Since 2003	53	Vice President, Regulatory Affairs and Quality Assurance
Joseph T. Schepers	Since 2003	46	Vice President, Corporate Communications
Thomas F. Ackerman(2)(3)	Since 2003	50	Director
Daniel J. Bevevino(1)(2)	Since 2003	45	Director
John M. Cook(1)(2)	Since 1999	62	Director
Ronald C. Elkins, M.D.	Since 1994	68	Director
Virginia C. Lacy(1)(3)(4)	Since 1997	63	Director
Ronald D. McCall, Esq.	Since 1984	68	Director
Bruce J. Van Dyne, M.D.(1)(3)	Since 1999	63	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

(4) Ms. Lacy is the Presiding Director of the Board.

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.

Sidney B. Ashmore has served as Vice President of Marketing since March 2001 and has been with the Company since September 1996 as Director of Marketing. Mr. Ashmore 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. Ashmore held senior marketing positions with Baxter Healthcare from 1991 until 1996, and general management positions with Amorient Aquafarms from 1985 until 1989. Mr. Ashmore received his B.A. from Vanderbilt University in 1981, his M.S. from the University of Hawaii in 1985, and his M.B.A. from Northwestern University in 1991.

David M. Fronk was appointed to the position of Vice President of Clinical Research in December 1998 and has been with the Company since 1992, serving as Director of Clinical Research from December 1997 until December 1998. Mr. Fronk is responsible for managing the pre-clinical and clinical investigations for all products, as well as monitoring product performance. 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 Ohio State University in 1985 and his M.S. in Biomedical Engineering from 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.

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.

Thomas J. Lynch, J.D., Ph.D. has served as Vice President, Regulatory Affairs and Quality Assurance since August 2003. Prior to joining the Company, Dr. Lynch served for three years as Senior Vice President, Regulatory Affairs and Quality Assurance for Clearant, Inc., where he was responsible for developing and implementing improved safety processes and procedures for new and existing biopharmaceutical products. Dr. Lynch previously served as deputy director for the U.S. Food and Drug Administration (FDA) Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research. He worked at this division of the FDA for six years, where he was involved in new product review and approvals, and in regulatory compliance. Prior to that, he worked as a research scientist in several positions in academia, at the National Institutes of Health (NIH), and the Biotech industry. Dr. Lynch holds a doctorate in biochemistry from Wayne State University, and a Law degree from Georgetown University.

Joseph T. Schepers has served as Vice President, Corporate Communications since April 2003. Mr. Schepers is responsible for CryoLife's external and internal communications. From 2000 to 2003, Mr. Schepers was employed as the Vice President of Corporate Communications and Investor

Relations for ICN Pharmaceuticals/Ribapharm, Inc. From 1992 to 2000, Mr. Schepers served as the Head of Investor Relations and Communications in North America for Novartis/CIBA. Mr. Schepers received his B.A. and M.B.A. from Seton Hall University.

Thomas F. Ackerman has served as a Director of CryoLife since December 2003. Mr. Ackerman is Senior Vice President and Chief Financial Officer of Charles River Laboratories International, Inc. (NYSE: CRL), a position he has held since 1999. Charles River Laboratories is a provider of critical research tools and integrated support services for drug and medical device discovery and development. From 1996 to 1999, he served as Vice President and Chief Financial Officer of Charles River Laboratories, where he has been employed since 1988. Mr. Ackerman is a Director for the University of Massachusetts Amherst Foundation. Mr. Ackerman received a B.S. in Accounting from the University of Massachusetts and is a certified public accountant.

Daniel J. Bevevino has served as a Director of CryoLife since December 2003. Mr. Bevevino is Vice President and Chief Financial Officer of Respironics, Inc. (Nasdaq: RESP), a position he has held since 1996. Respironics develops, manufactures and markets medical devices used primarily for the treatment of patients suffering from sleep and respiratory disorders. Mr. Bevevino has been employed by Respironics since 1988. He began his career as a certified public accountant with Ernst & Young. Mr. Bevevino received a B.S. in Business Administration from Duquesne University and an M.B.A. from the University of Notre Dame.

John M. Cook has served as a Director of CryoLife since August 1999. Mr. Cook is Chairman, President and Chief Executive Officer of PRG-Schultz International, Inc. (Nasdaq: PRGX), an international, publicly held audit recovery firm operating in over 40 countries, with 2003 revenues exceeding $375 million. Mr. Cook has served as Chief Executive Officer of PRG-Schultz since its founding in January 1991. Prior to PRG-Schultz, he served in a number of top financial and management positions in the retail industry, including Senior Vice President and Chief Financial Officer of Caldor Stores and Senior Vice President of Finance and Controller of Kaufmann's Department Stores, both May Department Stores affiliates. He holds a B.S. degree in accounting from Saint Louis University, where he serves as a member of the Board of Trustees and holds a seat on the Executive Advisory Board of the University's School of Business and Administration.

Ronald C. Elkins, M.D. has served as a Director of CryoLife since January 1994. Dr. Elkins is Professor Emeritus, Section of Thoracic and Cardiovascular Surgery, University of Oklahoma Health Science Center. Dr. Elkins has been a physician at the Health Science Center since 1971, and was Chief, Section of Thoracic and Cardiovascular Surgery from 1975 to 2002. Dr. Elkins is a graduate of the University of Oklahoma and Johns Hopkins Medical School.

Virginia C. Lacy has served as a Director of CryoLife since August 1997. Ms. Lacy received her B.A. degree from Northwestern University in 1963. Ms. Lacy is the Administrator of The Jeannette & John Cruikshank Memorial Foundation, which provides housing assistance to those in need throughout the greater Chicago area. Since 1997, Ms. Lacy has served as President, and since 1974 has served as Secretary-Treasurer and Chief Financial Officer, of Precision Devices Corporation, a distributor of medical devices. She was one of the founders of that company and serves as the Chairman of its Board of Directors. As an elected member of the Board of Education of District 203 of the State of Illinois for 12 years, she served on its budget committee, which was responsible for planning and reviewing the spending of $100 million in public funds each year in a school district having 2,500 employees. Ms. Lacy also provided leadership in state education by serving on committees that analyzed state funding for education.

Ronald D. McCall, Esq. has served as a Director of CryoLife since January 1984 and served as its Secretary and Treasurer from 1984 to 2002. From 1985 to the present, Mr. McCall has been the owner of the law firm of Ronald D. McCall, P.A., based in Tampa, Florida. Mr. McCall was admitted to the practice of law in Florida in 1961. Mr. McCall received his B.A. and J.D. degrees from the University of Florida.

Bruce J. Van Dyne, M.D. has served as a Director of CryoLife since August 1999. Dr. Van Dyne is a board-certified neurologist and has been in private practice in Minneapolis, Minnesota, since 1975. He has served in numerous advisory positions, including as an Examiner in Neurology for the American Board of Psychiatry and Neurology and as previous Chairman of the Department of Neurology for Park Nicollet Medical Center in Minneapolis. He is a graduate of Northwestern University Medical School and is the author of numerous medical publications in the field of neurology.

Stockholder Derivative Action

On August 30, 2002 a purported stockholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John M. 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 names CryoLife as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to CryoLife by causing or allowing CryoLife to engage in certain inappropriate practices that caused CryoLife to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that CryoLife'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 CryoLife's Board of Directors. Both complaints seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of CryoLife.

CryoLife's Board of Directors established an independent committee, consisting of Ms. Lacy, Mr. Cook and Dr. Van Dyne, to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty.

In October 2003 the two purported derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel, evaluated the consolidated amended complaint, and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint.

Based on the report of the independent committee, the Company moved to dismiss the derivative action in May 2004. In an order dated December 1, 2004, the Court denied the motion to dismiss, such that the case will proceed into the discovery phase. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of CryoLife. At this time, CryoLife is unable to predict the outcome of this litigation.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires that CryoLife's executive officers, Directors, and persons who beneficially own more than 10% of CryoLife's stock file initial reports of ownership and reports of changes in ownership with the SEC. Executive officers, Directors and greater than 10% beneficial owners are required by SEC regulations to furnish CryoLife with copies of all Section 16(a) forms they file.

Based solely on its review of copies of forms received by it pursuant to Section 16(a) of the Securities Exchange Act of 1934 or written representations from reporting persons, CryoLife believes that with respect to 2004, all Section 16(a) filing requirements applicable to its executive officers, Directors and greater than 10% beneficial owners were complied with.

Audit Committee

CryoLife's Audit Committee consisted of four non-employee Directors at December 31, 2004: Mr. Bevevino, Chairman, Mr. Cook, Ms. Lacy and Dr. Van Dyne. On June 29, 2004, Mr. Bevevino replaced Ms. Lacy as Chairman and Dr. Van Dyne replaced Dr. Elkins on the Committee. The Audit Committee reviews the general scope of CryoLife's annual audit and the nature of services to be performed for CryoLife in connection therewith, acting as liaison between the Board of Directors and the independent registered public accounting firm. The Audit Committee also formulates and reviews various company policies, including those relating to accounting practices and internal control systems of CryoLife. In addition, the Audit Committee is responsible for reviewing and monitoring the performance of CryoLife's independent registered public accounting firm and for engaging or discharging CryoLife's independent registered public accounting firm. Each of the members of the Audit Committee is "independent" as defined in Section 303.01(B)(2)(a) of the current New York Stock Exchange Listing Standards and also meets the criteria set forth in Section 303.01(B)(3). In addition, the Board of Directors has determined that at least one member of the Audit Committee meets the NYSE standard of having accounting or related financial management expertise. The Board of Directors has also determined that Mr. Bevevino meets the SEC criteria of an "audit committee financial expert."

The Audit Committee operates under a written charter, which was revised in February 2004 to give this committee broader authority to fulfill its obligations under SEC and NYSE requirements. A current copy can be viewed on the Company's website at *www.cryolife.com/investornew.htm*. The charter gives the Audit Committee the authority and responsibility for the appointment, retention, compensation and oversight of the Company's independent registered public accounting firm, including pre-approval of all audit and non-audit services to be performed by the Company's independent registered public accounting firm.

Policy and Procedures for Stockholders Submitting the Names of Candidates for Election to the Board of Directors

There have been no material changes to the procedures by which stockholders may recommend nominees to the CryoLife Board of Directors during 2004.

Code of Business Conduct and Ethics

CryoLife, Inc. was founded with a commitment to the highest ethical standards of business conduct and fair dealing in the company's relations with all employees, customers, suppliers and stockholders. CryoLife has established a Code of Business Conduct and Ethics that clarifies the Company's standards of conduct in potentially sensitive situations; makes clear that CryoLife expects all employees, officers and Directors to understand and appreciate the ethical considerations of their decisions; and reaffirms the Company's long-standing commitment to a culture of corporate and individual accountability and responsibility for the highest ethical and business practices.

This Code of Business Conduct and Ethics also serves as the code for the Company's Chief Executive Officer, Chief Financial Officer, Controller and all other financial officers and executives. A copy of the Code of Business Conduct and Ethics is posted on the Company's website at *www.cryolife.com/investornew.htm*. In the event that the company amends or waives any of the provisions of the Code of Business Conduct and Ethics applicable to the Company's Chief Executive Officer, Chief Financial Officer, or Controller, the Company intends to disclose the same on the Company's website at *www.cryolife.com/investornew.htm*.

Item 11. Executive Compensation.

The following table sets forth the compensation paid or accrued by CryoLife to CryoLife's Chief Executive Officer and the four other most highly paid executive officers of CryoLife for 2004 as well as two executive officers whose employment terminated in 2004 (collectively, the "Named Executives"). The information presented is for the three year period ended December 31, 2004.

SUMMARY COMPENSATION TABLE

		Annual Compensation		Long-Term Compensation		
Name and Principal Position	Year	Salary ($) (1)	Bonus ($)	Restricted Stock Award(s) ($)	Securities Underlying Options/SARs (#)(2)	All Other Compensation ($)(3)
Steven G. Anderson	2004	$ 600,000	$ —	$ —	10,000	$ 4,000
Chairman of the Board of Directors,	2003	600,000	—	—	45,000	2,250
President, and Chief Executive Officer	2002	600,000	300,000	—	50,000	29,974
David Ashley Lee	2004	300,656	—	138,200	15,000	4,000
Executive Vice President, Chief	2003	261,333	—	—	—	2,835
Operating Officer, and Chief Financial Officer	2002	220,000	120,000	—	72,500	5,000
Albert E. Heacox, Ph.D.	2004	252,898	—	34,550	15,000	3,795
Senior Vice President, Research and Development	2003	253,000	—	—	—	2,837
	2002	225,000	120,000	—	24,850	16,194
Kirby S. Black, Ph.D.(4)	2004	240,167	—	—	—	138,938
Former Senior Vice President,	2003	253,000	—	—	—	2,000
Research and Development	2002	225,000	120,000	—	48,276	20,975
James C. Vander Wyk, Ph.D.(4)	2004	228,585	—	—	—	409,629
Former Vice President, Product Integrity	2003	240,000	—	—	—	5,000
	2002	240,000	60,000	—	34,683	20,975
David M. Fronk	2004	214,500	—	34,550	10,000	3,933
Vice President, Clinical Research	2003	214,500	—	—	—	3,000
	2002	195,000	80,000	—	48,500	8,422
Thomas J. Lynch, J.D., Ph.D.(5)	2004	240,000	—	34,550	—	3,400
Vice President, Regulatory	2003	89,524	—	—	50,000	—
Affairs & Quality Assurance						

(1) Includes base salary earned by the Named Executives for the periods presented and includes compensation deferred under CryoLife's 401(K) plan, and amounts such officers elected to apply to CryoLife's supplemental life insurance program. Amounts for perquisites and other personal benefits extended to the Named Executives are less than the lesser of $50,000 or 10% of the total of annual salary and bonus of such Named Executive. Accordingly, the column for "Other Annual Compensation" has been omitted.

(2) During the periods presented, the only forms of long-term compensation utilized by CryoLife have been the grant of stock options and the award of restricted stock grants. CryoLife has not awarded stock appreciation rights, or made any long-term incentive payouts. Accordingly, the column for "Long-Term Incentive Payouts" has been omitted.

(3) Includes matching contributions to the CryoLife 401(K) plan for all years presented and CryoLife contributions to its supplemental life insurance program for certain executive officers in 2002. For Mr. Black, the 2004 total includes $4,000 in matching contributions to the CryoLife 401(K) plan, $5,087 in COBRA payments, $6,000 in outplacement services, $37,085 in distribution of CryoLife's aggregate contributions to supplemental life insurance program, $2,433 in accrued vacation payout, and $84,333 in severance payments. For Mr. Vander Wyk, the 2004 total includes $3,800 in matching contributions to the CryoLife 401(K) plan, $3,815 in COBRA payments, $4,500 in outplacement services, $37,514 in distribution of CryoLife's aggregate contributions to supplemental life insurance program, and $360,000 in severance payments.

(4) Messrs. Black and Vander Wyk ceased employment with CryoLife on December 13 & 14, 2004, respectively. Their 2004 Annual Compensation is the cumulative total compensation earned up to their final day of employment with CryoLife.

(5) Dr. Lynch began his employment with CryoLife in August of 2003.

The following table sets forth, for each of the Named Executives, the amount of CryoLife's contributions to the 401(K) plan and the supplemental life insurance program:

	2004		2003		2002		
	Total	401(K) Contribution	Total	401(K) Contribution	Total	401(K) Contribution	Supplemental Life Insurance Program
Steven G. Anderson	$ 4,000	$ 4,000	$ 2,250	$ 2,250	$ 29,974	$ 5,000	$ 24,974
David Ashley Lee	4,000	4,000	2,835	2,835	5,000	5,000	—
Albert E. Heacox, Ph.D.	3,795	3,795	2,837	2,837	16,194	5,000	11,194
Kirby S. Black, Ph.D.	4,000	4,000	2,000	2,000	20,975	5,000	15,975
James C. Vander Wyk, Ph.D.	3,800	3,800	5,000	5,000	20,975	5,000	15,975
David M. Fronk	3,933	3,933	3,000	3,000	10,586	4,616	5,970
Thomas J. Lynch, J.D., Ph.D.	3,400	3,400	—	—	—	—	—

Supplemental Life Insurance Program

Pursuant to a supplemental life insurance program for certain executive officers of the Company, the Company and the executives share in the premium payments and ownership of insurance policies on the lives of such executives. Upon death of the insured party, policy proceeds equal to the premium contribution are due to the Company with the remaining proceeds due to the designated beneficiaries of the insured party. The Company's Board of Directors is currently evaluating its options related to the termination of this plan and the creation of a new executive insurance plan that will fully comply with Section 402(a) of the Sarbanes-Oxley Act of 2002. Therefore, no premium contributions were made by the Company in 2004 or 2003. The Company's aggregate premium contributions under this program were approximately $74,000 for 2002. The aggregate Company contributions for each of the named executive officers who participated in the program were $187,600, $56,023, and $9,776, respectively for each of Messrs. Anderson, Heacox, and Fronk as of December 31, 2004. As of December 31, 2004 the Company distributed its aggregate contributions $37,085 and $37,514 to Messrs. Black and Vander Wyk, respectively.

Grant of Options. During 2004, options were granted to certain Named Executives. No stock appreciation rights (SARs) have been granted by CryoLife. The following table sets forth information regarding the option grants in 2004:

OPTION/SAR GRANTS IN LAST FISCAL YEAR (2004)

Name	Number of Securities Underlying Options/SARs Granted(#)	% of Total Options/SARs Granted to Employees in Fiscal Year	Exercise Price ($/Sh)(1)	Expiration Date(2)	Potential Realizable Value at Assumed Annual Rates of Appreciation for Option Term	
					5%($)	10%($)
Steven G. Anderson	10,000	4%	$ 5.36	12-29-09	$ 16,503	$ 36,949
David Ashley Lee	15,000	6%	5.36	12-29-09	24,754	55,423
Albert E. Heacox, Ph.D	15,000	6%	5.36	12-29-09	24,754	55,423
Kirby S. Black, Ph.D	—	—	—	—	—	—
James C. Vander Wyk, Ph.D.	—	—	—	—	—	—
David M. Fronk	10,000	4%	5.36	12-29-09	16,503	36,949
Thomas J. Lynch, JD, Ph. D.	—	—	—	—	—	—

(1) The exercise price was fixed as the closing price on the NYSE price on the date of grant.

(2) Options are subject to earlier termination in the event of death, disability, retirement, or termination of employment.

Options Exercised. The following table sets forth information regarding the exercise of options in 2004 and the number of options held by the Named Executives as listed in the Summary Compensation Table, including the value of unexercised in-the-money options, as of December 31, 2004. The closing price of CryoLife's common stock on December 31, 2004 used to calculate such values was $7.07 per share.

**AGGREGATED OPTION/SAR EXERCISES IN LAST FISCAL YEAR (2004)
AND FISCAL YEAR-END OPTION/SAR VALUES (AS OF DECEMBER 31, 2004)**

Name	Shares Acquired On Exercise(#)	Value Realized ($)	Number Of Securities Underlying Unexercised Options/SARs At Year End(#)		Value Of Unexercised In-The-Money Options/SARs At Year End($)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Steven G. Anderson	—	$ —	72,722	160,028	$ 79,095	$ 187,380
David Ashley Lee	12,500	32,875	59,369	75,631	60,875	208,275
Albert E. Heacox, Ph.D	—	—	27,790	36,910	48,408	98,262
Kirby S. Black, Ph.D	16,000	80,800	—	—	—	—
James C. Vander Wyk, Ph.D.	10,000	46,000	—	—	—	—
David M. Fronk.	—	—	59,029	50,471	74,998	129,597
Thomas J. Lynch, JD, Ph.D.	—	—	10,000	40,000	18,600	74,400

2004 Employee Stock Incentive Plan. On February 24, 2004, the Board of Directors adopted the 2004 Employee Stock Incentive Plan, which was subsequently approved by stockholders at the 2004 annual meeting of stockholders. CryoLife's 2004 Employee Stock Incentive Plan provides for the grant of options ("Options"), stock appreciation rights ("SARs") and stock units, performance shares, restricted stock awards and restricted stock unit awards (collectively referred to as "Other Stock Awards"). Options, SARs and Other Stock Awards are collectively referred to herein as "Awards," which may be granted under the 2004 Employee Stock Incentive Plan to employees and officers of CryoLife and its subsidiaries. The maximum number of shares of stock that may be awarded under the 2004 Plan shall be equal to the sum of: (i) 2,000,000 shares of stock; and (ii) up to 100,000 shares of stock tendered in connection with the exercise of Options granted under either the 2004 Employee Stock Incentive Plan, the 2002 Stock Incentive Plan, the 1998 Long-Term Incentive Plan, or the 1993 Employee Stock Incentive Plan resulting in a maximum (the "Plan Maximum") of 2,100,000 shares of common stock that may be granted under the 2004 Employee Stock Incentive Plan. In addition, the following provisions are imposed under the 2004 Employee Stock Incentive Plan: (i) a maximum of 2,000,000 shares issued under Options intended to be Incentive Stock Options ("ISOs") under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), (ii) a maximum of 400,000 shares may be issued under Options and SARs to any one individual during any consecutive twelve-month period, (iii) a maximum of 2,000,000 shares in the aggregate may be subject to Stock Awards, and (iv) no more than 2,000,000 shares may be subject to Awards that are intended to be "performance-based compensation" (as that term is used for purposes of Code Section 162(m)). The 2004 Employee Stock Incentive Plan terminates in June 2014, unless terminated by the Board prior to that date; provided that in the event of 2004 Employee Stock Incentive Plan termination, the 2004 Employee Stock Incentive Plan shall remain in effect as long as any options, Stock Appreciation Rights or other stock awards granted under it are outstanding. As of February 11, 2005, options for 234,500 shares were outstanding, no options had been exercised, and options for 1,681,530 shares remain available for grant pursuant to the 2004 Employee Stock Incentive Plan.

2002 Stock Incentive Plan. On March 7, 2002, the Board of Directors adopted the 2002 Stock Incentive Plan, which was subsequently approved by stockholders. Options may be granted under the 2002 Stock Incentive Plan to employees, officers or Directors of CryoLife and consultants and advisers to CryoLife and its subsidiaries. Unless sooner terminated by the Board, the 2002 Stock Incentive Plan terminates in March 2012. CryoLife's 2002 Stock Incentive Plan provides for the grant of Options, SARs and stock units, performance shares and restricted stock awards (collectively referred to as "Stock Awards"). Options, SARs and Stock Awards are collectively referred to herein as "Awards." Awards may be granted under the 2002 Stock Incentive Plan to acquire up to a maximum of 974,000 shares of common stock. In addition, the following limitations are imposed under the 2002 Stock Incentive Plan: (i) a maximum of 974,000 shares may be issued pursuant to Options intended to be

ISOs under Section 422 of the Code (ii) a maximum of 100,000 shares may be issued under Options and SARs to any one individual during any consecutive twelve-month period, (iii) a maximum of 100,000 shares in the aggregate may be subject to Stock Awards, and (iv) a maximum payment under Stock Awards of $400,000 may be made to any one individual for any performance goals established for any performance period (including the fair market value of stock subject to Awards denominated in shares). As of February 11, 2005, options for 780,050 shares were outstanding, options for 113,000 shares had been exercised, and options for 92,291 shares remain available for grant pursuant to the 2002 Stock Incentive Plan.

1998 Long-Term Incentive Plan. On December 19, 1997, the Board of Directors adopted the CryoLife 1998 Long-Term Incentive Plan, which was subsequently approved by stockholders. As amended in 2000, the 1998 Long-Term Incentive Plan provides for the grant of options, stock appreciation rights and other awards to acquire up to a maximum of 900,000 shares of common stock, subject to certain adjustments. As of February 11, 2005, options for 684,030 shares were outstanding, options for 77,395 shares had been exercised, and options for 148,198 shares remain available for grant pursuant to the 1998 Long-Term Incentive Plan.

1993 Employee Stock Incentive Plan. On July 6, 1993, the Board of Directors adopted the CryoLife 1993 Employee Stock Incentive Plan, which was subsequently approved by stockholders. As of February 11, 2005, options for 164,400 shares were outstanding, options for 794,194 shares had been exercised, and no options for shares remain available for grant pursuant to the 1993 Employee Stock Incentive Plan.

2004 Non-Employee Directors Stock Option Plan. On February 24, 2004, the Board of Directors adopted the 2004 Non-Employee Directors Stock Option Plan, which was subsequently approved by stockholders at the 2004 annual meeting of stockholders. Each individual who is appointed or elected as a Director of CryoLife for the first time shall automatically receive an option to purchase 10,000 shares of common stock on the next business day after such appointment or election. This option shall be in addition to any option granted pursuant to yearly service as described below. On the first business day following (i) CryoLife's 2004 Annual Meeting of Stockholders and (ii) each succeeding Annual Meeting thereafter, each individual who is at the time elected, reelected or continuing as a non-employee Director automatically will be granted an option to purchase 10,000 shares of common stock. Options granted under this plan are not transferable other than by will or the laws of descent and distribution. CryoLife's 2004 Non-Employee Directors Stock Option Plan provides for the grant of options to acquire up to a maximum of 500,000 shares of common stock, subject to certain adjustments. As of February 11, 2005, options for 70,000 shares were outstanding, options for zero shares had been exercised, and options for 430,000 shares remain available for grant pursuant to the 2004 Non-Employee Directors Stock Option Plan.

CryoLife Amended and Restated Non-Employee Directors Stock Option Plan. The CryoLife Amended and Restated Non-Employee Directors Stock Option Plan, which has now expired, provided for the grant of options to non-employee Directors of CryoLife. At each Annual Meeting of Stockholders, each non-employee Director elected, re-elected or continuing as a non-employee Director of CryoLife received an annual grant of options to purchase 7,500 shares on the first business day after such Annual Meeting, which options vested and became exercisable on the date of grant. Options granted under this plan are not transferable other than by will or the laws of descent and distribution. Notwithstanding the foregoing, the optionee may transfer the option for no consideration to or for the benefit of a member of the optionee's immediate family (including, without limitation, to a trust or IRA) subject to such limits as the Board may establish, and the transferee shall remain subject to all the terms and conditions that were applicable to such option prior to the transfer. Upon the death of a non-employee Director, options that were exercisable on the date of death are exercisable by his or her legal representatives or heirs, but in no event may the option be exercised after the last day on which it could have been exercised by the non-employee Director. As of February 11, 2005, options for 135,000 shares were outstanding, options for 7,500 shares had been exercised, and no options for shares remain available for grant pursuant to the Amended and Restated Non-Employee Directors Stock Option Plan.

Employment Agreements. With the exception of Mr. Lynch in September 2002, CryoLife entered into employment agreements with each of the Named Executives. CryoLife entered into an employment agreement with Mr. Lynch in August 2003. These employment agreements are substantially identical except for the length of employment and position-specific terms, such as duties of employment and compensation, and except as otherwise disclosed below. Under Messrs. Anderson, Lee, Heacox, Vander Wyk, Fronk, and Lynch's employment agreements, CryoLife has agreed to employ, and each officer has agreed to remain employed by CryoLife, for two years after the effective date of the employment agreement. The current annual salaries for Messrs. Lee, Heacox, Fronk, and Lynch are $340,000, $265,650, $225,225, and $240,000, respectively. Under Dr. Black's employment agreement, CryoLife had agreed to employ, and he had agreed to remain employed by CryoLife, for one year after the effective date of the employment agreement. With the exception of Lynch's employment agreements, each of the two year employment agreements has been automatically extended for an additional year. Lynch's employment agreement will automatically extend for an additional year upon expiration of the initial term on August 1, 2005, unless either CryoLife or Lynch provides 30 days prior written notice of termination. These employment agreements provide that employment may be terminated by either party with or without cause. Except for Lynch, each officer may terminate his employment for good reason, which includes, among other things, termination by the officer for any reason, at least 90, but not more than 120, days following a Change of Control (as defined in the employment agreements) or during the 30-day period immediately following the first anniversary of a Change of Control.

Under the employment agreements, upon termination by the employee for good reason or termination by the Company other than for cause, death or disability, CryoLife will pay an agreed-upon severance payment. The severance payments are $330,000, $337,500, $292,000, and $240,000 for Messrs. Lee, Heacox, Fronk, and Lynch, respectively. Upon termination by the Company for cause or by the employee for any reason other than for good reason, the employment agreements will terminate, and CryoLife will not be obligated to pay any severance amount. The employment agreements automatically terminate upon death. Each employee is required to devote his full and exclusive time and attention to his employment duties. Under the employment agreements, CryoLife has agreed to require any successor to all or substantially all of the business and/or assets of CryoLife to assume the employment agreements.

Mr. Anderson's agreement provides that Ms. Ann B. Anderson, the spouse of Mr. Anderson, will be provided with health care coverage throughout her life, regardless of whether the agreement is terminated. This provision is consistent with the terms of Mr. Anderson's employment agreements negotiated in 1995 and in 1999. In the event CryoLife terminates employment other than for cause, death or disability, or Mr. Anderson terminates employment for good reason, then Mr. Anderson will be entitled to be paid $900,000 as severance compensation. If Mr. Anderson's employment is terminated by reason of his death, Mr. Anderson's legal representatives receive one year's salary. The annual salary for Mr. Anderson is $600,000. Mr. Anderson and the Compensation Committee of CryoLife's Board of Directors are currently negotiating a new agreement.

Compensation Committee Interlocks and Insider Participation. The following five Directors served on the Compensation Committee of CryoLife's Board of Directors through June 29, 2004: Dr. Elkins, Chairman, Mr. Cook, Mr. McCall, Dr. Van Dyne and Mr. Ackerman. At the 2004 Annual Meeting Thomas Ackerman, Chairman, John Cook, and Dan Bevevino were appointed to serve on the Compensation Committee.

Director Compensation

During 2004, all non-employee Directors of the Board of Directors of CryoLife were paid $40,000 per year. Each committee Chairman received an additional $5,000. The Presiding Director is paid $65,000 per year, inclusive off the $40,000 Director fee.

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2004 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 stockholders. CryoLife does not intend to continue this practice except to the extent that shares are otherwise unavailable under stockholder-approved plans and the grants are permitted by applicable NYSE rules.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Plans Approved by Stockholders	2,073,680	$ 10.11	2,367,319
Plans Not Approved by Stockholders	218,925	$ 19.84	—
Total	2,292,605	$ 11.04	2,367,319

OWNERSHIP OF PRINCIPAL STOCKHOLDERS, BOARD OF DIRECTORS, NAMED EXECUTIVES, AND EXECUTIVE OFFICERS AND DIRECTORS AS A GROUP

The name and address of each person or entity who owned beneficially 5% or more of the outstanding shares of common stock of CryoLife on February 11, 2005, together with the number of shares owned and the percentage of outstanding shares that ownership represents is set forth in the following table. The table also shows information concerning beneficial ownership by each of the members of the Board of Directors, the Named Executives and by all Directors and executive officers as a group. The number of shares beneficially owned is determined under the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares that the individual has the right to acquire within 60 days after the date hereof through the exercise of any stock option or other right. Unless otherwise indicated, each person has sole investment and voting powers, or shares such powers with his or her spouse, with respect to the shares set forth in the following table:

Beneficial Owner	Number of Shares of CryoLife Stock Beneficially Owned	Percentage of Outstanding Shares of CryoLife Stock
Steven G. Anderson	1,669,727(1)	7.1%
Thomas F. Ackerman	10,000(2)	*
Daniel J. Bevevino	10,000(2)	*
John M. Cook	147,000(3)	*
Ronald C. Elkins, M.D.	141,020(4)	*
David M. Fronk	73,534(5)	*
Albert E. Heacox, Ph.D.	83,336(6)	*
Virginia C. Lacy	657,659(7)	2.8%
David Ashley Lee	100,126(8)	*
Thomas J. Lynch, J.D., Ph.D	15,000(2)	*
Ronald D. McCall, Esq.	254,613(9)	1.1%
Bruce J. Van Dyne, M.D.	97,800(10)	*
Kirby S. Black, Ph.D.	55,221(11)	*
James C. Vander Wyk, Ph.D.	36,165	*
IronBridge Capital Management, LLC	1,301,138(12)	5.6%
O.S.S. Capital Management., L.P.	1,232,400(13)	5.3%
The PNC Financial Services Group, Inc.	1,235,250(14)	5.3%
All current Directors and Executive Officers as a group (14 persons)	3,342,259(15)	13.8%

* Ownership represents less than 1% of outstanding CryoLife common stock.

(1) Includes 107,924 shares held of record by Ms. Ann B. Anderson, Mr. Anderson's spouse, as well as 171,885 shares held in a grantor-retained annuity trust. Also includes 83,722 shares subject to options which are either presently exercisable or will become exercisable within 60 days after February 11, 2005. The business address for Mr. Anderson is: c/o CryoLife, Inc., 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144.

(2) Includes 10,000 shares subject to options which are either presently exercisable or will become exercisable within 60 days after February 11, 2005.

(3) Includes 19,500 shares that are held by CT Investments, LLC of which Mr. Cook owns 90% of the membership interests. Includes options to acquire 97,500 shares of common stock that are presently exercisable or will become exercisable within 60 days after February 11, 2005.

(4) Includes options to acquire 97,500 shares of common stock which are presently exercisable or will become exercisable within 60 days after February 11, 2005.

(5) Includes 61,029 shares subject to options which are either presently exercisable or will become exercisable within 60 days after February 11, 2005.

(6) Includes 27,790 shares subject to options which are either presently exercisable or will become exercisable within 60 days after February 11, 2005. Also includes 45,000 shares owned by Dr. Heacox's spouse as trustee of a living trust, 5,346 shares owned by Dr. Heacox as trustee of a living trust, 100 shares owned by Albert E. Heacox C/F Rachel K. Heacox, UTMA/GA and 100 shares owned by Albert E. Heacox C/F Daniel A. Heacox, UTMA/GA. Dr. Heacox disclaims beneficial ownership of all shares owned by his son and daughter.

(7) Includes 355,280 shares held by three trusts of which Ms. Lacy is trustee, and as to which shares she has voting power and control. Also includes 165,879 shares held by an IRA of Ms. Lacy's deceased spouse, of which Ms. Lacy is the beneficiary. Includes 3,000 shares held by a foundation for which Ms. Lacy is the president of the board of directors. Includes 22,500 shares held by a pension plan of which Ms. Lacy is administrator. Excludes 25,200 shares beneficially owned by Ms. Lacy's adult child residing with Ms. Lacy. Ms. Lacy disclaims beneficial ownership of those shares. Includes 111,000 shares subject to options, which are presently exercisable or will become exercisable within 60 days after February 11, 2005.

(8) Includes 61,369 shares subject to options which are either presently exercisable or will become exercisable within 60 days after February 11, 2005. Also includes 1,700 shares held in Mr. Lee's parents' account over which Mr. Lee has signing authority. Also includes 1,500 shares held by Mr. Lee's minor children.

(9) Includes 16,000 shares of common stock owned of record by Ms. Marilyn B. McCall, Mr. McCall's spouse. Includes options to acquire 114,925 shares of common stock that are presently exercisable or will become exercisable within 60 days after February 11, 2005.

(10) Includes options to acquire 87,500 shares of common stock that are presently exercisable or will become exercisable within 60 days after February 11, 2005.

(11) Also includes 90 shares held by Dr. Black's minor children.

(12) Information is based in part on Schedule 13G filed on February 11, 2005 by IronBridge Capital Management, LLC, an investment advisor. The address for this stockholder is One Parkview Plaza, Suite 600, Oakbrook Terrace, Illinois.

(13) Information is based in part on Schedule 13G filed on January 18, 2005 by Oscar S. Schafer & Partners I LP, a Delaware limited partnership ("OSS I"); Oscar S. Schafer & Partners II LP, a Delaware limited partnership ("OSS II", and together with OSS I, the "Partnerships"); O.S.S. Advisors LLC, a Delaware limited liability company (the "General Partner"), which serves as the general partner of each of the Partnerships; O.S.S. Overseas Fund Ltd., a Cayman Islands exempted company ("OSS Overseas"); O.S.S. Capital Management LP, a Delaware limited partnership (the "Investment Manager"), which serves as investment manager, and management company, to OSS Overseas and the Partnerships, respectively, and has investment discretion with respect to shares of Common Stock directly owned by OSS Overseas and Partnerships; Schafer Brothers LLC, a Delaware limited liability company (the "SB LLC"), which serves as the general partner to the Investment Manager; and Mr. Oscar S. Schafer ("Mr. Schafer"), who serves as the senior managing member of the General Partner and of SB LLC. The address for all of these stockholders (or the investment adviser) is c/o 598 Madison Avenue New York, NY 10022.

(14) Information is based in part on Schedule 13G filed on February 10, 2005 by The PNC Financial Services Group, Inc. ("PNC Holding Company"); PNC Bancorp, Inc.; PNC Bank, National

Association; BlackRock Advisors, Inc.; BlackRock Capital Management, Inc.; and BlackRock Financial Management, Inc. The filing persons are direct or indirect subsidiaries of PNC Holding Company. Of the total shares reported herein, 1,250 shares are held in accounts at PNC Bank, National Association in a fiduciary capacity; for the rest of the shares the reporting persons report having sole voting and dispositive power. The addresses for these stockholders are as follows: The PNC Financial Services Group, Inc.—One PNC Plaza, 249 Fifth Avenue, Pittsburgh, PA 15222-2707; PNC Bancorp, Inc.—300 Delaware Avenue, Suite 304, Wilmington, DE 19801; PNC Bank, National Association—One PNC Plaza, 249 Fifth Avenue, Pittsburgh, PA 15222-2707; BlackRock Advisors, Inc.—100 Bellevue Parkway, Wilmington, DE 19809; BlackRock Capital Management, Inc.—100 Bellevue Parkway, Wilmington, DE 19809; BlackRock Financial Management, Inc.—100 Bellevue Parkway, Wilmington, DE 19809.

(15) Includes 835,509 shares subject to options, which are presently exercisable or will become exercisable within 60 days after February 11, 2005. Includes 50,346 shares held as trustees by an executive officer and his spouse. Includes 355,280 shares held as beneficiary of three trusts, and 165,879 shares held as beneficiary of an IRA, of Ms. Lacy's deceased spouse. Includes 22,500 shares held as administrator of a pension plan. Includes 3,000 shares held by a foundation for which Ms. Lacy is the president of the board of directors. Includes 19,500 shares held by CT Investments, LLC, which is controlled by Mr. Cook. Includes 123,924 shares held of record by the spouses of executive officers and Directors. Includes 1,700 shares held of record by the minor children of executive officers and Directors. Includes 1,700 shares held by Mr. Lee's parents.

Item 13. Certain Relationships and Related Transactions.

CryoLife employs Mr. Anderson's son, Bruce A. Anderson, 38, as Director of Cardiovascular Field Services in the Marketing Department. He has held various positions within the Company since 1994. His compensation during 2004, including commissions, was $215,414.

Item 14. Principal Accounting Fees and Services.

The following table presents fees for professional audit services rendered by Deloitte & Touche LLP for the audit of the Company's annual financial statements for the years ended December 31, 2004 and December 31, 2003, and fees billed for other services rendered by Deloitte & Touche LLP during those periods.

	2004	2003
Audit fees(1)	$ 625,000	$ 240,000
Audit-related fees(2)	129,000	60,000
Tax fees(3)	178,000	231,000
All other fees	—	—
Total	$ 932,000	$ 531,000

(1) Audit fees consisted of work performed in the integrated audit of the financial statements and internal control over financial reporting or the review of interim financial statements and the related SEC Form 10K and 10Q filings, respectively.

(2) Audit related fees consisted primarily of audits of employee benefit plans, grants, replies to regulatory agencies' requests, and other SEC filings.

(3) Tax fees consisted primarily of tax compliance and reporting ($174,000 in 2004 and $130,000 in 2003) as well as tax consulting work ($4,000 in 2004 and $101,000 in 2003). Additional tax services provided by other firms were not included in this disclosure.

Deloitte & Touche LLP was the independent registered public accounting firm for 2004 and 2003.

The Company's Audit Committee approved all of the services described above. The Audit Committee has determined that the payments made to its independent registered public accounting firm for these services are compatible with maintaining such firm's independence.

Audit Committee's Pre-approval Policies and Procedures

The Audit Committee has the sole authority to appoint or replace, compensate, and oversee the work of any independent registered public accounting firm, who must be, when required, a registered firm as defined by law, whose purpose is the preparation or issuance of an audit report or related work. The independent registered public accounting firm's reports and other communications are to be delivered directly to the Audit Committee, and the Audit Committee is responsible for the resolution of disagreements between management and the independent registered public accounting firm regarding financial reporting.

The Audit Committee pre-approves all audit and non-audit services performed by the independent registered public accounting firm and all engagement fees and terms in connection therewith, except as otherwise permitted by regulations or the exchange.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following are filed as part of this report:

(a) 1. Consolidated Financial Statements

See index included elsewhere herein.

2. Financial Statement Schedule

Schedule II—Valuation and Qualifying Accounts

All other financial statement schedules not listed above are omitted, as the required information is not applicable or the information is presented in the consolidated financial statements or related notes.

(b) Exhibits

The following exhibits are filed herewith or incorporated herein by reference:

Exhibit Number	Description
2.1	Reserved.
2.2	Agreement and Plan of Merger dated as of March 5, 1997 among Ideas for Medicine, Inc., J. Crayton Pruitt, Sr., M.D., Thomas Benham, Thomas Alexandris, Tom Judge, Natalie Judge, Helen Wallace, J. Crayton Pruitt, Jr., M.D., and Johanna Pruitt, and CryoLife, Inc. and CryoLife Acquisition Corporation. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on March 19, 1997.)
2.3	Asset Purchase Agreement by and between Horizon Medical Products, Inc. and Ideas for Medicine, Inc. dated September 30, 1998. (Incorporated by reference to Exhibit 2 to Horizon Medical Products, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 1998.)
2.4†	Asset Purchase Agreement, dated October 9, 2000, by and between Horizon and IFM. (Incorporated by reference to Exhibit 2.4 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
3.1	Restated Certificate of Incorporation of the Company. (Incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)
3.2	ByLaws of the Company, amendments adopted on December 8, 2004. (Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on December 10, 2004.)
3.3	Articles of Amendment to the Articles of Incorporation of the Company. (Incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000).
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).
4.2	Form of Certificate for the Company's Common Stock. (Incorporated 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 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 Jun 1, 1997, executed by the Company and American Stock Transfer & Trust Company, as successor Rights agent. (Incorporated by reference to Exhibit 4.4 to the Registrant's Form S-3 (File No. 333-112673) filed February 10, 2004).
10.1	Lease, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company, as Tenant, dated February 13, 1986, as amended by that Amendment to Lease, by and between the parties, dated April 7, 1986, as amended by that Amendment to Lease, by and between the parties, dated May 15, 1987, as amended by that Second Amendment to Lease, by and between the parties, dated June 22, 1988, as amended by that Third Amendment to Lease, by and between the parties, dated April 4, 1989, as amended by that Fourth Amendment to Lease, by and between the parties, dated April 4, 1989 as amended by that Fifth Amendment to Lease, by and between the parties, dated October 15, 1990. (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.1(a)*	Sixth Amendment to Lease dated February 13, 1986, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company as tenant, dated March 14, 1995.
10.1(b)	Seventh Amendment to Lease dated February 13, 1986, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company as tenant, dated May 15, 1996. (Incorporated by reference to Exhibit 10.1(a) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996.)
10.1(c)	Eighth Amendment to Lease dated February 13, 1986, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company as tenant, dated November 18, 1998. (Incorporated by reference to Exhibit 10.12 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.1(d)	Ninth Amendment to Lease dated February 13, 1986, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company as tenant, dated July 25, 2001. (Incorporated by reference to Exhibit 10.13 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.1(e)	Tenth Amendment to Lease dated February 13, 1986, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company as tenant, dated June 25, 2002. (Incorporated by reference to Exhibit 10.42 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.2*+	Credit Agreement by and between CryoLife, Inc., Certain Subsidiaries of CryoLife, Inc., and Wells Fargo Foothill, Inc., dated February 8, 2005.
10.3	1993 Employee Stock Incentive Plan adopted on July 6, 1993. (Incorporated 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	1989 Incentive Stock Option Plan for the Company, adopted on March 23, 1989. (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.5	Incentive Stock Option Plan, dated as of April 5, 1984. (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.6	Form of Stock Option Agreement and Grant under the Incentive Stock Option and Employee Stock Incentive Plans. (Incorporated 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 by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.8	Form of Supplemental Retirement Plan, by and between the Company and its Officers—Parties to Supplemental Retirement Plans: Steven G. Anderson, David M. Fronk, Sidney B. Ashmore, James C. Vander Wyk, Albert E. Heacox, Kirby S. Black, and David Ashley Lee. (Incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.9(a)	Employment Agreement, by and between the Company and Steven G. Anderson. (Incorporated by reference to Exhibit 10.9(a) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998.)
10.9(b)	Employment Agreement, by and between the Company and Albert E. Heacox. (Incorporated by reference to Exhibit 10.7(c) to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.9(c)	Employment Agreement, by and between the Company and D. Ashley Lee, dated December 12, 1994. (Incorporated by reference to Exhibit 10.9(c) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.9(d)*	Summary of increases in salaries for certain named executive officers.
10.9(e)	Reserved.
10.9(f)	Employment Agreement, by and between the Company and David M. Fronk. (Incorporated by reference to Exhibit 10.9(g) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998.)
10.9(g)	Employment Agreement, by and between the Company and Sidney B. Ashmore. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.)
10.9(h)	Employment Agreement, by and between the Company and D. Ashley Lee, dated September 3, 2002. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.9(i)	Employment Agreement, by and between the Company and Sidney B. Ashmore, dated September 3, 2002. (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.9(j)	Reserved.

10.9(k)	Employment Agreement, by and between the Company and Albert E. Heacox, dated September 3, 2002. (Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.9(l)	Employment Agreement, by and between the Company and David M. Fronk, dated September 3, 2002. (Incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.9(m)	Employment Agreement, by and between the Company and James C. Vander Wyk, dated September 3, 2002. (Incorporated by reference to Exhibit 10.9(o) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.9(n)	Employment Agreement, by and between the Company and Steven G. Anderson, dated September 3, 2002. (Incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.9(o)	Employment Agreement, by and between the Company and Thomas J. Lynch, J.D. Ph.D., dated August 1, 2003. (Incorporated by reference to Exhibit 10.9(o) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003.)
10.10	Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.11	Terms of Agreement Between Bruce J. Van Dyne, M.D. and CryoLife, Inc. dated November 1, 1999. (Incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)
10.12	Technology Acquisition Agreement between the Company and Nicholas Kowanko, Ph.D., dated March 14, 1996. (Incorporated 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 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.
10.15	CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated by reference to Appendix 2 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.16	Lease Agreement between the Company and Amli Land Development—I Limited Partnership, dated April 18, 1995. (Incorporated 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 Amli Land Development—I Limited Partnership dated August 6, 1999. (Incorporated by reference to Exhibit 10.16(a) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)

10.16(b)	Restatement and Amendment to Funding Agreement between the Company and Amli Land Development—I Limited Partnership, dated August 6, 1999. (Incorporated by reference to Exhibit 10.16(b) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.18	CryoLife, Inc. Employee Stock Purchase Plan (Incorporated 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 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 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 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 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 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 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	Commercial Premium Finance Agreement, dated April 13, 2004, by and between AFCO Premium Credit LLC and the Company. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.26	Commercial Premium Finance Agreement, dated May 5, 2004, by and between AFCO Premium Credit LLC and the Company. (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.27	Reserved.
10.28	Reserved.
10.29	Lease Agreement dated March 5, 1997 between the Company and J. Crayton Pruitt, Sr., M.D. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1997.)
10.30	Lease Guaranty dated March 5, 1997 between J. Crayton Pruitt Family Trust U/T/A and CryoLife, Inc., as Guarantor for CryoLife Acquisition Corporation. (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1997.)

10.31	Reserved.
10.32	Reserved.
10.33	Reserved.
10.34	Sublease Agreement between Horizon and IFM, dated October 9, 2000. (Incorporated by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.35	Terms of Agreement between Ronald C. Elkins, MD and CryoLife, Inc., dated November 7, 2000. (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
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	Assignment and Assumption Agreement, dated March 30, 2001, by and among Horizon, Vascutech and IFM. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.)
10.39	Assignment of Sublease, dated March 30, 2001, by and among Horizon, Vascutech, and IFM. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.)
10.40	Security Agreement, dated March 30, 2001, by Vascutech in favor of IFM. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.)
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	Reserved.
10.44	Reserved.
10.45	Reserved.
10.46	Reserved.
10.47	First Amendment to Employment Agreement, by and between the Company and Steven G. Anderson dated September 3, 2002. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly report in Form 10-Q for the quarter ended March 31, 2003.)
10.48	Reserved.
10.49	Form of Stock Purchase Agreement between the Company and each PIPE investor dated January 27, 2004. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K dated January 26, 2004.)
14*	Code of Business Conduct and Ethics.

21.1*	Subsidiaries of CryoLife, Inc.
23.1*	Consent of Deloitte & Touche LLP.
31.1*	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002.

* Filed herewith.

† In accordance with Item 601(b)(2) of Regulation S-K, the schedules and certain exhibits to this exhibit have been omitted and a list of the schedules and exhibits has been placed at the end of the Exhibit. The Registrant will furnish supplementally a copy of any omitted schedule or exhibit to the Commission upon request.

+ The Registrant has requested confidential treatment for certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

3. B. Executive Compensation Plans and Arrangements.

1. 1993 Employee Stock Incentive Plan adopted on July 6, 1993. (Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)

2. 1989 Incentive Stock Option Plan for the Company, adopted on March 23, 1989 (Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)

3. Incentive Stock Option Plan, dated as of April 5, 1984 (Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)

4. 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).)

5. 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).)

6. Form of Supplemental Retirement Plan, by and between the Company and its Officers—Parties to Supplemental Retirement Plans: Steven G. Anderson, David M. Fronk, Sidney B. Ashmore, James C. Vander Wyk, Albert E. Heacox, Kirby S. Black and David Ashley Lee. (Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)

7. Employment Agreement, by and between the Company and Steven G. Anderson. (Incorporated by reference to Exhibit 10.9(a) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.)

8. Employment Agreement, by and between the Company and David M. Fronk. (Incorporated by reference to Exhibit 10.9(g) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.)

9. Employment Agreement, by and between the Company and Albert E. Heacox. (Incorporated by reference to Exhibit 10.7(c) to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)

10. Summary of increases in salaries for certain executive officers. (Incorporated by reference to Exhibit 10.9(d) to this Form 10-K.)

11. Employment Agreement, by and between the Company and James C. Vander Wyk, Ph.D. (Incorporated by reference to Exhibit 10.9(f) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995.)

12. Employment Agreement, by and between the Company and D. Ashley Lee. (Incorporated by reference to Exhibit 10.9(c) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.)

13. Employment Agreement, by and between the Company and Sidney B. Ashmore. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.)

14. CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated by reference to Appendix 2 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)

15. CryoLife, Inc. Employee Stock Purchase Plan. (Incorporated by reference to Exhibit "A" of the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 10, 1996.)

16. Employment Agreement by and between the Company and Kirby S. Black (Incorporated by reference to Exhibit 10.9(g) to the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1996.)

17. CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated by reference to Appendix 2 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)

18. Terms of Agreement Between Bruce J. Van Dyne, M.D. and CryoLife, Inc., dated November 1, 1999. (Incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)

19. Terms of Agreement between Ronald C. Elkins, MD and CryoLife, Inc., dated November 7, 2000. (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)

20. 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.)

21. Employment Agreement, by and between the Company and D. Ashley Lee, dated September 3, 2002. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)

22. Employment Agreement, by and between the Company and Sidney B. Ashmore, dated September 3, 2002. (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)

23. Employment Agreement, by and between the Company and Kirby S. Black, dated September 3, 2002. (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)

24. Employment Agreement, by and between the Company and Albert E. Heacox, dated September 3, 2002. (Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)

25. Employment Agreement, by and between the Company and David M. Fronk, dated September 3, 2002. (Incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)

26. Employment Agreement, by and between the Company and James C. Vander Wyk, dated September 3, 2002. (Incorporated by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)

27. Employment Agreement, by and between the Company and Steven G. Anderson, dated September 3, 2002. (Incorporated by reference to Exhibit 10.10 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)

28. First Amendment to Employment Agreement, by and between the Company and Steven G. Anderson dated September 3, 2002. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly report in Form 10-Q for the quarter ended March 31, 2003.)

29. Employment Agreement, by and between the Company and Thomas J. Lynch, J.D. Ph.D., dated August 1, 2003. (Incorporated by reference to Exhibit 10.9(o) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003.)

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

31. CryoLife, Inc. Non-Employee Directors Stock Option Plan**,** as amended, adopted on June 29, 2004. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)

32. Form of Directors Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)

33. Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)

34. Form of Incentive Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.)

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.

March 2, 2005

By /s/ STEVEN G. ANDERSON

Steven G. Anderson
President, Chief Executive Officer and Chairman of the Board of Directors

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

Signature	Title	Date
/s/ STEVEN G. ANDERSON **Steven G. Anderson**	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	March 2, 2005
/s/ D. ASHLEY LEE **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial and Accounting Officer)	March 2, 2005
/s/ THOMAS F. ACKERMAN **Thomas F. Ackerman**	Director	March 2, 2005
/s/ DAN BEVEVINO **Dan Bevevino**	Director	March 2, 2005
/s/ JOHN M. COOK **John M. Cook**	Director	March 2, 2005
/s/ RONALD CHARLES ELKINS, M.D. **Ronald Charles Elkins, M.D.**	Director	March 2, 2005
/s/ VIRGINIA C. LACY **Virginia C. Lacy**	Director	March 2, 2005
/s/ RONALD D. MCCALL **Ronald D. McCall**	Director	March 2, 2005
/s/ BRUCE J. VAN DYNE, M.D. **Bruce J. Van Dyne, M.D.**	Director	March 2, 2005

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, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedules 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, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, 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, the Company changed its method of accounting for goodwill and other intangible assets to conform to Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets", which was adopted by the Company as of January 1, 2002.

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, 2004, 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 March 2, 2005 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
March 2, 2005

CryoLife, Inc.
Consolidated Balance Sheets
(in thousands)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,713	$ 4,897
Marketable securities, at market	3,956	6,047
Restricted cash and securities	563	972
Receivables:		
Trade accounts, less allowance for doubtful accounts of $85 in 2004 and $65 in 2003	8,293	6,377
Income taxes	1,203	1,783
Other	2,754	82
Total receivables	12,250	8,242
Deferred preservation costs, net	8,822	8,811
Inventories	4,767	4,450
Prepaid expenses and other assets	2,590	2,344
Total current assets	**37,661**	**35,763**
Property and equipment:		
Equipment	23,383	22,909
Furniture and fixtures	5,011	5,422
Leasehold improvements	33,026	32,800
Construction in progress	20	37
Total property and equipment	61,440	61,168
Less accumulated depreciation and amortization	32,716	28,282
Net property and equipment	**28,724**	**32,886**
Other assets:		
Patents, less accumulated amortization of $1,414 in 2004 and $1,281 in 2003	4,978	5,244
Trademarks and other intangibles, less accumulated amortization of $192 in 2004 and $374 in 2003	393	343
Other	1,505	791
Total assets	**$ 73,261**	**$ 75,027**

See accompanying notes to consolidated financial statements.

CryoLife, Inc.
Consolidated Balance Sheets
(in thousands)

LIABILITIES AND SHAREHOLDERS' EQUITY

	December 31, 2004		December 31, 2003	
Current liabilities:				
Accounts payable	$	2,569	$	2,171
Accrued expenses and other current liabilities		9,615		11,570
Accrued compensation		1,835		1,136
Accrued procurement fees		2,634		4,358
Current maturities of capital lease obligations		1,319		1,738
Total current liabilities		**17,972**		**20,973**
Capital lease obligations, less current maturities		530		751
Other long-term liabilities		5,099		4,965
Total liabilities		**23,601**		**26,689**
Shareholders' equity:				
Preferred stock $.01 par value per share; authorized 5,000 shares including 2,000 shares of series A junior participating preferred stock; no shares issued		—		—
Common stock $.01 par value per share; authorized 75,000 shares; issued 24,805 shares in 2004 and 21,130 shares in 2003		248		211
Additional paid-in capital		94,846		74,460
Retained deficit		(38,257)		(19,508)
Deferred compensation		(222)		(9)
Accumulated other comprehensive income, net of tax		361		365
Treasury stock; 1,390 shares in 2004 and 1,371 shares in 2003, at cost		(7,316)		(7,181)
Total shareholders' equity		**49,660**		**48,338**
Total liabilities and shareholders' equity	**$**	**73,261**	**$**	**75,027**

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31, 2004	2003	2002
Revenues:			
Products	$ 36,637	$ 28,263	$ 21,597
Human tissue preservation services	25,676	30,777	55,373
Research grants and distribution	71	492	825
Total revenues	**62,384**	**59,532**	**77,795**
Costs and expenses:			
Products	7,818	7,506	10,270
Human tissue preservation services (including write-down of $6,905 in 2004, $6,861 in 2003, and $32,715 in 2002)	29,807	23,976	55,363
General, administrative, and marketing	42,640	53,630	47,530
Research and development	3,938	3,644	4,597
Goodwill impairment	—	—	1,399
Interest expense	196	415	692
Interest income	(262)	(425)	(895)
Other expense, net	13	12	273
Total costs and expenses	**84,150**	**88,758**	**119,229**
Loss before income taxes	**(21,766)**	**(29,226)**	**(41,434)**
Income tax (benefit) expense	(3,017)	3,068	(13,673)
Net loss	**$ (18,749)**	**$ (32,294)**	**$ (27,761)**
Loss per share:			
Basic	$ (0.81)	$ (1.64)	$ (1.43)
Diluted	$ (0.81)	$ (1.64)	$ (1.43)
Weighted average shares outstanding:			
Basic	23,043	19,684	19,432
Diluted	23,043	19,684	19,432

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2004	**2003**	**2002**
Net cash flows from operating activities:			
Net loss	$ (18,749)	$ (32,294)	$ (27,761)
Adjustments to reconcile net loss to net cash from operating activities:			
(Gain) loss on sale of marketable equity securities	—	(19)	240
Loss (gain) on sale of assets	30	(65)	—
Depreciation of property and equipment	5,202	5,191	5,222
Amortization	281	316	201
Provision for doubtful accounts	53	29	50
Write-down of deferred preservation costs and inventories	7,105	6,861	35,816
Other non-cash adjustments to income	10	347	1,419
Deferred income taxes	—	5,726	(5,509)
Non-cash employee compensation	358	—	—
Changes in operating assets and liabilities:			
Trade and other receivables	(2,159)	954	7,076
Income taxes	665	9,620	(9,333)
Deferred preservation costs	(6,916)	(11,340)	(12,848)
Inventories	(517)	135	(1,427)
Prepaid expenses and other assets	1,325	2,281	(59)
Accounts payable	342	(1,717)	3,313
Accrued expenses and other liabilities	(3,256)	8,043	1,489
Net cash flows used in operating activities	**(16,226)**	**(5,932)**	**(2,111)**
Net cash flows from investing activities:			
Capital expenditures	(950)	(955)	(4,100)
Net proceeds from sale of assets	26	1,093	—
Other assets	(56)	155	(2,598)
Purchases of marketable securities	(563)	(15,430)	(23,170)
Sales and maturities of marketable securities	2,000	30,889	28,305
Proceeds from notes receivable	—	—	1,169
Net cash flows provided by (used in) investing activities	**457**	**15,752**	**(394)**
Net cash flows from financing activities:			
Principal payments of debt	—	(5,600)	(1,600)
Principal payments on obligations under capital leases	(717)	(651)	(609)
Principal payments on short-term note payable	(3,385)	(2,443)	—
Proceeds from exercise of options and issuance of stock	443	660	1,472
Proceeds from equity offering	19,265	—	—
Purchase of treasury stock	(54)	—	(663)
Net cash flows provided by (used in) financing activities	**15,552**	**(8,034)**	**(1,400)**
(Decrease) increase in cash	**(217)**	**1,786**	**(3,905)**
Effect of exchange rate changes on cash	33	9	303
Cash and cash equivalents, beginning of year	4,897	3,102	6,704
Cash and cash equivalents, end of year	**$ 4,713**	**$ 4,897**	**$ 3,102**

See accompanying notes to consolidated financial statements.

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

	Common Shares Outstanding		Additional Paid-In Capital	Retained Earnings (Deficit)	Deferred Compensation	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total Share-holders' Equity
	Shares	Amount					Shares	Amount	
Balance at December 31, 2001	**20,172**	**$ 202**	**$ 66,828**	**$ 40,547**	**$ (33)**	**$ (145)**	**(1,286)**	**$ (5,960)**	**$ 101,439**
Net loss	—	—	—	(27,761)	—	—	—	—	(27,761)
Other comprehensive income, net of taxes	—	—	—	—	—	427	—	—	427
Comprehensive loss									(27,334)
Exercise of options	119	1	1,578	—	—	—	(23)	(541)	1,038
Employee stock purchase plan	98	1	836	—	—	—	16	78	915
Conversion of convertible debenture	546	5	4,388	—	—	—	—	—	4,393
Amortization of deferred compensation	—	—	—	—	12	—	—	—	12
Purchase of treasury stock	—	—	—	—	—	—	(68)	(663)	(663)
Balance at December 31, 2002	**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
Balance at December 31, 2003	**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
Balance at December 31, 2004	**24,805**	**$ 248**	**$ 94,846**	**$ (38,257)**	**$ (222)**	**$ 361**	**(1,390)**	**$ (7,316)**	**$ 49,660**

See accompanying notes to consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Nature of Business

CryoLife, Inc. ("CryoLife" 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 50 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 including countries within Latin America and Asia. The recently available syringe delivery system provides BioGlue without a separate delivery system. This syringe design configuration was approved by the FDA and added to the CE Mark approval in May 2004, and is currently under review in Canada. CryoLife distributes preserved human cardiovascular, vascular, and orthopaedic tissue to implanting institutions throughout the United States, Canada and Europe. CryoLife preserves human tissue using special freezing techniques, or cryopreservation. 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 cash flows during 2005:

- 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),
- 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 have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,
- An expected use of cash related to the defense and resolution of lawsuits and claims, and
- 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 2005, although there can be no assurance that these factors will be successful:

- Expected increases in revenues due to increases in BioGlue list prices implemented in January 2005,
- Expected increases in the service fees for cardiovascular and vascular tissues due to fee increases implemented in July 2004 and January 2005, to reflect the higher cost of processing these tissues,
- Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2003 and 2004 through process changes and process directives,

- Expected increases in procurement of human tissues for processing over the levels experienced in 2004, and
- Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 and 2004.

The Company believes that the Company's existing cash, cash equivalents, and marketable securities will enable the Company to meet its liquidity needs through December 31, 2005. Additionally, in February 2005 the Company has entered into a credit agreement, discussed in Note 19, and depending on market conditions may sell equity securities pursuant to its Form S-3 shelf registration statement in the first half of 2005. As of February 21, 2005 no offering of securities had been commenced in accordance with this registration statement, and there can be no assurance any offering will be commenced or consummated.

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

- The success of BioGlue and other products using related technology,
- The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,
- The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,
- The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- The resolution of the remaining outstanding product liability lawsuits and other claims (see Note 8),
- The outcome of other litigation against the Company (see Note 8), and
- To a lesser degree, the Company's success at resolving the issues with the FDA regarding SynerGraft processing of human tissue.

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, 2005. 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 the current year the Company has determined that its investments in variable rate demand notes, which have interest rates that reset daily or weekly but have maturity dates in excess of 90 days from the date of acquisition, are more appropriately classified as marketable securities. The Company had previously classified these notes as cash equivalents. Therefore, a total of $775,000 and $7.2 million has been reclassified from cash equivalents to marketable securities as of December 31, 2003 and 2002, respectively. Corresponding changes have been made to the Company's Consolidated Balance Sheets, Consolidated Statements of Cash Flows, and related Notes to Consolidated Financial Statements as appropriate.

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, disclosure of the fair value of stock based compensation and the related pro-forma expense, certain accrued expenses, including accrued procurement fees, and income taxes.

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.

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. As of December 31, 2004 and 2003 zero and $972,000, respectively, of the

Company's cash and cash equivalents was held in escrow and its future use is restricted to payments for the settlement of lawsuits within the 2002/2003 insurance policy year.

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

	2004	2003	2002
Cash paid during the year for:			
Interest	$ 127	$ 358	$ 636
Income taxes	200	169	2,874
Non-cash investing and financing activities:			
Finance insurance policies through issuance of short-term notes payable	$ 3,385	$ 2,443	$ —
Non-cash employee compensation	358	—	—
Establishment of capital lease obligation	77	—	—
Purchase of property and equipment in accounts payable and accrued expenses	70	—	6
Conversion of convertible debenture	—	—	4,393

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 debt 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. Debt securities not classified as held-to-maturity or trading and marketable equity securities not classified as trading are classified as available-for-sale. As of December 31, 2003 all marketable securities were designated as available-for-sale. 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. 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 are reported in the restricted cash and securities line of the December 31, 2004 Consolidated Balance Sheet.

Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of tax, reported in a separate component of shareholders' equity. Interest income, 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. Held-to-maturity securities are stated at amortized cost.

Deferred Preservation Costs

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 related to tissue held by the Company are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities. Deferred 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. Deferred preservation costs are stated on a first-in, first-out basis.

During 2002 the Company recorded write-downs of deferred preservation costs totaling $32.7 million. These write-downs were recorded as a result of the FDA Order as defined and discussed in Note 2. 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 differed 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 2003 and 2004 was favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services 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 $6.6 million and $6.9 million, respectively, in the twelve months ended December 31, 2004 and 2003 as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs from tissues that exceeded market value. The amount of these write-downs reflects management's estimates of market value based on recent average service fees. Actual results may differ from these estimates.

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.

Property and Equipment

Property and equipment are stated at cost. Depreciation is provided over the estimated useful lives of the assets, generally five 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 Company used an eleven-year period for the undiscounted future cash flows. This period of time was selected based upon the remaining life of the primary assets of the asset groups, which are leasehold improvements. The undiscounted future cash flows related to these asset groups exceeded their carrying values as of December 31, 2004 and, therefore, management has concluded that there is not an impairment of the Company's long-lived intangible assets and tangible assets related to the medical device business or tissue preservation 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 under the provisions of SFAS 144.

Intangible Assets

Beginning with the Company's adoption of SFAS No. 142,"Goodwill and Other Intangible Assets" ("SFAS 142") on January 1, 2002 the goodwill resulting from business acquisitions is not amortized, but is instead subject to periodic impairment testing in accordance with SFAS 142. Patent costs, consisting of legal fees and other costs related to the filing of patents, are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method. Other intangibles, which consist primarily of manufacturing rights and agreements, are amortized over the expected useful lives of the related assets (primarily five years). As a result of the FDA Order, the Company determined that an evaluation of the possible impairment of non-amortizing intangible assets under SFAS 142 was necessary. The Company engaged an independent valuation expert to perform the valuation using a discounted cash flow methodology, and as a result of this analysis, the Company determined that goodwill related to its tissue processing reporting unit was fully impaired as of September 30, 2002. Therefore, the Company recorded a write-down of $1.4 million in goodwill during the quarter ended September 30, 2002. As of December 31, 2004 the Company does not believe an additional impairment exists related to its other non-amortizing intangible assets. Management does not believe that an impairment exists related to the other intangible assets that were assessed in accordance with SFAS 144.

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

2005	$	277
2006		277
2007		277
2008		276
2009		274
Total	$	1,381

Accrued Procurement Fees

Tissue is procured from deceased human donors by organ procurement agencies and tissue banks ("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 has historically been experienced have been 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 2005 as of December 31, 2004. 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.

Based on the information included in the actuarial valuation, management has included an accrual of $8.2 million as of December 31, 2004 for estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2004. This accrual reflected management's estimate based on information available to it at the time the estimate was made. Actual results may differ from this estimate. 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.

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. As of December 31, 2004 the Company had accrued a total of $2.8 million for uninsured product liability claims. The $2.8 million balance is included as a component of accrued expenses and other current liabilities on the December 31, 2004 Consolidated Balance Sheet.

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 Per Share

Earnings per share is computed 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.

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 has 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 because, as discussed below, the alternative fair value accounting provided for under SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") as amended by SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" ("SFAS 148") requires use of option valuation models that were not developed for use in valuing 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 is recognized. In accordance with APB 25 the compensation recorded for employee stock grants is 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 is recorded as deferred compensation in the equity section of the Company's Consolidated Balance Sheets, and is expensed on a straight-line basis 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 these options were estimated at the dates of grant using a Black-Scholes option-pricing model assuming a 5% annual forfeiture rate in all periods presented. The Company periodically reviews its forfeiture rate through a comparison to actual forfeitures experienced by the Company. Additionally, the following weighted-average assumptions were used:

	2004	2003	2002
Expected dividend yield	0%	0%	0%
Expected stock price volatility	.589	.616	.630
Risk-free interest rate	3.09%	2.35%	3.67%
Expected life of options	3.7 Years	3.6 Years	5.3 Years

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

	2004	2003	2002
Net loss—as reported	$ (18,749)	$ (32,294)	$ (27,761)
Add: Total stock-based employee compensation expense included in the determination of net loss	358	—	—
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards	3,093	1,715	2,703
Net loss—pro forma	$ (21,484)	$ (34,009)	$ (30,464)
Loss per share—as reported:			
Basic	$ (0.81)	$ (1.64)	$ (1.43)
Diluted	$ (0.81)	$ (1.64)	$ (1.43)
Loss per share—pro forma:			
Basic	$ (0.93)	$ (1.73)	$ (1.57)
Diluted	$ (0.93)	$ (1.73)	$ (1.57)

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.

New Accounting Pronouncements

The Company was required to adopt EITF issue 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("EITF 03-1"). The Company adopted the recognition and measurement guidance of EITF 03-1 for the interim period ending September 30, 2004 and the annual disclosure requirements for its year ended December 31, 2004. EITF 03-1 clarifies the definition of and accounting treatment for other-than-temporary losses on debt and equity investments. The adoption of the recognition and measurement guidance of EITF 03-1 did not have a material effect on the results of operations or financial position of the Company. The Financial Accounting Standards Board has delayed implementation of certain requirements under EITF 03-1. Until the requirements are finalized the Company cannot determine the effect of fully adopting EITF 03-1 on the results of operations or financial position.

The Company adopted EITF 03-8 "Accounting for Claims-Made Insurance and Retroactive Insurance Contracts by the Insured Entity" ("EITF 03-8") for the interim period ended June 30, 2004. EITF 03-8 clarifies reporting for insurance policies, including providing guidance in accounting for prospective and retroactive insurance policies and guidance for situations when a company's fiscal year and insurance policy period do not coincide. The adoption of EITF 03-8 resulted in the Company recording additional legal accruals and offsetting amounts recoverable from insurance as discussed in Note 8.

The Company will be required to adopt SFAS 123 Revised "Share-Based Payment" ("SFAS 123-R") for the interim period ending September 30, 2005. SFAS 123-R requires companies to recognize the cost of all share-based payments in the financial statements using a fair-value based measurement method. Based on its preliminary analysis, the Company anticipates that the effect of implementing SFAS 123-R on its results of operations will be less than the amounts in the pro-forma footnote disclosures currently required, but will have a significant impact on the Company's results of operations, assuming that the Company's stock price, option terms, and amounts of 2005 option grants are comparable with 2004. The Company anticipates it will adopt SFAS 123-R using the modified version of prospective application, as defined in SFAS 123-R. However, the Company is continuing to evaluate the adoption of SFAS 123-R.

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 currently evaluating the impact of the adoption of SFAS 151 on its results of operations and financial position.

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

FDA Order

The FDA inspected the Company's tissue processing operations in December 2001, after it was reported that a Minnesota man had died after receiving an implant of orthopaedic tissue processed by the Company. The FDA conducted another inspection in March 2002. In April 2002 the FDA issued a Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter was issued, dated June 17, 2002 ("Warning Letter"). 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 steps to ensure that the tissue was used for approved purposes and that patients were notified of risks associated with tissue use. The FDA Agreement had a renewable 45-business day term and the final renewal expired on September 5, 2003. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). A renewal of the FDA Agreement that expired on September 5, 2003 was not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

In addition, pursuant to the FDA Agreement, the Company agreed to perform additional procedures in the processing of non-valved cardiac and vascular tissues and subsequently resumed processing these tissues. The Company also agreed to establish a corrective action plan within 30 days from September 5, 2002 with steps to validate processing procedures. The corrective action plan was submitted on October 5, 2002, and executed thereafter. The corrective actions taken have been reviewed by the FDA during three subsequent inspections as discussed in "Other FDA Correspondence and Notices" below.

Accounting Treatment

As a result of the FDA Order the Company recorded a reduction to pretax income of $12.6 million in the quarter ended June 30, 2002. The reduction was comprised of a net $8.9 million increase to cost of human tissue preservation services, a $2.4 million reduction to revenues (and accounts receivable) for the estimated return of the tissues subject to recall by the FDA Order, and a $1.3 million accrual recorded in general, administrative, and marketing expenses consisting of an accrual for retention levels under the Company's product liability and directors' and officers' insurance policies of $1.2 million and for estimated expenses for packaging and handling for the return of affected tissues under the FDA Order of $75,000. The net increase of $8.9 million to cost of preservation services was comprised of a $10.0 million write-down of deferred preservation costs for tissues subject to the FDA Order, offset by a $1.1 million decrease in cost of preservation services due to the estimated tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the $10.0 million write-down). The Company evaluated multiple factors in determining the magnitude of impairment to deferred preservation costs as of June 30, 2002, including the impact of the FDA Order, the possibility of continuing action by the FDA or other U.S. and foreign government agencies, and the possibility of unfavorable actions by physicians, customers, procurement organizations, and others. As a result of this evaluation, management believed that since all non-valved cardiac, vascular, and orthopaedic allograft tissues processed since October 3, 2001 were under recall pursuant to the FDA Order, and since the Company did not know if it would obtain a favorable resolution of its appeal and request for modification of the FDA Order, the deferred preservation costs for tissues subject to the FDA Order had been significantly impaired. The Company estimated that this impairment approximated the full balance of the deferred preservation costs of the tissues subject to the FDA Order, which included the tissues stored by the Company and the tissues to be returned to the Company, and, therefore, recorded a write-down of $10.0 million for these assets.

In the quarter ended September 30, 2002 the Company recorded a reduction to pretax income of $24.6 million as a result of the FDA Order. The reduction was comprised of a net $22.2 million increase to cost of human tissue preservation services, a $1.4 million write-down of goodwill, and a $1.0 million reduction to revenues (and accounts receivable) for the estimated return of the tissues shipped during the third quarter subject to recall by the FDA Order. The net $22.2 million increase to cost of preservation services was comprised of a $22.7 million write-down of deferred preservation costs, offset by a $535,000 decrease in cost of preservation services due to the estimated and actual tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the $22.7 million write-down).

The Company evaluated multiple factors in determining the magnitude of impairment to deferred preservation costs at September 30, 2002, including the impact of the FDA Order, the possibility of continuing action by the FDA or other U.S. and foreign government agencies, the possibility of unfavorable actions by physicians, customers, procurement organizations, and others, the progress made to date on the corrective action plan, and the requirement in the Agreement that tissues subject to the FDA Order be replaced with tissues processed under validated methods. As a result of this evaluation, management believed that all tissues subject to the FDA Order, as well as the majority of tissues processed prior to October 3, 2001, including heart valves, which were not subject to the FDA Order, were fully impaired. Management believed that most of the Company's customers would only order tissues processed after the September 5, 2002 Agreement or tissues processed under future procedures approved by the FDA once those tissues were available. The Company anticipated that the tissues processed under the Agreement would be available early to mid-November. Thus, the Company recorded a write-down of deferred preservation costs for processed tissues in excess of the supply required to meet demand prior to the release of these interim processed tissues.

As a result of the write-down of deferred preservation costs, the Company recorded $6.3 million in income tax receivables and $4.5 million in deferred tax assets as of December 31, 2002. Upon destruction or shipment of the remaining tissues associated with the deferred preservation costs write-down, the related cost of the tissue becomes deductible in the Company's related tax return and the deferred tax asset is realized assuming there is sufficient taxable income to offset the tax deduction. A refund of approximately $8.9 million related to 2002 federal income taxes was generated through a carry back of operating losses and write-downs of deferred preservation costs. The Company filed its 2002 federal income tax returns in April of 2003 and received its tax refund during the second quarter of 2003. In addition, estimated tax payments for 2002 of $2.5 million were recorded as a receivable by the Company as of December 31, 2002 and were received in January 2003.

On September 3, 2002 the Company announced a reduction in employee force of approximately 105 employees. In the third quarter of 2002 the Company recorded accrued restructuring costs of approximately $690,000, for severance and related costs of the employee force reduction. The expense was recorded in general, administrative, and marketing expenses and was included as a component of accrued expenses and other current liabilities on the Consolidated Balance Sheet. During the year ended December 31, 2002 the Company utilized $580,000 of the accrued restructuring costs, including $505,000 for salary and severance payments, $64,000 for placement services for affected employees, and $11,000 in other related costs. During the quarter ended March 31, 2003 the Company utilized $64,000 of the accrued restructuring costs, including $57,000 for salary and severance payments and $7,000 in other related costs. In March 2003 the Company reversed the remaining accrual of $46,000 in unused restructuring costs, which was primarily due to lower than anticipated medical claims costs for affected employees. The Company has not incurred and does not expect to incur any additional restructuring costs associated with the employee force reduction subsequent to March 31, 2003.

In the quarter ended March 31, 2003 the Company recorded a favorable adjustment of $848,000 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 $92,000, vascular tissue revenues by $711,000, and orthopaedic tissue revenues by $45,000 in the first quarter of 2003. In the quarter ended September 30, 2003 the Company recorded a favorable adjustment of $52,000 to reverse the remaining unused portion of the estimated tissue recall returns due to lower overall actual tissue returns under the FDA Order than were estimated. Although vascular and orthopaedic returns were lower than expected, cardiac returns were higher than expected. Therefore, the $52,000 adjustment decreased cardiac tissue revenues by $7,000 and increased vascular tissue revenues by $41,000 and orthopaedic tissue revenues by $18,000 in the third quarter of 2003. 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

FDA Form 483 Notices of Observations ("483") were issued in connection with the FDA inspections of the Company's facilities in February 2003, October 2003, and February 2004. The Company responded to the February 2003 483 in March 2003, responded to the October 2003 483 in October 2003, November 2003, and April 2004, and responded to the February 2004 483 in March 2004, April 2004, and June 2004. On September 24, 2004 CryoLife received an inquiry from the FDA Atlanta District Office seeking additional information on four items submitted by CryoLife in response to the February 2004 483 to which CryoLife responded on November 8, 2004. In response to the Form 483 Notice of Observations, the Company has implemented new and revised existing processing, preservation, and testing procedures. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information. The Company continues 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. CryoLife anticipates responding to some of the additional requests and has initiated an appeal of others through administrative procedures. 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 is currently subject to an administrative appeal. Unless this appeal is successful, CryoLife will be unable to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted. In the event that the Company is not successful in appealing the FDA's decision to regulate SynerGraft cardiovascular tissue as a medical device, the Company will evaluate 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 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, 2004 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Consolidated Balance Sheet.

3. Cash Equivalents and Marketable Securities

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

December 31, 2004	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 2,290	$ —	$ 2,290
Marketable securities:			
Municipal obligations	$ 3,913	$ 43	$ 3,956
Restricted securities:			
Debt securities	$ 563	$ —	$ 563

December 31, 2003	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 1,079	$ —	$ 1,079
Marketable securities:			
Municipal obligations	$ 5,923	$ 124	$ 6,047

Gross realized gains on sales of available-for-sale securities totaled zero in 2004 and gross realized losses on sales of available-for-sale securities totaled $19,000 in 2003. Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of $15,000 and $42,000, at December 31, 2004 and 2003, respectively, are included as a separate component of other comprehensive income in shareholders' equity.

At December 31, 2004 and 2003 approximately zero and $2.0 million, respectively, of marketable securities had a maturity date of less than 90 days, approximately $2.2 million and zero, respectively, had a maturity date between 90 days and 1 year, approximately $1.0 million and $3.3 million, respectively, had a maturity date between 1 and 5 years, and approximately $775,000 and $775,000, respectively, had a maturity date of greater than 5 years.

4. Inventories

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

	2004	2003
Raw materials	$ 2,780	$ 2,906
Work in process	246	229
Finished goods	1,741	1,315
	$ 4,767	$ 4,450

5. Debt

The Company had no outstanding long-term debt as of December 31, 2004 and 2003.

In March 1997 the Company issued a $5.0 million convertible debenture in connection with the Ideas for Medicine, Inc. acquisition. The debenture accrued interest at 7% and was convertible into common stock of the Company at any time prior to the due date of March 5, 2002 at $8.05 per common share. On March 30, 1998 $607,000 of the convertible debenture was converted into 75,000 shares of the Company's common stock, and on March 4, 2002 the remaining $4.4 million was converted into 546,000 shares of the Company's common stock.

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, 2003 the Company entered into two agreements to finance $2.9 million in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. This amount was later reduced to $2.4 million due to refunds related to policy changes made during 2003. The amount financed accrued interest at a 3.75% rate and was payable in equal monthly payments through December 2003. As of December 31, 2003 the balance due on these two 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 aggregate outstanding balance under the agreements was zero.

Total interest expense was $196,000, $415,000, and $692,000 in 2004, 2003, and 2002, respectively.

6. Derivatives

On April 25, 2000 the Company entered into a loan agreement permitting the Company to borrow up to $8 million under a line of credit during the expansion of the Company's corporate headquarters and manufacturing facilities. Borrowings under the line of credit accrued interest equal to Adjusted LIBOR plus 2% adjusted monthly. On June 1, 2001, the line of credit was converted to a term loan (the "Term Loan") to be paid in 60 equal monthly installments of principal plus interest computed at Adjusted LIBOR plus 1.5%, which exposed the Company to changes in interest rates going forward. On March 16, 2000 the Company entered into a $4.0 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and was to expire in 2006. 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. This agreement involved the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement, without an exchange of the underlying principal amounts. The differential to be paid or received was recognized in the period in which it accrued as an adjustment to interest expense on the Term Loan.

In conjunction with the payoff of the outstanding balance of the Term Loan, 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.

7. 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, 2004 and 2003.

8. 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. Due to cross default provisions included in the Company's Term Loan which was paid in full on August 15, 2003, the Company was in default of certain capital lease agreements maintained with the lender under the Term Loan. Therefore, the $1.0 million due under these capital leases is reflected as a current liability on the Consolidated Balance Sheets as of December 31, 2004. Additional capital lease obligations result from the lease of a building related to Company's Ideas for Medicine ("IFM") manufacturing business, which the Company sold in 2000. The Company has a sublease agreement with a wholly owned subsidiary of LeMaitre Vascular, Inc., the current parent of IFM, to sublet the building housing the IFM manufacturing facilities, which effectively reduces the Company's future obligations under this capital lease to zero.

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. Future minimum lease payments under noncancelable leases as of December 31, 2004 are as follows (in thousands):

	Capital Leases	Operating Leases
2005	$ 884	$ 2,360
2006	860	2,107
2007	266	2,075
2008	—	2,108
2009	—	2,149
2010	—	2,190
Thereafter	—	11,040
Total minimum lease payments	2,010	$ 24,029
Less amount representing interest	161	
Present value of net minimum lease payments	1,849	
Less current maturities	1,319	
Capital lease obligations, less current maturities	$ 530	

Property acquired under capital leases through December 31, 2004 consists of the following (in thousands):

Equipment	$ 480
Furniture and fixtures	890
Leasehold improvements	3,199
Total	$ 4,569

Total rental expense for operating leases was $2.5 million, $2.6 million, and $2.5 million, for 2004, 2003, and 2002, respectively. Total rental income under the sublease was $310,000 in 2004, 2003, and 2002.

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 than has historically been experienced have been filed. As of February 21, 2005 the Company was aware of eight pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, three 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, one alleges product liability claims arising from BioGlue, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, Inc. when it was a subsidiary of the Company.

As of February 21, 2005 the Company had three outstanding product liability lawsuits against the Company that are covered by three separate insurance policies, beginning with the policy year 2000/2001. The Company believes its insurance policies to be adequate to defend against the covered lawsuits in each of these time periods. Additionally, the Company has five 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 that have not resulted in lawsuits. The Company is monitoring these claims.

The Company performed an analysis as of December 31, 2004 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, 2004 the Company had accrued a total of $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. This amount represents the Company's estimate of the probable losses related to two settled but unpaid claims and three of the eight pending product liability claims. The Company has not recorded an accrual for the remaining five 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 amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. Prior to 2004, the Company recorded accruals for the uninsured portion of product liability claims for which the amount of probable loss was reasonably estimable. Had the Company recorded the total amounts of the reasonably estimable probable losses as a liability and recorded an asset for the estimated amount recoverable from the insurance carrier, the impact on the financial statements as of December 31, 2003 would not have been material. 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 many 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, 2004 the Company bound coverage for the 2004/2005 insurance policy year. This policy is a two-year claims made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2005 and reported during the period April 1, 2004 through March 31, 2005 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 sold. In January 2005, the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of December 31, 2004. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- A ceiling of $5 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of $5 million,

- The future claim reporting lag time would be a blend of the Company's experiences and industry data,

- The frequency of unreported claims for accident years 2001 through 2004 would be lower than the Company experienced during the 2002/2003 policy year, but higher than the Company's historical claim frequency in prior policy years,

- The average cost per claim would be lower than the Company experienced during the 2002/2003 policy year, but higher than the Company's historical cost per claim in prior policy years,

- The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and

- The number of BioGlue claims per million dollars of BioGlue revenue would be 20% lower than non-BioGlue claims per million dollars to adjust for the increase of BioGlue revenue as a percentage of total revenues since 2002 and the BioGlue claims history to date.

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 and 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.

Beginning April 1, 2004 and concurrent with signing the claims-made insurance policy for the policy year from April 1, 2004 to March 31, 2005, the Company implemented the provisions of Emerging Issues Task Force Issue 03-8, Accounting for Claims-Made Insurance and Retroactive Contracts by the Insured Entity ("EITF 03-8"). Pursuant to EITF 03-8, the Company continues to record an estimated liability for unreported product liability claims and has begun to record a related recoverable from insurance. Prior to the effective date of EITF 03-8, the Company did not record a recoverable from insurance related to the unreported product liability claims.

Based on the actuarial valuation performed in January 2005 as of December 31, 2004, the Company estimated that its liability for unreported product liability claims was $8.2 million as of December 31, 2004. In accordance with EITF 03-8, the Company has accrued $8.2 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, 2004. 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. Further analysis indicated that the liability could be estimated to be as high as $14.6 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, 2004, $1.9 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. 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. These amounts represent management's estimate of the probable losses and anticipated recoveries related to unreported product liability claims related to services performed and products sold prior to December 31, 2004. Actual results may differ from this estimate.

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 seeks 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. At present, discovery in the case has closed, and the Court has instructed the parties to serve their dispositive motions, if any, by March 11, 2005. Although the Company carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment 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. At this time, the Company is unable to predict the outcome of this litigation. Therefore, the Company has not recorded any accruals for future expenses related to this case, as the Company is currently unable to estimate these amounts. As of December 31, 2004 the Company had accrued $632,000 for legal fees incurred but unpaid related to this case and recorded an asset of $632,000 representing the anticipated recovery of these fees from the Company's insurance carrier. The $632,000 accrual is included as a component of accrued expenses and other current liabilities and the $632,000 insurance receivable is included as a component of other receivables on the December 31, 2004 Consolidated Balance Sheet. The Company believes that the receivable will be fully collectible.

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 names the Company as a nominal defendant, alleges 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 seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of the Company. As previously disclosed, the Company's Board of Directors has established an independent committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel, evaluated the consolidated amended complaint and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of the Company. Based on the report of the independent committee, the Company moved to dismiss the derivative action in May 2004. In an order dated December 1, 2004, the Court denied the motion to dismiss, such that the case will proceed into the discovery phase. At this time, the Company is unable to predict the outcome of this litigation. Although the derivative suit is brought nominally on behalf of the Company, the Company expects to continue to incur defense costs and other expenses in connection with the derivative litigation.

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 regarding 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 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. As of the date hereof, the SEC has had no discussions with CryoLife representatives as to whether or against whom it will seek 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.

Other Litigation

In October 2003 an action was filed against multiple defendants, including the Company, titled Donald Payne and Candace Payne v. Community Blood Center, et al., in the Circuit Court of the State of Oregon, County of Multnomah, seeking noneconomic damages of $9.0 million and other damages of $4.7 million. The suit alleged that Mr. Payne received a tissue implant processed by one of the other defendants, and that he was subsequently diagnosed with an infection attributed to the implant. The claim against the Company asserted that CryoLife had processed tissue from the same donor and been notified that a recipient of that tissue had contracted the same virus, and further that the Company had a duty to notify governmental authorities and the other defendants. A second action, titled L.L.R. and W.C.R. v. Community Blood Center, et al., was filed in October 2003 in the same court as the Payne case, against the same defendants, seeking the same amounts of damages. In this case the plaintiffs alleged the recipient received an implant processed by the same co-defendant tissue processor, from the same donor as Mr. Payne, and contracted an infection. In late July 2004 a third action was filed against multiple defendants, including the Company, titled Anthony F. Spadaro v. Community Blood Center, et al., in the same court as the other two cases, seeking noneconomic damages of $6.0 million, $1.7 million in economic damages, and punitive and exemplary damages. This suit alleged that Mr. Spadaro received a tissue implant processed by the same defendant tissue processor that was named in the other two suits, and that he was subsequently diagnosed with an infection attributed to the implant. This claim also asserted that the Company had processed tissue from the same donor and been notified that a recipient of the tissue had contracted the same virus, and that the Company had a duty to notify governmental authorities and the other defendants.

The trial for the Payne and L.L.R. cases began on October 18, 2004. CryoLife reached a settlement agreement with the plaintiffs on October 25, 2004 concerning the Payne, L.L.R. and Spadaro cases totaling $3.0 million in the aggregate, which CryoLife paid on November 5, 2004. The Company did not have insurance coverage for these claims. The $3.0 million is included in the Company's general, administrative and marketing expenses for the year ended December 31, 2004. A cross-claim for indemnification by another defendant was dismissed earlier in the lawsuit because the claim is subject to a contractual obligation to arbitrate. As of the date of this filing, the arbitration clause has not been invoked by either party and CryoLife has not accrued any amounts for any potential loss. Although the Company believes there are defenses it can and would assert against such a claim, such a claim, if successfully brought, would not be insured and could have a material impact on the Company's liquidity and financial condition.

9. Stock Option and Stock 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, which generally expire within ten years of the grant dates. Options granted to employees typically become exercisable over a five-year vesting period and options granted to directors typically vest immediately.

The Company is authorized to grant under the Company's plans up to the following number of shares:

Plan	Shares
1993 Employee Incentive Stock Option Plan	1,050,000
1998 Long-Term Incentive Plan	900,000
2002 Stock Incentive Plan	974,000
Amended and Restated Nonemployee Director's Plan	594,000
2004 Employee Stock Incentive Plan	2,000,000
2004 Non-Employee Directors Stock Option Plan	500,000

As of December 31, 2004 and 2003, there were 2,367,000 and 88,000, respectively, shares of common stock reserved for future issuance under the Company's stock option and stock incentive plans.

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. For the twelve months ended December 31, 2004 the Company recorded $358,000 in compensation expense related to these stock grants.

A summary of stock grants under the plans follows:

	Shares	Market Value
For the Year Ended December 31, 2004		
Granted	84,000	6.91

A summary of stock option transactions under the plans follows:

	Exercise Shares	Price	Weighted Average Exercise Price
Outstanding at December 31, 2001	1,762,000	$ 6.83-34.10	$ 14.94
Granted	1,133,000	2.20-29.25	9.94
Exercised	(119,000)	6.83-11.63	9.21
Canceled	(390,000)	2.20-34.10	19.55
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

The following table summarizes information concerning currently outstanding and exercisable options:

Options Outstanding				Options Exercisable	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 2.20-2.20	477,000	3.02	$ 2.20	246,000	$ 2.20
4.78-5.36	459,000	4.42	5.17	103,000	5.16
6.21-8.50	509,000	2.66	7.26	281,000	7.82
11.50-12.92	385,000	1.38	11.66	303,000	11.65
23.68-30.86	336,000	2.47	28.67	212,000	28.45
31.99-31.99	127,000	1.46	31.99	118,000	31.99
$ 2.20-31.99	2,293,000	2.78	$ 11.04	1,263,000	$ 13.16

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.

Other information concerning stock options follows:

	2004	2003	2002
Weighted average fair value of options granted during the year	$ 2.80	$ 2.88	$ 4.23
Number of shares as to which options are exercisable at end of year	1,263,000	1,293,000	1,175,000

10. Shareholder Rights Plan

On November 27, 1995 the Board of Directors adopted a shareholder rights plan to protect long-term share value for the Company's shareholders. Under the plan, the Board declared a distribution of one Right for each outstanding share of the Company's Common Stock to shareholders of record on December 11, 1995. Additionally, the Company has further authorized and directed the issuance of one Right with respect to each Common Share that has or shall become outstanding between December 11, 1995 and the earliest of the Right's exercise date or expiration date. After adjustments for Company stock splits to date, each Right entitles its registered holder to purchase from the Company one-thirtieth of a share of Series A Junior Participating Preferred Stock for a Purchase Price of $100. The Rights, which expire on November 27, 2005, 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 ("Acquiring Person").

In the event the Rights become exercisable, each Right will enable the owner, other than the Acquiring Person, to purchase, for an Exercise Price equal to the Purchase Price multiplied by the number of one one-tenths of a Preferred Share which a Right entitles its holder to purchase (after adjustments for Company stock splits to date, $33.33), that number of shares of Common Stock with a market value equal to twice the Exercise Price ($66.66). In addition, unless the Acquiring Person owns more than 50% of the outstanding shares of Common Stock, the Board of Directors may elect to exchange all outstanding Rights (other than those owned by such Acquiring Person) at an exchange ratio of one share of Common Stock per Right appropriately adjusted to reflect any stock split, stock dividend or similar transaction.

11. Stock Offerings and Stock Repurchases

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. As of December 31, 2004 no offering of securities had been commenced in accordance with this registration statement.

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 the employee stock grants.

On July 18, 2002 the Company's Board of Directors authorized the purchase of up to $10 million in shares of its common stock. The purchase of shares was to be made from time-to-time in open market or privately negotiated transactions on such terms as management deemed appropriate. As of December 31, 2002 the Company had repurchased 68,000 shares of its common stock for an aggregate purchase price of $663,000 and an average price of $9.69 per share. This purchase authorization expired during 2003, therefore no further purchases will be made under this authorization.

On March 27, 2002 the Company's Board of Directors authorized the Company to purchase up to 1.0 million shares of its common stock. As of December 31, 2004, the Company had made no purchases under this authorization. This purchase authorization was rescinded in 2004, therefore no further purchases will be made under this authorization.

12. Accumulated Other Comprehensive Loss

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

	2004	2003	2002
Net loss	$ (18,749)	$ (32,294)	$ (27,761)
Unrealized (loss) gain on investments	(53)	(119)	95
Change in fair value of interest rate swap (including cumulative effect of adopting SFAS 133 in 2001)	—	172	29
Translation adjustment	49	30	303
Comprehensive loss	$ (18,753)	$ (32,211)	$ (27,334)

The tax effect on the change in unrealized (loss) gain on investments is $28,000, $65,000, and $55,000 for the years ended December 31, 2004, 2003, and 2002 respectively. The tax effect on the change in fair value of the interest rate swap is zero, $88,000, and $4,000 for the years ended December 31, 2004, 2003, and 2002 respectively. The tax effect of the translation adjustment is $17,000, $167,000, and zero for the years ended December 31, 2004, 2003, and 2002, respectively.

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

	2004	2003
Unrealized gain on investments	$ 32	$ 85
Translation adjustment	329	280
Total accumulated other comprehensive income	$ 361	$ 365

13. 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. In 2004, 2003, and 2002 the Company made matching contributions of 50% of each participant's contribution for up to 4% of each participant's salary in 2004 and up to 5% of each participant's salary in 2003 and 2002. Total Company contributions approximated $312,000, $350,000, and $404,000, for 2004, 2003, and 2002, respectively. Additionally, the Company may make discretionary contributions to the Plan that are allocated to each participant's account. No such discretionary contributions were made in 2004, 2003, or 2002.

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, 2004 and 2003 there were 331,000 and 407,000, respectively, shares of common stock reserved under the ESPP and there were 569,000 and 493,000, respectively, shares issued under the plan.

14. Loss Per Share

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

	2004	2003	2002
Numerator for basic and diluted loss per share:			
loss available to common shareholders	$ (18,749)	$ (32,294)	$ (27,761)
Denominator for basic loss per share:			
weighted-average shares	23,043	19,684	19,432
Effect of dilutive stock options	—	—	—
Denominator for diluted earnings per share:			
adjusted weighted-average shares	23,043	19,684	19,432
Loss per share:			
Basic	$ (0.81)	$ (1.64)	$ (1.43)
Diluted	$ (0.81)	$ (1.64)	$ (1.43)

Since the Company has a net loss in 2004, 2003, and 2002 all common stock equivalents are anti-dilutive for those years. For the years ended December 31, 2004, 2003, and 2002 the Company had stock options that are considered common stock equivalents and would have resulted in 345,000, 412,000, and 966,000, respectively, in additional dilutive shares for 2004, 2003, and 2002 pursuant to the provisions of SFAS 128.

15. Income Taxes

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

	2004	2003	2002
Current:			
Federal	$ (3,017)	$ (2,502)	$ (8,000)
State	27	(23)	(164)
	(2,990)	(2,525)	(8,164)
Deferred	(27)	5,593	(5,509)
	$ (3,017)	$ 3,068	$ (13,673)

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.

Such amounts differ from the amounts computed by applying the U.S. federal and state income tax rate of 34% in 2004, 2003, and 2002 to pretax income as a result of the following (in thousands):

	2004	2003	2002
Tax benefit at statutory rate	$ (7,400)	$ (9,937)	$ (14,088)
Increase (reduction) in income taxes			
Resulting from:			
Deferred tax valuation	4,477	13,701	658
Entertainment expenses	67	70	83
State income taxes, net of federal benefit	(182)	(218)	(167)
Nontaxable interest income	(27)	(110)	(202)
Foreign sales corporation	(54)	(20)	(27)
Other	102	(418)	70
	$ (3,017)	$ 3,068	$ (13,673)

For the year ended December 31, 2004, the Company generated federal income tax losses that can be carried back to prior years to offset income taxes paid and are expected to result in approximately $1.3 million in refunds to the Company.

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

	2004	2003
Long-term deferred tax (liabilities) assets:		
Property	$ (1,016)	$ (1,408)
Intangible assets	(23)	52
Loss carryforwards	16,779	10,605
Other	—	65
Less valuation allowance	(15,740)	(9,314)
	—	—
Current deferred tax (liabilities) assets:		
Unrealized loss on marketable securities	(15)	(25)
Allowance for bad debts	29	22
Accrued expenses	2,929	4,763
Prepaid items	(661)	(609)
Deferred preservation costs and inventory reserves	533	610
Other	281	284
Less valuation allowance	(3,096)	(5,045)
	—	—
Net deferred tax assets	$ —	$ —

As of December 31, 2004 the Company updated the evaluation of its deferred tax assets. The Company reviewed its historic operating results, including the operating losses which continued in 2004, 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, 2004 the Company had a total of $18.8 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.

16. Executive Insurance Plan

Pursuant to a supplemental life insurance program for certain executive officers of the Company, the Company and the executives share in the premium payments and ownership of insurance policies on the lives of such executives. Upon death of the insured party, policy proceeds equal to the premium contribution are due to the Company with the remaining proceeds due to the designated beneficiaries of the insured party. The Company's Board of Directors is currently evaluating its options related to the termination of this plan and the creation of a new executive insurance plan that will fully comply with Section 402(a) of the Sarbanes-Oxley Act of 2002. Therefore, no premium contributions were made by the Company in 2004 or 2003. The Company's aggregate premium contributions under this program were $74,000 for 2002.

17. Transactions with Related Parties

The Company expensed zero, $101,000, and $90,000, during 2004, 2003, and 2002, respectively, 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. The Company expensed zero, $5,000, and $100,000 in 2004, 2003, and 2002, respectively, relating to consulting services performed by a member of the Company's Board of Directors and a shareholder of the Company. In addition, the Company expensed zero, $19,000, and $240,000 in 2004, 2003, and 2002, respectively, relating to research performed by the university where the same Director and shareholder holds a significant position. The Company expensed zero, zero, and $8,000 in 2004, 2003 and 2002, respectively, relating to consulting services performed by a member of the Company's Board of Directors and a shareholder of the Company. The Company expensed zero, zero, and $35,000 in 2004, 2003, and 2002, respectively, relating to consulting services performed by a shareholder of the Company. The Company expensed $30,000, $83,000, and $100,000 in 2004, 2003, and 2002 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.

18. Segment and Geographic Information

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

The Implantable Medical Devices segment includes external revenue from product sales of BioGlue and bioprosthetic devices, including stentless porcine heart valves, SynerGraft processed porcine heart valves, and SynerGraft processed bovine vascular grafts, and Cerasorb Ortho bone graft substitute. The Human Tissue Preservation Services segment includes external revenue from cryopreservation services of cardiovascular, vascular, and orthopaedic human tissue. There are no intersegment revenues.

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

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

	Revenue	Cost of Preservation Services and Products	Gross Margin
2004:			
Implantable Medical Devices	$ 36,637	$ 7,818	$ 28,819
Human Tissue Preservation Services	25,676	29,807	(4,131)
All Other[a]	71	—	71
	$ 62,384	$ 37,625	$ 24,759
2003:			
Implantable Medical Devices	$ 28,263	$ 7,506	$ 20,757
Human Tissue Preservation Services	30,777	23,976	6,801
All Other[a]	492	—	492
	$ 59,532	$ 31,482	$ 28,050
2002:			
Implantable Medical Devices	$ 21,597	$ 10,270	$ 11,327
Human Tissue Preservation Services	55,373	55,363	10
All Other[a]	825	—	825
	$ 77,795	$ 65,633	$ 12,162

a The All Other designation includes 1) grant revenue and 2) distribution revenues.

Net revenues by product for the years ended December 31, 2004, 2003, and 2002 were as follows (in thousands):

	2004	2003	2002
BioGlue	$ 35,745	$ 27,784	$ 20,898
Human tissue preservation services:			
Cardiovascular tissue	12,504	17,059	23,413
Vascular tissue	10,293	12,655	17,826
Orthopaedic tissue	2,879	1,063	14,134
Total preservation services	25,676	30,777	55,373
Bioprosthetic devices	892	479	699
Grant and distribution revenue	71	492	825
	$ 62,384	$ 59,532	$ 77,795

Net revenues[b] by geographic location for the years ended December 31, 2004, 2003, and 2002 were as follows (in thousands):

	2004	2003	2002
U.S.	$ 53,244	$ 51,949	$ 71,188
International	9,140	7,583	6,607
	$ 62,384	$ 59,532	$ 77,795

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

At December 31, 2004, 2003, and 2002, 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.

19. Subsequent Events

On February 8, 2005, CryoLife and its subsidiaries entered into a new credit agreement with Wells Fargo Foothill, Inc. as lender. 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 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") and 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 expects that its aggregate borrowing availability under the credit agreement will equal $15.0 million, there can be no assurance that the availability 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. Amounts borrowed under the revolving credit facility bear interest at the bank's prime rate plus 1%. Amounts borrowed under the credit facility are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries. On February 8, 2005, CryoLife borrowed approximately $265,000 against the $15.0 million then available under its revolving credit facility, and used such borrowings to pay certain expenses of the transaction.

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

	Year	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE	2004	$ 15,086	$ 15,314	$ 16,118	$ 15,866
	2003	15,920	15,713	15,097	12,802
	2002	25,471	23,264	16,889	12,171
GROSS MARGIN	2004	$ 4,036	$ 5,877	$ 6,996	$ 7,850
	2003	11,836	8,547	5,834	1,833
	2002	15,173	4,218	(15,828)	8,599
NET (LOSS) INCOME	2004	$ (7,026)	$ (3,352)	$ (6,008)	$ (2,363)
	2003	(434)	(19,921)	(4,695)	(7,244)
	2002	3,104	(5,522)	(19,646)	(5,697)
(LOSS) EARNINGS PER SHARE—DILUTED	2004	$ (0.32)	$ (0.14)	$ (0.26)	$ (0.10)
	2003	(0.02)	(1.01)	(0.24)	(0.37)
	2002	0.16	(0.28)	(1.01)	(0.29)

SCHEDULE II

CRYOLIFE, INC. AND SUBSIDIARIES
VALUATION AND QUALIFYING ACCOUNTS
Years ended December 31, 2004, 2003, and 2002

Description	Balance beginning of period	Additions	Deductions	Balance end of period
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
Year ended December 31, 2002				
Allowance for doubtful accounts	$ 100,000	$ 53,000	$ 78,000	$ 75,000
Deferred preservation costs	300,000	320,000	570,000	50,000

QuickLinks

Exhibit 10.1(a)

SIXTH AMENDMENT TO LEASE

THIS AGREEMENT, made and entered into this 14th day of March, 1995 by and between Newmarket Partners III, Limited, a Georgia Limited Partnership, whose general partners are Laing Properties, Inc. and Laing Management Company (hereinafter called "Landlord") and Cryolife, Inc., a Florida corporation (hereinafter called "Tenant").

WITNESSETH THAT:

WHEREAS, Landlord and Tenant entered into a certain Lease Agreement dated February 13, 1986, as amended April 7, 1986, May 15, 1987, June 22, 1988, April 4, 1989, and October 15, 1990 (collectively hereinafter "Lease") for Suites 122, 130, 140, 142, 144 (hereinafter "Premises") at 2211 Newmarket Parkway, Building 8, Marietta, Georgia 30067.

WHEREAS, Landlord and Tenant desire to amend the Lease in order to modify some of the terms and conditions of the Lease;

NOW, THEREFORE in consideration of the mutual agreements of the undersigned and other good valuable consideration, this Lease is hereby amended, effective July 1, 1996 as follows:

38. ***BROKER DISCLOSURE***

Pursuant to Georgia Real Estate Commission Regulation 520-1-08, Laing Marketing Company makes the following disclosures concerning this Lease transaction:

a) In this transaction, Laing Marketing Company represents Landlord and not Tenant.

b) In this transaction, Richard Bowers and Company represents Tenant and not Landlord.

c) In this transaction, both Laing Marketing Company and Richard Bowers and Company shall receive their compensation from Landlord exclusively.

Both Tenant and Landlord acknowledge, agree with and consent to the representation and compensation disclosed above.

39. Tenant will be subject to the provisions contained in Exhibit "K" entitled "Environmental Matters' attached hereto and by this reference made a part hereof.

40. Paragraph 2 of the Lease, shall be amended to read:

Landlord and Tenant agree to extend the Lease for five (5) months from July 1, 1996 to November 30, 1996.

41. Landlord and Tenant agree that Tenant's rental schedule as stated in Paragraph 3 of the Lease shall be amended to read:

From July 1, 1996 through November 30, 1996 @ $43,481.96 per month.

Except as herein amended, all terms and conditions of the Lease shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereunto have executed this Sixth Amendment to Lease as of the day and year first above written.

[Signature blocks on next page]

Signed, sealed and delivered in the presence of:	LANDLORD: Newmarket Partners III, Limited, a Georgia Limited Partnership, whose general partners are Laing Properties, Inc. and Laing Management Company
	BY: LAING PROPERTIES, INC. MANAGING GENERAL PARTNER
	BY: ______________________
Witness ______________________	TITLE: ______________________
	ATTEST: ______________________
Notary Public ______________________	TITLE: ______________________
	(CORPORATE SEAL)
Signed, sealed and delivered in the presence of:	TENANT: Cryolife, Inc., a Florida corporation
	BY: ______________________
Witness ______________________	TITLE: ______________________
	ATTEST: ______________________
Notary Public ______________________	TITLE: ______________________
	(CORPORATE SEAL)

EXHIBIT "K"

ENVIRONMENTAL MATTERS

A. Tenant covenants that it will not cause or permit, knowingly or unknowingly, any Hazardous Wastes to be brought upon, disposed on or stored in or on the Premises or any Hazardous Material to be released in, on or about the Premises and that it will comply with any and all applicable laws, ordinances, rules, regulations and requirements respecting the presence, use or release of Hazardous Materials in, on or about the Premises.

B. Tenant covenants that it will immediately notify Landlord, in writing, of any existing, pending or threatened (a) investigation, inquiry, claim or action by any governmental authority in connection with any Environmental Laws; (b) third party claims; (c) regulatory actions: and/or (d) contamination of the Premises.

C. Tenant shall, at Tenant's expense, investigate, monitor, remediate, and/or clean up any Hazardous Material, Hazardous Waste, or other environmental condition on, about, or under the Premises required as a result of Tenant's use or occupancy of the Premises.

D. Tenant covenants that it shall keep the Premises free of any lien imposed pursuant to any Environmental Laws

E. Tenant shall indemnify, defend and hold Landlord harmless from and against any and all claims, judgments, damages, penalties, fines, costs (including without limitation, attorney's fees and court costs), liabilities or losses (collectively, the "Tenant Indemnified Claims") resulting from (i) the presence of Hazardous Wastes in or about the Premises or the release of Hazardous Materials in, on or about the Premises on or after the date of this Lease, and (ii) any Hazardous Waste placed or any Hazardous Substances released elsewhere in Newmarket Business Park by Tenant, its agents, invitees, employees and contractors.

F. The provisions of this Exhibit K shall survive the expiration or termination of this Lease.

G. For purposes of this Lease, the term "Hazardous Waste" has the same meaning as the term is defined in the Resource Conservation and Response Act, as amended, 42 U.S.C. §6901 *et. seq.* ("RCRA").

H. For the purposes of this Lease, the term "Hazardous Material", is defined to include those matters described in the Environmental Response Compensation and Liability Act, as amended, 42 U.S.C. §6901 et. seq. ("CERCLA"). As used herein the term "Hazardous Materials" shall also mean (1) asbestos, or any substance containing asbestos; (2) polychlorinated biphenyls; (3) lead; (4) radon: (5) pesticides; (6) petroleum or any other substance containing hydrocarbons; (7) any substance which, when on the Premises, is prohibited by any Environmental Laws; and (8) any other substance, material or waste which, (i) by any Environmental Laws requires special handling or notification of any governmental authority in its collection, storage, treatment, or disposal or (ii) is defined or classified as hazardous, dangerous or toxic pursuant to any legal requirement.

I. For purposes of this Lease, Environmental Laws shall mean: any and all federal, state and local laws, statutes, codes, ordinances, regulations, rules or other requirements relating to human health or safety or to the environment, including, but not limited to, those applicable to the storage, treatment, disposal, handling and release of any Hazardous Waste or Hazardous Materials, all as amended or modified from time to time.

IN WITNESS WHEREOF, the parties hereunto have executed this First Amendment to Lease as of the day and year first above written.

Signed, sealed and delivered in the presence of:	TENANT: Cryolife Inc.
	By:
Witness	Title:
	[Corporate Seal]
	Attest:
Notary Public	Title:

Signed, sealed and delivered in the presence of:	LANDLORD: Newmarket Partners III, Laing Properties, Inc., General Partner
	By:
Witness	Title:
	[Corporate Seal]
	Attest:
Notary Public	Title:

Exhibit "A-1"

[plat drawing]

QuickLinks -- Click here to rapidly navigate through this document

Exhibit 10.2

CONFIDENTIAL TREATMENT REQUESTED

EXECUTION VERSION

CREDIT AGREEMENT

by and among

CRYOLIFE, INC.

and

EACH OF ITS SUBSIDIARIES THAT ARE SIGNATORIES HERETO

as Borrowers,

and

WELLS FARGO FOOTHILL, INC.

as Lender

Dated as of February 8, 2005

TABLE OF CONTENTS

EXHIBITS AND SCHEDULES

CREDIT AGREEMENT

THIS CREDIT AGREEMENT (this "*Agreement*"), is entered into as of February 8, 2005, by and among, on the one hand, **WELLS FARGO FOOTHILL, INC.,** a California corporation ("Lender"), and, on the other hand, **CRYOLIFE, INC.**, a Florida corporation ("*Parent*"), and each of Parent's Subsidiaries identified on the signature pages hereof (such Subsidiaries, together with Parent, are referred to hereinafter each individually as a "*Borrower*", and individually and collectively, jointly and severally, as the "*Borrowers*").

The parties agree as follows:

1. DEFINITIONS AND CONSTRUCTION.

1.1 ***Definitions.*** Capitalized terms used in this Agreement shall have the meanings specified therefor on *Schedule 1.1*.

1.2 ***Accounting Terms.*** All accounting terms not specifically defined herein shall be construed in accordance with GAAP. When used herein, the term "financial statements" shall include the notes and schedules thereto. Whenever the term "Borrowers" or the term "Parent" is used in respect of a financial covenant or a related definition, it shall be understood to mean Parent and its Subsidiaries on a consolidated basis unless the context clearly requires otherwise.

1.3 ***Code.*** Any terms used in this Agreement that are defined in the Code shall be construed and defined as set forth in the Code unless otherwise defined herein, *provided*, *however*, that to the extent that the Code is used to define any term herein and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 shall govern.

1.4 ***Construction.*** Unless the context of this Agreement or any other Loan Document clearly requires otherwise, references to the plural include the singular, references to the singular include the plural, the terms "includes" and "including" are not limiting, and the term "or" has, except where otherwise indicated, the inclusive meaning represented by the phrase "and/or." The words "hereof," "herein," "hereby," "hereunder," and similar terms in this Agreement or any other Loan Document refer to this Agreement or such other Loan Document, as the case may be, as a whole and not to any particular provision of this Agreement or such other Loan Document, as the case may be. Section, subsection, clause, schedule, and exhibit references herein are to this Agreement unless otherwise specified. Any reference in this Agreement or in the other Loan Documents to any agreement, instrument, or document shall include all alterations, amendments, changes, extensions, modifications, renewals, replacements, substitutions, joinders, and supplements, thereto and thereof, as applicable (subject to any restrictions on such alterations, amendments, changes, extensions, modifications, renewals, replacements, substitutions, joinders, and supplements set forth herein). Any Event of Default shall "exist," "continue" or be "continuing" until such Event of Default has been waived in writing in accordance with *Section 14.1*. Any reference herein to the satisfaction or repayment in full of the Obligations shall mean the repayment in full in cash (or cash collateralization in accordance with the terms hereof) of all Obligations other than contingent indemnification Obligations and other than any Bank Product Obligations that, at such time, are allowed by the applicable Bank Product Provider to remain outstanding and are not required to be repaid or cash collateralized pursuant to the provisions of this Agreement. Any reference herein to any Person shall be construed to include such Person's successors and assigns. Any requirement of a writing contained herein or in the other Loan Documents shall be satisfied by the transmission of a Record and any Record transmitted shall constitute a representation and warranty as to the accuracy and completeness of the information contained therein.

1.5 ***Schedules and Exhibits.*** All of the schedules and exhibits attached to this Agreement shall be deemed incorporated herein by reference.

2. LOAN AND TERMS OF PAYMENT.

2.1 ***Revolver Advances.***

(a) Subject to the terms and conditions of this Agreement, and during the term of this Agreement, Lender agrees to make advances ("*Advances*") to Borrowers in an amount at any one time outstanding not to exceed an amount equal *to the lesser of* (i) the Maximum Revolver Amount *less* the Letter of Credit Usage, or (ii) the Borrowing Base *less* the Letter of Credit Usage.

(b) Anything to the contrary in this *Section 2.1* notwithstanding, Lender shall have the right to establish reserves in such amounts, and with respect to such matters, as Lender in its Permitted Discretion shall deem necessary or appropriate, against the Borrowing Base, including reserves (i) with respect to (A) sums that Borrowers are required to pay by any Section of this Agreement or any other Loan Document (such as taxes, assessments, insurance premiums, or, in the case of leased assets, rents or other amounts payable under such leases) and have failed to pay, and (B) amounts owing by Borrowers or their Subsidiaries to any Person to the extent secured by a Lien on, or trust over, any of the Collateral (other than a Permitted Lien), which Lien or trust, in the Permitted Discretion of Lender likely would have a priority superior to the Lender's Liens (such as Liens or trusts in favor of landlords, warehousemen, carriers, mechanics, materialmen, laborers, or suppliers, or Liens or trusts for *ad valorem*, excise, sales, or other taxes where given priority under applicable law) in and to such item of the Collateral, and (ii) after the occurrence and during the continuance of an Event of Default, with respect to such other matters as Lender in its Permitted Discretion shall deem necessary or appropriate. In addition to the foregoing, Lender shall have the right to have the Borrower's business reappraised by a qualified appraisal company selected by Lender from time to time after the occurrence of a Default or Event of Default for the purpose of redetermining the Enterprise Valuation and, as a result, redetermining the Borrowing Base.

(c) Amounts borrowed pursuant to this *Section 2.1* may be repaid and, subject to the terms and conditions of this Agreement, reborrowed at any time during the term of this Agreement.

2.2 Intentionally omitted.

2.3 ***Borrowing Procedures and Settlements.***

(a) **Procedure for Borrowing.** Each Borrowing shall be made by an irrevocable written request by an Authorized Person delivered to Lender. Such notice must be received by Lender no later than 10:00 a.m. (California time) on the Business Day that is the requested Funding Date specifying (i) the amount of such Borrowing, and (ii) the requested Funding Date, which shall be a Business Day. At Lender's election, in lieu of delivering the above-described written request, any Authorized Person may give Lender telephonic notice of such request by the required time. In such circumstances, Borrowers agree that any such telephonic notice will be confirmed in writing within 24 hours of the giving of such telephonic notice, but the failure to provide such written confirmation shall not affect the validity of the request.

(b) **Making of Advances**. If Lender has received a timely request for a Borrowing in accordance with the provisions hereof, and subject to the satisfaction of the applicable terms and conditions set forth herein, Lender shall make the proceeds of such Advance available to Borrowers on the applicable Funding Date by transferring available funds equal to such proceeds to Administrative Borrower's Designated Account.

2.4 ***Payments.***

(a) **Payments by Borrowers.** Except as otherwise expressly provided herein, all payments by Borrowers shall be made to Lender's Account for the account of Lender and shall be made in immediately available funds, no later than 11:00 a.m. (California time) on the date specified herein. Any payment received by Lender later than 11:00 a.m. (California time), shall be deemed to have been received on the following Business Day and any applicable interest or fee shall continue to accrue until such following Business Day.

(b) **Apportionment and Application.**

(i) All payments shall be remitted to Lender and all such payments, and all proceeds of Collateral received by Lender, shall be applied as follows:

(A) *first*, to pay any Lender Expenses then due to Lender under the Loan Documents, until paid in full,

(B) *second*, to pay any fees or premiums then due to Lender under the Loan Documents until paid in full,

(C) *third*, to pay interest due in respect of Advances until paid in full,

(D) *fourth*, so long as no Event of Default has occurred and is continuing, and at Lender's election, to pay amounts then due and owing by Administrative Borrower or its Subsidiaries in respect of Bank Products, until paid in full,

(E) *fifth*, so long as no Event of Default has occurred and is continuing, to pay the principal of all Advances until paid in full,

(F) *sixth*, if an Event of Default has occurred and is continuing, ratably (i) to pay the principal of all Advances until paid in full, (ii) to Lender, to be held by Lender as cash collateral in an amount up to 105% of the Letter of Credit Usage until paid in full, and (iii) to Lender, to be held by Lender, for the benefit of the Bank Product Providers, as cash collateral in an amount up to the amount of the Bank Product Reserve established prior to the occurrence of, and not in contemplation of, the subject Event of Default until Borrowers' and their Subsidiaries' obligations in respect of Bank Products have been paid in full or the cash collateral amount has been exhausted,

(G) *seventh*, if an Event of Default has occurred and is continuing, to pay any other Obligations (including the provision of amounts to Lender, to be held by Lender, for the benefit of the Bank Product Providers, as cash collateral in an amount up to the amount determined by Lender in its Permitted Discretion as the amount necessary to secure Borrowers' and its Subsidiaries' obligations in respect of Bank Products), and

(H) *eighth*, to Borrowers (to be wired to the Designated Account) or such other Person entitled thereto under applicable law; provided, however, that any such amount remitted to Borrowers from a Lender Deposit Account shall be limited to the amount of collected funds in such account (after payment of the amounts described in items (A) through (G) above) in excess of $10,000 (which $10,000 amount shall be held in such account as cash collateral (i) to pay any amounts due to the applicable depository bank from time to time in respect of such account or any lockbox services provided by such depository bank in connection with such account which are not otherwise paid by Borrowers directly, through a debit against the Designated Account or otherwise or (ii) to pay any other Obligations that may be due from time to time).

(ii) In each instance, so long as no Event of Default has occurred and is continuing, this *Section 2.4(b)* shall not apply to any payment made by Borrowers to Lender and specified by Borrowers to be for the payment of specific Obligations then due and payable (or prepayable) under any provision of this Agreement.

(iii) For purposes of the foregoing, "paid in full" means payment of all amounts owing under the Loan Documents according to the terms thereof, including loan fees, service fees, professional fees, interest (and specifically including interest accrued after the commencement of any Insolvency Proceeding), default interest, interest on interest, and expense reimbursements, whether or not any of the foregoing would be or is allowed or disallowed in whole or in part in any Insolvency Proceeding.

(iv) In the event of a direct conflict between the priority provisions of this *Section 2.4* and other provisions contained in any other Loan Document, it is the intention of the parties hereto that such priority provisions in such documents shall be read together and construed, to the fullest extent possible, to be in concert with each other. In the event of any actual, irreconcilable conflict that cannot be resolved as aforesaid, the terms and provisions of this *Section 2.4* shall control and govern.

2.5 ***Overadvances.*** If, at any time or for any reason, the amount of Obligations owed by Borrowers to Lender pursuant to *Section 2.1* or *Section 2.12* is greater than any of the limitations set forth in *Section 2.1* or *Section 2.12*, as applicable (an "*Overadvance*"), Borrowers immediately shall pay to Lender, in cash, the amount of such excess, which amount shall be used by Lender to reduce the Obligations in accordance with the priorities set forth in *Section 2.4(b)*. In addition, Borrowers hereby promise to pay the Obligations (including principal, interest, fees, costs, and expenses) in Dollars in full as and when due and payable under the terms of this Agreement and the other Loan Documents.

2.6 ***Interest Rates and Letter of Credit Fee: Rates, Payments, and Calculations*.**

(a) **Interest Rates.** Except as provided in clause (c) below, all Obligations (except for undrawn Letters of Credit and except for Bank Product Obligations) that have been charged to the Loan Account pursuant to the terms hereof shall bear interest on the Daily Balance thereof at a per annum rate equal to the Base Rate plus the Base Rate Margin.

The foregoing notwithstanding, at no time shall any portion of the Obligations (other than Bank Product Obligations) bear interest on the Daily Balance thereof at a per annum rate less than 5.25%. To the extent that interest accrued hereunder at the rate set forth herein would be less than the foregoing minimum daily rate, the interest rate chargeable hereunder for such day automatically shall be deemed increased to the minimum rate.

(b) **Letter of Credit Fee.** Borrowers shall pay Lender a Letter of Credit fee (in addition to the charges, commissions, fees, and costs set forth in *Section 2.12(d)*) which shall accrue at a rate equal to 2.00% per annum times the Daily Balance of the undrawn amount of all outstanding Letters of Credit.

(c) **Default Rate.** Upon the occurrence and during the continuation of an Event of Default (and at the election of Lender),

(i) all Obligations (except for undrawn Letters of Credit and except for Bank Product Obligations) that have been charged to the Loan Account pursuant to the terms hereof shall bear interest on the Daily Balance thereof at a per annum rate equal to 2 percentage points above the per annum rate otherwise applicable hereunder, and

(ii) the Letter of Credit fee provided for above shall be increased to 2 percentage points above the per annum rate otherwise applicable hereunder.

(d) **Payment.** Except as provided to the contrary in *Section 2.11*, interest, Letter of Credit fees, and all other fees payable hereunder shall be due and payable, in arrears, on the first day of each month at any time that any Obligations are outstanding or at any time that Lender has an obligation to extend credit hereunder. Borrowers hereby authorize Lender, from time to time, without prior notice to Borrowers, to charge all interest and fees (when due and payable), all Lender Expenses (as and when incurred), all charges, commissions, fees, and costs provided for in *Section 2.12(e)* (as and when accrued or incurred), all fees and costs provided for in *Section 2.11* (as and when accrued or incurred), and all other payments as and when due and payable under any Loan Document (including any amounts due and payable to the Bank Product Providers in respect of Bank Products up to the amount of the Bank Product Reserve) to Borrowers' Loan Account, which amounts thereafter shall constitute Advances hereunder and shall accrue interest at the rate then applicable to Advances hereunder. Any interest not paid when due shall be compounded by being charged to Borrowers' Loan Account and shall thereafter constitute Advances hereunder and shall accrue interest at the rate then applicable to Advances.

(e) **Computation.** All interest and fees chargeable under the Loan Documents shall be computed on the basis of a 360 day year for the actual number of days elapsed. In the event the Base Rate is changed from time to time hereafter, the rates of interest hereunder based upon the Base Rate automatically and immediately shall be increased or decreased by an amount equal to such change in the Base Rate.

(f) **Intent to Limit Charges to Maximum Lawful Rate.** In no event shall the interest rate or rates payable under this Agreement, plus any other amounts paid in connection herewith, exceed the highest rate permissible under any law that a court of competent jurisdiction shall, in a final determination, deem applicable. Borrowers and Lender, in executing and delivering this Agreement, intend legally to agree upon the rate or rates of interest and manner of payment stated within it; *provided*, *however*, that, anything contained herein to the contrary notwithstanding, if said rate or rates of interest or manner of payment exceeds the maximum allowable under applicable law, then, *ipso facto*, as of the date of this Agreement, Borrowers are and shall be liable only for the payment of such maximum as allowed by law, and payment received from Borrowers in excess of such legal maximum, whenever received, shall be applied to reduce the principal balance of the Obligations to the extent of such excess.

2.7 ***Cash Management.***

(a) Borrowers shall and shall cause each of their Subsidiaries to establish and maintain cash management services of a type and on terms satisfactory to Lender at one or more of the banks or securities intermediaries set forth on *Schedule 2.7(a)* (each a "*Cash Management Bank*"). Borrowers shall and shall cause each of their Subsidiaries to (i) request in writing and otherwise take such reasonable steps to ensure that all of their and their Subsidiaries' Account Debtors forward payment of the amounts owed by them directly to a Cash Management Account with respect to which the applicable Borrower or Subsidiary has delivered to Lender a Control Agreement or an account with respect to which Lender is the customer of the depository bank (each a "*Lender Deposit Account*"), and (ii) deposit or cause to be deposited promptly, and in any event no later than the first Business Day after the date of receipt thereof, all of their Collections (including those sent directly by their Account Debtors to Borrowers or their Subsidiaries) into a Cash Management Account with respect to which the applicable Borrower or Subsidiary has delivered a Control Agreement or a Lender Deposit Account; provided, however, that foreign Account Debtors of CryoLife Europa Ltd. may make payments directly to an Excluded Account and any Collections received by CryoLife Europa Ltd. in respect of its foreign Account Debtors may be deposited into an Excluded Account.

(b) Each Cash Management Bank shall establish and maintain Control Agreements with Lender and a Borrower or Subsidiary of a Borrower, as applicable, in form and substance acceptable to Lender; provided, however, that Borrowers and their Subsidiaries shall not be required to deliver a Control Agreement with respect to any Deposit Account or Securities Account so long as the aggregate balance in all such accounts not subject to Control Agreements does not exceed in the aggregate $5,000,000 at any time (or, if either (i) Parent has not received at least $15,000,000 in net proceeds from an offering of Stock on or before March 31, 2005 or (ii) at any time after March 31, 2005, the collected balance in Cash Management Accounts subject to

Control Agreements is less than $10,000,000 in the aggregate, such $5,000,000 limit shall be reduced to $2,000,000 from and after March 31, 2005 or, in the case of clause (ii), from and after the date such collected balance in Cash Management Accounts subject to Control Agreements is less than $10,000,000 in the aggregate) (collectively, such accounts with respect to which a Control Agreement is not required, the "*Excluded Accounts*" and each an "*Excluded Account*"). Each such Control Agreement shall provide, among other things, that (i) the Cash Management Bank will comply with any instructions originated by Lender directing the disposition of the funds in such Deposit Account (or, in the case of a Securities Account, entitlement orders originated by Lender) without further consent by Borrowers or their Subsidiaries, as applicable, (ii) the Cash Management Bank has no rights of setoff or recoupment or any other claim against the applicable Deposit Account or Securities Account, other than for payment of its service fees and other charges directly related to the administration of such account and, in the case of a Deposit Account, for returned checks or other items of payment, and (iii) upon written notice by Lender without further consent by Borrower or their Subsidiaries, it will forward by daily sweep all amounts in the applicable Deposit Account or Securities Account to the Lender's Account. Notwithstanding the foregoing, Lender agrees that it shall not send any such notice or otherwise direct the disposition of funds in any such Cash Management Account unless and until an Event of Default has occurred or Excess Availability first drops below $7,500,000 after the Closing Date.

(c) So long as no Default or Event of Default has occurred and is continuing, Administrative Borrower may amend *Schedule 2.7(a)* to add or replace a Cash Management Bank or Cash Management Account; *provided*, *however*, that (i) such prospective Cash Management Bank shall be reasonably satisfactory to Lender, and (ii) unless such account is an Excluded Account, prior to the time of the opening of such Cash Management Account, a Borrower or its Subsidiary, as applicable, and such prospective Cash Management Bank shall have executed and delivered to Lender a Control Agreement. Borrowers (or their Subsidiaries, as applicable) shall close any of their Cash Management Accounts (and establish replacement cash management accounts in accordance with the foregoing sentence) promptly and in any event within 30 days of notice from Lender that such Cash Management Bank no longer has an issuer credit rating of A2 or A or better from Moody's or S&P, respectively, and is no longer acceptable to Lender in Lender's reasonable judgment, or as promptly as practicable and in any event within 60 days of notice from Lender that the operating performance, funds transfer, or availability procedures or performance of such Cash Management Bank with respect to such accounts or Lender's liability under any Control Agreement with such Cash Management Bank is no longer acceptable in Lender's reasonable judgment.

(d) Except for the Excluded Accounts, all Cash Management Accounts shall be cash collateral accounts subject to Control Agreements.

2.8 ***Crediting Payments; Clearance Charge*.** The receipt of any payment item by Lender (whether from transfers to Lender by the Cash Management Banks pursuant to the Control Agreements or otherwise) shall not be considered a payment on account unless such payment item is a wire transfer of immediately available federal funds made to the Lender's Account or unless and until such payment item is honored when presented for payment. Should any payment item not be honored when presented for payment, then Borrowers shall be deemed not to have made such payment and interest shall be calculated accordingly. Anything to the contrary contained herein notwithstanding, any payment item shall be deemed received by Lender only if it is received into the Lender's Account on a Business Day on or before 11:00 a.m. (California time). If any payment item is received into the Lender's Account on a non-Business Day or after 11:00 a.m. (California time) on a Business Day, it shall be deemed to have been received by Lender as of the opening of business on the immediately following Business Day. The parties acknowledge and agree that the economic benefit of the foregoing provisions of this *Section 2.8* shall be for the exclusive benefit of Lender.

2.9 ***Designated Account.*** Lender is authorized to make the Advances, and Lender is authorized to issue the Letters of Credit, under this Agreement based upon telephonic or other instructions received from anyone purporting to be an Authorized Person or, without instructions, if pursuant to *Section 2.6(d)*. Administrative Borrower agrees to establish and maintain the Designated Account with the Designated Account Bank for the purpose of receiving the proceeds of the Advances requested by Borrowers and made by Lender hereunder. Unless otherwise agreed by Lender and Administrative Borrower, any Advance requested by Borrowers and made by Lender hereunder shall be made to the Designated Account.

2.10 ***Maintenance of Loan Account; Statements of Obligations.*** Lender shall maintain an account on its books in the name of Borrowers (the "*Loan Account*") on which Borrowers will be charged with, all Advances made by Lender to Borrowers or for Borrowers' account, the Letters of Credit issued by Lender for Borrowers' account, and with all other payment Obligations hereunder or under the other Loan Documents (except for Bank Product Obligations), including, accrued interest, fees and expenses, and Lender Expenses. In accordance with *Section 2.8*, the Loan Account will be credited with all payments received by Lender from Borrowers or for Borrowers' account, including all amounts received in the Lender's Account from any Cash Management Bank. Lender shall render statements regarding the Loan Account to Administrative Borrower, including principal, interest, fees, and including an itemization of all charges and expenses constituting Lender Expenses owing, and such statements, absent manifest error, shall be conclusively presumed to be correct and accurate and constitute an account stated between Borrowers and Lender unless, within 30 days after receipt thereof by Administrative Borrower, Administrative Borrower shall deliver to Lender written objection thereto describing the error or errors contained in any such statements.

2.11 ***Fees.*** Borrowers shall pay to Lender, as and when due and payable under the terms of the Fee Letter, the fees set forth in the Fee Letter.

2.12 ***Letters of Credit.***

(a) Subject to the terms and conditions of this Agreement, Lender agrees to issue letters of credit for the account of Borrowers (each, an "*L/C*") or to purchase participations or execute indemnities or reimbursement obligations (each such undertaking, an "*L/C Undertaking*") with respect to letters of credit issued by an Underlying Issuer (as of the Closing Date, the prospective Underlying Issuer is to be Wells Fargo) for the account of Borrowers. Each request for the issuance of a Letter of Credit or the amendment, renewal, or extension of any outstanding Letter of Credit shall be made in writing by an Authorized Person and delivered to Lender via hand delivery, telefacsimile, or other electronic method of transmission reasonably in advance of the requested date of issuance, amendment, renewal, or extension. Each such request shall be in form and substance satisfactory to Lender in its Permitted Discretion and shall specify (i) the amount of such Letter of Credit, (ii) the date of issuance, amendment, renewal, or extension of such Letter of Credit, (iii) the expiration date of such Letter of Credit, (iv) the name and address of the beneficiary thereof (or the beneficiary of the Underlying Letter of Credit, as applicable), and (v) such other information (including, in the case of an amendment, renewal, or extension, identification of the outstanding Letter of Credit to be so amended, renewed, or extended) as shall be necessary to prepare, amend, renew, or extend such Letter of Credit. If requested by Lender, Borrowers also shall be an applicant under the application with respect to any Underlying Letter of Credit that is to be the subject of an L/C Undertaking. Lender shall have no obligation to issue a Letter of Credit if any of the following would result after giving effect to the issuance of such requested Letter of Credit:

(i) the Letter of Credit Usage would exceed the Borrowing Base *less* the outstanding amount of Advances, or

(ii) the Letter of Credit Usage would exceed $2,000,000, or

(iii) the Letter of Credit Usage would exceed the Maximum Revolver Amount *less* the outstanding amount of Advances.

Borrowers and Lender acknowledge and agree that certain Underlying Letters of Credit may be issued to support letters of credit that already are outstanding as of the Closing Date. Each Letter of Credit (and corresponding Underlying Letter of Credit) shall be in form and substance acceptable to Lender (in the exercise of its Permitted Discretion), including the requirement that the amounts payable thereunder must be payable in Dollars. If Lender is obligated to advance funds under a Letter of Credit, Borrowers immediately shall reimburse such L/C Disbursement to Lender by paying to Lender an amount equal to such L/C Disbursement not later than 11:00 a.m., California time, on the date that such L/C Disbursement is made, if Administrative Borrower shall have received written or telephonic notice of such L/C Disbursement prior to 10:00 a.m., California time, on such date, or, if such notice has not been received by Administrative Borrower prior to such time on such date, then not later than 11:00 a.m., California time, on the Business Day that Administrative Borrower receives such notice, if such notice is received prior to 10:00 a.m., California time, on the date of receipt, and, in the absence of such reimbursement, the L/C Disbursement immediately and automatically shall be deemed to be an Advance hereunder and, thereafter, shall bear interest at the rate then applicable to Advances under *Section 2.6*. To the extent an L/C Disbursement is deemed to be an Advance hereunder, Borrowers' obligation to reimburse such L/C Disbursement shall be discharged and replaced by the resulting Advance.

(b) Each Borrower hereby agrees to indemnify, save, defend, and hold Lender harmless from any loss, cost, expense, or liability, and reasonable attorneys fees incurred by Lender arising out of or in connection with any Letter of Credit; *provided*, *however*, that no Borrower shall be obligated hereunder to indemnify for any loss, cost, expense, or liability to the extent that it is caused by the gross negligence or willful misconduct of Lender. Each Borrower agrees to be bound by the Underlying Issuer's regulations and interpretations of any Underlying Letter of Credit or by Lender's interpretations of any L/C issued by Lender to or for such Borrower's account, even though this interpretation may be different from such Borrower's own, and each Borrower understands and agrees that Lender shall not be liable for any error, negligence, or mistake, whether of omission or commission, in following Borrowers' instructions or those contained in the Letter of Credit or any modifications, amendments, or supplements thereto. Each Borrower understands that the L/C Undertakings may require Lender to indemnify the Underlying Issuer for certain costs or liabilities arising out of claims by Borrowers against such Underlying Issuer. Each Borrower hereby agrees to indemnify, save, defend, and hold Lender harmless with respect to any loss, cost, expense (including reasonable attorneys fees), or liability incurred by Lender under any L/C Undertaking as a result of Lender's indemnification of any Underlying Issuer; *provided*, *however*, that no Borrower shall be obligated hereunder to indemnify for any loss, cost, expense, or liability to the extent that it is caused by the gross negligence or willful misconduct of Lender. Each Borrower hereby acknowledges and agrees that Lender shall not be responsible for delays, errors, or omissions resulting from the malfunction of equipment in connection with any Letter of Credit.

(c) Each Borrower hereby authorizes and directs any Underlying Issuer to deliver to Lender all instruments, documents, and other writings and property received by such Underlying Issuer pursuant to such Underlying Letter of Credit and to accept and rely upon Lender's instructions with respect to all matters arising in connection with such Underlying Letter of Credit and the related application.

(d) Any and all issuance charges, commissions, fees, and costs incurred by Lender relating to Underlying Letters of Credit shall be Lender Expenses for purposes of this Agreement and immediately shall be reimbursable by Borrowers to Lender for the account of Lender; it being acknowledged and agreed by each Borrower that, as of the Closing Date, the issuance charge imposed by the prospective Underlying Issuer is .825% per annum times the face amount of each Underlying Letter of Credit, that such issuance charge may be changed from time to time, and that the Underlying Issuer also imposes a schedule of charges for amendments, extensions, drawings, and renewals.

(e) If by reason of (i) any change after the Closing Date in any applicable law, treaty, rule, or regulation or any change in the interpretation or application thereof by any Governmental Authority, or (ii) compliance by the Underlying Issuer or Lender with any direction, request, or requirement (irrespective of whether having the force of law) of any Governmental Authority or monetary authority including, Regulation D of the Federal Reserve Board as from time to time in effect (and any successor thereto):

(i) any reserve, deposit, or similar requirement is or shall be imposed or modified in respect of any Letter of Credit issued hereunder, or

(ii) there shall be imposed on the Underlying Issuer or Lender any other condition regarding any Underlying Letter of Credit or any Letter of Credit issued pursuant hereto;

and the result of the foregoing is to increase, directly or indirectly, the cost to Lender of issuing, making, guaranteeing, or maintaining any Letter of Credit or to reduce the amount receivable in respect thereof by Lender, then, and in any such case, Lender may, at any time within a reasonable period after the additional cost is incurred or the amount received is reduced, notify Administrative Borrower, and Borrowers shall pay on demand such amounts as Lender may specify to be necessary to compensate Lender for such additional cost or reduced receipt, together with interest on such amount from the date of such demand until payment in full thereof at the rate then applicable to Advances. The determination by Lender of any amount due pursuant to this Section, as set forth in a certificate setting forth the calculation thereof in reasonable detail, shall, in the absence of manifest or demonstrable error, be final and conclusive and binding on all of the parties hereto.

2.13 ***Intentionally Omitted.***

2.14 ***Capital Requirements.*** If, after the date hereof, Lender determines that (i) the adoption of or change in any law, rule, regulation or guideline regarding capital requirements for banks or bank holding companies, or any change in the interpretation or application thereof by any Governmental Authority charged with the administration thereof, or (ii) compliance by Lender or its parent bank holding company with any guideline, request or directive of any such entity regarding capital adequacy (whether or not having the force of law), has the effect of reducing the return on Lender's or such holding company's capital as a consequence of Lender's obligations hereunder to a level below that which Lender or such holding company could have achieved but for such adoption, change, or compliance (taking into consideration Lender's or such holding company's then existing policies with respect to capital adequacy and assuming the full utilization of such entity's capital) by any amount deemed by Lender to be material, then Lender may notify Administrative Borrower thereof. Following receipt of such notice, Borrowers agree to pay Lender on demand the amount of such reduction of return of capital as and when such reduction is determined, payable within 90 days after presentation by Lender of a statement in the amount and setting forth in reasonable detail Lender's calculation thereof and the assumptions upon which such calculation was based (which statement shall be deemed true and correct absent manifest error). In determining such amount, Lender may use any reasonable averaging and attribution methods.

2.15 ***Joint and Several Liability of Borrowers.***

(a) Each Borrower is accepting joint and several liability hereunder and under the other Loan Documents in consideration of the financial accommodations to be provided by Lender under this Agreement, for the mutual benefit, directly and indirectly, of each Borrower and in consideration of the undertakings of the other Borrowers to accept joint and several liability for the Obligations.

(b) Each Borrower, jointly and severally, hereby irrevocably and unconditionally accepts, not merely as a surety but also as a co-debtor, joint and several liability with the other Borrowers, with respect to the payment and performance of all of the Obligations (including, without limitation, any Obligations arising under this *Section 2.15*), it being the intention of the parties hereto that all the Obligations shall be the joint and several obligations of each Borrower without preferences or distinction among them.

(c) If and to the extent that any Borrower shall fail to make any payment with respect to any of the Obligations as and when due or to perform any of the Obligations in accordance with the terms thereof, then in each such event the other Borrowers will make such payment with respect to, or perform, such Obligation.

(d) The Obligations of each Borrower under the provisions of this *Section 2.15* constitute the absolute and unconditional, full recourse Obligations of each Borrower enforceable against each such Borrower to the full extent of its properties and assets, irrespective of the validity, regularity or enforceability of this Agreement or any other circumstances whatsoever.

(e) Except as otherwise expressly provided in this Agreement, each Borrower hereby waives notice of acceptance of its joint and several liability, notice of any Advances or Letters of Credit issued under or pursuant to this Agreement, notice of the occurrence of any Default, Event of Default, or of any demand for any payment under this Agreement, notice of any action at any time taken or omitted by Lender under or in respect of any of the Obligations, any requirement of diligence or to mitigate damages and, generally, to the extent permitted by applicable law, all demands, notices and other formalities of every kind in connection with this Agreement (except as otherwise provided in this Agreement). Each Borrower hereby assents to, and waives notice of, any extension or postponement of the time for the payment of any of the Obligations, the acceptance of any payment of any of the Obligations, the acceptance of any partial payment thereon, any waiver, consent or other action or acquiescence by Lender at any time or times in respect of any default by any Borrower in the performance or satisfaction of any term, covenant, condition or provision of this Agreement, any and all other indulgences whatsoever by Lender in respect of any of the Obligations, and the taking, addition, substitution or release, in whole or in part, at any time or times, of any security for any of the Obligations or the addition, substitution or release, in whole or in part, of any Borrower. Without limiting the generality of the foregoing, each Borrower assents to any other action or delay in acting or failure to act on the part of Lender with respect to the failure by any Borrower to comply with any of its respective Obligations, including, without limitation, any failure strictly or diligently to assert any right or to pursue any remedy or to comply fully with applicable laws or regulations thereunder, which might, but for the provisions of this *Section 2.15* afford grounds for terminating, discharging or relieving any Borrower, in whole or in part, from any of its Obligations under this *Section 2.15*, it being the intention of each Borrower that, so long as any of the Obligations hereunder remain unsatisfied, the Obligations of each Borrower under this *Section 2.15* shall not be discharged except by performance and then only to the extent of such performance. The Obligations of each Borrower under this *Section 2.15*shall not be diminished or rendered unenforceable by any winding up, reorganization, arrangement, liquidation, reconstruction or similar proceeding with respect to any Borrower or Lender.

(f) Each Borrower represents and warrants to Lender that such Borrower is currently informed of the financial condition of Borrowers and of all other circumstances which a diligent inquiry would reveal and which bear upon the risk of nonpayment of the Obligations. Each Borrower further represents and warrants to Lender that such Borrower has read and understands the terms and conditions of the Loan Documents. Each Borrower hereby covenants that such

Borrower will continue to keep informed of Borrowers' financial condition, the financial condition of other guarantors, if any, and of all other circumstances which bear upon the risk of nonpayment or nonperformance of the Obligations.

(g) Each Borrower waives all rights and defenses arising out of an election of remedies by Lender, even though that election of remedies, such as a nonjudicial foreclosure with respect to security for a guaranteed obligation, has destroyed Lender's rights of subrogation and reimbursement against such Borrower.

(h) Intentionally omitted.

(i) The provisions of this *Section 2.15* are made for the benefit of Lender and its successors and assigns, and may be enforced by it or them from time to time against any or all Borrowers as often as occasion therefor may arise and without requirement on the part of Lender, successor or assign first to marshal any of its or their claims or to exercise any of its or their rights against any Borrower or to exhaust any remedies available to it or them against any Borrower or to resort to any other source or means of obtaining payment of any of the Obligations hereunder or to elect any other remedy. The provisions of this *Section 2.15* shall remain in effect until all of the Obligations shall have been paid in full or otherwise fully satisfied. If at any time, any payment, or any part thereof, made in respect of any of the Obligations, is rescinded or must otherwise be restored or returned by Lender upon the insolvency, bankruptcy or reorganization of any Borrower, or otherwise, the provisions of this *Section 2.15* will forthwith be reinstated in effect, as though such payment had not been made.

(j) Each Borrower hereby agrees that it will not enforce any of its rights of contribution or subrogation against any other Borrower with respect to any liability incurred by it hereunder or under any of the other Loan Documents, any payments made by it to Lender with respect to any of the Obligations or any collateral security therefor until such time as all of the Obligations have been paid in full in cash. Any claim which any Borrower may have against any other Borrower with respect to any payments to Lender hereunder or under any other Loan Documents are hereby expressly made subordinate and junior in right of payment, without limitation as to any increases in the Obligations arising hereunder or thereunder, to the prior payment in full in cash of the Obligations and, in the event of any insolvency, bankruptcy, receivership, liquidation, reorganization or other similar proceeding under the laws of any jurisdiction relating to any Borrower, its debts or its assets, whether voluntary or involuntary, all such Obligations shall be paid in full in cash before any payment or distribution of any character, whether in cash, securities or other property, shall be made to any other Borrower therefor.

(k) Each Borrower hereby agrees that, after the occurrence and during the continuance of any Default or Event of Default, the payment of any amounts due with respect to the indebtedness owing by any Borrower to any other Borrower is hereby subordinated to the prior payment in full in cash of the Obligations. Each Borrower hereby agrees that after the occurrence and during the continuance of any Default or Event of Default, such Borrower will not demand, sue for or otherwise attempt to collect any indebtedness of any other Borrower owing to such Borrower until the Obligations shall have been paid in full in cash. If, notwithstanding the foregoing sentence, such Borrower shall collect, enforce or receive any amounts in respect of such indebtedness, such amounts shall be collected, enforced and received by such Borrower as trustee for Lender, and such Borrower shall deliver any such amounts to Lender for application to the Obligations in accordance with *Section 2.4(b)*.

3. CONDITIONS; TERM OF AGREEMENT.

3.1 ***Conditions Precedent to the Initial Extension of Credit.*** The obligation of Lender to make the initial extension of credit provided for hereunder, is subject to the fulfillment, to the satisfaction of Lender of each of the conditions precedent set forth on *Schedule 3.1* (the making of such initial extension of credit by Lender being conclusively deemed to be its satisfaction or waiver of the conditions precedent).

3.2 ***Conditions Precedent to all Extensions of Credit.*** The obligation of Lender to make any Advances hereunder at any time (or to extend any other credit hereunder) shall be subject to the following conditions precedent:

(a) the representations and warranties contained in this Agreement or in the other Loan Documents shall be true and correct in all material respects on and as of the date of such extension of credit, as though made on and as of such date (except to the extent that such representations and warranties relate solely to an earlier date);

(b) no Default or Event of Default shall have occurred and be continuing on the date of such extension of credit, nor shall either result from the making thereof;

(c) no injunction, writ, restraining order, or other order of any nature restricting or prohibiting, directly or indirectly, the extending of such credit shall have been issued and remain in force by any Governmental Authority against any Borrower, Lender, or any of their Affiliates; and

(d) no Material Adverse Change shall have occurred.

3.3 ***Term.*** This Agreement shall continue in full force and effect for a term ending on the date three (3) years following the Closing Date (the "*Maturity Date*"). The foregoing notwithstanding, Lender shall have the right to terminate its obligations under this Agreement immediately and without notice upon the occurrence and during the continuation of an Event of Default.

3.4 ***Effect of Termination.*** On the date of termination of this Agreement, all Obligations (including contingent reimbursement obligations of Borrowers with respect to outstanding Letters of Credit and including all Bank Product Obligations) immediately shall become due and payable without notice or demand (including (a) either (i) providing cash collateral to be held by Lender in an amount equal to 105% of the Letter of Credit Usage, or (ii) causing the original Letters of Credit to be returned to Lender, and (b) providing cash collateral (in an amount determined by Lender as sufficient to satisfy the reasonably estimated credit exposure) to be held by Lender for the benefit of the Bank Product Providers with respect to the Bank Product Obligations). No termination of this Agreement, however, shall relieve or discharge Borrowers or their Subsidiaries of their duties, Obligations, or covenants hereunder or under any other Loan Document and the Lender's Liens in the Collateral shall remain in effect until all Obligations have been paid in full and Lender's obligations to provide additional credit hereunder have been terminated. When this Agreement has been terminated and all of the Obligations have been paid in full and Lender's obligations to provide additional credit under the Loan Documents have been terminated irrevocably, Lender will, at Borrowers' sole expense, execute and deliver any termination statements, lien releases, mortgage releases, re-assignments of trademarks, discharges of security interests, and other similar discharge or release documents (and, if applicable, in recordable form) as are reasonably necessary to release, as of record, the Lender's Liens and all notices of security interests and liens previously filed by Lender with respect to the Obligations.

3.5 ***Early Termination by Borrowers.*** Borrowers have the option, at any time upon 90 days prior written notice by Administrative Borrower to Lender, to terminate this Agreement by paying to Lender, in cash, the Obligations (including (a) either (i) providing cash collateral to be held by Lender in an amount equal to 105% of the Letter of Credit Usage, or (ii) causing the original Letters of Credit to be returned to Lender, and (b) providing cash collateral (in an amount determined by Lender as sufficient to satisfy the reasonably estimated credit exposure) to be held by Lender for the benefit of the Bank Product Providers with respect to the Bank Product Obligations), in full. If Administrative Borrower has sent a notice of termination pursuant to the provisions of this Section, then Lender's obligations to extend credit hereunder shall terminate and Borrowers shall be obligated to repay the Obligations (including (a) either (i) providing cash collateral to be held by Lender in an amount equal to 105% of the Letter of Credit Usage, or (ii) causing the original Letters of Credit to be returned to Lender, and (b) providing cash collateral (in an amount determined by Lender as sufficient to satisfy the reasonably estimated credit exposure) to be held by Lender for the benefit of the Bank Product Providers with respect to the Bank Products Obligations), in full, on the date set forth as the date of termination of this Agreement in such notice.

4. REPRESENTATIONS AND WARRANTIES.

In order to induce Lender to enter into this Agreement, each Borrower makes the following representations and warranties to Lender which shall be true, correct, and complete, in all material respects, as of the date hereof, and shall be true, correct, and complete, in all material respects, as of the Closing Date, and at and as of the date of the making of each Advance (or other extension of credit) made thereafter, as though made on and as of the date of such Advance (or other extension of credit) (except to the extent that such representations and warranties relate solely to an earlier date) and such representations and warranties shall survive the execution and delivery of this Agreement:

4.1 ***No Encumbrances*****.** Each Borrower and its Subsidiaries has good and indefeasible title to, or a valid leasehold interest in, their personal property assets and good and marketable title to, or a valid leasehold interest in, their Real Property, in each case, free and clear of Liens except for Permitted Liens.

4.2 ***Intentionally Omitted*****.**

4.3 ***Intentionally Omitted*****.**

4.4 ***Equipment*****.** Each material item of Equipment of Borrowers and their Subsidiaries is used or held for use in their business and is in good working order, ordinary wear and tear and damage by casualty excepted.

4.5 ***Location of Inventory and Equipment*****.** The Inventory and Equipment (other than vehicles or Equipment out for repair) of Borrowers and their Subsidiaries are not stored with a bailee, warehouseman, or similar party and are located only at, or in-transit between, the locations identified on *Schedule 4.5* (as such Schedule may be updated pursuant to *Section 5.9*).

4.6 ***Inventory Records*****.** Each Borrower keeps correct and accurate records itemizing and describing the type, quality, and quantity of its and its Subsidiaries' Inventory and the book value thereof.

4.7 ***State of Incorporation; Location of Chief Executive Office; Organizational Identification Number; Commercial Tort Claims*****.**

(a) The jurisdiction of organization of each Borrower and each of its Subsidiaries is set forth on *Schedule 4.7(a)*.

(b) The chief executive office of each Borrower and each of its Subsidiaries is located at the address indicated on *Schedule 4.7(b)* (as such Schedule may be updated pursuant to *Section 5.9*).

(c) Each Borrower's and each of its Subsidiaries' organizational identification number, if any, is identified on *Schedule 4.7(c)*.

(d) As of the Closing Date, Borrowers and their Subsidiaries do not hold any commercial tort claims, except as set forth on *Schedule 4.7(d)*.

4.8 ***Due Organization and Qualification; Subsidiaries.***

(a) Each Borrower and each Subsidiary of a Borrower is duly organized and existing and in good standing under the laws of the jurisdiction of its organization and qualified to do business in any state where the failure to be so qualified reasonably could be expected to result in a Material Adverse Change.

(b) Set forth on *Schedule 4.8(b)*, is a complete and accurate description of the authorized capital Stock of each Borrower, by class, and, as of the Closing Date, a description of the number of shares of each such class that are issued and outstanding. Other than as described on *Schedule 4.8(b)*, there are no subscriptions, options, warrants, or calls relating to any shares of each Borrower's capital Stock, including any right of conversion or exchange under any outstanding security or other instrument.

(c) Set forth on *Schedule 4.8(c)*, is a complete and accurate list of each Borrower's direct and indirect Subsidiaries, showing: (i) the jurisdiction of their organization, (ii) the number of shares of each class of common and preferred Stock authorized for each of such Subsidiaries, and (iii) the number and the percentage of the outstanding shares of each such class owned directly or indirectly by the applicable Borrower. All of the outstanding capital Stock of each such Subsidiary has been validly issued and is fully paid and non-assessable.

(d) Except as set forth on *Schedule 4.8(c)*, there are no subscriptions, options, warrants, or calls relating to any shares of any Borrower's Subsidiaries' capital Stock, including any right of conversion or exchange under any outstanding security or other instrument. No Borrower or any of its respective Subsidiaries is subject to any obligation (contingent or otherwise) to repurchase or otherwise acquire or retire any shares of any Borrower's Subsidiaries' capital Stock or any security convertible into or exchangeable for any such capital Stock.

4.9 ***Due Authorization; No Conflict.***

(a) As to each Borrower, the execution, delivery, and performance by such Borrower of this Agreement and the other Loan Documents to which it is a party have been duly authorized by all necessary action on the part of such Borrower.

(b) As to each Borrower, the execution, delivery, and performance by such Borrower of this Agreement and the other Loan Documents to which it is a party do not and will not (i) violate any provision of federal, state, or local law or regulation applicable to any Borrower, the Governing Documents of any Borrower, or any order, judgment, or decree of any court or other Governmental Authority binding on any Borrower, (ii) conflict with, result in a breach of, or constitute (with due notice or lapse of time or both) a default under any material contractual obligation of any Borrower, (iii) result in or require the creation or imposition of any Lien of any nature whatsoever upon any properties or assets of Borrower, other than Permitted Liens, or (iv) require any approval of any Borrower's interestholders or any approval or consent of any Person under any material contractual obligation of any Borrower, other than consents or approvals that have been obtained and that are still in force and effect.

(c) Other than the filing of financing statements, and the recordation of the Mortgages, the execution, delivery, and performance by each Borrower of this Agreement and the other Loan Documents to which such Borrower is a party do not and will not require any registration with, consent, or approval of, or notice to, or other action with or by, any Governmental Authority, other than consents or approvals that have been obtained and that are still in force and effect.

(d) As to each Borrower, this Agreement and the other Loan Documents to which such Borrower is a party, and all other documents contemplated hereby and thereby, when executed and delivered by such Borrower will be the legally valid and binding obligations of such Borrower, enforceable against such Borrower in accordance with their respective terms, except as enforcement may be limited by equitable principles or by bankruptcy, insolvency, reorganization, moratorium, or similar laws relating to or limiting creditors' rights generally.

(e) The Lender's Liens are validly created, perfected, and first priority Liens, subject only to Permitted Liens.

(f) The execution, delivery, and performance by each Guarantor of the Loan Documents to which it is a party have been duly authorized by all necessary action on the part of such Guarantor.

(g) The execution, delivery, and performance by each Guarantor of the Loan Documents to which it is a party do not and will not (i) violate any provision of federal, state, or local law or regulation applicable to such Guarantor, the Governing Documents of such Guarantor, or any order, judgment, or decree of any court or other Governmental Authority binding on such Guarantor, (ii) conflict with, result in a breach of, or constitute (with due notice or lapse of time or both) a default under any material contractual obligation of such Guarantor, (iii) result in or require the creation or imposition of any Lien of any nature whatsoever upon any properties or assets of such Guarantor, other than Permitted Liens, or (iv) require any approval of such Guarantor's interestholders or any approval or consent of any Person under any material contractual obligation of such Guarantor, other than consents or approvals that have been obtained and that are still in force and effect.

(h) Other than the filing of financing statements and the recordation of the Mortgages, the execution, delivery, and performance by each Guarantor of the Loan Documents to which such Guarantor is a party do not and will not require any registration with, consent, or approval of, or notice to, or other action with or by, any Governmental Authority, other than consents or approvals that have been obtained and that are still in force and effect.

(i) The Loan Documents to which each Guarantor is a party, and all other documents contemplated hereby and thereby, when executed and delivered by such Guarantor will be the legally valid and binding obligations of such Guarantor, enforceable against such Guarantor in accordance with their respective terms, except as enforcement may be limited by equitable principles or by bankruptcy, insolvency, reorganization, moratorium, or similar laws relating to or limiting creditors' rights generally.

4.10 ***Litigation.*** Other than those matters disclosed on *Schedule 4.10*, and other than matters arising after the Closing Date that reasonably could not be expected to result in a Material Adverse Change, there are no actions, suits, or proceedings pending or, to the best knowledge of each Borrower, threatened against any Borrower or any of its Subsidiaries.

4.11 ***No Material Adverse Change.*** All financial statements relating to Borrowers and their Subsidiaries or Guarantor that have been delivered by Borrowers to Lender have been prepared in accordance with GAAP (except, in the case of unaudited financial statements, for the lack of footnotes and being subject to year-end audit adjustments) and present fairly in all material respects, Borrowers' and their Subsidiaries' (or any Guarantor's, as applicable) financial condition as of the date thereof and results of operations for the period then ended. There has not been a Material Adverse Change with respect to Borrowers and their Subsidiaries (or any Guarantor, as applicable) since the date of the latest financial statements submitted to Lender on or before the Closing Date.

4.12 ***Fraudulent Transfer.***

(a) Each Borrower and each Subsidiary of a Borrower is Solvent.

(b) No transfer of property is being made by any Borrower or any Subsidiary of a Borrower and no obligation is being incurred by any Borrower or any Subsidiary of a Borrower in connection with the transactions contemplated by this Agreement or the other Loan Documents with the intent to hinder, delay, or defraud either present or future creditors of Borrowers or their Subsidiaries.

4.13 ***Employee Benefits.*** None of Borrowers, any of their Subsidiaries, or any of their ERISA Affiliates maintains or contributes to any Benefit Plan.

4.14 ***Environmental Condition.*** Except as set forth on *Schedule 4.14*, (a) to Borrowers' knowledge, none of Borrowers' or their Subsidiaries' properties or assets has ever been used by Borrowers, their Subsidiaries, or by previous owners or operators in the disposal of, or to produce, store, handle, treat, release, or transport, any Hazardous Materials, where such use, production, storage, handling, treatment, release or transport was in violation, in any material respect, of any applicable Environmental Law, (b) to Borrowers' knowledge, none of Borrowers' nor their Subsidiaries' properties or assets has ever been designated or identified in any manner pursuant to any environmental protection statute as a Hazardous Materials disposal site, (c) none of Borrowers nor any of their Subsidiaries have received notice that a Lien arising under any Environmental Law has attached to any revenues or to any Real Property owned or operated by Borrowers or their Subsidiaries, and (d) none of Borrowers nor any of their Subsidiaries have received a summons, citation, notice, or directive from the United States Environmental Protection Agency or any other federal or state governmental agency concerning any action or omission by any Borrower or any Subsidiary of a Borrower resulting in the releasing or disposing of Hazardous Materials into the environment.

4.15 ***Intellectual Property.*** Each Borrower and each Subsidiary of a Borrower owns, or holds licenses in, all trademarks, trade names, copyrights, patents, patent rights, and licenses that are necessary to the conduct of its business as currently conducted, and attached hereto as *Schedule 4.15* (as updated from time to time) is a true, correct, and complete listing of all material patents, patent applications, trademarks, trademark applications, copyrights, and copyright registrations as to which each Borrower or one of its Subsidiaries is the owner or is an exclusive licensee.

4.16 ***Leases.*** Borrowers and their Subsidiaries enjoy peaceful and undisturbed possession under all leases material to their business and to which they are parties or under which they are operating and all of such material leases are valid and subsisting and no material default by Borrowers or their Subsidiaries exists under any of them.

4.17 ***Deposit Accounts and Securities Accounts.*** Set forth on *Schedule 2.7* is a listing of all of Borrowers' and their Subsidiaries' Deposit Accounts and Securities Accounts, including, with respect to each bank or securities intermediary (a) the name and address of such Person, and (b) the account numbers of the Deposit Accounts or Securities Accounts maintained with such Person.

4.18 ***Complete Disclosure.*** All factual information (taken as a whole) furnished by or on behalf of Borrowers or their Subsidiaries in writing to Lender (including all information contained in the Schedules hereto or in the other Loan Documents) for purposes of or in connection with this Agreement, the other Loan Documents, or any transaction contemplated herein or therein is, and all other such factual information (taken as a whole) hereafter furnished by or on behalf of Borrowers or their Subsidiaries in writing to Lender will be, true and accurate in all material respects on the date as of which such information is dated or certified and not incomplete by omitting to state any fact necessary to make such information (taken as a whole) not misleading in any material respect at such time in light of the circumstances under which such information was provided. On the Closing Date, the Closing Date Projections represent, and as of the date on which any other Projections are delivered to Lender, such additional Projections represent Borrowers' good faith estimate of their and their Subsidiaries' future performance for the periods covered thereby.

4.19 ***Indebtedness.*** Set forth on *Schedule 4.19* is a true and complete list of all Indebtedness of each Borrower and each Subsidiary of a Borrower outstanding immediately prior to the Closing Date that is to remain outstanding after the Closing Date and such Schedule accurately reflects the aggregate principal amount of such Indebtedness and describes the principal terms thereof.

5. AFFIRMATIVE COVENANTS.

Each Borrower covenants and agrees that, so long as any credit hereunder shall be available and until the payment in full of the Obligations, Borrowers shall and shall cause each of their respective Subsidiaries to do all of the following:

5.1 ***Accounting System*.** Maintain a system of accounting that enables Borrowers to produce financial statements in accordance with GAAP and maintain records pertaining to the Collateral that contain information as from time to time reasonably may be requested by Lender. Borrowers also shall keep a reporting system that shows all additions, sales, claims, returns, and allowances with respect to their and their Subsidiaries' sales.

5.2 ***Collateral Reporting*.** Provide Lender with each of the reports set forth on *Schedule 5.2*at the times specified therein.

5.3 ***Financial Statements, Reports, Certificates*.** Deliver to Lender each of the financial statements, reports, or other items set forth on *Schedule 5.3* at the times specified herein. In addition, Parent agrees that no Subsidiary of Parent will have a fiscal year different from that of Parent.

5.4 ***Intentionally Omitted*.**

5.5 ***Inspection*.** Permit Lender, and its duly authorized representatives or agents to visit any of its properties and inspect any of its assets or books and records, to examine and make copies of its books and records, and to discuss its affairs, finances, and accounts with, and to be advised as to the same by, its officers and employees at such reasonable times and intervals as Lender may designate and, so long as no Default or Event of Default exists, with reasonable prior notice to Administrative Borrower.

5.6 ***Maintenance of Properties*.** Maintain and preserve all of their properties which are necessary or useful in the proper conduct to their business in good working order and condition, ordinary wear, tear, and casualty excepted (and except where the failure to do so could not be expected to result in a Material Adverse Change), and comply at all times with the provisions of all material leases to which it is a party as lessee, so as to prevent any loss or forfeiture thereof or thereunder; *provided*, *however*, that if Borrowers determine in their reasonable business judgment not to continue their tissue business, they shall not be required to maintain assets used solely for such business.

5.7 ***Taxes*.** Cause all assessments and taxes, whether real, personal, or otherwise, due or payable by, or imposed, levied, or assessed against Borrowers, their Subsidiaries, or any of their respective assets to be paid in full, before delinquency or before the expiration of any extension period, except to the extent that the validity of such assessment or tax shall be the subject of a Permitted Protest. Borrowers will and will cause their Subsidiaries to make timely payment or deposit of all tax payments and withholding taxes required of them by applicable laws, including those laws concerning F.I.C.A., F.U.T.A., state disability, and local, state, and federal income taxes, and will, upon request, furnish Lender with proof satisfactory to Lender indicating that the applicable Borrower or Subsidiary of a Borrower has made such payments or deposits.

5.8 ***Insurance; Litigation Settlement*.**

(a) At Borrowers' expense, maintain insurance respecting their and their Subsidiaries' assets wherever located, covering loss or damage by fire, theft, explosion, and all other hazards and risks as ordinarily are insured against by other Persons engaged in the same or similar businesses. Borrowers also shall maintain business interruption, public liability, and product liability insurance, as well as insurance against larceny, embezzlement, and criminal misappropriation. All such policies of insurance shall be in such amounts and with such insurance companies as are reasonably satisfactory to Lender. Borrowers shall deliver copies of all such policies to Lender with an endorsement naming Lender as the sole loss payee (under a satisfactory lender's loss payable endorsement) or additional insured, as appropriate. Each policy of insurance or endorsement shall contain a clause requiring the insurer to give not less than 30 days prior written notice to Lender in the event of cancellation of the policy for any reason whatsoever.

(b) Administrative Borrower shall give Lender prompt notice of any casualty loss or liability claim exceeding **[***]** that is not already disclosed on *Schedule 4.10*. With respect to losses or liability claims arising under litigation matters disclosed on *Schedule 4.10,* Borrowers shall have the exclusive right to adjust any losses payable under any insurance policies described above and, so long as (i) no Event of Default has occurred and is continuing and (ii) Excess Availability is equal to or greater than $7,500,000, Borrowers shall have the exclusive right to settle any such liability claims that are not covered by insurance. Following the occurrence and during the continuation of an Event of Default or if Excess Availability is less than $7,500,000, Borrowers shall not settle any such liability claim without the prior written consent of Lender. **[***]** Following the occurrence and during the continuation of an Event of Default, or in the case of any losses payable under such property/casualty insurance exceeding **[***]** or uninsured liability claims in excess of **[***]**, Lender shall have the exclusive right to adjust any such losses payable under any such insurance policies, without any liability to Borrowers whatsoever in respect of such adjustments, and Borrowers shall not settle any such uninsured liability claims without the prior written consent of Lender. Any monies received as payment for any loss under any insurance policy mentioned above (other than liability insurance policies) or as payment of any award or compensation for condemnation or taking by eminent domain, shall be paid over to Lender to be applied at the option of Lender either to the prepayment of the Obligations or to be disbursed to Administrative Borrower under staged payment terms reasonably satisfactory to Lender for application to the cost of repairs, replacements, or restorations; *provided*, *however*, that, with respect to any such monies in an aggregate amount during any 12 consecutive month period not in excess of **[***]**, so long as (A) no Default or Event of Default shall have occurred and is continuing, (B) Borrowers' Excess Availability is greater than $7,500,000, (C) Administrative Borrower shall have given Lender prior written notice of the Borrowers or their respective Subsidiaries' intention to apply such monies to the costs of repairs, replacement, or restoration of the property which is the subject of the loss, destruction, or taking by condemnation, (D) the monies are held in a cash collateral account in which Lender has a perfected first-priority security interest, and (E) Borrowers or their Subsidiaries complete such repairs, replacements, or restoration within 180 days after the initial receipt of such monies, Borrowers shall have the option to apply such monies to the costs of repairs, replacement, or restoration of the property which is the subject of the loss, destruction, or taking by condemnation unless and to the extent that such applicable period shall have expired without such repairs, replacements, or restoration being made, in which case, any amounts remaining in the cash collateral account shall be paid to Lender and applied as set forth above.

5.9 ***Location of Inventory and Equipment*.** Keep Borrowers' and their Subsidiaries' Inventory and Equipment (other than vehicles and Equipment out for repair) only at the locations identified on *Schedule 4.5* and their chief executive offices only at the locations identified on *Schedule 4.7(b)*;

provided, *however*, that Administrative Borrower may amend *Schedule 4.5* or *Schedule 4.7(b)* so long as such amendment occurs by written notice to Lender not less than 30 days prior to the date on which such Inventory or Equipment is moved to such new location or such chief executive office is relocated, so long as such new location is within the continental United States, and so long as, at the time of such written notification, the applicable Borrower provides Lender a Collateral Access Agreement with respect thereto.

5.10 ***Compliance with Laws.*** Comply with the requirements of all applicable laws, rules, regulations, and orders of any Governmental Authority, other than laws, rules, regulations, and orders the non-compliance with which, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Change.

5.11 ***Leases.*** Pay when due all rents and other amounts payable under any material leases to which any Borrower or any Subsidiary of a Borrower is a party or by which any Borrower's or any of its Subsidiaries' properties and assets are bound, unless such payments are the subject of a Permitted Protest.

5.12 ***Existence.*** At all times preserve and keep in full force and effect each Borrower's and each of its Subsidiaries' valid existence and good standing and any rights and franchises material to their businesses.

5.13 ***Environmental.***

(a) Keep any property either owned or operated by any Borrower or any Subsidiary of a Borrower free of any Environmental Liens or post bonds or other financial assurances sufficient to satisfy the obligations or liability evidenced by such Environmental Liens, (b) comply, in all material respects, with Environmental Laws and provide to Lender documentation of such compliance which Lender reasonably requests, (c) promptly notify Lender of any release of a Hazardous Material in any reportable quantity from or onto property owned or operated by any Borrower or any Subsidiary of a Borrower and take any Remedial Actions required to abate said release or otherwise to come into compliance with applicable Environmental Law, and (d) promptly, but in any event within 5 days of its receipt thereof, provide Lender with written notice of any of the following: (i) notice that an Environmental Lien has been filed against any of the real or personal property of any Borrower or any Subsidiary of a Borrower, (ii) commencement of any Environmental Action or notice that an Environmental Action will be filed against any Borrower or any Subsidiary of a Borrower, and (iii) notice of a violation, citation, or other administrative order which reasonably could be expected to result in a Material Adverse Change.

5.14 ***Disclosure Updates.*** Promptly and in no event later than 5 Business Days after obtaining knowledge thereof, notify Lender if any written information, exhibit, or report furnished to Lender contained, at the time it was furnished, any untrue statement of a material fact or omitted to state any material fact necessary to make the statements contained therein not misleading in light of the circumstances in which made. The foregoing to the contrary notwithstanding, any notification pursuant to the foregoing provision will not cure or remedy the effect of the prior untrue statement of a material fact or omission of any material fact nor shall any such notification have the affect of amending or modifying this Agreement or any of the Schedules hereto.

5.15 ***Control Agreements.*** Take all reasonable steps in order for Lender to obtain control in accordance with Sections 8-106, 9-104, 9-105, 9-106, and 9-107 of the Code with respect to (subject to the proviso contained in *Section 6.12*) all of its Securities Accounts, Deposit Accounts, electronic chattel paper, investment property, and letter of credit rights.

5.16 ***Formation of Subsidiaries.*** At the time that any Borrower or any Guarantor forms any direct or indirect Subsidiary or acquires any direct or indirect Subsidiary after the Closing Date, such

Borrower or such Guarantor shall (a) cause such new Subsidiary to provide to Lender a joinder to the Guaranty and the Security Agreement, together with such other security documents (including Mortgages with respect to any Real Property of such new Subsidiary), as well as appropriate financing statements (and with respect to all property subject to a Mortgage, fixture filings), all in form and substance satisfactory to Lender (including being sufficient to grant Lender a first priority Lien (subject to Permitted Liens) in and to the assets of such newly formed or acquired Subsidiary), (b) provide to Lender a pledge agreement and appropriate certificates and powers or financing statements, hypothecating all of the direct or beneficial ownership interest in such new Subsidiary, in form and substance satisfactory to Lender, and (c) provide to Lender all other documentation, including one or more opinions of counsel satisfactory to Lender (which opinions shall be substantially similar to the opinion delivered on the Closing Date or in such other form as shall be acceptable to Lender), which in its opinion is appropriate with respect to the execution and delivery of the applicable documentation referred to above (including policies of title insurance or other documentation with respect to all property subject to a Mortgage). Any document, agreement, or instrument executed or issued pursuant to this *Section 5.16* shall be a Loan Document.

6. NEGATIVE COVENANTS.

Each Borrower covenants and agrees that, so long as any credit hereunder shall be available and until the payment in full of the Obligations, Borrowers will not and will not permit any of their respective Subsidiaries to do any of the following:

6.1 ***Indebtedness.*** Create, incur, assume, suffer to exist, guarantee, or otherwise become or remain, directly or indirectly, liable with respect to any Indebtedness, except:

(a) Indebtedness evidenced by this Agreement and the other Loan Documents, together with Indebtedness owed to Underlying Issuers with respect to Underlying Letters of Credit,

(b) Indebtedness set forth on *Schedule 4.19*,

(c) Permitted Purchase Money Indebtedness,

(d) Indebtedness arising from issuances by Borrowers of subordinated debt or debentures, provided that Borrowers enter into a subordination agreement relating to such Indebtedness in form and substance satisfactory to Lender, or

(e) refinancings, renewals, or extensions of Indebtedness permitted under clauses (b) and (c) of this *Section 6.1* (and continuance or renewal of any Permitted Liens associated therewith) so long as: (i) the terms and conditions of such refinancings, renewals, or extensions do not, in Lender's reasonable judgment, materially impair the prospects of repayment of the Obligations by Borrowers or materially impair Borrowers' creditworthiness, (ii) such refinancings, renewals, or extensions do not result in an increase in the principal amount of, or interest rate (by more than two percent (2%)) with respect to, the Indebtedness so refinanced, renewed, or extended or add one or more Borrowers as liable with respect thereto if such additional Borrowers were not liable with respect to the original Indebtedness, (iii) such refinancings, renewals, or extensions do not result in a shortening of the average weighted maturity of the Indebtedness so refinanced, renewed, or extended, nor are they on terms or conditions, that, taken as a whole, are materially more burdensome or restrictive to the applicable Borrower, (iv) if the Indebtedness that is refinanced, renewed, or extended was subordinated in right of payment to the Obligations, then the terms and conditions of the refinancing, renewal, or extension Indebtedness must include subordination terms and conditions that are at least as favorable to Lender as those that were applicable to the refinanced, renewed, or extended Indebtedness, and (v) the Indebtedness that is refinanced, renewed, or extended is not recourse to any Person that is liable on account of the

Obligations other than those Persons which were obligated with respect to the Indebtedness that was refinanced, renewed, or extended,

(f) endorsement of instruments or other payment items for deposit,

(g) Indebtedness composing Permitted Investments, and

(h) Indebtedness owed to insurance companies consisting of financed insurance premiums by such insurance companies so long as the aggregate principal amount of such Indebtedness does not exceed $3,000,000 at any time outstanding and the term of any such notes payable does not exceed one year.

6.2 ***Liens.*** Create, incur, assume, or suffer to exist, directly or indirectly, any Lien on or with respect to any of its assets, of any kind, whether now owned or hereafter acquired, or any income or profits therefrom, except for Permitted Liens (including Liens that are replacements of Permitted Liens to the extent that the original Indebtedness is refinanced, renewed, or extended under *Section 6.1(e)* and so long as the replacement Liens only encumber those assets that secured the refinanced, renewed, or extended Indebtedness).

6.3 ***Restrictions on Fundamental Changes.***

(a) Enter into any merger, consolidation, reorganization, or recapitalization, or reclassify its Stock; provided, however, that Parent may reorganize its tissue and products lines into separate lines of business,

(b) Liquidate, wind up, or dissolve itself (or suffer any liquidation or dissolution),

(c) Convey, sell, lease, license, assign, transfer, or otherwise dispose of, in one transaction or a series of transactions, all or any substantial part of its assets,

(d) Suspend or go out of a substantial portion of its or their business; provided, however, that Parent may elect to sell or discontinue its tissue line of business upon the prior written consent of Lender,

(e) Create or acquire any Subsidiary; provided, however, that Borrowers may create any wholly owned United States domestic Subsidiary so long as Borrowers and such Subsidiary comply with *Section 5.16*.

6.4 ***Disposal of Assets.*** Other than Permitted Dispositions, convey, sell, lease, license, assign, transfer, or otherwise dispose of any of the assets of any Borrower or any Subsidiary of a Borrower.

6.5 ***Change Name.*** Change any Borrower's or any of its Subsidiaries' name, organizational identification number, state of organization, or organizational identity; *provided*, *however*, that a Borrower or a Subsidiary of a Borrower may change its name upon at least 30 days prior written notice by Administrative Borrower to Lender of such change and so long as, at the time of such written notification, such Borrower or such Subsidiary provides any financing statements necessary to perfect and continue perfected the Lender's Liens.

6.6 ***Nature of Business.*** Make any change in the principal nature of their business other than changes that are reasonable extensions of their business as of the Closing Date.

6.7 ***Prepayments and Amendments.*** Except in connection with a refinancing permitted by *Section 6.1(e)* ,

(a) optionally prepay, redeem, defease, purchase, or otherwise acquire any Indebtedness of any Borrower or any Subsidiary of a Borrower, other than the Obligations in accordance with this Agreement, and on the Closing Date Borrower may prepay certain Capitalized Lease Obligations described on *Schedule 6.7*,

(b) make any payment on account of Indebtedness that has been contractually subordinated in right of payment if such payment is not permitted at such time under the subordination terms and conditions, or

(c) directly or indirectly, amend, modify, alter, increase, or change any of the terms or conditions of any agreement, instrument, document, indenture, or other writing evidencing or concerning Indebtedness permitted under *Section 6.1(b)* or *(c)*.

6.8 ***Change of Control.*** Cause, permit, or suffer, directly or indirectly, any Change of Control.

6.9 ***Consignments.*** Except for Inventory with an aggregate market value of less than $500,000, consign any of their Inventory or sell any of their Inventory on bill and hold, sale or return, sale on approval, or other conditional terms of sale.

6.10 ***Distributions.*** Other than (a) distributions or declaration and payment of dividends by a Borrower or a Subsidiary of a Borrower to a Borrower or (b) so long as Excess Availability plus Qualified Cash exceeds $7,500,000, declaration and payment of dividends by Parent on any of its preferred stock (whether currently outstanding or hereafter issued), make any distribution or declare or pay any dividends (in cash or other property, other than common Stock) on, or purchase, acquire, redeem, or retire any of any Borrower's Stock, of any class, whether now or hereafter outstanding.

6.11 ***Accounting Methods.*** Modify or change their fiscal year or their method of accounting (other than as may be required to conform to GAAP) or enter into, modify, or terminate any agreement currently existing, or at any time hereafter entered into with any third party accounting firm or service bureau for the preparation or storage of Borrowers' or their Subsidiaries' accounting records without said accounting firm or service bureau agreeing to provide Lender information regarding Borrowers' and their Subsidiaries' financial condition; *provided*, *however*, that Borrowers and their Subsidiaries shall be entitled to change their accounting firm to the extent required pursuant to any settlement agreement entered into in connection with any litigation matter referred to on *Schedule 4.10* or as required by an order of a court of competent jurisdiction.

6.12 ***Investments.*** Except for Permitted Investments, directly or indirectly, make or acquire any Investment, or incur any liabilities (including contingent obligations) for or in connection with any Investment; *provided*, *however*, that Administrative Borrower and its Subsidiaries shall not have Permitted Investments in Deposit Accounts or Securities Accounts at any time unless either

(a) Administrative Borrower or its Subsidiary, as applicable, and the applicable securities intermediary or bank have entered into Control Agreements governing such Permitted Investments in order to perfect (and further establish) the Lender's Liens in such Permitted Investments or (b) such Deposit Accounts or Securities Accounts are Excluded Accounts. Subject to the foregoing proviso, Borrowers shall not and shall not permit their Subsidiaries to establish or maintain any Deposit Account or Securities Account unless Lender shall have received a Control Agreement in respect of such Deposit Account or Securities Account.

6.13 ***Transactions with Affiliates.*** Directly or indirectly enter into or permit to exist any transaction with any Affiliate of any Borrower except for transactions that (a) are in the ordinary course of Borrowers' business, (b) are upon fair and reasonable terms, (c) if they involve one or more payments by any Borrower or any of its Subsidiaries in excess of $5,000,000, are fully disclosed to Lender, and (d) are no less favorable to Borrowers or their respective Subsidiaries, as applicable, than would be obtained in an arm's length transaction with a non-Affiliate.

6.14 ***Use of Proceeds.*** Use the proceeds of the Advances for any purpose other than (a) on the Closing Date, to pay transactional fees, costs, and expenses incurred in connection with this Agreement, the other Loan Documents, and the transactions contemplated hereby and thereby, and (b) thereafter, consistent with the terms and conditions hereof, for its lawful and permitted purposes.

6.15 ***Inventory and Equipment with Bailees.*** Store the Inventory or Equipment of Borrowers or their Subsidiaries at any time now or hereafter with a bailee, warehouseman, or similar party, *provided*, *however*, that (i) Borrowers and their Subsidiaries may store Inventory from their BioGlue Product Line in hospitals that use such products in the ordinary course of business so long as such products are segregated from Inventory owned by such hospitals and so long as such products are clearly marked as property of Borrowers and their Subsidiaries and (ii) Borrowers and their Subsidiaries may store Inventory at leased or bailee locations so long as a Collateral Access Agreement with respect to each such location (other than leased or bailee locations that in the aggregate do not have in excess of $500,000 of Inventory located there at any time) is delivered to Lender.

6.16 ***Financial Covenants.***

With respect to any period ending as of the last day of any quarter, fail to maintain or achieve either:

(a) average Excess Availability plus Qualified Cash of at least $12,500,000 for the quarter then ended, or

(b) each of the following:

(i) EBITDA, measured on a quarter-end basis, of at least the required amount set forth in the following table for the applicable period set forth opposite thereto:

Applicable Amount	Applicable Period
$(12,500,000)	For the 12 month period ending March 31, 2005
$(11,000,000)	For the 12 month period ending June 30, 2005
$(5,000,000)	For the 12 month period ending September 30, 2005
$770,000	For the 12 month period ending December 31, 2005
The greater of $770,000 or 80% of the EBITDA projected by Borrowers for such period as set forth in the most recently delivered Projections approved by Lender	For the 12 month period ending on each fiscal quarter end thereafter

(ii) a BioGlue Gross Margin, measured on a fiscal quarter-end basis for the immediately preceding 12 month period, of at least 70%, and

(iii) Excess Availability plus Qualified Cash, as of any date, of at least $5,000,000.

7. EVENTS OF DEFAULT.

Any one or more of the following events shall constitute an event of default (each, an "*Event of Default*") under this Agreement:

7.1 If Borrowers fail to pay when due and payable, or when declared due and payable, (a) all or any portion of the Obligations consisting of interest, fees, or charges due Lender, reimbursement of Lender Expenses, or other amounts (other than any portion thereof constituting principal) constituting Obligations (including any portion thereof that accrues after the commencement of an Insolvency Proceeding, regardless of whether allowed or allowable in whole or in part as a claim in any such Insolvency Proceeding), and such failure continues for a period of 3 Business Days, or (b) all or any portion of the principal of the Obligations);

7.2 If any Borrower or any Subsidiary of any Borrower

(a) fails to perform or observe any covenant or other agreement contained in any of *Sections 2.7*, *5.2*, *5.3*, *5.5*, *5.8*, *5.12*, *5.14*, *5.16*, and *6.1* through *6.16* of this Agreement;

(b) fails to perform or observe any covenant or other agreement contained in any of *Sections 5.6*, *5.7*, *5.9*, *5.10*, *5.11*, and *5.15* of this Agreement and such failure continues for a period of 10 days after the earlier of (i) the date on which such failure shall first become known to any officer of any Borrower or (ii) written notice thereof is given to Administrative Borrower by Lender; or

(c) fails to perform or observe any covenant or other agreement contained in such Agreement, or in any of the other Loan Documents; in each case, other than any such covenant or agreement that is the subject of another provision of this *Section 7* (in which event such other provision of this *Section 7* shall govern), and such failure continues for a period of 20 days after the earlier of (i) the date on which such failure shall first become known to any officer of any Borrower or (ii) written notice thereof is given to Administrative Borrower by Lender;

7.3 If any material portion of any Borrower's or any of its Subsidiaries' assets is attached, seized, subjected to a writ or distress warrant, or is levied upon, or comes into the possession of any third Person and the same is not discharged before the earlier of 30 days after the date it first arises or 5 days prior to the date on which such property or asset is subject to forfeiture by such Borrower or the applicable Subsidiary;

7.4 If an Insolvency Proceeding is commenced by any Borrower or any Subsidiary of a Borrower;

7.5 If an Insolvency Proceeding is commenced against any Borrower or any Subsidiary of a Borrower, and any of the following events occur: (a) the applicable Borrower or such Subsidiary consents to the institution of such Insolvency Proceeding against it, (b) the petition commencing the Insolvency Proceeding is not timely controverted, (c) the petition commencing the Insolvency Proceeding is not dismissed within 60 calendar days of the date of the filing thereof; (d) an interim trustee is appointed to take possession of all or any substantial portion of the properties or assets of, or to operate all or any substantial portion of the business of, any Borrower or any Subsidiary of a Borrower, or (e) an order for relief shall have been issued or entered therein;

7.6 If any Borrower or any Subsidiary of a Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs;

7.7 If one or more judgments or other claims involving an aggregate amount of $1,000,000, or more (except to the extent covered by insurance pursuant to which the insurer has accepted liability therefor in writing) shall be entered or filed against (or, in the case of a settlement claim, entered into by) any Borrower or any Subsidiary of any Borrower or with respect to any of their respective assets, and (except in the case of a settlement) the same is not released, discharged, bonded against, or stayed pending appeal before the earlier of 30 days after the date it first arises or 5 days prior to the date on which such asset is subject to being forfeited by the applicable Borrower or the applicable Subsidiary;

7.8 If there is a default in one or more agreements to which any Borrower or any Subsidiary of a Borrower is a party with one or more third Persons relative to Indebtedness of any Borrower or any Subsidiary of any Borrower involving an aggregate amount of $1,000,000 or more, and such default (i) occurs at the final maturity of the obligations thereunder, or (ii) results in a right by such third Person(s), irrespective of whether exercised, to accelerate the maturity of the applicable Borrower's or Subsidiary's obligations thereunder;

7.9 If any warranty, representation, statement, or Record made herein or in any other Loan Document or delivered to Lender in connection with this Agreement or any other Loan Document proves to be untrue in any material respect as of the date of issuance or making or deemed making thereof;

7.10 If the obligation of any Guarantor under the Guaranty is limited or terminated by operation of law or by such Guarantor;

7.11 If the Security Agreement or any other Loan Document that purports to create a Lien, shall, for any reason, fail or cease to create a valid and perfected and, except to the extent permitted by the terms hereof or thereof, first priority Lien on or security interest in the Collateral covered hereby or thereby, except as a result of a disposition of the applicable Collateral in a transaction permitted under this Agreement; or

7.12 Any provision of any Loan Document shall at any time for any reason be declared to be null and void, or the validity or enforceability thereof shall be contested by any Borrower or any Subsidiary of a Borrower, or a proceeding shall be commenced by any Borrower or any Subsidiary of a Borrower, or by any Governmental Authority having jurisdiction over any Borrower or any Subsidiary of a Borrower, seeking to establish the invalidity or unenforceability thereof, or any Borrower or any

Subsidiary of a Borrower shall deny that it has any liability or obligation purported to be created under any Loan Document.

8. LENDER'S RIGHTS AND REMEDIES.

8.1 ***Rights and Remedies.*** Upon the occurrence, and during the continuation, of an Event of Default, Lender (at its election but without notice of its election and without demand) may do any one or more of the following, all of which are authorized by Borrowers:

(a) Declare all or any portion of the Obligations, whether evidenced by this Agreement, by any of the other Loan Documents, or otherwise, immediately due and payable;

(b) Cease advancing money or extending credit to or for the benefit of Borrowers under this Agreement, under any of the Loan Documents, or under any other agreement between Borrowers and Lender;

(c) Terminate this Agreement and any of the other Loan Documents as to any future liability or obligation of Lender, but without affecting any of the Lender's Liens in the Collateral and without affecting the Obligations; and

(d) Lender shall have all other rights and remedies available at law or in equity or pursuant to any other Loan Document.

The foregoing to the contrary notwithstanding, upon the occurrence of any Event of Default described in *Section 7.4* or *Section 7.5*, in addition to the remedies set forth above, without any notice to Borrowers or any other Person or any act by Lender, Lender's obligation to extend credit hereunder shall terminate and the Obligations then outstanding, together with all accrued and unpaid interest thereon, and all fees and all other amounts due under this Agreement and the other Loan Documents, shall automatically and immediately become due and payable, without presentment, demand, protest, or notice of any kind, all of which are expressly waived by Borrowers.

8.2 ***Remedies Cumulative.*** The rights and remedies of Lender under this Agreement, the other Loan Documents, and all other agreements shall be cumulative. Lender shall have all other rights and remedies not inconsistent herewith as provided under the Code, by law, or in equity. No exercise by Lender of one right or remedy shall be deemed an election, and no waiver by Lender of any Event of Default shall be deemed a continuing waiver. No delay by Lender shall constitute a waiver, election, or acquiescence by it.

8.3 ***Bank Product Providers.*** Each Bank Product Provider shall be deemed a party hereto for purposes of any reference in any Loan Document with respect to the Bank Product Providers or the Bank Product Obligations; it being understood and agreed that the rights and benefits of such Bank Product Provider under the Loan Documents consist exclusively of such Bank Provider's right to share in payments and collections out of the Collateral as more fully set forth herein. In connection with any such distribution of payments and collections, Lender shall be entitled to assume no amounts are due to any Bank Product Provider unless such Bank Product Provider has notified Lender in writing of the amount of any such liability owed to it prior to such distribution.

9. TAXES AND EXPENSES.

If any Borrower fails to pay any monies (whether taxes, assessments, insurance premiums, or, in the case of leased properties or assets, rents or other amounts payable under such leases) due to third Persons, or fails to make any deposits or furnish any required proof of payment or deposit, all as required under the terms of this Agreement, then, Lender, in its sole discretion and without prior notice to any Borrower, may do any or all of the following: (a) make payment of the same or any part thereof, (b) set up such reserves against the Borrowing Base or the Maximum Revolver Amount as

Lender deems necessary to protect Lender from the exposure created by such failure, or (c) in the case of the failure to comply with *Section 5.8* hereof, obtain and maintain insurance policies of the type described in *Section 5.8* and take any action with respect to such policies as Lender deems prudent. Any such amounts paid by Lender shall constitute Lender Expenses and any such payments shall not constitute an agreement by Lender to make similar payments in the future or a waiver by Lender of any Event of Default under this Agreement. Lender need not inquire as to, or contest the validity of, any such expense, tax, or Lien and the receipt of the usual official notice for the payment thereof shall be conclusive evidence that the same was validly due and owing.

10. WAIVERS; INDEMNIFICATION.

10.1 ***Demand; Protest; etc.*** Each Borrower waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, nonpayment at maturity, release, compromise, settlement, extension, or renewal of documents, instruments, chattel paper, and guarantees at any time held by Lender on which any such Borrower may in any way be liable.

10.2 ***Lender's Liability for Borrower Collateral.*** Each Borrower hereby agrees that: (a) so long as Lender complies with its obligations, if any, under the Code, Lender shall not in any way or manner be liable or responsible for: (i) the safekeeping of the Borrower Collateral, (ii) any loss or damage thereto occurring or arising in any manner or fashion from any cause, (iii) any diminution in the value thereof, or (iv) any act or default of any carrier, warehouseman, bailee, forwarding agency, or other Person, and (b) all risk of loss, damage, or destruction of the Borrower Collateral shall be borne by Borrowers.

10.3 ***Indemnification.*** Each Borrower shall pay, indemnify, defend, and hold the Lender-Related Persons and each Participant (each, an "*Indemnified Person*") harmless (to the fullest extent permitted by law) from and against any and all claims, demands, suits, actions, investigations, proceedings, and damages, and all reasonable attorneys fees and disbursements and other costs and expenses actually incurred in connection therewith or in connection with the enforcement of this indemnification (as and when they are incurred and irrespective of whether suit is brought), at any time asserted against, imposed upon, or incurred by any of them (a) in connection with or as a result of or related to the execution, delivery, enforcement, performance, or administration (including any restructuring or workout with respect hereto) of this Agreement, any of the other Loan Documents, or the transactions contemplated hereby or thereby or the monitoring of Borrowers' and their Subsidiaries' compliance with the terms of the Loan Documents, and (b) with respect to any investigation, litigation, or proceeding related to this Agreement, any other Loan Document, or the use of the proceeds of the credit provided hereunder (irrespective of whether any Indemnified Person is a party thereto), or any act, omission, event, or circumstance in any manner related thereto (all the foregoing, collectively, the "*Indemnified Liabilities*"). The foregoing to the contrary notwithstanding, Borrowers shall have no obligation to any Indemnified Person under this *Section 10.3* with respect to any Indemnified Liability that a court of competent jurisdiction finally determines to have resulted from the gross negligence or willful misconduct of such Indemnified Person. This provision shall survive the termination of this Agreement and the repayment of the Obligations. If any Indemnified Person makes any payment to any other Indemnified Person with respect to an Indemnified Liability as to which Borrowers were required to indemnify the Indemnified Person receiving such payment, the Indemnified Person making such payment is entitled to be indemnified and reimbursed by Borrowers with respect thereto. **WITHOUT LIMITATION, THE FOREGOING INDEMNITY SHALL APPLY TO EACH INDEMNIFIED PERSON WITH RESPECT TO INDEMNIFIED LIABILITIES WHICH IN WHOLE OR IN PART ARE CAUSED BY OR ARISE OUT OF ANY NEGLIGENT ACT OR OMISSION OF SUCH INDEMNIFIED PERSON OR OF ANY OTHER PERSON.**

11. NOTICES.

Unless otherwise provided in this Agreement, all notices or demands by Borrowers or Lender to the other relating to this Agreement or any other Loan Document shall be in writing and (except for financial statements and other informational documents which may be sent by first-class mail, postage prepaid) shall be personally delivered or sent by registered or certified mail (postage prepaid, return receipt requested), overnight courier or telefacsimile to Borrowers in care of Administrative Borrower or to Lender, as the case may be, at its address set forth below:

If to Administrative Borrower:	**CRYOLIFE, INC.** 1655 Roberts Boulevard N.W. Kennesaw, GA 30144 Attn: Mr. D. Ashley Lee Fax No.: (770) 419-3355
with copies to:	**ARNALL GOLDEN GREGORY LLP** 171 17th Street Suite 2100 Atlanta, Georgia 30363-1031 Attn: Sherman A. Cohen, Esq. Fax No.: (404) 873-8631
If to Lender:	**WELLS FARGO FOOTHILL, INC.** 1000 Abernathy Road, N.E., Suite 1450 Atlanta, GA 30328 Attn: Business Finance Division Manager Fax No.: 770—508-1374
with a copy to:	**FOOTHILL CAPITAL CORPORATION** 2450 Colorado Avenue, Suite 3000 West Santa Monica, CA 90404 Attn: Business Finance Division Manager Fax No.: 310—453-7442
with copies to:	**PAUL, HASTINGS, JANOFSKY & WALKER LLP** 600 Peachtree Street, NE, Suite 2400 Atlanta, GA 30308 Attn: Chris D. Molen, Esq. Fax No.: 404—815-2424

Lender and Borrowers may change the address at which they are to receive notices hereunder, by notice in writing in the foregoing manner given to the other party. All notices or demands sent in accordance with this *Section 11*, other than notices by Lender in connection with enforcement rights against the Borrower Collateral under the provisions of the Code, shall be deemed received on the earlier of the date of actual receipt or 3 Business Days after the deposit thereof in the mail. Each Borrower acknowledges and agrees that notices sent by Lender in connection with the exercise of enforcement rights against Borrower Collateral under the provisions of the Code shall be deemed sent when deposited in the mail or personally delivered, or, where permitted by law, transmitted by telefacsimile or any other method set forth above.

12. CHOICE OF LAW AND VENUE; JURY TRIAL WAIVER.

(a) **THE VALIDITY OF THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS (UNLESS EXPRESSLY PROVIDED TO THE CONTRARY IN ANOTHER LOAN DOCUMENT IN RESPECT OF SUCH OTHER LOAN DOCUMENT), THE CONSTRUCTION, INTERPRETATION, AND ENFORCEMENT HEREOF AND THEREOF, AND THE RIGHTS OF THE PARTIES HERETO AND THERETO WITH RESPECT TO ALL MATTERS ARISING HEREUNDER OR THEREUNDER OR RELATED HERETO OR THERETO SHALL BE DETERMINED UNDER, GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF GEORGIA.**

(b) **THE PARTIES AGREE THAT ALL ACTIONS OR PROCEEDINGS ARISING IN CONNECTION WITH THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS SHALL BE TRIED AND LITIGATED ONLY IN THE STATE AND TO THE EXTENT PERMITTED BY APPLICABLE LAW, FEDERAL COURTS LOCATED IN THE COUNTY OF FULTON, STATE OF GEORGIA, *PROVIDED*, *HOWEVER*, THAT ANY SUIT SEEKING ENFORCEMENT AGAINST ANY COLLATERAL OR OTHER PROPERTY MAY BE BROUGHT, AT LENDER'S OPTION, IN THE COURTS OF ANY JURISDICTION WHERE LENDER ELECTS TO BRING SUCH ACTION OR WHERE SUCH COLLATERAL OR OTHER PROPERTY MAY BE FOUND. BORROWERS AND LENDER WAIVE, TO THE EXTENT PERMITTED UNDER APPLICABLE LAW, ANY RIGHT EACH MAY HAVE TO ASSERT THE DOCTRINE OF *FORUM NON CONVENIENS* OR TO OBJECT TO VENUE TO THE EXTENT ANY PROCEEDING IS BROUGHT IN ACCORDANCE WITH THIS *SECTION 12(b)*.**

(c) **BORROWERS AND LENDER HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF ANY OF THE LOAN DOCUMENTS OR ANY OF THE TRANSACTIONS CONTEMPLATED THEREIN, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW OR STATUTORY CLAIMS. BORROWERS AND LENDER REPRESENT THAT EACH HAS REVIEWED THIS WAIVER AND EACH KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL. IN THE EVENT OF LITIGATION, A COPY OF THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.**

13. ASSIGNMENTS AND PARTICIPATIONS; SUCCESSORS.

13.1 ***Assignments and Participations*.**

(a) Lender may assign and delegate to one or more assignees (each an "*Assignee*") that are Eligible Transferees all, or any ratable part of all, of the Obligations and the other rights and obligations of Lender hereunder and under the other Loan Documents, in a minimum amount of $5,000,000; *provided*, *however*, that Borrowers may continue to deal solely and directly with Lender in connection with the interest so assigned to an Assignee until (i) written notice of such assignment, together with payment instructions, addresses, and related information with respect to the Assignee, have been given to Administrative Borrower by Lender and the Assignee, and (ii) Lender and its Assignee have delivered to Administrative Borrower an Assignment and Acceptance. Anything contained herein to the contrary notwithstanding, the Assignee need not be an Eligible Transferee if such assignment is in connection with any merger, consolidation, sale, transfer, or other disposition of all or any substantial portion of the business or loan portfolio of the assigning Lender.

(b) From and after the date that Lender provides Administrative Borrower with such written notice and an executed Assignment and Acceptance, (i) the Assignee thereunder shall be a party hereto and, to the extent that rights and obligations hereunder have been assigned to it pursuant to such Assignment and Acceptance, shall have the rights and obligations of Lender under the Loan Documents, and (ii) Lender shall, to the extent that rights and obligations hereunder and under the other Loan Documents have been assigned by it pursuant to such Assignment and Acceptance, relinquish its rights (except with respect to *Section 10.3* hereof) and be released from any future obligations under this Agreement (and in the case of an Assignment and Acceptance covering all or the remaining portion of an assigning Lender's rights and obligations under this Agreement and the other Loan Documents, Lender shall cease to be a party hereto and thereto), and such assignment shall effect a novation between Borrowers and the Assignee; *provided*, *however*, that nothing contained herein shall release Lender from obligations that survive the termination of this Agreement, including such assigning Lender's obligations under *Article 15* of this Agreement.

(c) By executing and delivering an Assignment and Acceptance, the assigning Lender thereunder and the Assignee thereunder confirm to and agree with each other and the other parties hereto as follows: (1) other than as provided in such Assignment and Acceptance, such assigning Lender makes no representation or warranty and assumes no responsibility with respect to any statements, warranties or representations made in or in connection with this Agreement or the execution, legality, validity, enforceability, genuineness, sufficiency or value of this Agreement or any other Loan Document furnished pursuant hereto, (2) such assigning Lender makes no representation or warranty and assumes no responsibility with respect to the financial condition of any Borrower or the performance or observance by any Borrower of any of its obligations under this Agreement or any other Loan Document furnished pursuant hereto, (3) such Assignee confirms that it has received a copy of this Agreement, together with such other documents and information as it has deemed appropriate to make its own credit analysis and decision to enter into such Assignment and Acceptance, (4) such Assignee will, independently and without reliance upon such assigning Lender, and based on such documents and information as it shall deem appropriate at the time, continue to make its own credit decisions in taking or not taking action under this Agreement, and (5) such Assignee agrees that it will perform all of the obligations which by the terms of this Agreement are required to be performed by it as a Lender.

(d) Immediately upon Borrower's receipt of the fully executed Assignment and Acceptance, this Agreement shall be deemed to be amended to the extent, but only to the extent, necessary to reflect the addition of the Assignee and the resulting adjustment of the rights and duties of Lender arising therefrom.

(e) Lender may at any time sell to one or more commercial banks, financial institutions, or other Persons (a "*Participant*") participating interests in Obligations and the other rights and interests of Lender hereunder and under the other Loan Documents; *provided*, *however*, that (i) Lender shall remain the "Lender" for all purposes of this Agreement and the other Loan Documents and the Participant receiving the participating interest in the Obligations and the other rights and interests of Lender hereunder shall not constitute a "Lender" hereunder or under the other Loan Documents and Lender's obligations under this Agreement shall remain unchanged, (ii) Lender shall remain solely responsible for the performance of such obligations, (iii) Borrowers and Lender shall continue to deal solely and directly with each other in connection with Lender's rights and obligations under this Agreement and the other Loan Documents, (iv) Lender shall not transfer or grant any participating interest under which the Participant has the right to approve any amendment to, or any consent or waiver with respect to, this Agreement or any other Loan Document, except to the extent such amendment to, or consent or waiver with respect to this Agreement or of any other Loan Document would (A) extend the final maturity date of the Obligations hereunder in which such Participant is participating, (B) reduce the interest rate applicable to the Obligations hereunder in which such Participant is participating, (C) release all or substantially all of the Collateral or guaranties (except to the extent expressly provided herein or in any of the Loan Documents) supporting the Obligations hereunder in which such Participant is participating, (D) postpone the payment of, or reduce the amount of, the interest or fees payable to such Participant through Lender, or (E) change the amount or due dates of scheduled principal repayments or prepayments or premiums, and (v) all amounts payable by Borrowers hereunder shall be determined as if Lender had not sold such participation, except that, if amounts outstanding under this Agreement are due and unpaid, or shall have been declared or shall have become due and payable upon the occurrence of an Event of Default, each Participant shall be deemed to have the right of set off in respect of its participating interest in amounts owing under this Agreement to the same extent as if the amount of its participating interest were owing directly to it as a Lender under this Agreement. The rights of any Participant only shall be derivative through Lender and no Participant shall have any rights under this Agreement or the other Loan Documents or any direct rights as to Borrowers, the Collections of Borrowers or their Subsidiaries, the Collateral, or otherwise in respect of the Obligations. No Participant shall have the right to participate directly in the making of decisions by Lender.

(f) In connection with any such assignment or participation or proposed assignment or participation, a Lender may, subject to the provisions of *Section 15.8*, disclose all documents and information which it now or hereafter may have relating to Borrowers and their Subsidiaries and their respective businesses.

(g) Any other provision in this Agreement notwithstanding, Lender may at any time create a security interest in, or pledge, all or any portion of its rights under and interest in this Agreement in favor of any Federal Reserve Bank in accordance with Regulation A of the Federal Reserve Bank or U.S. Treasury Regulation 31 CFR § 203.24, and such Federal Reserve Bank may enforce such pledge or security interest in any manner permitted under applicable law.

13.2 ***Successors.*** This Agreement shall bind and inure to the benefit of the respective successors and assigns of each of the parties; *provided*, *however*, that Borrowers may not assign this Agreement or any rights or duties hereunder without Lender's prior written consent and any prohibited assignment shall be absolutely void *ab initio*. No consent to assignment by Lender shall release any Borrower from its Obligations. Lender may assign this Agreement and the other Loan Documents and its rights and duties hereunder and thereunder pursuant to *Section 13.1* hereof and, except as expressly required pursuant to *Section 13.1* hereof, no consent or approval by any Borrower is required in connection with any such assignment.

14. AMENDMENTS; WAIVERS.

14.1 ***Amendments and Waivers.*** No amendment or waiver of any provision of this Agreement or any other Loan Document (other than Bank Product Agreements), and no consent with respect to any departure by Borrowers therefrom, shall be effective unless the same shall be in writing and signed by Lender and Administrative Borrower (on behalf of all Borrowers) and then any such waiver or consent shall be effective, but only in the specific instance and for the specific purpose for which given.

14.2 ***No Waivers; Cumulative Remedies.*** No failure by Lender to exercise any right, remedy, or option under this Agreement or any other Loan Document, or delay by Lender in exercising the same, will operate as a waiver thereof. No waiver by Lender will be effective unless it is in writing, and then only to the extent specifically stated. No waiver by Lender on any occasion shall affect or diminish Lender's rights thereafter to require strict performance by Borrowers of any provision of this Agreement. Lender's rights under this Agreement and the other Loan Documents will be cumulative and not exclusive of any other right or remedy that Lender may have.

15. GENERAL PROVISIONS.

15.1 ***Effectiveness.*** This Agreement shall be binding and deemed effective when executed by Borrowers and Lender.

15.2 ***Section Headings.*** Headings and numbers have been set forth herein for convenience only. Unless the contrary is compelled by the context, everything contained in each Section applies equally to this entire Agreement.

15.3 ***Interpretation.*** Neither this Agreement nor any uncertainty or ambiguity herein shall be construed against Lender or Borrowers, whether under any rule of construction or otherwise. On the contrary, this Agreement has been reviewed by all parties and shall be construed and interpreted according to the ordinary meaning of the words used so as to accomplish fairly the purposes and intentions of all parties hereto.

15.4 ***Severability of Provisions.*** Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

15.5 ***Withholding Taxes.*** All payments made by any Borrower hereunder or under any note or other Loan Document will be made without setoff, counterclaim, or other defense. In addition, all such payments will be made free and clear of, and without deduction or withholding for, any present or future Taxes, and in the event any deduction or withholding of Taxes is required, each Borrower shall comply with the penultimate sentence of this *Section 15.5*. "Taxes" shall mean, any taxes, levies, imposts, duties, fees, assessments or other charges of whatever nature now or hereafter imposed by any jurisdiction or by any political subdivision or taxing authority thereof or therein with respect to such payments (but excluding any tax imposed by any jurisdiction or by any political subdivision or taxing authority thereof or therein measured by or based on the net income or net profits of Lender) and all interest, penalties or similar liabilities with respect thereto. If any Taxes are so levied or imposed, each Borrower agrees to pay the full amount of such Taxes and such additional amounts as may be necessary so that every payment of all amounts due under this Agreement, any note, or Loan Document, including any amount paid pursuant to this *Section 15.5* after withholding or deduction for or on account of any Taxes, will not be less than the amount provided for herein; provided, however, that Borrowers shall not be required to increase any such amounts if the increase in such amount payable results from Lender's own willful misconduct or gross negligence (as finally determined by a court of competent jurisdiction). Each Borrower will furnish to Lender as promptly as possible after the date the payment of any Tax is due pursuant to applicable law certified copies of tax receipts evidencing such payment by any Borrower.

15.6 ***Counterparts; Electronic Execution.*** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement. Delivery of an executed counterpart of this Agreement by telefacsimile or other electronic method of transmission shall be equally as effective as delivery of an original executed counterpart of this Agreement. Any party delivering an executed counterpart of this Agreement by telefacsimile or other electronic method of transmission also shall deliver an original executed counterpart of this Agreement but the failure to deliver an original executed counterpart shall not affect the validity, enforceability, and binding effect of this Agreement. The foregoing shall apply to each other Loan Document *mutatis mutandis*.

15.7 ***Revival and Reinstatement of Obligations.*** If the incurrence or payment of the Obligations by any Borrower or Guarantor or the transfer to Lender of any property should for any reason subsequently be declared to be void or voidable under any state or federal law relating to creditors' rights, including provisions of the Bankruptcy Code relating to fraudulent conveyances, preferences, or other voidable or recoverable payments of money or transfers of property (collectively, a "*Voidable Transfer*"), and if Lender is required to repay or restore, in whole or in part, any such Voidable Transfer, or elects to do so upon the reasonable advice of its counsel, then, as to any such Voidable Transfer, or the amount thereof that Lender is required or elects to repay or restore, and as to all reasonable costs, expenses, and attorneys fees of Lender related thereto, the liability of Borrowers or Guarantor automatically shall be revived, reinstated, and restored and shall exist as though such Voidable Transfer had never been made.

15.8 ***Confidentiality.*** Lender agrees that material, non-public information regarding Borrowers and their Subsidiaries, their operations, assets, and existing and contemplated business plans shall be treated by Lender in a confidential manner, and shall not be disclosed by Lender to Persons who are not parties to this Agreement, except: (a) to attorneys for and other advisors, accountants, auditors, and consultants to any member of Lender, (b) to Subsidiaries and Affiliates of Lender (including the Bank Product Providers), provided that any such Subsidiary or Affiliate shall have agreed to receive such information hereunder subject to the terms of this *Section 15.8*, (c) as may be required by statute, decision, or judicial or administrative order, rule, or regulation, (d) as may be agreed to in advance by Administrative Borrower or its Subsidiaries or as requested or required by any Governmental Authority pursuant to any subpoena or other legal process, (e) as to any such information that is or becomes generally available to the public (other than as a result of prohibited disclosure by Lender), (f) in connection with any assignment, prospective assignment, sale, prospective sale, participation or prospective participations, or pledge or prospective pledge of Lender's interest under this Agreement, provided that any such assignee, prospective assignee, purchaser, prospective purchaser, participant, prospective participant, pledgee, or prospective pledgee shall have agreed in writing to receive such information hereunder subject to the terms of this Section, and (g) in connection with any litigation or other adversary proceeding involving parties hereto which such litigation or adversary proceeding involves claims related to the rights or duties of such parties under this Agreement or the other Loan Documents. The provisions of this *Section 15.8* shall survive for 2 years after the payment in full of the Obligations.

15.9 ***Integration.*** This Agreement, together with the other Loan Documents, reflects the entire understanding of the parties with respect to the transactions contemplated hereby and shall not be contradicted or qualified by any other agreement, oral or written, before the date hereof.

15.10 ***Parent as Agent for Borrowers.*** Each Borrower hereby irrevocably appoints Parent as the borrowing agent and attorney-in-fact for all Borrowers (the "Administrative Borrower") which appointment shall remain in full force and effect unless and until Lender shall have received prior written notice signed by each Borrower that such appointment has been revoked and that another Borrower has been appointed Administrative Borrower. Each Borrower hereby irrevocably appoints and authorizes the Administrative Borrower (i) to provide Lender with all notices with respect to Advances and Letters of Credit obtained for the benefit of any Borrower and all other notices and instructions under this Agreement and (ii) to take such action as the Administrative Borrower deems appropriate on its behalf to obtain Advances and Letters of Credit and to exercise such other powers as are reasonably incidental thereto to carry out the purposes of this Agreement. It is understood that the handling of the Loan Account and Collateral of Borrowers in a combined fashion, as more fully set forth herein, is done solely as an accommodation to Borrowers in order to utilize the collective borrowing powers of Borrowers in the most efficient and economical manner and at their request, and that Lender shall not incur liability to any Borrower as a result hereof. Each Borrower expects to derive benefit, directly or indirectly, from the handling of the Loan Account and the Collateral in a combined fashion since the successful operation of each Borrower is dependent on the continued successful performance of the integrated group. To induce Lender to do so, and in consideration thereof, each Borrower hereby jointly and severally agrees to indemnify Lender harmless against any and all liability, expense, loss or claim of damage or injury, made against Lender by any Borrower or by any third party whosoever, arising from or incurred by reason of (a) the handling of the Loan Account and Collateral of Borrowers as herein provided, (b) Lender's relying on any instructions of the Administrative Borrower, or (c) any other action taken by Lender hereunder or under the other Loan Documents, except that Borrowers will have no liability to any Lender-Related Person under this *Section 15.10* with respect to any liability that has been finally determined by a court of competent jurisdiction to have resulted solely from the gross negligence or willful misconduct of such Lender-Related Person.

[Signature pages to follow.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed and delivered as of the date first above written.

CRYOLIFE, INC.,
a Florida corporation, as Borrower

By: ______________________________

Title: ______________________________

CRYOLIFE TECHNOLOGY, INC.,
a Nevada corporation, as Borrower

By: ______________________________

Title: ______________________________

AURAZYME PHARMACEUTICALS, INC.,
a Florida corporation, as
Borrower

By: ______________________________

Title: ______________________________

WELLS FARGO FOOTHILL, INC.,
a California corporation, as Lender

By: ______________________________

Title: ______________________________

Schedule 1.1

As used in the Agreement, the following terms shall have the following definitions:

"*Account*" means an account (as that term is defined in the Code).

"*Account Debtor*" means any Person who is obligated on an Account, chattel paper, or a general intangible.

"*ACH Transactions*" means any cash management or related services (including the Automated Clearing House processing of electronic fund transfers through the direct Federal Reserve Fedline system) provided by a Bank Product Provider for the account of Administrative Borrower or its Subsidiaries.

"*Administrative Borrower*" has the meaning specified therefor in *Section 15.10*.

"*Advances*" has the meaning specified therefor in *Section 2.1(a)*.

"*Affiliate*" means, as applied to any Person, any other Person who controls, is controlled by, or is under common control with, such Person. For purposes of this definition, "control" means the possession, directly or indirectly through one or more intermediaries, of the power to direct the management and policies of a Person, whether through the ownership of Stock, by contract, or otherwise.

"*Agreement*" means the Credit Agreement to which this *Schedule 1.1* is attached.

"*Assignee*" has the meaning specified therefor in *Section 13.1(a)*.

"*Assignment and Acceptance*" means an Assignment and Acceptance Agreement substantially in the form of *Exhibit A-1*.

"*Authorized Person*" means any officer or employee of Administrative Borrower.

"*Availability*" means, as of any date of determination, the amount that Borrowers are entitled to borrow as Advances hereunder (after giving effect to all then outstanding Obligations (other than Bank Product Obligations) and all sublimits and reserves then applicable hereunder).

"*Bank Product*" means any financial accommodation extended to Administrative Borrower or its Subsidiaries by a Bank Product Provider (other than pursuant to the Agreement) including: (a) credit cards, (b) credit card processing services, (c) debit cards, (d) purchase cards, (e) ACH Transactions, (f) cash management, including controlled disbursement, accounts or services, or (g) transactions under Hedge Agreements.

"*Bank Product Agreements*" means those agreements entered into from time to time by Administrative Borrower or its Subsidiaries with a Bank Product Provider in connection with the obtaining of any of the Bank Products.

"*Bank Product Obligations*" means all obligations, liabilities, contingent reimbursement obligations, fees, and expenses owing by Administrative Borrower or its Subsidiaries to any Bank Product Provider pursuant to or evidenced by the Bank Product Agreements and irrespective of whether for the payment of money, whether direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, and including all such amounts that Administrative Borrower or its Subsidiaries are obligated to reimburse to Lender as a result of Lender purchasing participations from, or executing indemnities or reimbursement obligations to, a Bank Product Provider with respect to the Bank Products provided by such Bank Product Provider to Administrative Borrower or its Subsidiaries.

"*Bank Product Provider*" means Wells Fargo or any of its Affiliates.

"*Bank Product Reserve*" means, as of any date of determination, the amount of reserves that Lender has established (based upon the Bank Product Providers' reasonable determination of the credit exposure of Administrative Borrower and its Subsidiaries in respect of Bank Products) in respect of Bank Products then provided or outstanding.

"*Bankruptcy Code*" means title 11 of the United States Code, as in effect from time to time.

"*Base Rate*" means, the rate of interest announced, from time to time, within Wells Fargo at its principal office in San Francisco as its "prime rate", with the understanding that the "prime rate" is one of Wells Fargo's base rates (not necessarily the lowest of such rates) and serves as the basis upon which effective rates of interest are calculated for those loans making reference thereto and is evidenced by the recording thereof after its announcement in such internal publications as Wells Fargo may designate.

"*Base Rate Margin*" means 1 percentage point.

"*Benefit Plan*" means a "defined benefit plan" (as defined in Section 3(35) of ERISA) for which any Borrower or any Subsidiary or ERISA Affiliate of any Borrower has been an "employer" (as defined in Section 3(5) of ERISA) within the past six years.

"*BioGlue Gross Margin*" means, with respect to any period, the ratio (expressed as a percentage) of Borrowers' and its Subsidiaries' consolidated (a) gross revenues (net of allowances, discounts, returns and rebates) less cost of goods sold in respect of its BioGlue Product Line, to (b) the gross revenues (net of allowances, discounts, returns and rebates) in respect of its BioGlue Product Line.

"*BioGlue Product Line*" means Borrowers' two-component surgical adhesive product line that is dispersed via a controlled delivery system and crosslinks to the repair site creating a flexible mechanical seal independently of the body's clotting mechanism.

"*Board of Directors*" means the board of directors (or comparable managers) of Parent or any committee thereof duly authorized to act on behalf of the board of directors (or comparable managers).

"*Borrower*" and "*Borrowers*" have the respective meanings specified therefor in the preamble to the Agreement.

"*Borrowing*" means a borrowing hereunder consisting of Advances made on the same day by Lender.

"*Borrowing Base*" means, as of any date of determination, the result of:

(a) 20% of the amount of the Enterprise Valuation, *minus*

(b) the sum of (i) the Bank Product Reserve and (ii) the aggregate amount of reserves, if any, established by Lender under *Section 2.1(b)*.

"*Business Day*" means any day that is not a Saturday, Sunday, or other day on which banks are authorized or required to close in the state of Georgia.

"*Capital Expenditures*" means, with respect to any Person for any period, the aggregate of all expenditures by such Person and its Subsidiaries during such period that are capital expenditures as determined in accordance with GAAP, whether such expenditures are paid in cash or financed.

"*Capitalized Lease Obligation*" means that portion of the obligations under a Capital Lease that is required to be capitalized in accordance with GAAP.

"*Capital Lease*" means a lease that is required to be capitalized for financial reporting purposes in accordance with GAAP.

"*Cash Equivalents*" means (a) marketable direct obligations issued by, or unconditionally guaranteed by, the United States or issued by any agency thereof and backed by the full faith and credit of the United States, in each case maturing within 1 year from the date of acquisition thereof, (b) marketable direct obligations issued by any state of the United States or any political subdivision of any such state or any public instrumentality thereof maturing within 1 year from the date of acquisition thereof and, at the time of acquisition, having one of the two highest ratings obtainable from either Standard & Poor's Rating Group ("S&P") or Moody's Investors Service, Inc. ("Moody's"), (c) commercial paper maturing no more than 270 days from the date of creation thereof and, at the time of acquisition, having a rating of at least A-1 from S&P or at least P-1 from Moody's, (d) certificates of deposit or bankers' acceptances maturing within 1 year from the date of acquisition thereof issued by any bank organized under the laws of the United States or any state thereof having at the date of acquisition thereof combined capital and surplus of not less than $250,000,000, (e) Deposit Accounts maintained with (i) any bank that satisfies the criteria described in clause (d) above, or (ii) any other bank organized under the laws of the United States or any state thereof so long as the amount maintained with any such other bank is less than or equal to $100,000 and is insured by the Federal Deposit Insurance Corporation, and (f) Investments in money market funds substantially all of whose assets are invested in the types of assets described in clauses (a) through (e) above.

"*Cash Management Account*" means a Deposit Account or Securities Account of a Borrower or a Subsidiary of a Borrower (a "*Cash Management Account*") at a Cash Management Bank.

"*Cash Management Bank*" has the meaning specified therefor in *Section 2.7(a)*.

"*Change of Control*" means that (a) any "person" or "group" (within the meaning of Sections 13(d) and 14(d) of the Exchange Act), becomes the beneficial owner (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 25%, or more, of the Stock of Parent having the right to vote for the election of members of the Board of Directors, or (b) a majority of the members of the Board of Directors do not constitute Continuing Directors.

"*Closing Date*" means the date of the making of the initial Advance (or other extension of credit) hereunder.

"*Code*" means the Georgia Uniform Commercial Code, as in effect from time to time.

"*Collateral*" means all assets and interests in assets and proceeds thereof now owned or hereafter acquired by Administrative Borrower or its Subsidiaries in or upon which a Lien is granted under any of the Loan Documents.

"*Collateral Access Agreement*" means a landlord waiver, bailee letter, or acknowledgement agreement of any lessor, warehouseman, processor, consignee, or other Person in possession of, having a Lien upon, or having rights or interests in Administrative Borrower's or its Subsidiaries' books and records, Equipment or Inventory, in each case, in form and substance satisfactory to Lender.

"*Collections*" means *all* cash, checks, notes, instruments, and other items of payment (including insurance proceeds, proceeds of cash sales, rental proceeds, and tax refunds).

"*Compliance Certificate*" means a certificate substantially in the form of *Exhibit C-1* delivered by the chief financial officer of Parent to Lender.

"*Continuing Director*" means (a) any member of the Board of Directors who was a director (or comparable manager) of Parent on the Closing Date, and (b) any individual who becomes a member of the Board of Directors after the Closing Date if such individual was appointed or nominated for election to the Board of Directors by a majority of the Continuing Directors, but excluding any such individual originally proposed for election in opposition to the Board of Directors in office at the Closing Date in an actual or threatened election contest relating to the election of the directors (or comparable managers) of Parent and whose initial assumption of office resulted from such contest or the settlement thereof.

"*Control Agreement*" means a control agreement, in form and substance satisfactory to Lender, executed and delivered by Administrative Borrower or one of its Subsidiaries, Lender, and the applicable securities intermediary (with respect to a Securities Account) or bank (with respect to a Deposit Account).

"*Daily Balance*" means, as of any date of determination and with respect to any Obligation, the amount of such Obligation owed at the end of such day.

"*Default*" means an event, condition, or default that, with the giving of notice, the passage of time, or both, would be an Event of Default.

"*Deposit Account*" means any deposit account (as that term is defined in the Code).

"*Designated Account*" means the Deposit Account of Administrative Borrower identified on *Schedule D-1*.

"*Designated Account Bank*" has the meaning specified therefor in *Schedule D-1*.

"*Dollars*" or "*$*" means United States dollars.

"*EBITDA*" means, with respect to any fiscal period, Parent's and its Subsidiaries' consolidated net earnings (or loss), minus extraordinary gains and interest income, plus interest expense, income taxes, and depreciation and amortization for such period, in each case, as determined in accordance with GAAP.

"*Eligible Transferee*" means (a) a commercial bank organized under the laws of the United States, or any state thereof, and having total assets in excess of $250,000,000, (b) a commercial bank organized under the laws of any other country which is a member of the Organization for Economic Cooperation and Development or a political subdivision of any such country and which has total assets in excess of $250,000,000, provided that such bank is acting through a branch or agency located in the United States, (c) a finance company, insurance company, or other financial institution or fund that is engaged in making, purchasing, or otherwise investing in commercial loans in the ordinary course of its business and having (together with its Affiliates) total assets in excess of $250,000,000, (d) any Affiliate (other than individuals) of Lender, (e) so long as no Event of Default has occurred and is continuing, any other Person approved by Administrative Borrower (which approval of Administrative Borrower shall not be unreasonably withheld, delayed, or conditioned), and (f) during the continuation of an Event of Default, any other Person approved by Lender.

"*Enterprise Valuation*" means the most recent appraised valuation of Borrower's business and its assets acceptable to Lender and determined at the direction or request of Lender by a third party appraiser acceptable to Lender.

"*Environmental Actions*" means any complaint, summons, citation, notice, directive, order, claim, litigation, investigation, judicial or administrative proceeding, judgment, letter, or other communication from any Governmental Authority, or any third party involving violations of Environmental Laws or releases of Hazardous Materials from (a) any assets, properties, or businesses of any Borrower, any Subsidiary of a Borrower, or any of their predecessors in interest, (b) from adjoining properties or businesses, or (c) from or onto any facilities which received Hazardous Materials generated by any Borrower, any Subsidiary of a Borrower, or any of their predecessors in interest.

"*Environmental Law*" means any applicable federal, state, provincial, foreign or local statute, law, rule, regulation, ordinance, code, binding and enforceable guideline, binding and enforceable written policy or rule of common law now or hereafter in effect and in each case as amended, or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent decree or judgment, in each case, to the extent binding on any Borrower or any Subsidiary of a Borrower, relating to the environment, the effect of the environment on employee health, or Hazardous Materials, in each case as amended from time to time.

"*Environmental Liabilities*" means all liabilities, monetary obligations, losses, damages, punitive damages, consequential damages, treble damages, costs and expenses (including all reasonable fees, disbursements and expenses of counsel, experts, or consultants, and costs of investigation and feasibility studies), fines, penalties, sanctions, and interest incurred as a result of any claim or demand, or Remedial Action required, by any Governmental Authority or any third party, and which relate to any Environmental Action.

"*Environmental Lien*" means any Lien in favor of any Governmental Authority for Environmental Liabilities.

"*Equipment*" means equipment (as that term is defined in the Code).

"*ERISA*" means the Employee Retirement Income Security Act of 1974, as amended, and any successor statute thereto.

"*ERISA Affiliate*" means (a) any Person subject to ERISA whose employees are treated as employed by the same employer as the employees of a Borrower or a Subsidiary of a Borrower under IRC Section 414(b), (b) any trade or business subject to ERISA whose employees are treated as employed by the same employer as the employees of a Borrower or a Subsidiary of a Borrower under IRC Section 414(c), (c) solely for purposes of Section 302 of ERISA and Section 412 of the IRC, any organization subject to ERISA that is a member of an affiliated service group of which a Borrower or a Subsidiary of a Borrower is a member under IRC Section 414(m), or (d) solely for purposes of Section 302 of ERISA and Section 412 of the IRC, any Person subject to ERISA that is a party to an arrangement with a Borrower or a Subsidiary of a Borrower and whose employees are aggregated with the employees of a Borrower or a Subsidiary of a Borrower under IRC Section 414(o).

"*Event of Default*" has the meaning specified therefor in *Section 7*.

"*Excess Availability*" means, as of any date of determination, the amount equal to Availability *minus* the aggregate amount, if any, of all trade payables of Borrowers and their Subsidiaries aged in excess of their historical levels with respect thereto and all book overdrafts of Borrowers and their Subsidiaries in excess of their historical practices with respect thereto, in each case as determined by Lender in its Permitted Discretion.

"*Exchange Act*" means the Securities Exchange Act of 1934, as in effect from time to time.

"*Excluded Accounts*" and "*Excluded Account*" have the respective meanings specified therefor in Section 2.7.

"*Fee Letter*" means that certain fee letter between Borrowers and Lender, in form and substance satisfactory to Lender.

"*Funding Date*" means the date on which a Borrowing occurs.

"*GAAP*" means generally accepted accounting principles as in effect from time to time in the United States, consistently applied.

"*Governing Documents*" means, with respect to any Person, the certificate or articles of incorporation, by-laws, or other organizational documents of such Person.

"*Governmental Authority*" means any federal, state, local, or other governmental or administrative body, instrumentality, board, department, or agency or any court, tribunal, administrative hearing body, arbitration panel, commission, or other similar dispute-resolving panel or body.

"*Guarantors*" means each Subsidiary of each Borrower that is not itself a Borrower (other than CryoLife Europa Ltd., a company organized under the laws of England and Wales), and "*Guarantor*" means any one of them.

"*Guaranty*" means that certain general continuing guaranty executed and delivered by each Guarantor in favor of Lender and the Bank Product Providers, in form and substance satisfactory to Lender.

"*Hazardous Materials*" means (a) substances that are defined or listed in, or otherwise classified pursuant to, any applicable laws or regulations as "hazardous substances," "hazardous materials," "hazardous wastes," "toxic substances," or any other formulation intended to define, list, or classify substances by reason of deleterious properties such as ignitability, corrosivity, reactivity, carcinogenicity, reproductive toxicity, or "EP toxicity", (b) oil, petroleum, or petroleum derived substances, natural gas, natural gas liquids, synthetic gas, drilling fluids, produced waters, and other wastes associated with the exploration, development, or production of crude oil, natural gas, or geothermal resources, (c) any flammable substances or explosives or any radioactive materials, and (d) asbestos in any form or electrical equipment that contains any oil or dielectric fluid containing levels of polychlorinated biphenyls in excess of 50 parts per million.

"*Hedge Agreement*" means any and all agreements, or documents now existing or hereafter entered into by Administrative Borrower or any of its Subsidiaries that provide for an interest rate, credit, commodity or equity swap, cap, floor, collar, forward foreign exchange transaction, currency swap, cross currency rate swap, currency option, or any combination of, or option with respect to, these or similar transactions, for the purpose of hedging Administrative Borrower's or any of its Subsidiaries' exposure to fluctuations in interest or exchange rates, loan, credit exchange, security or currency valuations or commodity prices.

"*Indebtedness*" means (a) all obligations for borrowed money, (b) all obligations evidenced by bonds, debentures, notes, or other similar instruments and all reimbursement or other obligations in respect of letters of credit, bankers acceptances, interest rate swaps, or other financial products, (c) all obligations as a lessee under Capital Leases, (d) all obligations or liabilities of others secured by a Lien on any asset of a Person or its Subsidiaries, irrespective of whether such obligation or liability is assumed, (e) all obligations to pay the deferred purchase price of assets (other than trade payables incurred in the ordinary course of business and repayable in accordance with customary trade practices), (f) all obligations owing under Hedge Agreements, and (g) any obligation guaranteeing or intended to guarantee (whether directly or indirectly guaranteed, endorsed, co-made, discounted, or sold with recourse) any obligation of any other Person that constitutes Indebtedness under any of clauses (a) through (f) above.

"*Indemnified Liabilities*" has the meaning specified therefor in *Section 10.3*.

"*Indemnified Person*" has the meaning specified therefor in *Section 10.3*.

"*Insolvency Proceeding*" means any proceeding commenced by or against any Person under any provision of the Bankruptcy Code or under any other state or federal bankruptcy or insolvency law, assignments for the benefit of creditors, formal or informal moratoria, compositions, extensions generally with creditors, or proceedings seeking reorganization, arrangement, or other similar relief.

"*Intercompany Subordination Agreement*" means a subordination agreement executed and delivered by Borrowers and each of their Subsidiaries and Lender, the form and substance of which is satisfactory to Lender.

"*Interest Expense*" means, for any period, the aggregate of the interest expense of Parent and its Subsidiaries for such period, determined on a consolidated basis in accordance with GAAP.

"*Inventory*" means inventory (as that term is defined in the Code).

"*Investment*" means, with respect to any Person, any investment by such Person in any other Person (including Affiliates) in the form of loans, guarantees, advances, or capital contributions (excluding (a) commission, travel, and similar advances to officers and employees of such Person made in the ordinary course of business, and (b) bona fide Accounts arising in the ordinary course of business consistent with past practice), purchases or other acquisitions of Indebtedness, Stock, or all or substantially all of the assets of such other Person (or of any division or business line of such other Person), and any other items that are or would be classified as investments on a balance sheet prepared in accordance with GAAP.

"*IRC*" means the Internal Revenue Code of 1986, as in effect from time to time.

"*L/C*" has the meaning specified therefor in *Section 2.12(a)*.

"*L/C Disbursement*" means a payment made by Lender pursuant to a Letter of Credit.

"*L/C Undertaking*" has the meaning specified therefor in *Section 2.12(a)*.

"*Lender*" has the meaning specified therefor in the preamble to the Agreement, and shall include any other Person made a party to the Agreement in accordance with the provisions of *Section 13.1*.

"*Lender Deposit Account*" has the meaning specified in *Section 2.7*.

"*Lender Expenses*" means all (a) costs or expenses (including taxes, and insurance premiums) required to be paid by a Borrower or its Subsidiaries under any of the Loan Documents that are paid, advanced, or incurred by Lender, (b) fees or charges paid or incurred by Lender in connection with Lender's transactions with Borrowers or their Subsidiaries, including, fees or charges for photocopying, notarization, couriers and messengers, telecommunication, public record searches (including tax lien, litigation, and Uniform Commercial Code searches and including searches with the patent and trademark office, the copyright office, or the department of motor vehicles), filing, recording, publication, appraisal (including periodic collateral appraisals or business valuations to the extent of the fees and charges (and up to the amount of any limitation) contained in the Agreement, real estate surveys, real estate title policies and endorsements, and environmental audits, (c) costs and expenses incurred by Lender in the disbursement of funds to or for the account of Borrowers (by wire transfer or otherwise), (d) charges paid or incurred by Lender resulting from the dishonor of checks, (e) reasonable costs and expenses paid or incurred by Lender to correct any default or enforce any provision of the Loan Documents, or in gaining possession of, maintaining, handling, preserving, storing, shipping, selling, preparing for sale, or advertising to sell the Collateral, or any portion thereof, irrespective of whether a sale is consummated, (f) audit fees and expenses of Lender related to any inspections or audits to the extent of the fees and charges (and up to the amount of any limitation) contained in the Agreement, (g) reasonable costs and expenses of third party claims or any other suit paid or incurred by Lender in enforcing or defending the Loan Documents or in connection with the transactions contemplated by the Loan Documents or Lender's relationship with any Borrower or any Subsidiary of a Borrower, (h) Lender's reasonable costs and expenses (including attorneys fees) incurred in advising, structuring, drafting, reviewing, administering, syndicating, or amending the Loan Documents, and (i) Lender's reasonable costs and expenses (including attorneys, accountants, consultants, and other advisors fees and expenses) incurred in terminating, enforcing (including attorneys, accountants, consultants, and other advisors fees and expenses incurred in connection with a "workout," a "restructuring," or an Insolvency Proceeding concerning any Borrower or any Subsidiary of a Borrower or in exercising rights or remedies under the Loan Documents), or defending the Loan Documents, irrespective of whether suit is brought, or in taking any Remedial Action concerning the Collateral.

"*Lender-Related Person*" means Lender, together with its Affiliates, officers, directors, employees, attorneys, and agents.

"*Lender's Account*" means the account identified in *Schedule L-1*.

"*Lender's Liens*" means the Liens granted by Borrowers or their Subsidiaries to Lender under the Agreement or the other Loan Documents.

"*Letter of Credit*" means an L/C or an L/C Undertaking, as the context requires.

"*Letter of Credit Usage*" means, as of any date of determination, the aggregate undrawn amount of all outstanding Letters of Credit.

"*Lien*" means any interest in an asset securing an obligation owed to, or a claim by, any Person other than the owner of the asset, irrespective of whether (a) such interest is based on the common law, statute, or contract, (b) such interest is recorded or perfected, and (c) such interest is contingent upon the occurrence of some future event or events or the existence of some future circumstance or circumstances. Without limiting the generality of the foregoing, the term "Lien" includes the lien or security interest arising from a mortgage, deed of trust, encumbrance, notice of Lien, levy or assessment, pledge, hypothecation, assignment, deposit arrangement, security agreement, conditional sale or trust receipt, or from a lease, consignment, or bailment for security purposes and also includes reservations, exceptions, encroachments, easements, rights-of-way, covenants, conditions, restrictions, leases, and other title exceptions and encumbrances affecting Real Property.

"*Loan Account*" has the meaning specified therefor in *Section 2.10*.

"*Loan Documents*" means the Agreement, the Bank Product Agreements, the Control Agreements, the Fee Letter, the Guaranty, the Intercompany Subordination Agreement, the Letters of Credit, any Mortgages, the Security Agreement, any note or notes executed by a Borrower in connection with the Agreement and payable Lender, and any other agreement entered into, now or in the future, by any Borrower and Lender in connection with the Agreement.

"*Material Adverse Change*" means (a) a material adverse change in the business, prospects, operations, results of operations, assets, liabilities or condition (financial or otherwise) of Borrowers and their Subsidiaries, taken as a whole, (b) a material impairment of a Borrower's or any of its Subsidiaries' ability to perform its obligations under the Loan Documents to which it is a party or of Lender's ability to enforce the Obligations or realize upon the Collateral, or (c) a material impairment of the enforceability or priority of the Lender's Liens with respect to the Collateral as a result of an action or failure to act on the part of a Borrower or a Subsidiary of a Borrower.

"*Maturity Date*" has the meaning specified therefor in *Section 3.3*.

"*Maximum Revolver Amount*" means $15,000,000.

"*Moody's*" means Moody's Investor Service, Inc.

"*Mortgages*" means, individually and collectively, one or more mortgages, deeds of trust, or deeds to secure debt, executed and delivered by a Borrower or a Subsidiary of a Borrower in favor of Lender, in form and substance satisfactory to Lender, that encumber the Real Property Collateral.

"*Obligations*" means (a) all loans, Advances, debts, principal, interest (including any interest that accrues after the commencement of an Insolvency Proceeding regardless of whether allowed or allowable in whole or in part as a claim in any such Insolvency Proceeding), contingent reimbursement obligations with respect to outstanding Letters of Credit, premiums, liabilities (including all amounts charged to Borrowers' Loan Account pursuant hereto), obligations (including indemnification obligations), fees (including the fees provided for in the Fee Letter), charges, costs, Lender Expenses (including any fees or expenses that accrue after the commencement of an Insolvency Proceeding, regardless of whether allowed or allowable in whole or in part as a claim in any such Insolvency Proceeding), lease payments, guaranties, covenants, and duties of any kind and description owing by Borrowers to Lender pursuant to or evidenced by the Loan Documents and irrespective of whether for the payment of money, whether direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, and including all interest not paid when due and all Lender Expenses that Borrowers are required to pay or reimburse by the Loan Documents, by law, or otherwise, and (b) all Bank Product Obligations. Any reference in the Agreement or in the Loan Documents to the Obligations shall include all or any portion thereof and any extensions, modifications, renewals, or alterations thereof, both prior and subsequent to any Insolvency Proceeding.

"*Overadvance*" has the meaning specified therefor in *Section 2.5*.

"*Parent*" has the meaning specified therefor in the preamble to the Agreement.

"*Participant*" has the meaning specified therefor in *Section 13.1(e)*.

"*Permitted Discretion*" means a determination made in the exercise of reasonable (from the perspective of a secured lender) business judgment.

"*Permitted Dispositions*" means (a) sales or other dispositions of Equipment that is substantially worn, damaged, or obsolete in the ordinary course of business, (b) sales of Inventory or services to buyers in the ordinary course of business, (c) the use or transfer of money or Cash Equivalents in a manner that is not prohibited by the terms of the Agreement or the other Loan Documents, (d) the licensing of patents, trademarks, copyrights and other intellectual property rights in the ordinary course of business, on a non-exclusive basis, and (e) the licensing of patents, trademarks, copyrights and other intellectual property rights on an exclusive basis where exclusivity is restricted to a limited field of use that does not prohibit Borrowers and their Subsidiaries, or any of them, from commercializing the intellectual property rights so licensed in applications outside the limited field of use or in any application presently commercialized by the Borrowers and their Subsidiaries; provided, however, that Lender shall be granted a perfected first priority security interest in each license described in clause (d) or (e) above and Borrowers and their Subsidiaries shall not enter into any such license if an Event of Default has occurred and is continuing.

"*Permitted Investments*" means (a) Investments in cash and Cash Equivalents, (b) Investments in negotiable instruments for collection, (c) advances made in connection with purchases of goods or services in the ordinary course of business, (d) Investments received in settlement of amounts due to a Borrower or any Subsidiary of a Borrower effected in the ordinary course of business or owing to a Borrower or any Subsidiary of a Borrower as a result of Insolvency Proceedings involving an Account Debtor or upon the foreclosure or enforcement of any Lien in favor of a Borrower or any Subsidiary of a Borrower, (e) purchases of additional patents or non-patented intellectual property to enhance the BioGlue Product Line or equipment or other capital assets used in connection therewith so long as no Default or Event of Default exists or would be caused thereby and so long as the aggregate purchase price therefor does not exceed $3,000,000, and (f) other investments consistent with Borrowers' investment policy set forth on *Schedule P-1*.

"*Permitted Liens*" means (a) Liens held by Lender, (b) Liens for unpaid taxes, assessments, or other governmental charges or levies that either (i) are not yet delinquent, or (ii) do not have priority over the Lender's Liens and the underlying taxes, assessments, or charges or levies are the subject of Permitted Protests, (c) judgment Liens that do not constitute an Event of Default under *Section 7.7* of the Agreement, (d) Liens set forth on *Schedule P-2*, (e) the interests of lessors under operating leases, (f) purchase money Liens or the interests of lessors under Capital Leases to the extent that such Liens or interests secure Permitted Purchase Money Indebtedness and so long as such Lien attaches only to the asset purchased or acquired and the proceeds thereof, (g) Liens arising by operation of law in favor of warehousemen, landlords, carriers, mechanics, materialmen, laborers, or suppliers, incurred in the ordinary course of Borrowers' business and not in connection with the borrowing of money, and which Liens either (i) are for sums not yet delinquent, or (ii) are the subject of Permitted Protests, (h) Liens on amounts deposited in connection with obtaining worker's compensation or other unemployment insurance, (i) Liens on amounts deposited in connection with the making or entering into of bids, tenders, or leases in the ordinary course of business and not in connection with the borrowing of money, (j) Liens on amounts deposited as security for surety or appeal bonds in connection with obtaining such bonds in the ordinary course of business, and (k) with respect to any Real Property, easements, rights of way, and zoning restrictions that do not materially interfere with or impair the use or operation thereof.

"*Permitted Protest*" means the right of Administrative Borrower or any of its Subsidiaries to protest any Lien (other than any Lien that secures the Obligations), taxes (other than payroll taxes or taxes that are the subject of a United States federal tax lien), or rental payment, provided that (a) a reserve with respect to such obligation is established on a Borrower's or any of its Subsidiaries' books and records in such amount as is required under GAAP, (b) any such protest is instituted promptly and prosecuted diligently by Administrative Borrower or any of its Subsidiaries, as applicable, in good faith, and (c) Lender is satisfied that, while any such protest is pending, there will be no impairment of the enforceability, validity, or priority of any of the Lender's Liens.

"*Permitted Purchase Money Indebtedness*" means, as of any date of determination, Purchase Money Indebtedness incurred after the Closing Date in an aggregate principal amount outstanding at any one time not in excess of $3,000,000.

"*Person*" means natural persons, corporations, limited liability companies, limited partnerships, general partnerships, limited liability partnerships, joint ventures, trusts, land trusts, business trusts, or other organizations, irrespective of whether they are legal entities, and governments and agencies and political subdivisions thereof.

"*Projections*" means Parent's (on a consolidated [and consolidating] basis with its Subsidiaries) forecasted (a) balance sheets, (b) profit and loss statements, and (c) cash flow statements, all prepared on a basis consistent with Parent's historical financial statements, together with appropriate supporting details and a statement of underlying assumptions.

"*Purchase Money Indebtedness*" means Indebtedness (other than the Obligations, but including Capitalized Lease Obligations) incurred at the time of, or within 20 days after, the acquisition of any fixed assets for the purpose of financing all or any part of the acquisition cost thereof.

"*Qualified Cash*" means, as of any date of determination, the amount of unrestricted cash and Cash Equivalents of Borrowers and their Subsidiaries that is in Deposit Accounts or in Securities Accounts, or any combination thereof, and which such Deposit Account or Securities Account is the subject of a Control Agreement and is maintained by a branch office of the bank or securities intermediary located within the United States.

"*Real Property*" means any estates or interests in real property now owned or hereafter acquired by any Borrower or a Subsidiary of any Borrower and the improvements thereto.

"*Real Property Collateral*" means any fee owned Real Property hereafter acquired by a Borrower or any Subsidiary of a Borrower.

"*Record*" means information that is inscribed on a tangible medium or which is stored in an electronic or other medium and is retrievable in perceivable form.

"*Remedial Action*" means all actions taken to (a) clean up, remove, remediate, contain, treat, monitor, assess, evaluate, or in any way address Hazardous Materials in the indoor or outdoor environment, (b) prevent or minimize a release or threatened release of Hazardous Materials so they do not migrate or endanger or threaten to endanger public health or welfare or the indoor or outdoor environment, (c) restore or reclaim natural resources or the environment, (d) perform any pre-remedial studies, investigations, or post-remedial operation and maintenance activities, or (e) conduct any other actions with respect to Hazardous Materials authorized by Environmental Laws.

"*Required Availability*" means that the sum of (a) Excess Availability, *plus*(b) Qualified Cash exceeds $12,000,000.

"*Revolver Usage*" means, as of any date of determination, the sum of (a) the amount of outstanding Advances, *plus* (b) the amount of the Letter of Credit Usage.

"*S&P*" means Standard & Poor's Ratings Group, a division of McGraw Hill, Inc.

"*SEC*" means the United States Securities and Exchange Commission and any successor thereto.

"*Securities Account*" means a "securities account" (as that term is defined in the Code).

"*Security Agreement*" means a pledge and security agreement, in form and substance satisfactory to Lender, executed and delivered by Borrower to Lender.

"*Solvent*" means, with respect to any Person on a particular date, that, at fair valuations, the sum of such Person's assets is greater than all of such Person's debts.

"*Stock*" means all shares, options, warrants, interests, participations, or other equivalents (regardless of how designated) of or in a Person, whether voting or nonvoting, including common stock, preferred stock, or any other "equity security" (as such term is defined in Rule 3a11-1 of the General Rules and Regulations promulgated by the SEC under the Exchange Act).

"*Subsidiary*" of a Person means a corporation, partnership, limited liability company, or other entity in which that Person directly or indirectly owns or controls the shares of Stock having ordinary voting power to elect a majority of the board of directors (or appoint other comparable managers) of such corporation, partnership, limited liability company, or other entity.

"*Taxes*" has the meaning specified therefor in *Section 15.5*.

"*Underlying Issuer*" means a third Person which is the beneficiary of an L/C Undertaking and which has issued a letter of credit at the request of Lender for the benefit of Borrowers.

"*Underlying Letter of Credit*" means a letter of credit that has been issued by an Underlying Issuer.

"*United States*" means the United States of America.

"*Voidable Transfer*" has the meaning specified therefor in *Section 15.7*.

"*Wells Fargo*" means Wells Fargo Bank, National Association, a national banking association.

Schedule 3.1

The obligation of Lender to make its initial extension of credit provided for in the Agreement is subject to the fulfillment, to the satisfaction of Lender (the making of such initial extension of credit by Lender being conclusively deemed to be its satisfaction or waiver of the following), of each of the following conditions precedent:

(a) the Closing Date shall occur on or before February 9, 2005;

(b) Lender shall have received a letter duly executed by each Borrower and each Guarantor authorizing Lender to file appropriate financing statements in such office or offices as may be necessary or, in the opinion of Lender, desirable to perfect the security interests to be created by the Loan Documents;

(c) Lender shall have received evidence that appropriate financing statements have been duly filed in such office or offices as may be necessary or, in the opinion of Lender, desirable to perfect the Lender "s Liens in and to the Collateral, and Lender shall have received searches reflecting the filing of all such financing statements;

(d) Lender shall have received each of the following documents, in form and substance satisfactory to Lender, duly executed, and each such document shall be in full force and effect:

(i) the Control Agreements,

(ii) a disbursement letter executed and delivered by Borrowers to Lender regarding the extensions of credit to be made on the Closing Date, the form and substance of which is satisfactory to Lender,

(iii) the Fee Letter,

(iv) the Guaranty,

(v) the Intercompany Subordination Agreement,

(vi) the Patent Security Agreement,

(vii) the Security Agreement, together with all certificates representing the shares of Stock pledged thereunder, as well as Stock powers with respect thereto endorsed in blank,

(viii) the Trademark Security Agreement;

(e) Lender shall have received a certificate from the Secretary of each Borrower (i) attesting to the resolutions of such Borrower's Board of Directors authorizing its execution, delivery, and performance of this Agreement and the other Loan Documents to which such Borrower is a party, (ii) authorizing specific officers of such Borrower to execute the same, and (iii) attesting to the incumbency and signatures of such specific officers of such Borrower;

(f) Lender shall have received copies of each Borrower's Governing Documents, as amended, modified, or supplemented to the Closing Date, certified by the Secretary of such Borrower;

(g) Lender shall have received a certificate of status with respect to each Borrower, dated within 10 days of the Closing Date, such certificate to be issued by the appropriate officer of the jurisdiction of organization of such Borrower, which certificate shall indicate that such Borrower is in good standing in such jurisdiction;

(h) Lender shall have received certificates of status with respect to each Borrower, each dated within 30 days of the Closing Date, such certificates to be issued by the appropriate officer of the jurisdictions (other than the jurisdiction of organization of such Borrower) in which its failure to be duly qualified or licensed would constitute a Material Adverse Change, which certificates shall indicate that such Borrower is in good standing in such jurisdictions;

(i) Lender shall have received a certificate from the Secretary of each Guarantor (i) attesting to the resolutions of such Guarantor's Board of Directors authorizing its execution, delivery, and performance of the Loan Documents to which such Guarantor is a party, (ii) authorizing specific officers of such Guarantor to execute the same and (iii) attesting to the incumbency and signatures of such specific officers of Guarantor;

(j) Lender shall have received copies of each Guarantor's Governing Documents, as amended, modified, or supplemented to the Closing Date, certified by the Secretary of such Guarantor;

(k) Lender shall have received a certificate of status with respect to each Guarantor, dated within 10 days of the Closing Date, such certificate to be issued by the appropriate officer of the jurisdiction of organization of such Guarantor, which certificate shall indicate that such Guarantor is in good standing in such jurisdiction;

(l) Lender shall have received certificates of status with respect to each Guarantor, each dated within 30 days of the Closing Date, such certificates to be issued by the appropriate officer of the jurisdictions (other than the jurisdiction of organization of such Guarantor) in which its failure to be duly qualified or licensed would constitute a Material Adverse Change, which certificates shall indicate that such Guarantor is in good standing in such jurisdictions;

(m) Lender shall have received a certificate of insurance, together with the endorsements thereto, as are required by *Section 5.8*, the form and substance of which shall be satisfactory to Lender;

(n) Lender shall have received Collateral Access Agreements with respect to the following location: 1655 Roberts Blvd., NW, Kennesaw, Georgia;

(o) Lender shall have received an opinion of Borrowers' counsel in form and substance satisfactory to Lender;

(p) Borrowers shall have the Required Availability after giving effect to the initial extensions of credit hereunder and the payment of all fees and expenses required to be paid by Borrowers on the Closing Date under this Agreement or the other Loan Documents;

(q) Lender shall have completed its business, legal, and collateral due diligence, including (i) a collateral audit and review of Borrowers' and their Subsidiaries' books and records and verification of Borrowers' representations and warranties to Lender, the results of which shall be satisfactory to Lender, (ii) an inspection of each of the locations where Borrowers' and their Subsidiaries' Inventory is located, the results of which shall be satisfactory to Lender, (iii) completion of Uniform Commercial Code and intellectual property Lien searches, the results of which shall be satisfactory to Lender, and (iv) review of all litigation, including, without limitation, SEC investigations, the results of which shall be satisfactory to Lender;

(r) Lender shall have received completed reference checks with respect to Borrowers' senior management, the results of which are satisfactory to Lender in its sole discretion;

(s) Lender shall have received the Enterprise Valuation, the results of which shall be satisfactory to Lender;

(t) Lender shall have received a set of Projections of the Parent and its Subsidiaries for the 3 year period following the Closing Date (on a year by year basis, and for the 1 year period following the Closing Date, on a month by month basis), in form and substance (including as to scope and underlying assumptions) satisfactory to Lender;

(u) Borrowers shall have paid all Lender Expenses incurred in connection with the transactions evidenced by this Agreement;

(v) Lender shall have received copies of each of Parent's material contracts, together with a certificate of the Secretary of the Parent certifying each such document as being a true, correct, and complete copy thereof;

(w) Borrowers and each of their Subsidiaries shall have received all licenses, approvals or evidence of other actions required by any Governmental Authority in connection with the execution and delivery by Borrowers or their Subsidiaries of the Loan Documents or with the consummation of the transactions contemplated thereby; and

(x) all other documents and legal matters in connection with the transactions contemplated by this Agreement shall have been delivered, executed, or recorded and shall be in form and substance satisfactory to Lender.

Schedule 5.2

Provide Lender with each of the documents set forth below at the following times in form satisfactory to Lender:

Quarterly (no later than the 30th day after each quarter)	(a) a detailed aging, by total, of Borrowers' Accounts, together with a reconciliation and supporting documentation for any reconciling items noted, (b) a summary, by vendor, of Borrowers' and their Subsidiaries' accounts payable and any book overdrafts and of any held checks, (c) a detailed report regarding Borrowers' and their Subsidiaries' cash and Cash Equivalents, including an indication of which amounts constitute Qualified Cash, and (d) a report regarding Borrowers' and their Subsidiaries' accrued, but unpaid, ad valorem taxes.
Upon request by Lender	(e) such other reports as to the Collateral or the financial condition of Borrowers and their Subsidiaries, as Lender may reasonably request.

Schedule 5.3

Deliver to Lender each of the financial statements, reports, or other items set forth set forth below at the following times in form satisfactory to Lender:

as soon as available, but in any event within 30 days (45 days in the case of a month that is the end of one of Parent's fiscal quarters) after the end of each month during each of Parent's fiscal years	(a) an unaudited consolidated balance sheet, income statement, and statement of cash flow (and consolidating balance sheet and income statement) covering Parent's and its Subsidiaries' operations during such period, and (b) a Compliance Certificate.
as soon as available, but in any event within 90 days after the end of each of Parent's fiscal years	(c) consolidated financial statements of Parent and its Subsidiaries for each such fiscal year, audited by independent certified public accountants reasonably acceptable to Lender and certified, without any qualifications (including any (A) "going concern" or like qualification or exception, (B) qualification or exception as to the scope of such audit, or (C) qualification which relates to the treatment or classification of any item and which, as a condition to the removal of such qualification, would require an adjustment to such item, the effect of which would be to cause any noncompliance with the provisions of Section 6.16), by such accountants to have been prepared in accordance with GAAP (such audited financial statements to include a balance sheet, income statement, and statement of cash flow and, if prepared, such accountants' letter to management), (d) unaudited consolidating balance sheet and income statement of Parent and its Subsidiaries for such fiscal year, and (e) a Compliance Certificate.
as soon as available, but in any event within 30 days prior to the start of each of Parent's fiscal years,	(f) copies of Parent's Projections, in form and substance (including as to scope and underlying assumptions) satisfactory to Lender, in its Permitted Discretion, for the forthcoming year, quarter by quarter, certified by the chief financial officer of Parent as being such officer's good faith estimate of the financial performance of Parent during the period covered thereby.
if and when filed by any Borrower,	(g) Form 10-Q quarterly reports, Form 10-K annual reports, and Form 8-K current reports, (h) any other filings made by any Borrower with the SEC, and (i) any other information that is provided by Parent to its shareholders generally.

promptly, but in any event within 5 days after a Borrower has knowledge of any event or condition that constitutes a Default or an Event of Default,	(j) notice of such event or condition and a statement of the curative action that Borrowers proposes to take with respect thereto.
promptly after the commencement thereof (or, in the case of a threat described in clause (ii), promptly upon such threat), but in any event within 5 days after the service of process with respect thereto (or, in the case of any threat described in clause (ii), within 5 days of such threat) on any Borrower or any Subsidiary of a Borrower,	(k) (i) notice of all actions, suits, or proceedings brought by or against any Borrower or any Subsidiary of a Borrower before any Governmental Authority (other than the United States Food and Drug Administration) which reasonably could be expected to result in a Material Adverse Change, and (ii) notice of all actions, suits, or proceedings brought by or against (or threatened by or against) any Borrower or any Subsidiary of a Borrower before the United States Food and Drug Administration.
promptly upon receipt thereof, but in any event within 5 days after receipt,	(l) copies of all Warning Letters, Notices of Observation or Orders (as such terms are defined under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, or applicable regulations issued thereunder) received by any Borrower or any Subsidiary of a Borrower from the United States Food and Drug Administration.
promptly upon Borrowers' obtaining knowledge thereof, but in any event within 5 days after obtaining such knowledge,	(m) notice of any material default under any intellectual property license of the type described in clause (d) or (e) of the definition of Permitted Disposition.
upon the request of Lender,	(n) any other information reasonably requested relating to the financial condition of Borrowers or their Subsidiaries.

QuickLinks

Schedule 5.3

Exhibit 10.9 (d)

Named Executive Officer Salaries

On November 3, 2004, when the Company promoted D. Ashley Lee from Vice President Finance, Treasurer and Chief Financial Officer to Executive Vice President, Chief Operating Officer and Chief Financial Officer his annual salary was increased to $340,000.

On February 18, 2005, the Compensation Committee of the Board of Directors of CryoLife, Inc. approved the following new salary levels for these "Named Executive Officers."

Officer	Salary
David M. Fronk	$ 225,225
Albert Heacox	$ 265,650

QuickLinks -- Click here to rapidly navigate through this document

Exhibit 10.14

AMENDED AND RESTATED TECHNOLOGY ACQUISITION AGREEMENT

This Amended and Restated Technology Acquisition Agreement (the "Agreement") is entered into effective as of the 14th day of March, 1996, by and between Nicholas Kowanko, Ph.D. of 618 South Fifth Street, Moorhead, Minnesota 56560 ("Dr. Kowanko") and CryoLife, Inc. of 2211 New Market Parkway, Suite 142, Marietta, Georgia 30067 ("CryoLife").

WHEREAS, Dr. Kowanko has invented and may develop in the future, pursuant to his services under this Agreement, certain Trade Secrets, Know-How and Patents (as defined below and collectively referred to as the "Technology") related to methods, procedures, and sciences for creating a bioadhesive ("Adhesive") which is more particularly described in *Exhibit A* attached hereto;

WHEREAS, Dr. Kowanko is the owner of all right, title, and interest in and to the Technology;

WHEREAS, CryoLife desires to acquire the Technology in order to continue its product development and eventually commercialize products utilizing the Technology and to obtain certain assistance from Dr. Kowanko;

WHEREAS, the parties entered into a Technology Acquisition Agreement (the "TA Agreement") on March 14, 1996 to transfer the Technology and provide for Dr. Kowanko's assistance upon the terms and conditions set forth therein; and

WHEREAS, the parties desire to amend the TA Agreement in certain particulars by entering into this Agreement, which Agreement the parties intend to supersede the original TA Agreement.

NOW, THEREFORE, in consideration of the premises, the promises hereinafter set forth, and other valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

I. *Definitions.* The following terms shall have the following meanings when used in this Agreement:

A. "Improvements" shall mean any and all (i) changes or enhancements to the Adhesive (including, without limitation, formulation changes to reduce Adhesive and component toxicity), (ii) new bioadhesive inventions, and (iii) information relating to any delivery devices for the Adhesive, developed by Dr. Kowanko pursuant to his services under this Agreement.

B. "Know-How" shall mean any and all non-confidential information relating to the Adhesive or its formulation currently owned by Dr. Kowanko or developed by Dr. Kowanko pursuant to his services under this Agreement.

C. "Patent(s)" shall mean any and all domestic and foreign patents or patent applications of Dr. Kowanko, which relates to the Adhesive or its formulation, or which may in the future be filed on the Trade Secrets or Know-How, including, without limitation, U.S. Patent No. 5385606. The term Patent(s) also shall include any and all U.S. or foreign divisions, continuations, continuation-in-part, substitutions, reissues, and extensions of said Patent(s).

D. "Technology" shall mean the Know-How, Patent(s), Trade Secrets, and Improvements.

E. "Trade Secrets" shall mean any and all confidential information, relating to the Adhesive or its formulation currently owned by Dr. Kowanko or developed by Dr. Kowanko pursuant to his services under this Agreement.

II. *Assignment of Technology.* Dr. Kowanko hereby sells, assigns, and transfers, and agrees to sell, assign, and transfer all of his right, title, and interest in and to the Technology to CryoLife. Dr. Kowanko agrees to execute such further documents and instruments as CryoLife may reasonably request in order to further evidence the transfer of the Technology as contemplated hereunder.

III. *Purchase Price.*

A. *Purchase Price.* CryoLife shall pay Dr. Kowanko the sum of $1,200,000 (the "Purchase Price") for the assignment of the Technology. The Purchase Price shall be payable as follows: $290,000 shall be payable upon execution of this Agreement (which amount has been paid) and the balance shall be payable (i) in three equal installments of $290,000 each of the first, second, and third anniversaries of the date of this Agreement and (ii) one final installment of $40,000 on the fourth anniversary of the date of this Agreement. The Purchase Price shall also include a 1.7% royalty on Net Revenues (gross revenues minus sales tax, returns, discounts, freight and return freight, if any) from future commercial sales of the Adhesive by CryoLife which exceed $25 million in the aggregate. In the case where the right to sell Adhesive is licensed to a third party, the royalty rate shall be computed, at CryoLife's discretion, as 1.7% of the Net Revenues of the licensee from commercial sales of the Adhesive or as 10% of CryoLife's revenues from the licensee (in which later event, CryoLife will not be obliged to pay a 1.7% royalty based on its licensee's sales of Adhesives). The first payment of royalties shall be due within 90 days after the end of the calendar year in which CryoLife first generates revenues from the Adhesive in excess of $25 million in the aggregate and shall be accompanied by a written report showing all Net Revenues and royalties accrued during the preceding calendar year. Royalty payments and written reports shall be made and furnished annually thereafter. Notwithstanding the foregoing, the royalty portion of the Purchase Price shall not be payable at any time after, if ever, the Patents expire or are declared invalid by a court of law and such judgment is not overruled. If CryoLife chooses to license the Adhesive to a third party for a lump sum or fixed payment (as opposed to a royalty) before an aggregate of $25 million in commercial sales has been reached, it must condition sub-licensing on accurate accounting by the licensee on an annual basis of all net revenues received from sales of the Adhesive. CryoLife must add these accounting figures to all sales from other sources for purposes of computing aggregate sales and the computation of amounts owed to Dr. Kowanko.

B. *Consulting Fee.* For so long as Dr. Kowanko provides consulting services pursuant to Section 9 below, Dr. Kowanko shall receive a consulting fee of $10,000 per year. Such consulting fee shall be payable each year in advance.

C. *Records.* CryoLife shall maintain a true and correct set of records pertaining to commercial sales of Adhesive and license revenues obtained from the licenses of the Adhesive. CryoLife shall be obliged to maintain records relating to any year for a period of five years. CryoLife agrees to permit an auditor selected by Dr. Kowanko and reasonably acceptable to CryoLife to have access during normal business hours to such records to determine the correctness of any report and/or royalty payment made under this Agreement. In the event that the audit reveals an underpayment of royalty by more than 7%, the cost of the audit shall be paid by CryoLife. Such accountant shall maintain in confidence, and shall not report to Dr. Kowanko or others, any information concerning CryoLife or its operations or properties other than information directly relating to the correctness of such reports and payments.

IV. *Representations of Dr. Kowanko.* Dr. Kowanko hereby represents and warrants that he independently developed the Technology, that no university or governmental agency with or for whom Dr. Kowanko works or has worked in the past, or any student or employee thereof (other than Dr. Kowanko), has any right, title or interest in or to the Technology, and that Dr. Kowanko has the authority to enter into and perform his obligations under this Agreement. Dr. Kowanko further represents and warrants that he knows of no other compound or adhesive similar to the Adhesive or which provides the same or substantially similar functionality. Dr. Kowanko warrants that said Technology has not been assigned, licensed, pledged, mortgaged or conveyed in whole or in part to any third party. Dr. Kowanko warrants that he has no agreement with any third party which conflicts with his obligations to CryoLife under this Agreement. Dr. Kowanko does not warrant that the practice of the Patent or the use by CryoLife of the Technology does not infringe or impinge upon any patent rights of others.

V. *Indemnification.* Subject to the accuracy of the representations and warranties of Dr. Kowanko set forth elsewhere in this Agreement and the provisions of Section 6 below, CryoLife shall indemnify, defend, and hold Dr. Kowanko harmless from and against any and all damages, liability, losses, and expenses incurred by Dr. Kowanko arising our of any claim, lawsuit, action or proceeding (collectively, "Claim") against Dr. Kowanko by a third party based upon the production, distribution, or marketing by CryoLife of the Technology. As between the parties hereto, CryoLife shall defend, settle, or compromise all litigation (including action, suits and proceedings before judicial or administrative tribunals, and arbitration proceedings), in which CryoLife, or its vendees, are charged by virtue of the manufacture, use or sale of Products or the use of the Technology under this Agreement with infringement of any patent held by any third party.

VI. *Liability.*

A. *Infringement; Misappropriation.* Dr. Kowanko warrants that he has received no notice that the manufacture, use, or sale of any Products or the use of Technology is an infringement or misappropriation of the right of any third party and that to the best of his knowledge and belief, the manufacture, use, or sale of Products or the use of the Technology is not an infringement or misappropriation of the rights of any third party. In the event CryoLife is obliged to defend any action for such infringement or misappropriation of any patents held by any third party, Dr. Kowanko shall provide such assistance, including the furnishing of documents and information and the execution of all necessary documents as CryoLife may reasonably require, but under no circumstances does Dr. Kowanko warrant or guarantee that the Products or the Technology is not or will not be in infringement or misappropriation of any patent rights of any third party. No monies received by Dr. Kowanko from CryoLife shall be returned to CryoLife in the event of a third party suit, whether or not it is successful. Dr. Kowanko does not warrant or represent that the Products or the Technology is free of infringement of any patent that may be existent at any time and Dr. Kowanko does not offer or extend any indemnity for infringement of any patent, including those which may at any time be in existence at a place of business of CryoLife or the place of manufacture of the Products.

B. *Disclaimer of Liability.* In no event shall Dr. Kowanko be liable for: (a) special, indirect, incidental or consequential damages, or (b) any damages whatsoever resulting from the loss of use, data or profits arising out of or in connection with this Agreement or the use or performance of any Technology, whether in an action based on contract or tort, including negligence. Dr. Kowanko shall not be liable for property damage or personal injury, including death, resulting from the act done or not done in connection with an obligation assumed by either Dr. Kowanko or CryoLife hereunder other than an act done or not done as a result of willful wrongdoing or negligence of Dr. Kowanko as determined by a court of law.

VII. *Prevention of Infringement.* Dr. Kowanko will assist CryoLife in connection with any actions by CryoLife to prevent or stop any infringement or misappropriation by others of the Technology. CryoLife shall reimburse Dr. Kowanko for Dr. Kowanko's necessary and reasonable out-of-pocket costs incurred in cooperating with Cryolife, at CryoLife's request, with respect to litigation hereunder.

VIII. *Confidentiality.* Dr. Kowanko shall keep confidential and shall not disclose or otherwise permit access to the Trade Secrets to any other entity without CryoLife's prior written approval and will limited access to Know-How to the extent reasonably possible. Dr. Kowanko agrees to submit to CryoLife's publications review committee any articles or writings he proposes to publish and to permit the committee a reasonable period of time consistent with its general practices to review such material and to require deletions of confidential or proprietary information prior to publication or to delay publication up to nine months for the convenience of CryoLife. Dr. Kowanko may, if he chooses, become a member of the committee as part of his consulting services to CryoLife. If Dr. Kowanko disagrees as to whether material is confidential or proprietary so as to permit the committee to require its deletion from publishable material, Dr. Kowanko may submit his disagreement to arbitration conducted by two qualified scientists, one each selected by Dr. Kowanko and CryoLife, for resolution. Unless the parties agree to other procedures, the arbitration will be conducted in accordance with the rules of the American Arbitration Association. Each party shall bear its own costs associated with arbitration.

IX. *Consulting Services.* Dr. Kowanko shall provide consulting services to CryoLife for a period of five years following the date of this Agreement on those projects described in (a) that certain letter dated October 6, 1995 from Dr. Kowanko to April L. O'Hara at CryoLife and (b) that certain letter dated October 6, 1995 from Dr. Kowanko to Dr. Brenda Smith Morse at CryoLife, copies of each of which are attached hereto as *Exhibit B*, and on such other projects as may be proposed by Dr. Kowanko and approved by CryoLife. Dr. Kowanko shall devote sufficient time and attention to the performance of services hereunder to complete the projects agreed to by CryoLife and Dr. Kowanko within such time frames as CryoLife may reasonably assign. After the initial five-year period, Dr. Kowanko agrees to continue to provide consulting services to CryoLife pursuant to this Section 9 on a year to year basis, provided (1) neither Dr. Kowanko nor CryoLife has notified the other in writing at least 60 days prior to the end of the then current consulting term and (ii) the parties have agreed upon a consulting fee to be payable for Dr. Kowanko's services during the extended term.

X. *Patent Responsibilities.* CryoLife shall have the sole right, at its sole cost and expense, to take any action in connection with the preparation, filing, and maintenance of any patents and patent applications, including any continuations, continuations-in-part, substitutions, reissues, and extensions thereof, with respect to the Technology. Dr. Kowanko shall assist CryoLife, at CryoLife's cost and expense, in connection with any such efforts.

XI. *General Provisions.*

A. *Entire Agreement.* This Agreement constitutes the entire agreement and understanding of the parties with respect to the Technology and supersedes and terminates all other prior commitments, arrangements, or understandings, both oral and written between the parties with respect to the Technology, including, without limitation, the Technology Investigation and Option Agreement dated June 15, 1993 between the parties and the TA Agreement.

B. *Modification.* This Agreement may not be modified or amended except by an instrument in writing executed by each of the parties.

C. *Binding.* This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns.

D. *Governing Law.* This Agreement shall be governed and construed in accordance with the laws of the State of Georgia.

E. *Notices.* Any notices or other communications required or permitted hereunder shall be in writing and shall be sent by (a) personal delivery (including delivery by Federal Express or similar overnight courier), (b) mailed by registered or certified mail, return receipt requested, postage prepaid, or (c) transmitted by facsimile, telex, or telecopy to the numbers set forth below and with originals of such transmissions sent by registered or certified mail. Notices shall be sent to the addresses as set forth below or to such other addresses as may be hereafter furnished by one party to the other party in compliance with the terms, hereof.

If to Dr. Kowanko:	at the address set forth for Dr. Kowanko in the first paragraph of this Agreement
If to CryoLife:	at the address set forth for CryoLife in the first paragraph of this Agreement

Notices shall be effective (a) upon receipt by the addressee, if sent by personal delivery or mail, or (b) upon transmission, if sent by telecopy, telex, or facsimile.

F. *Waiver.* None of the provisions of the Agreement shall be deemed to have been waived by any act or acquiescence on the part of either party, their agents or employees, but may be waived only by instruments in writing signed by an authorized officer of the respective party. No waiver of any provision of this Agreement shall constitute a waiver of any other provision or of the same provisions on another occasion.

G. *Counterparts.* This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original an all of which together shall constitute but one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date set forth herein by their duly authorized representatives.

Sworn to and subscribed before me
the day of , 1996.

NICHOLAS KOWANKO, Ph.D.

Notary Public

(Notarial Seal)
My commission expires:

Sworn to and subscribed before me
the 8th day of August, 1996.

/s/ SUZANNE K. GABBERT

Suzanne K. Gabbert

Notary Public

(Notarial Seal)
My commission expires: Notary Public, Cobb County, Georgia
My Commission Expires
Sept. 13, 1996.

CRYOLIFE, INC.

By: [Illegible]

Title: President/CEO

F. *Waiver.* None of the provisions of the Agreement shall be deemed to have been waived by any act or acquiescence on the part of either party, their agents or employees, but may be waived only by instruments in writing signed by an authorized officer of the respective party. No waiver of any provision of this Agreement shall constitute a waiver of any other provision or of the same provisions on another occasion.

G. *Counterparts.* This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original an all of which together shall constitute but one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date set forth herein by their duly authorized representatives.

Sworn to and subscribed before me
the 24th day of July, 1996.

/s/ GAIL L. SMITH

Notary Public

(Notarial Seal)
My commission expires: GAIL L. SMITH
Notary Public, STATE OF NORTH DAKOTA
My Commission Expires
FEB 26, 2002

/s/ NICHOLAS KOWANKO

NICHOLAS KOWANKO, Ph.D.

Sworn to and subscribed before me
the day of , 1996.

Notary Public

(Notarial Seal)
My commission expires:

CRYOLIFE, INC.

By:

Title:

EXHIBIT A

Definition of Adhesive

An adhesive composition, primarily intended as tissue adhesive, comprise of dialdehydes and proteinaceous material, and methods for its use. The adhesive property is gained primarily by chemical reaction of these components with each other. "Adhesive" includes all inventions described in the Patents, which the parties acknowledge include all those patents and patent applications described on the attached Nicholas Kowanko Patent Inventory dated March 13, 1996.

QuickLinks

AMENDED AND RESTATED TECHNOLOGY ACQUISITION AGREEMENT

Exhibit 14

Code of Business Conduct and Ethics
Effective June 19, 2003
(revised to correct typographical errors on 2/24/04)
(amended Sections 15, 16 and 17 on 2/18/05)

Dear CryoLife Employees, Officers and Directors,

CryoLife, Inc. was founded with a commitment to the highest ethical standards of business conduct and fair dealing in the Company's relations with all employees, customers, suppliers and shareholders.

This Code of Business Conduct and Ethics clarifies our standards of conduct in potentially sensitive situations; it makes clear that CryoLife, Inc. expects all employees, officers and directors to understand and appreciate the ethical considerations of their decisions; and it reaffirms our long-standing commitment to a culture of corporate and individual accountability and responsibility for the highest ethical and business practices.

We encourage you to carefully read this Code of Business Conduct and Ethics, discuss any questions that you may have with your immediate supervisor and retain it for future use.

Very truly yours,

Steven G. Anderson
Chairman of the Board, President,
and Chief Executive Officer

Introduction

The Board of Directors of CryoLife, Inc. has adopted this Code of Business Conduct and Ethics to clarify the standards under which CryoLife and its Board of Directors operate and the principles under which the Board and all CryoLife officers and employees carry out their duties. CryoLife, Inc. and its subsidiaries and divisions are referred to collectively in this Code as "CryoLife." The Board of Directors may revise this Code from time to time and will make publicly available any changes as they are adopted. A copy of the Code, as amended, shall be posted on the CryoLife, Inc. website. Nothing in the Code is intended or will be considered (i) to amend the Restated Certificate of Incorporation or Bylaws of CryoLife, (ii) to change the legal duties imposed upon employees, officers or directors under Florida, federal and other applicable statutes, rules and regulations or (iii) to change any rights of the employees, officers or directors, to indemnification under Florida and other applicable law or CryoLife's Restated Certificate of Incorporation or Bylaws or otherwise. References herein to federal, state, local or other applicable laws refer to the laws of the United States and all other applicable jurisdictions.

Preamble

This Code applies to all employees, officers and directors of CryoLife, Inc. It is important to the success of the Code that each employee, officer and director of CryoLife understands that:

- He or she is personally responsible for his or her own conduct in complying with this Code and for promptly reporting known or suspected violations to the individual designated for this purpose.

- No one has the authority or right to order, direct, request or even attempt to influence someone else to violate this Code or the law. Thus, no one will be excused for violating this Code or the law at the direction or request of someone else.

- Any attempt by any employee, officer or director to have another employee, officer or director violate this Code, whether successful or not, shall be a violation of this Code and may be a violation of law.

- Any retaliation or threat to retaliate against an employee, officer or director for refusing to violate this Code or for reporting in good faith a violation or a suspected violation of this Code shall be a violation of this Code and may be a violation of law.

- Every suspected violation of this Code by an employee, officer or director will be investigated and every actual violation will constitute grounds for removal of such director and for dismissal of such employee or officer.

1. Overall Standard

The highest legal, moral and ethical standards of honesty, integrity and fairness are to be practiced in the conduct of CryoLife's affairs. All employees, officers and directors of CryoLife must always act in full compliance with all applicable United States and foreign, federal, state, local and other laws, ordinances and regulations and with this Code. Failure to do so or to report promptly apparent violations of law or this Code may result in removal, dismissal, or other appropriate disciplinary action.

2. Equal Opportunity

It is the policy of CryoLife to provide recruitment, hiring, training, promotion and other conditions of employment without regard to race, color, age, gender, sexual preference, religion, disability, national origin or veteran status, and to otherwise comply with all applicable anti-discrimination laws. It is the policy of CryoLife to provide and maintain a working environment free of harassment, intimidation or exploitation of any nature, including sexual and racial harassment. CryoLife expects its employees, officers and directors to treat all CryoLife employees with respect and dignity and to fully support CryoLife's objectives of providing equal opportunity employment and maintaining a workplace free of harassment.

3. Conflicts of Interest

No employee, officer or director of CryoLife may engage in any activity that would conflict with or be contrary to the best interests of CryoLife. A "conflict of interest" occurs when an individual's private interest interferes in any way—or even appears to interfere—with the interests of CryoLife. A conflict situation can arise when an employee, officer or director takes actions or has interests that may make it difficult to perform his or her work objectively and effectively. Conflicts of interest also arise when an employee, officer or director, or a member of his or her family, receives improper personal benefits as a result of his or her position with CryoLife. Loans to, or guarantees of obligations of, such persons are of special concern. CryoLife shall not make a loan to or guarantee any obligation of any executive officer or director, other than as allowed by applicable law. In addition, no employee, officer or director of CryoLife may participate in the management, revenues or equity ownership of any competing business. Furthermore, no officer of CryoLife may participate in the management, revenues or equity ownership of any CryoLife customer, supplier or consultant, and such participation by all other employees is discouraged. Any employee participating in the management, revenues or equity ownership of any customer, supplier or consultant shall disclose in writing the nature and extent of such participation to the Chief Executive Officer or his designee. Any director participating in the management, revenues or equity ownership of any customer, supplier or consultant shall disclose in writing the nature and extent of such participation to the Board's Chairman. An investment in the equity or debt of less than 3% of the relevant class of securities in a publicly held competing business, customer, supplier or consultant will not be deemed to be a violation of this policy, but must nonetheless be reported as specified above.

4. Payment of Gratuities

In all dealings with suppliers, customers, governmental officials and employees of CryoLife, no director (in connection with his or her efforts or role as a director of CryoLife), employee or officer shall offer to give any payment or other significant thing of value that has as its purpose, or potential purpose, or may appear to have as its purpose, improperly influencing the business relationships between CryoLife and such persons or entities. This paragraph shall not, however, prohibit a CryoLife employee from giving a reasonable and customary holiday gift to a CryoLife customer or supplier.

5. Receipt of Payments or Gifts

No employee or officer and no director (in connection with his or her efforts or role as a director of CryoLife) may receive payments or gifts in exchange for business opportunities with or otherwise from customers, vendors, suppliers or employees of CryoLife. This applies to anyone with whom CryoLife has an existing or prospective relationship known to such employee, officer or director. In our continuing effort to maintain high ethical standards and to avoid appearances of impropriety, it is required that all employees, officers and directors and members of their immediate families decline any such payment or gift, except to the extent specifically permitted below.

The only exception to the foregoing is that a gift can be accepted if such gift can be consumed or fully utilized within a 24-hour period, AND the gift is promptly disclosed, in the case of an employee to an officer with responsibility for his or her department, in the case of a director, to the Board's Chairman, and in the case of the Chairman of the Board, to the Chairman of the Audit Committee.

6. Corporate Opportunities

Employees, officers and directors must advance the legitimate interests of CryoLife when the opportunity to do so arises. Employees, officers and directors, for their own accounts or the account of another, may not (i) pursue an opportunity discovered through the use of CryoLife property, information or position or (ii) use CryoLife's property, information or position for personal gain.

7. Political Contributions

Corporate political contributions to any candidate for United States federal office or to any party or campaign in connection with any election for United States federal office are prohibited. Corporate political contributions to any other political candidate, party or campaign are generally discouraged and are prohibited where such contributions are unlawful. Furthermore, any payments to any foreign officials, political candidates or political parties outside the United States are prohibited without the advance written approval of CryoLife, Inc.'s Chief Executive Officer.

8. Competition and Fair Dealing

CryoLife seeks to outperform its competition fairly and honestly. We seek competitive advantages through superior performance, never through unethical or illegal business practices. Stealing proprietary information, possessing trade secret information that was wrongfully obtained, or inducing such disclosures by past or present employees of other companies is prohibited. Each employee, officer and director should endeavor to respect the rights of and deal fairly with CryoLife's customers, suppliers, competitors and employees. No employee, officer or director should take improper advantage of anyone through manipulation, concealment, abuse of proprietary information, misrepresentation of material facts, or any other intentional improper practice.

9. Protection and Proper Use of CryoLife's Assets

All employees, officers and directors must endeavor to protect CryoLife's assets and ensure their efficient use. Theft, carelessness, and waste have a direct impact on CryoLife's profitability. Any suspected incident of fraud or theft must be immediately reported for investigation. All CryoLife assets should be used for legitimate business purposes.

The obligation of employees, officers and directors to protect CryoLife's assets includes its proprietary information. Proprietary information includes intellectual property such as trade secrets, patents, trademarks, and copyrights, as well as business, marketing and service plans, engineering and manufacturing ideas, designs, databases, records, salary information, any financial data and reports that have not been publicly disclosed and any other information not generally made available without restriction to third parties. Unauthorized use or distribution of this information violates this Code and may be illegal.

10. Financial Records, SEC Filings and Public Communications

The Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and Controller of CryoLife, Inc., and all other persons performing similar functions for CryoLife, Inc., shall be responsible for taking such actions and instituting such policies and procedures as they believe will most efficiently and effectively help to ensure full, fair, accurate, timely and understandable disclosure in all reports and other documents that CryoLife files with or submits to the Securities and Exchange Commission and other applicable regulatory authorities and in all other public communications made by CryoLife.

11. Contractual Commitments

It is of utmost importance to the integrity and reputation of CryoLife that CryoLife honors and fully complies with all contractual commitments.

12. Antitrust Law Compliance

All employees, officers and directors of CryoLife must comply in all respects with all applicable Unites States and foreign federal and state antitrust and other comparable laws. To that end, no CryoLife employee, officer or director may under any circumstances or in any context enter into any understanding or agreement (whether expressed or implied, formal or informal, written or oral) with a competitor or potential competitor, limiting or restricting in any way the actions of either party, including the offers of either party to any third party, as to prices, costs, profits, products, services, terms or conditions of sale, market share, decisions to quote or not to quote, customer or supplier classification or selection, sales territories or distribution methods.

13. Legal Compliance

Employees, officers and directors must always act in full and timely compliance with all applicable federal, state, local and other laws, ordinances and regulations, the rules and regulations of the Securities and Exchange Commission and the New York Stock Exchange and with this Code. Applicable federal, state, local and other laws and regulatory agency rules with which compliance is required include, without limitation, statutes, court and agency rulings and Securities and Exchange Commission and New York Stock Exchange rules concerning:

- prohibitions on trading in securities of CryoLife while aware of material, nonpublic information, as discussed in greater detail in CryoLife's Policy on Trading in Company Securities, which is incorporated by reference herein; and

- reporting of directors' and Section 16 reporting officers' ownership of CryoLife equity securities and changes therein.

14. Confidentiality

Employees, officers and directors must not disclose any confidential information of CryoLife until such time as the information has been publicly disclosed by CryoLife, except that disclosure may be made to professional advisors (such as CryoLife's counsel and auditors) where such disclosure is in furtherance of an employee's, officer's or director's duty as a CryoLife employee, officer or director. Absent unusual circumstances and subject always to the employee's, officer's or director's responsibilities under applicable law, employees, officers, and directors should refer media inquires to the Chief Executive Officer or his or her designee.

15. Ethics Compliance Board

The Chairman of the Board of Directors of CryoLife, Inc. will designate a Compliance Officer. The Compliance Officer will be responsible for investigating and reporting to the Nominating and Corporate Governance Committee and the Audit Committee on all reports of Code violations and for assuring the confidentiality thereof, subject to disclosure obligations to the U.S. Government, any foreign government or state, local or other applicable law enforcement authorities. The Compliance Officer is responsible for the maintenance of the Code and for the administration of the training and compliance programs to insure compliance with the Code at the corporate level and will from time to time issue instructions and procedures relating to the Code.

16. Compliance and Training Program

The Compliance Officer shall be responsible for developing and implementing a compliance and training program to assist employees in becoming aware of and complying with the Code and other legal obligations imposed by law or regulation. Such programs will be under procedures established by the Compliance Officer, which procedures shall provide at least the following elements:

- Initial distribution of the Code to all employees, officers and directors and subsequent distribution of the Code when modifications and/or updates have been made to the Code. (A written acknowledgment will be obtained from all employees, officers and directors indicating that they have received, read, understood and agreed to comply with the Code.)

- Training for all new employees, officers and directors at the time of their hiring and all existing employees, officers and directors on at least an annual basis concerning the Code.

- A mechanism (for example, a hot-line) to report actual or reasonably suspected violations of the Code or any applicable laws or regulations.

- Maintenance of a register of all training satisfactorily completed by each employee.
- Internal operations review programs to determine compliance with the Code on a periodic or other appropriate basis.

17. Reporting Violations of the Code

It is the obligation of every employee, officer and director to report promptly any actual or reasonably suspected violations of the Code in the manner established by CryoLife's Compliance Officer, the Nominating and Corporate Governance Committee, or by the CryoLife Board of Directors (including anonymous "hot-line" reports). All reports will be kept confidential and will be promptly investigated, and appropriate corrective or disciplinary action will be taken, including dismissal and notification of regulatory authorities when appropriate. No such report shall result in negative consequences to any individual who in good faith reports a violation of this Code, and it shall be a violation of this Code for any director, officer or employee to take retaliatory action as a result of any such report.

18. Waivers of the Code

Any waiver of this Code may be made only by the Board and will be promptly disclosed as and to the extent required by law or the rules of any stock exchange on which the Company's securities are listed.

Conclusion

The central purpose of this Code is to serve as an ongoing reminder of CryoLife, Inc.'s policy of conducting its business in a legal and proper manner. This includes not only complying with all applicable laws but also treating CryoLife's customers, suppliers and employees with dignity and respect.

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Exhibit 21.1

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

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-112673 and 333-121406 of CryoLife, Inc. on Form S-3 and Registration Statement Nos. 333-16581, 33-83996, 33-84048, 333-03513, 333-59853, 333-06141, 333-34025, 333-75535, 333-47310, 333-10463, 333-112673 and 333-119137 of CryoLife, Inc on Form S-8 of our reports dated March 2, 2005 relating to the consolidated financial statements and financial statement schedules of CryoLife, Inc. (which expresses an unqualified opinion and includes an explanatory paragraph relating to the adoption of Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets", 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, 2004.

DELOITTE & TOUCHE LLP
Atlanta, Georgia
March 2, 2005

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Exhibit 31.1

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 realizability 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: March 2, 2005

/s/ STEVEN G. ANDERSON

Chairman, President, and
Chief Executive Officer

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Exhibit 31.1

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Exhibit 31.2

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 realizability 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: March 2, 2005

/s/ DAVID ASHLEY LEE

Executive Vice President,
Chief Operating Officer, and
Chief Financial Officer

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[Exhibit 31.2](#)

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Exhibit 32

**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, 2004, 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	/s/ DAVID ASHLEY LEE
STEVEN G. ANDERSON Chairman, President, and Chief Executive Officer	DAVID ASHLEY LEE Executive Vice President, Chief Operating Officer, and Chief Financial Officer
March 2, 2005	March 2, 2005